The Profile and selected outcomes of Coronary Artery
Bypass Graft (CABG) patients in the Cape Metropolitan
Area. A baseline study

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DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my
own original work and that I have not previously in its entirety or in part submitted
it for any degree or examination at any university. This study has been approved
by the research Ethics Committee of the Faculty of Health Sciences, University of
Stellenbosch, protocol number NO5/04/072
Signed by:
Date:

ABSTRACT

Study Aim: To describe the profile and selected outcomes of CABG patients admitted in the Cape metropolitan area. **Design:** A prospective descriptive study design with a multicentre observational approach was followed. Method: All patients undergoing isolated CABG surgery, whether elective or emergency, during a three-month period (15 August–15 November 2005) were included in the study. Demographic data, pre-operative medical status, intra-operative, as well as post-operative information were collected using a self-designed structured initial assessment form (SIA). Means and standard deviations were calculated where applicable. Relationships between different variables were analyzed by means of: ANOVA, correlations, linear and logistic regressions. Where it appeared that the ANOVA assumptions were violated, non-parametric bootstrap techniques were employed. Results: Two hundred and forty five patients were admitted to the seven hospitals which provide CABG surgery in the Cape metropolitan area in the allotted period. The profile of patients admitted to private and state institutions were similar. The mean age of the sample was 60 (±10). The mean LOS of the total cohort was 12 (±5.5) days, with patients in the state hospitals staying longer 13.4 days (± 7.1). Patients who were older than 60 were twice as likely to have a LOS >12days (odds ratio = 2.49; 95% confidence interval = 1.33 to 4.65). The development of a pleural effusion or pneumothorax was associated with an increased LOS (p<0.01). At least one PPC was reported in 65% of the population. A mortality rate of only 3% was reported. Conclusion: Patients in this cohort were younger than in developed countries. An age greater than 60 years was a predictor of an LOS >12days in the current cohort. Patients were most likely to develop a PPC on day three after CABG surgery. Physiotherapeutic intervention, if any, would be well aimed at those patients older than 60 years of age. Screening of patients in the first three post-operative days for the development of PPCs is also advised.

ABSTRAK

Doelstelling: Om die profiel en geselekteerde uitkomste van kroonaaromleiding (KAO) pasiënte in die Kaapse metropool te beskryf. Ontwerp: 'n Prospektiewe beskrywende studie ontwerp met 'n multisentrum waarneemende benadering was gevolg. Metode: Alle pasiënte wat geïsoleerde KAO chirurgie altans elektief of noodsaaklik in die Kaapse metropool ontvang het gedurende 'n drie-maande periode tussen 15 Augustus 2005 en 15 November 2005. Demografiese data, pre-operatiewe mediese status so wel as post-operatiewe inligting was ingesamel met behulp van 'n self-ontwerpde "structured initial assessment" (SIA) vorm. Waar toepaslik. was gemiddeldes en standaard afwykings bereken. Verwantskappe tussen verskillende veranderlikes was deur middel van ANOVA. korrelasies, linière en logistieke regressie geanaliseer. Wanneer ANOVA hipoteses klaarblyklik oortree was, was non-parametriese boostrap tegnieke gebruik. Resultate: Gedurende die drie-maande periode, was 'n totaal van 245 pasiënte toegelaat in die sewe hospitale wat KAO chirurgie in die Kaapse metropool verskaf. Die profiele van die pasiënte toegelaat in private en staat instansies was vergelykbaar. Die gemiddelde ouderdom van die steekproef was 60 (±10) jaar oud. Die gemiddelde hospitaal verblyf van die studie was 12 (±5.5) dae, met die staat hospitaal pasiënte wat 13.4 (± 7.1 dae) gebly het. Pasiënte wat ouer as 60 was, was twee keer meer geneig om 12 dae of meer in die hospitaal te bly (odds ratio = 2.49 95%; vertroubaarheidsinterval = 1.33 tot 4.65). Die ontwikkeling van 'n pleurale effusie of pneumotorax was ook geassosieer met 'n langer hospitaal verblyf (p<0.01). Ten minste een post-operatiewe pulmonale komplikasie was gerapporteer in 65% van die studie populasie. Die prevalensie van mortaliteit gerapporteer in die huidige studie was 3%. Samevatting: Pasiënte in hierdie studie was jonger as pasiënte in ontwikkelde lande. 'n Ouderdom van 60 jaar of ouer was voorspellend van 'n hospitaal veblyf van meer as 12 dae in die huidige studie. Die pasiënt sou waarskynlik 'n post-operatiewe pulmonale komplikasie op dag drie na KAO chirurgie ontwikkel. Fisioterapeutiese intervensie as sulks sou dus toepaslik wees op pasiënte ouer as 60 jaar. Om hierdie rede word sifting deur die fisioterapeut, van pasiënte met KAO chirurgie, binne die eerste drie dae post-operatief aanbeveel ten einde die ontwikkeling van n post-operatiewe pulmonale komplikasie te identifiseer.

DEDICATION

This thesis is decidated to my loving husband Ridaa and my daughters Laila and Rania Manie for their unwavering support and understanding.

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CHAPTER 1:

INTRODUCTION

1.1 INTRODUCTION TO THE STUDY

Cardiovascular diseases (CVD) are the most common cause of death worldwide and are predicted to continue until 2020 (Okrainec *et al.*, 2004; World Health Organization [WHO], 2005). Coronary artery disease (CAD) along with hypertension and stroke are amongst the entities which encompass cardiovascular diseases. It is reported that of the 4 million deaths annually attributed to cardiovascular diseases in Europe, 2 million deaths are exclusively due to coronary artery disease (WHO, 2005). Management of CAD includes preventative strategies (education of risk factors), curative strategies (stenting, coronary artery bypass surgery), and long-term maintenance of the disease (Eagle *et al.*, 1999). Coronary Artery Bypass Grafting (CABG) is a surgical procedure which alleviates the symptoms of CAD such as angina, by bypassing the blocked artery resulting in revascularization of the heart.

CABG surgery is one of the most common major operations in the developed world (Kurki *et al.*, 2003). In Sweden, approximately 40 of 100 000 people undergo CABG surgery annually. In 1996 alone, it was reported as one of the most commonly used major surgical intervention in America, and accounted for the use of more health care resources than any other therapeutic technique (Chen-Scarabelli, 2002). In 1994, the South African Department of Health reported that in the public sector alone, 200 per million patients underwent major cardiothoracic surgery (Department of Health, 2002).

In a global context, South Africa's health care is similarly serviced by both the public and private health sectors (Department of Health, 2002). However, the burden of cardiothoracic surgery is borne by the private sector which performs 860 operations per million annually, as compared to the 59 per million in the public sector (Department of Health, 2002). In a population of approximately 45 million (Statistics South Africa, 2001), only a total of 7.6 million people (16% of the population) are linked to medical aid organizations. The remaining 84% is solely dependent upon the public health sector for specialized care such as cardiothoracic surgery (Department of Health, 2002).

In Cape Town alone, in the last decade, a mushrooming of townships has occurred, stretching the already meager public health budget. It is estimated that 25 000 Eastern Cape citizens flock to Cape Town townships yearly (Statistics South Africa, 2001). This trend shows no sign of abating, as the Eastern Cape economy is not able to provide the largely unskilled rural population with employment. This scenario is playing itself out in all major cities within South Africa (SA). Coupled with this urbanization comes a change in lifestyle and specifically diet, which contributes to the increased occurrence of high blood pressure, tobacco addiction, high blood cholesterol, diabetes and obesity (Medical Research Council, 2001). These are the major risk factors and behaviours for chronic diseases of lifestyle such as cardiovascular disease (CVD).

Thus, the change in lifestyle and increased risk factors for the development of CVD provides RSA with the two components which have made CABG the most common surgical intervention performed in America. However, unlike America, South Africa's

public health sector cannot accommodate an expanding service for cardiothoracic surgery due to budgetary constraints (Department of Health, 2002). This means that the public centres which provide CABG surgery have to utilize their resources cost-effectively, or that alternative interventions be investigated. To this end, any factors which could have an impact on length of stay and post-operative complications, may greatly improve on service delivery.

Over the last decade, risk scores have been developed exclusively for mortality and not morbidity after CABG surgery. However, according to Higgins (1998), it has been acknowledged that morbidity is the major determinant of hospital cost and quality of life post heart surgery. Despite numerous advances in peri-operative care, post-operative pulmonary complications (PPCs) still contribute to patient morbidity (Brooks-Brunn, 1995) as well as mortality, length of stay and overall use of resources (Hulzebos *et al.*, 2003). Hulzebos *et al.* (2003) describes the high-risk CABG patient profile for increased morbidity as those with advanced age (>70yrs), increased body mass index (BMI), a history of cigarette smoking, diabetes mellitus, abnormal pulmonary function and chronic obstructive pulmonary disease (COPD).

It has been observed in the Cape metropolitan area that chest physiotherapy is given routinely to all patients undergoing CABG surgery. The intention is to reduce the risk of PPCs. This is achieved by a treatment regime consisting of a combination of physiotherapy techniques. The latter includes deep breathing exercises, early mobilization, intermittent positive pressure breathing (IPPB), positioning, and supportive coughing (Gosselink *et al.*, 2000). However, several studies have failed to show the efficacy of these treatment techniques on pulmonary function and length of

stay (Dull and Dull, 1984; Jenkins *et al.*, 1989; Stiller *et al.*, 1994) and question the effectiveness of the techniques used in the post-operative management of uncomplicated CABG surgery patients. A systematic review conducted by Pasquina *et al.* (2003) on prophylactic respiratory physiotherapy after cardiac surgery, concluded that evidence is inconclusive on the benefit from these treatment techniques after cardiac surgery due to poor study design and small study samples.

There is also controversy about the identification of patients that are at risk of developing complications post-operatively and of those that could possible benefit from physiotherapy (Hulzebos *et al.*, 2003). Identifying these patients pre-operatively could potentially help physiotherapists to direct their interventions to people who could possible benefit from these interventions.

1.2 RESEARCH QUESTION

Thus, the question for study was: What is the profile and selected outcomes of the Coronary Artery Bypass Graft (CABG) patients in the Cape Metropolitan Area?

1.3 AIM OF THE STUDY

To describe the profile and selected outcomes of CABG patients admitted in the Cape Metropolitan Area.

1.4 OBJECTIVES OF THE STUDY

The objectives of the study are to describe and determine the:

demographics of CABG patients;

- pre-operative medical status of the patient with respect to cardiac; renal,
 diabetic and pulmonary status;
- health behaviour of patients prior to CABG surgery with regard to smoking and activity level;
- profile of CABG patients in both state and private hospitals in the Cape metropolitan area; and
- following selected outcomes of CABG patients:
 - o mortality rate;
 - o intra-operative length of anaesthesia;
 - length of intubation;
 - o incidence of PPCs;
 - o re-intubation rate; and
 - length of stay (LOS).

1.5 OUTLINE OF THE THESIS

CHAPTER 1: This chapter orientates the reader to the study. An overview, motivation and background to the study is given and includes the research question and aim.

CHAPTER 2: Discusses reviewed literature pertaining to the history and developments of CABG surgery, in particular the role of physiotherapy. Also elaborates on the demographics and outcome measures for the CABG patient as well as factors which influence outcome.

CHAPTER 3: The research design and methodology are discussed in detail.

CHAPTER 4: Results of the study are reported and displayed.

CHAPTER 5: Discusses the findings of the study in relation to the research question.

CHAPTER 6: Summarizes the study findings and includes limitations of the study.

Recommendations for further research are also included.

CHAPTER 2:

LITERATURE REVIEW

2.1 INTRODUCTION

Coronary Artery Bypass Graft (CABG) surgery is one of the most expensive and frequently performed surgeries in the world (Kurki *et al.*, 2003). In the United States alone, CABG surgery accounted for the use of more health care resources than any other therapeutic technique (Chen-Scarabelli, 2002).

This chapter will include literature pertaining to (CABG) surgery under four broad headings:

- History and developments of CABG surgery, including the role of physiotherapy;
- Demographic studies of the CABG patient;
- ➤ The main outcome measures of the CABG patient; and
- Factors influencing the outcome of CABG surgery patients.

Particular emphasis will be given to the role of physiotherapy in treating CABG surgery patients.

2.2 HISTORY OF CORONARY ARTERY BYPASS GRAFT (CABG) SURGERY

Coronary Artery Bypass Graft (CABG) is a surgical procedure which alleviates the symptoms of coronary artery disease by bypassing the blocked artery resulting in

revascularization of the myocardium (University of Southern California, 2005). Kouchoukos *et al.* (2003) stated that it was the development, by Sones and Shirley in the 1960s, of coronary cinearteriography to directly identify a blocked artery, which led to the birth of coronary artery surgery. Developments in the field of cardiac surgery are driven by the need for cost containment while maintaining excellence in post-operative outcomes such as reduced mortality, morbidity, length of stay and improved functional quality of life after surgery (Konstantakos & Lee, 2000).

2.2.1 Developments in CABG surgery

As early as 1900 pioneers such as Dr. Alexis Carell, were investigating procedures to improve blood supply to the heart when arteries were blocked due to disease (Levinson, n.d). Between 1910 and 1960 several attempts were made to directly suture a saphenous vein bypass graft into the coronary circulation, in animals, with minimum success. In 1967, Dr. Renee Favalaro an Argentinian working at the Cleveland Clinic, was the first to report success in a small number of human patients where coronary artery bypass was performed using the saphenous vein from the leg (University of Southern California, 2005).

During this period CABG surgery was performed through a sternal incision of 10–12 inches long while the heart was still beating. This was later termed Off-Pump CABG or OPCAB (University of Southern California, 2005). Other cardiac procedures such as congenital defects were, however, already at that stage being performed with the aid of a mechanical device, the heart–lung machine. The heart–lung machine, or Cardio-Pulmonary Bypass (CPB) machine as it is now termed, allowed circulation to continue outside of the body while the heart was temporarily stopped. Surgeons who

performed CABG surgery, soon recognized that the bloodless and motionless environment offered by the CPB machine was of benefit when performing the precision surgery of revascularization of the heart (University of Southern California, 2005). This resulted in the conventional on- pump CABG surgery performed until recently. Currently, OPCABG surgery is once again being used owing to the adverse effects (refer to section 2.5.1) documented of CPB (Al-Ruzzeh *et al.*, 2006). However, studies conducted to date are still contradictory as to the advantages of OPCAB (Bull *et al.*, 2001).

Many advances in surgical procedures, technology and improved medical management have resulted in practice changes (University of Southern California, 2005). Surgical procedures in the 21st century include routine OPCAB surgery, smaller incisions (3–6 inches), routine use of arteries – specifically the internal mammary artery – for grafting, and normothermia during on pump CABG surgery (University of Southern California, 2005).

Technological advances currently incorporate robotic surgery, use of drug-eluting stents and transmyocardial laser revascularization, all of which are aimed at minimal invasive therapy for partial revascularization of arteries (Aupart *et al.*, 2003). Medical management too, has evolved with surgical procedures. Management of the CABG patient comprises of fast-track anaesthesia, early removal from mechanical ventilation, discharge from the ICU on the first post-operative day as well as early ambulation (Estafanous *et al.*, 1998). The effect of these practice changes on the outcome is still, however, debatable.

2.2.2 Developments in physiotherapy of CABG surgery patients

Historically, chest physiotherapy has been given prophylactically to all patients undergoing CABG surgery (Brasher *et al.*, 2003). The intention is to reduce the risk of post-operative pulmonary complications (Bourne & Jenkins, 1992; Stiller *et al.*, 1995; Hulzebos *et al.*, 2003; Brasher *et al.*, 2003). This is reportedly achieved by a treatment regime consisting of a combination of physiotherapy techniques. The latter includes deep breathing exercises (DBE), early mobilization, intermittent positive pressure breathing (IPPB), incentive spirometry (IS), positioning, and supportive coughing (Stiller *et al.*, 1995; Tucker *et al.*, 1996; Johnson *et al.*, 1996; Gosselink *et al.*, 2000; De Charmoy & Eales, 2000). However, several studies have failed to show the efficacy of these treatment techniques on post-operative pulmonary complications (PPCs) and length of stay (Dull & Dull, 1984; Jenkins *et al.*, 1994; Stiller *et al.*, 1994; Gosselink *et al.*, 2000; Brasher *et al.*, 2003). The abovementioned authors have questioned the effectiveness of the techniques used in the post-operative management in patients who have undergone uncomplicated CABG surgery.

A study conducted by Stiller *et al.* (1994) investigated the efficacy of breathing and coughing exercise after uncomplicated CABG surgery. In this study, a total of 120 patients were included in a randomized controlled trial. Patients were randomly allocated to one of three groups. The first group received no pre- or post-operative routine chest physiotherapy, except for post-operative shoulder girdle movements on the first and fourth post-operative day. The physiotherapy techniques used in both the second and the third group consisted of pre-operative education and instruction in breathing exercises. Post-operative supervision and assistance from the therapists when performing the aforementioned exercises were included. The second group

received physiotherapy bi-daily for the first two post-operative days and once daily on the third and fourth post-operative days. The third group received the same physiotherapy as the second group, but the frequency was increased to four times on the first two post-operative days and bi-daily on the third and fourth post-operative days. This study showed that clinically significant PPCs (acute respiratory failure, and chest infection) were not higher in the control group and suggested that prophylactic chest physiotherapy after routine uncomplicated CABG surgery should be reviewed.

In 2003, Brasher *et al.* conducted a study which investigated whether the removal of DBE from a regime of pre-operative education and early ambulation altered patient outcome after CABG surgery. A total sample of 230 patients was randomly allocated to one of two groups. All patients received pre- and post-operative physiotherapy. In the control group (breathing exercise group), patients were instructed to perform a set routine of DBE compared to the intervention group which did not perform this routinely. Mobilization was performed in both groups as soon as possible after surgery. Outcome measures in this study included: the incidence of PPCs, post-operative Length of Stay (LOS), pulmonary function tests, readmission rate, as well as post-operative oxyhaemoglobin saturation (SpO₂). The study showed no significant differences between the control and intervention group with respect to the aforementioned outcome measures. Therefore, the author concluded that the removal of DBE from the routine physiotherapy management did not adversely affect patient outcome after CABG surgery.

A review of the literature pertaining to cardiac surgery patients between 1977 and 1995 by South African authors De Charmoy and Eales (1997) also found that routine chest physiotherapy in the uncomplicated CABG surgery patient was not indicated.

This review included 11 studies which were aimed at investigating the efficacy of physiotherapeutic techniques in the prevention of PPCs after CABG surgery. Many of the studies were shown to be of poor quality as clarity with regard to definition and detailed intervention was lacking in most, and only two studies had control groups. Furthermore, the outcome measures varied greatly amongst studies. Thus, it could be argued that the reliability of the findings of these studies, that routine chest physiotherapy after uncomplicated CABG surgery is ineffective, is questionable and therefore inconclusive.

This opinion was also highlighted by Pasquina *et al.* in 2003. Following their systematic review of prophylactic respiratory physiotherapy after cardiac surgery, they concluded that the efficacy of treatment techniques such as IPPB, IS, physical therapy and CPAP, was inconclusive. These authors suggested that more randomized control trials were needed, with no intervention controls, to prove the effectiveness of treatment techniques used to reduce the risk of PPCs in uncomplicated CABG surgery patients.

In 1996, Tucker *et al.* conducted a questionnaire survey regarding the management, of patients undergoing CABG surgery in Australia and New Zealand. The aims of the study were to identify the management of CABG patients, the criteria used to identify those patients at high risk for the development of PPCs after CABG surgery, and the rationale for treatment choice. The questionnaire was distributed to 42 hospitals across both countries in both public and private hospitals. A total of 35 (response of 83%) completed questionnaires were analyzed. In both of these countries, physiotherapy was reported to be part of the medical management and was performed on those patients identified as having a high risk for the development of

PPCs. These risk factors were identified pre-operatively by the therapists and included the following: pre-existing pulmonary dysfunction, smoking history, pre-existing mobility/neurological disorder and body weight (Tucker *et al.*, 1996). Nearly 90% of respondents indicated that all patients received physiotherapy as they were pre-operatively identified as having a higher risk for the development of PPCs. In the institutions where patients were not treated post-operatively, therapists had excluded the patients on the basis that they had an uncomplicated post-operative recovery.

The recent review by Pasquina et al. (2003) showed that the rationale for treatment choice was largely influenced on personal choice and that recommendations, hospital policy and financial constraints had minimal influence on physiotherapy treatment choice". Furthermore, this view is supported by Tucker et al. (1996) and Brasher et al. (2003) who found that, although indicating that recent literature influenced treatment choice, it was not reflected in practice as most patients were treated with DBE and cough post-operatively. The authors suggest that a possible reason for physiotherapists not being guided by the findings of recent studies is due to "the perceived difference between the patients in the studies conducted by Stiller et al. (1994) and those treated by the physiotherapists in the survey". According to Tucker et al. (1996), therapists felt that the baseline profile of for example: age, severity of CAD, duration of CPB and left ventricular function, of their patients differed from those patients studied by Stiller et al. (1994), thus requiring physiotherapy after CABG surgery.

2.3 RISK SCORES DEVELOPED FOR CABG PATIENTS

"careful study of cardiac patients' demographics is essential as it impacts on patient management at every stage of care".

Aggarwal et al., 2006

Demographic studies of CABG patients allow surgeons to better identify patients who are at greater pre-operative risk for mortality as well as morbidity with CABG surgery. Estafanous et al. (1998) conducted a study in which they sought to compare preoperative risk profile of patients who underwent CABG surgery during two separate periods. The first period was July 1986–June 1988 and the second period from January 1993–March 1994. The study compared the changes between the two groups with respect to pre-operative risk factors, overall and risk-adjusted morbidity and mortality rates, and intensive care unit length of stay. These authors used the National Cardiovascular anaesthesia registry to obtain the abovementioned information. The study showed that pre-operative risk scores for patients in the second period were significantly higher than during the first period (1986–1988). However risk-adjusted morbidity for major cardiac, renal, neurologic, pulmonary, serious infection and ICU length of stay for the second group, was significantly lower while mortality rates were similar in both groups. Estafanous et al. (1998) contributed the lower morbidity with higher-risk patients to improvements in surgical technique, better anaesthesia management, and post-operative care. Thus, it is evident from this early research that the profile of patients undergoing CABG surgery was changing overtime.

2.3.1 Current international profile of the CABG patient

Octogenarians and septuagenarians are the fastest growing sector of the USA population and other westernized countries, such as Japan and Spain, have also reported a growth in their older population (Engoren *et al.*, 2002; Fuster *et al.*, 2005). According to Engoren *et al.* (2002), "40% of this elderly population have symptomatic heart disease". Older patients also have more coexisting problems such as renal disease, peripheral vascular disease, diabetes and chronic obstructive pulmonary disease (Engoren *et al.*, 2002; Abramov *et al.*, 2000; Ghali, 2003). Thus, future patients are anticipated to have a higher risk for mortality after CABG surgery.

A study conducted by Fuster et al. (2005) investigated whether the patients undergoing CABG surgery were indeed older with more comorbidities and, therefore, at higher risk for mortality. In this retrospective study, the sample consisted of 1 360 patients who underwent CABG surgery between 1993 and 2001 at a single centre in Spain. The sample was divided into three cohorts namely: 1993–1995, 1996–1998 and 1999-2001. Demographic results over the nine-year period showed an increase in the mean patient age as well as an increase in the number of female patients undergoing CABG surgery. Comorbitdities such as hypertension, diabetes mellitus (type 1), Peripheral Vascular disease (PVD) and Chronic Obstructive Pulmonary Disease (COPD), were also more prevalent in the later cohorts. These findings were similar to an earlier prospective study conducted by Abramov et al. (2000). The aforementioned authors also investigated the demographics of patients (n=4,839) undergoing CABG surgery over three time cohorts namely: 1990–1992, 1993–1995 and 1996–1998. Their study showed that their population of CABG patients was older and had more comorbidities in the later cohorts. Similar, decreased mortality and

morbidity rates were found in the studies conducted by Abromov *et al.* (2000) and Fuster *et al.* (2005). Abramov *et al.* (2000) attributed this decline to the increased usage of the left internal mammary artery (LIMA) and warm blood cardioplegia in the later cohorts.

However, a recent study by Aggarwal *et al.* (2006) contradicts the assumption that patients in the 21st century have higher-risk profiles. When compared to the sample of Abramov *et al.* (2000), the study showed that patients in their study were not significantly older and did not have more comorbidities. However, Aggarwal *et al.* (2006) acknowledged that these results could be institution-based and due to their centre's specific surgical and management procedure. The centre's operative procedure included fast-track anaesthesia, sternal incision, warm cardioplegia and use of more than one artery, commonly the LIMA.

Currently there is no literature available describing the profile of South African CABG surgery patients. The above demographic studies have all been conducted in developed countries such as America and may, therefore, not be applicable to developing countries such as SA. As demographics have an effect on all aspects of management, physiotherapists in this country would need to know what possible differences in populations may imply regarding the provision of care.

2.3.2 Risk scores for mortality

As early as the 1970s, several studies were undertaken to develop a risk stratification method that would be able to predict the risk for mortality following adult cardiac surgery. The development of risk scores was seen as an essential tool for risk

assessment, cost-benefit analysis, as well as the study of effectiveness of therapy and trends in medical management (Geissler *et al.*, 2000). These risk stratification methods, although able to predict operative mortality for cardiac surgery, were not widely used.

This was largely due to the instrument requiring detailed data that was not always readily available. Successful use of these initial risk scores was dependent upon resources and the availability of personnel to collect and process such data, which was costly and thus not for universal application (Parsonnet *et al.*, 1989). The aforementioned authors undertook a study to develop a uniform way for surgeons and hospitals to identify patients at risk for mortality after adult cardiac surgery. The study was conducted retrospectively using data from an existing New Jersey (USA) data base. The data of a total of 3 500 consecutive patients who had undergone openheart surgery was included, covering a five-year period (1982–1987). Through univariate analysis, 15 variables were identified as risk factors that were significant in predicting mortality within 30 days after cardiac surgery. The study only included variables which fulfilled the following criteria:

- 1) predictive value was demonstrated by univariate analysis;
- 2) data was available for every patient;
- 3) data had to be available at each hospital;
- 4) the variable had to be free of bias as far as possible; and
- 5) the variable had to be simple and direct and not derived from other information.

The method was then tested prospectively on a sample of 1 332 patients who had undergone open-heart surgery at a single centre (Newark Beth Israel Medical

Center). Using the risk factors, patients were categorized into five groups of increasing risk, namely: good (0–4%), fair (5–9%), poor (10–14%), high (15–19%) and extremely high (≥20%). The results of this risk stratification method showed a 0.99 correlation coefficient for predicting operative mortality. Operative mortality in this study was defined as death occurring within 30 days of the surgery. This method was then implemented at two other hospitals and, although sample size in both these hospitals was smaller, the outcome in each risk group was comparable to the initial centre.

Various other risk scores, such as the Euroscore (Nashef *et al.*, 1999) Cleveland Clinic score (Kurki *et al.*, 2002), French and Pons scores were subsequently developed over the next decade (Geissler *et al.*, 2000). Further development of risk scores was done to establish whether the earlier risk score (Parsonnet *et al.*, 1989) was applicable to a population other than the one for which it was developed. In the review done by Geissler *et al.* (2000), six commonly used scoring systems for mortality were compared for validity and use in different populations. These were the following:

- 1. Initial Parsonnet Score;
- 2. Cleveland Clinic Score;
- 3. French Score;
- 4. Euroscore;
- 5. Pons Score; and
- 6. Ontario Province Risk Score

The Euroscore, which was developed by European Cardiothoracic surgeons, was identified as yielding the highest predictive values for mortality (Geissler *et al*, 2000) and will be outlined next.

The Euroscore focuses specifically on three main categories, namely patient-related, cardiac-related and operation-related factors (see Appendix A). In each category, risk factors were allocated a number and these numbers were added to give an approximate per cent predicted mortality for the procedure. The Euroscore has also been validated in South African on a population that have undergone CABG surgery by Swart and Joubert (2004). In this study, all patients who underwent CABG surgery by a single surgeon at three hospitals in Bloemfontein South Africa, were scored for operative mortality using the Parsonnet, Cleveland and Euro scores. Swart and Joubert (2004) concluded that the Euroscore is the preferred risk model even outside the original database (European population) for which it was designed. It is on this finding, when developing the structured initial assessment form for this study, that the researcher incorporated appropriate items such as: age, gender, left ventrical ejection fraction, preoperative creatinine and emergency surgery from the Euroscore.

2.3.3 Risk of morbidity after CABG surgery

The aforementioned scores enable one to categorize patients into high- or low-risk groups for mortality. However, morbidity has been acknowledged as the major determinant of hospital cost and quality of life after heart surgery (Higgins, 1998; Hulzebos *et al.*, 2003). Post-operative pulmonary complications (PPCs) still contribute to patient morbidity as well as mortality, length of stay and overall use of resources

despite the advances in pre-operative care (Brooks-Brunn, 1995; Hulzebos et al., 2003)

Hulzebos *et al.* (2003) developed a risk model in order to assist clinicians to evaluate pre-operative risk factors which could predict morbidity in patients undergoing CABG surgery. According to Hulzebos *et al.* (2003), their model would enable clinicians, including physiotherapists, to identify those patients at higher risk for developing PPCs after CABG surgery. Their sample consisted of 117 patients who underwent elective CABG surgery at a single centre over a one-year period. Based on the definitions for risk factors by the Society of Thoracic surgeons and a review conducted by Brooks-Brunn (1995), the following pre-operative risk factors were indentified:

- ➤ Age
- Gender
- Body Mass Index (BMI),
- Pulmonary functions (i.e. Inspiratory Vital Capacity, Forced Expiratory Volume,
 Maximal Expiratory Pressure and Maximal Inspiratory Pressure)
- Diabetes mellitus
- Productive cough
- Chronic Obstructive Pulmonary Disease (COPD)
- History of cigarette smoking
- ➤ A class 3 or 4 score on the Specific Activity Scale

The study showed that advanced age (≥70yrs), productive cough with sputum, a history of cigarette smoking (8 weeks prior to surgery), and diabetes mellitus were

pre-operative risk factors predictive of the development of PPCs. In addition, this study also identified two pre-operative protective factors against the development of PPCs after CABG surgery. The protective factors were: a predicted inspiratory vital capacity of ≥75% and a predicted maximal expiratory pressure of ≥75%. These findings have, however, not been validated as this study has not been replicated in other populations.

2.4 OUTCOMES OF CABG SURGERY PATIENTS

"Measuring patient outcomes after cardiac surgery is a complex process that continues to evolve as clinicians and researchers refine outcome measurement methods".

Barnason et al., 2000

During the early developments in cardiac surgery, broad outcome measures such as mortality and morbidity were conventionally measured after cardiac surgery (Barnason *et al.*, 2000; Eales *et al.*, 2005). Other commonly-reported outcome measures include perceived psychological well-being, return to work and return to daily activities (Barnason *et al.*, 2000).

This section will only discuss three of these namely: mortality (Katz et al, 1995), length of stay (Peterson *et al*, 2002) and quality of life (Hunt *et al*, 2000) after CABG surgery. These outcomes have been chosen as they are the most commonly reported after CABG surgery and are likely to have implications for the management of patients by physiotherapists.

2.4.1 Mortality

The main objective of CABG surgery is to reduce mortality. Other aims of this intervention include relieving symptoms of coronary arteries disease such as angina, as well as improving the patients' quality of life (Eales *et al.*, 2005). According to Abramov *et al.* (2000) and Fuster *et al.* (2005), the increased risk profile of CABG surgery patients has not led to an increase in mortality (refer to section 2.3.1). These authors suggest that improvements in surgical and medical management of these high risk patients have mitigated the expected increase in mortality. A study conducted by Aggarwal *et al.* (2006) also investigated the pre-operative risk profile of current CABG surgery patients and found that his population was not getting older as in the studies conducted by Abramov *et al.* (2000) and Fuster *et al.* (2005). However, he found that mortality rates were unchanged.

Mortality after CABG surgery is an outcome and can be measured at different time points (Karachi *et al.*, 2005). Common time end-points measured by researchers are I.C.U or in-hospital survival, 30-day, three months, six months (Barnason *et al.*, 2000), and one year (Eales *et al.*, 2005) after surgery.

2.4.2 Length of Stay (LOS)

Efficient use of health care resources is receiving more attention as health insurers are constantly investigating ways to diminish the cost of expensive elective procedures such as CABG surgery. Post-operative length of stay has long been identified as "one of the chief drivers of hospital resource consumption by CABG surgery patients" (Peterson *et al.*, 2002).

A study done by Lazar *et al.* (2001) found that, prior to the re-establishment of fast-tracking in the mid 1990s, average LOS for patients undergoing CABG surgery was $9.2 \text{ days} \pm 4.3 \text{ compared}$ to the $5.4 \text{ days} \pm 2.5 \text{ nearly}$ a decade later. In this study, the authors analyzed the discharge patterns of patients who had undergone CABG surgery in two different periods. The earlier period was prior to the use of fast-tracking, which was compared to the second period which was after the implementation of fast-tracking. According to the authors, patients in the second group were discharged earlier from acute care facilities. However, this did not translate into early discharge home, as patients on average spent $10 \pm 15 \text{ days}$ in a step-down facility.

In developed countries such as America, Britain and Australia, where fast-tracking is the norm, the average LOS ranged from six to eight days after uncomplicated CABG surgery (Wynne 2004). In South Africa, there is a lack of published literature stating the average LOS for patients after uncomplicated CABG surgery as well as the routine use of fast-tracking.

2.4.3 Quality of Life (QoL) after CABG surgery

CABG surgery is aimed at improving not only survival but also quality of life. For several decades, quality of life (QoL) has been the key end-point of adult cardiac surgery. According to Järvinen *et al.* (2003), survival of surgery does not necessarily translate to an improvement in QoL. QoL is an objective measurement to assess a patient's outcome after CABG surgery. It encompasses aspects of a patient's life such as family, education, sport/hobbies, social responsibilities, financial and health

status. All these areas affect a patient's perception of his or her QoL (Charboyer *et al.*, 2004; Eales *et al.*, 2005; Mishoe and Maclean, 2001; Karachi *et al.*, 2005).

However, current studies have shifted their focus to more functional end-points and resumption of patients to daily activities which are defined as Health related Quality of Life (HRQoL) (Järvinen *et al.*, 2003). HRQoL is defined as a subjective indicator of QoL for patient outcomes (Eales *et al.*, 2005; Barnason *et al.*, 2000). It includes aspects such as emotional, social, psychological, physical and mental status of the patient (Barnason *et al.*, 2000). It is essential that clinicians incorporate both these aspects when evaluating outcomes for CABG surgery patients.

2.5 FACTORS AFFECTING THE OUTCOME OF CABG SURGERY PATIENTS

Measurement of cardiac surgical patients' outcomes is necessitated in determining cardiac surgery efficacy as a treatment of coronary artery disease (Barnason *et al.*, 2000). However, there is some controversy in the literature regarding what should be measured as on outcome after CABG surgery. Factors affecting patient outcome after CABG surgery are multi-factorial and many relate to the pathophysiology of cardio-pulmonary bypass (CPB), which will be outlined next.

2.5.1 Pathophysiology of Cardio-Pulmonary Bypass with CABG surgery

Cardiac surgery, since its successful application with Cardio-Pulmonary Bypass (CPB), has been associated with post-operative cardiovascular instability and organ dysfunction (Murphy & Angelini, 2004; Massoudy *et al.*, 2001). The organs affected commonly are the kidneys, brain, heart and the lungs. During CPB and aortic cross-clamping, both the heart and lungs are excluded from the circulation. This results in

only the bronchial arteries supplying nutrients to the lungs. When the aortic cross-clamp is released, reperfusion of the heart leads to a Systemic Inflammatory Response (Massoudy *et al.*, 2001). Although neurological complications such as stroke after CABG surgery do have implications for the physiotherapy management of the patient, this study will concentrate on the pulmonary changes prevalent with CPB.

Physiological changes in the lung are primarily due to abnormal gas exchange and poor lung mechanics (Ng et al., 2002). According to Weissman (1999), changes in lung mechanics during cardiac surgery cause a reduction in vital capacity (VC), functional residual capacity (FRC) and static and dynamic lung compliance. Parameters of assessment of abnormal lung function are commonly measured through alveolar-arterial oxygen pressure gradient (P{A-a}O₂), intrapulmonary shunt, degree of pulmonary oedema, lung compliance, and pulmonary vascular resistance (Ng et al., 2002; Bull et al., 2001).

Several studies investigating the effect of on-pump versus off-pump CABG surgery on lung dysfunction are contradictory. Ng *et al.* (2002) reported that off-pump CABG surgery was related to a reduced inflammatory response and thus may lead to less impaired post-operative pulmonary dysfunction. A study conducted by Montes *et al.* (2004) in South America (Colombia) investigated the affects of OPCAB vs on-pump CABG on pulmonary function. The sample consisted of 39 adult patients undergoing CABG surgery with or without CPB. According to Montes *et al.* (2004), off-pump CABG did not offer any protection from pulmonary dysfunction. The aforementioned author suggests that further research into the strategies on how to reduce pulmonary

complications after CABG surgery, would be better directed towards factors such as surgical procedure and the effects of anaesthesia.

2.5.2 Development of Post-operative Pulmonary Dysfunction (PPD) and Postoperative Pulmonary Complications (PPC)

The contribution of Post-operative Pulmonary Complications (PPCs) to patient morbidity and mortality was recognized with the advent of cardiac surgery (Wynne, 2004; Pasquina *et al.*, 2003). The term Post-operative Pulmonary Complication (PPC) is commonly used interchangeably with that of Post-operative Pulmonary Dysfunction (PPD). However, according to Wynne and Botti (2004), these terms are two separate entities. Weissman (1999) stated that a PPD refers to the expected changes in pulmonary function after surgery. Thus, all adults who undergo surgery are at risk of having a PPD. Cardiac surgery changes pulmonary mechanics, by virtue of the procedure, which includes median sternotomy, cardio-pulmonary bypass, and depressed cardiac function (Weissman, 1999; Montes *et al.*, 2004).

PPDs are associated with abnormalities in gas exchange, alterations in lung mechanics or both. These changes, which occur during CABG surgery with respect to gas exchange, are a result of the widened alveolar-arterial oxygen gradient, increased pulmonary vascular resistance, increased pulmonary shunt fraction, as well as intrapulmonary aggression of leukocytes and platelets (Wynne & Botti, 2004; Massoudy *et al.*, 2001). Alteration in lung mechanics during cardiac surgery is due to reduction in Vital Capacity (VC), Functional residual Capacity (FRC) and static and dynamic lung compliance (Weissman, 1999; Wynne, 2004). PPD results in shallow respirations, increased work of breathing, an ineffective cough and hypoxemia

(Wynne & Botti, 2004). These clinical manifestations are usually transient in patients with uncomplicated CABG surgery (Smetana, 2000; Wynne & Botti, 2004).

However, the confusion in current literature relates to the clinical manifestations of PPD, which can range from hypoxemia, which is present in >70% of patients, to full blown Acute Respiratory Distress Syndrome which is noted in less than 2% of patients undergoing on-pump CABG (Ng *et al.*, 2002; Montes *et al.*, 2004). However, Post-operative Pulmonary Dysfunction (PPD) may develop into a PPC (Hulzebos *et al.*, 2003; Wynne, 2004). According to the latter author, there is no current literature available to determine when a PPD becomes a PPC. It has been suggested that the transition from a PPD to a PPC occurs when abnormalities of gas exchange, altered lung mechanics, or both cause an identifiable disease which is clinically significant and which adversely affects the clinical course of the patient (Wynne, 2004). Hulzebos *et al.* (2003), however, defined PPCs according to clinical, radiologic and Centres for Disease Control and Prevention (CDC) criteria for bronchitis, atelectasis and pneumonia.

It could be argued that speculation in the literature as to when a PPD becomes a clinically significant PPC might be the "missing information or link" in the development of standardized definitions PPCs. Identifying the key components to this progression might be beneficial to physiotherapists in identifying those patients who are at risk for developing a PPC and, therefore, might require physiotherapy interventions.

PPCs after cardiac surgery can contribute to increased length of stay and, therefore, cost of health care (Brooks-Brunn, 1997; Pasquina *et al.*, 2003). Common PPCs

which are experienced by cardiac patients post-operatively and which are treated by physiotherapists include diaphragmatic dysfunction, atelectasis, pneumonia and pleural effusion (Wynne, 2004; Pasquina *et al.*, 2003). The incidence of these PPCs, range from 6–88% after cardiac surgery (Wynne, 2004). The variability in incidence of these PPCs can be attributed to "the inconsistencies in diagnostic and subsequent outcome definitions" (Wynne, 2004). Although each complication has a specific definition, the contradiction lies in the measurement of the individual variable as well as the discrepancies in the way in which the variable is combined to form a diagnosis. These discrepancies have implications not only for the interpretation of research but the also the management of PPCs (Wynne, 2004). This variability of definitions might be a reason why clinicians are unable to identify those patients who may benefit from their intervention.

Reporting of PPCs has also been problematic as there are few objective measurement tools. PPCs such as ventilator associated pneumonia (VAP) are commonly reported by either Clinical Pulmonary Infection Score (CPIS) or by radiological (CXR) findings. The CPIS, which is a scoring system developed especially for the prediction of ventilator associated pneumonia, uses six clinical and laboratory values (Schurink et al, 2004). These variables are: increased temperature, blood leucocytes, tracheal secretions, oxygenation (PAO₂ / FiO₂,) chest X-ray and culture of tracheal aspirate (Schurink *et al.*, 2004). Another discrepancy in the predictability of the CPIS is that it does not identify transient or self-limiting problems. Similarly, radiological reports alone do not allow clinicians to differentiate between transient and significant PPC. Clinically significant PPCs such as pneumonia could

change the clinical course of the patient and result in a lengthened hospital stay (Hulzebos *et al.*, 2003).

In this study, the measurement tool chosen to report on PPCs was radiological (CXR) findings. The reason for this choice was that CXR are relatively inexpensive when compared to Computerized Tomography (CT Scan) and routinely taken on the first, third and fifth post-operative day, as well as on the day of discharge (Narayan *et al.*, 2005; Bonacchi *et al.*, 2001). The use of CXR in reporting on PPCs has also been documented in several studies (Thomas *et al.*, 1997; Tenling *et al.*, 1998; Gust *et al.*, 1999; Bonacchi *et al.*, 2001). It is, however, important to recognize that the use of CXR, although alerting the clinician to the presence of a complication, cannot report on "clinical significance" of the complication.

2.5.3 Fast-tracking

Fast-tracking is an approach to cardiac surgery which entails the accelerated progress from admission, through surgery, to discharge. The essential components of the fast-track approach are: the use of short-acting anaesthetic drugs, standardized surgical procedures, early extubation, re-warming and sustained post-operative normothermia, post-operative pain control, early ambulation, alimentation and discharge, and follow-up after discharge (Pande *et al.*, 2003).

As early as the 1970s and throughout the 1980s, small clinical trials were being conducted on the safety of early extubation (London *et al.*, 1997; Cheng, 1996). The procedure of early extubation was facilitated by the use of lower dosage of intravenous anaesthetics for patients undergoing CABG surgery (Cheng, 1996).

During the 1980s, the routine use of high doses of intra-operative and post-operative opiates was common practice. This resulted in patients being intubated for at least 12 hours after surgery (Arom *et al.*, 1995).

Krohn *et al.* (1990) demonstrated that a pathway using family education, early extubation, pharmacologic adjuvant (including peri-operative steroids), aggressive mobilization (mobilization out of bed on the day of surgery), ambulation, and early hospital discharge (within seven days) was possible and safe. His study of 240 patients showed that less than 3% were re-admitted within six months of discharge, with a median LOS of four days. Despite these findings, his approach was not readily adopted until the early 1990s, when a study conducted at the Baystate Medical Center used a similar protocol and obtained similar positive results. Due to increased emphasis on cost containment from health care providers, fast-track management of cardiac surgery patients has become the norm in the 21st century (Gravlee, 1998; Quigley *et al.*, 1997).

2.5.4 Length of intubation

Prolonged duration of mechanical ventilation with CABG surgery patients is no longer necessitated due to the improvements in both intra- and post-operative care (Jacobsohn *et al.*, 1999). This is largely due to the introduction of fast-tracking in the early 1990s as a key feature of cardiac surgery programs (refer to section 2.5.3).

Prior to 1995, overnight mechanical ventilation for CABG patients was routine clinical practice (Arom *et al.*, 1995). Early findings from studies conducted by Higgins (1992) showed that early extubation, within four hours after surgery, was safe. Similar results

were found by Konstantakos and Lee (2000), who conducted a study on early extubation of 412 isolated CABG surgery patients. Early extubation in this study was defined as extubation within eight hours of ICU admission. Patients were allocated to one of two groups, namely those extubated in less than four hours and those extubated within four to eight hours. Results showed that patients who were extubated within less than four hours were discharged earlier from ICU and overall LOS.

In contrast to the above studies, a study conducted by Nicholson *et al.* (2002) found that short-term mechanical ventilation did not adversely affect post-operative pulmonary function when compared to early extubation. In this prospective randomized study, the population consisted of 35 patients undergoing CABG surgery. Patients were randomly allocated to one of two groups. The first group was extubated as soon as possible whereas the second was ventilated for a minimum of three hours. Both groups were only extubated if they reached predetermined extubation criteria. Although his study found that short-term mechanical ventilation did not affect pulmonary outcomes (VC, FEV₁, TLC, FRC), it must be noted that the sample size was small and cannot necessarily be inferred to the broader patient population.

Duration of intubation also has cost implications as the patient is monitored continually. Previous studies pertaining to cost-effectiveness of cardiac surgery advocate early extubation and discharge from the I.C.U. (Arom *et al.*, 1995; Konstantakos & Lee, 2000). It is well established that CABG surgery is one of the most expensive elective surgeries and that most of this cost is incurred in the ICU stay (Doering, 1997).

2.6 CONCLUSION

In conclusion, the various aspects discussed in the literature review aids the profile and selected outcomes of CABG surgery patients. Research in developed countries with regard to profiles, risk factors and outcomes of CABG patients is numerous. However, the current literature is still equivocal with regard to the optimal outcome measures used after CABG surgery. It is also important to note that current literature is conducted mainly in developed countries and their findings may therefore not be applicable to developing nations such as South Africa.

CHAPTER 3:

METHODOLOGY

3.1 INTRODUCTION

In this chapter, the methodology used to answer the research question will be described in detail. This will encompass, firstly, the research setting to provide the background against which the study took place. The sampling procedure, instrumentation, piloting of the instrument, procedure followed for collection of data, statistical analysis and ethical considerations will then be set out in detail.

3.2 RESEARCH SETTING

Coronary Artery Bypass Graft (CABG) surgery is highly specialized. In South Africa, as in developed countries, this specialized service is available from both state and private institutions. In the Cape metropolitan area there are six private and two state hospitals which provide CABG surgery.

This study was conducted in five of the six private hospitals and in both state hospitals in the Cape Metropolitan Area which currently provide cardiothoracic surgery, specifically CABG surgery. The sixth private hospital was not included in this study as the cardiothoracic unit at this hospital was not operational at the time of the submission of the study proposal. For the purpose of this study, hospitals 1–5 will refer to the private hospitals and hospitals 6–7 to the state hospitals.

In 1994, the government of national unity created a unified but decentralized national health system based on the District Health System (DHS) model (White Paper on the Transformation of Health System, 1994). This model made provision for the more equal distribution of health services by means of Health Districts (HD), which coincide with municipal boundaries (Department of Health Annual Report, 2001/2002). The Cape Metropolitan Area consists of 11 such health districts (see Addendum B). These districts are serviced by the two state tertiary hospitals. However, neighbouring provinces such as the Eastern and Northern Cape, who are without tertiary hospitals, also refer patients to these two state institutions.

The private hospitals, unlike the state hospitals, are not restricted to providing their specialized services according to municipal boundaries, with the result that patients may be referred from any geographic area, even from neighbouring states. Thus, the inclusion of both the state and private hospitals in this study allowed for variety, not only in socio-economic data, but also in diverse cultural and demographic data.

3.3 AIM OF THE STUDY

The aim of the study is to describe the profile and selected outcomes of CABG patients admitted in the Cape metropolitan area.

3.4 OBJECTIVES OF THE STUDY

The objectives of the study are to describe and determine the:

- demographics of CABG patients;
- pre-operative medical status of the patient with respect to cardiac; renal,
 diabetic and pulmonary status;

- health behaviour of patients prior to CABG surgery with regard to smoking and activity level;
- profile of CABG patients in both state and private hospitals in the Cape metropolitan area; and
- following selected outcomes of CABG patients:
 - o mortality rate;
 - intra-operative length of anaesthesia;
 - o length of intubation;
 - o incidence of PPCs;
 - o re-intubation rate; and
 - o length of stay (LOS).

3.5 STUDY DESIGN

A multicentre prospective cohort observational study design was used.

3.6 POPULATION

The population consists of all patients who underwent isolated CABG surgery at the seven hospitals which provide this service in the Cape Metropolitan Area.

3.6.1 Sample

All patients who underwent isolated CABG surgery in the Cape metropolitan area, whether elective or emergency during the period of 15 August 2005–15 November 2005 were included in the sample. In consultation with the statistician, a preliminary analysis of 100 patients proved to be too small a sample size for any correlations or inferences to be made, and he recommended that a total of more than 200 patients

would allow correlations to be made. During the data collection period, a total of 245 patients were sampled. The researcher was able to collect data for a sufficient number of patients in both the private (n=187) and public (n=58) institutions to allow for comparison between these two groups of patients.

3.6.2 Sampling procedure

Two sampling procedures were followed during the data collection period. This occurred due to the prevailing administrative systems at the respective hospitals.

Sampling procedure one took place at hospitals six and seven as well as at private hospital number four. At these hospitals, patients scheduled for elective CABG surgery were identified daily by physiotherapists from a theatre list which was available at the nursing stations of both the admission ward and the cardiothoracic intensive care unit (ICU). Emergency surgery patients were added manually to this list by the ward/ICU nursing staff.

Sampling procedure two was followed at the remaining four hospitals (i.e. hospitals one, two, three, and five), where the patients undergoing either elective or emergency surgery were identified by the physiotherapists from the patient register book kept in the cardiothoracic intensive care unit.

3.7 INSTRUMENTATION

In consultation with the physiotherapy practices involved in the cardiothoracic units, it was established that both the state and private hospitals provide daily chest physiotherapy for all patients undergoing CABG surgery. To facilitate data collection,

a structured initial assessment (SIA) form was developed in consultation with these practices (see Addendum C).

3.7.1 Development of the Structured Initial Assessment (S.I.A) form

A structured initial assessment (SIA) form was developed by the researcher for the purpose of this study. Based on current literature, the researcher developed a first draft document that included the following categories:

- demographic data (age, sex and BMI);
- medical status, which consisted of cardiac, renal and pulmonary status prior to surgery based on the Euroscore (Geissler et al., 2000) as a predictor of risk level and/or mortality;
- intra- and post-operative information which included anaesthetic time and duration of intubation, level of activity, and Post-operative Pulmonary Complications (PPCs) (Hulzebos *et al.*, 2003) as predictors of morbidity. PPCs would be recorded when diagnosed clinically by the attending surgeon (refer to 2.5.2.); and
- inclusion of race, which was based on South African studies done on chronic disease of lifestyle (Medical Research Council, 2001).

This first draft document was then distributed amongst all the physiotherapy practices at the seven hospitals where further information from focus group discussions was added. All information gathered was then collated by the researcher into a form which was named the structured initial assessment (SIA) form. The SIA form would thus allow the researcher to obtain the same categories of information at the various

hospitals (see Addendum C). The SIA form was colour-coded for easy comparison of information between the seven hospitals.

3.7.2 Pilot study

A pilot study was completed a month prior to the commencement of the study. The aim was to ascertain the following:

- ease or degree of difficulty with which the therapists could extract relevant information required to complete the SIA form; and
- time taken for therapists to complete the SIA form.

Therapists were also asked to give verbal and or written feedback regarding any further suggestions.

The following feedback was obtained from the pilot study:

- The physiotherapists reported that they could easily extract the relevant information required to complete the SIA form, excluding reporting of PPCs. Therapists reported that the diagnosis of PPCs by surgeons was not consistently documented. Also noted by therapists was that carbon copy paper provided with each SIA form notebook, distorted information documented.
- The time taken to complete the form was not more than five minutes.

Following the pilot study, the following amendments were made to the SIA form:

➤ Instead of using carbon copy paper with each notebook, self-carbonating books were printed as the latter did not distort the information documented.

- An option of "other" was included in the section on pre-operative cardiac status as the therapists wanted to know about any previous cardiac history.
- ➤ Radiological reports were subsequently used to report on the diagnosis of PPCs. In hospitals 1–6, radiological reports were done routinely for all patients when X-rays were requested. Surgeons requested chest X-rays (CXR) routinely post-extubation, post-drain removal and on clinical signs of complications. However, at hospital number 7 (where reports are not routinely given) reports were given retrospectively after a request by the researcher to the Radiology department (see Addendum G).
- ➤ Each book was coded with a study number range which ran in duplicate (e.g. 001–050) to ensure patient confidentiality.

3.8 PROCEDURE

In this section, the procedure followed by both the therapists completing the SIA form and the researcher collecting the SIA form will be described in detail.

3.8.1 Training of therapists

Training of therapists for correct completion of the SIA form took place after the pilot study. This was to ensure that all therapists were familiar with where to find the additional information, not routinely collected by them, for the completion of the SIA form.

At hospitals 6 and 7, physiotherapists rotated through various clinical areas. During the data collection period a total of three staff members at hospital 7 and two at hospital 6 were responsible for treating patients within the cardiothoracic intensive care unit and ward. The researcher explained to therapists where they could obtain the relevant information from patient documentation needed to complete the SIA form.

In total there were five private physiotherapy practices who serviced hospitals 1–5. Similarly, a session was arranged with each practice to show all members of the practice where to obtain the additional information.

The SIA form was provided by the researcher to each physiotherapy practice in self-carbonating notebook format. This was implemented so that the original copy, which is a legal document, would remain in the patients' medical records as proof of his or her physiotherapy management. Notebooks provided had the respective institutions/practices' names printed on the SIA form.

3.8.2 Routine physiotherapy procedure

Theatre lists and patient register books were consulted daily by the attending physiotherapists at each of the seven hospitals to identify those patients undergoing CABG surgery. Once identified, patients were allocated a SIA form (see Addendum C) instead of the practice's own form. This allowed practices to collect all relevant pre-operative medical information they usually would, but only in a more structured manner.

Therapists completed the categories concerning demographic, cardiac, renal, pulmonary, and health behaviour pre-operatively in all patients undergoing elective CABG surgery. In emergency patients, all information was collected post-operatively.

The SIA forms were also completed retrospectively by the attending therapist for those patients who had died intra-operatively.

Intra-operative information was collected by the attending therapist post-operatively. Extubation times were obtained from patients' ICU bedcharts. The occurrence of PPCs was checked daily by attending therapists. These were only reported if documented in radiological reports. Therapists were asked to document only the date of the initial occurrence of PPCs as diagnosed on CXR.

3.8.3 Research procedures

These were the procedures which attending physiotherapists did not routinely perform and included the allocation of study numbers, obtaining consent for patient participation into the study and storage of SIA forms.

3.8.3.1 Allocation of study numbers

The physiotherapists were requested to document the study number of the SIA form and the patient's folder number on a separate sheet provided by the researcher (see Addendum D). This allowed for later retrieval by the researcher, if any information was omitted.

3.8.3.2 Consent of patient participation

In hospitals 1–5, patients who were allocated with a SIA form were approached by the attending physiotherapists to obtain written consent (see Addendum E) for participation in this study. In hospitals 6 and 7, proxy consent was obtained from the

respective superintendents, prior to commencement of the study (see Addendum F)

Therapists filed consent forms in a secure cupboard within their practices.

3.8.3.3 Storage of SIA form

Both copies of the SIA form were kept in the patients' nursing folder for the duration of their hospital period. On discharge of the patient, the copy of the SIA form was removed by the attending therapist and filed at the respective physiotherapy practices for the researcher to collect.

3.9 DATA COLLECTION BY THE RESEARCHER

For the entire duration of the study, a copy of the theatre list was provided for the researcher on request. The researcher checked the theatre lists/patient register book against the separate data sheet (see Addendum D) kept by the physiotherapists on a weekly basis to ensure that all patients who underwent CABG surgery were included in the study. Any patients who were omitted from the abovementioned data sheet were then followed up by the researcher or the attending physiotherapist immediately if the patients were still in hospital or retrospectively if they had already been discharged.

Completed SIA forms were collected on a weekly basis from each hospital. Collected forms were checked for any omission of data by the researcher. In the event that data was omitted or the SIA form was not timeously removed from the patient's nursing folder on discharge, the researcher requested the patients' medical records.

In hospitals 1–5, requests for medical records of the patient was accompanied by a copy of the patients' written consent form. In hospitals 6 and 7 where proxy consent was obtained, however, only a request form with the patient's folder number had to be filled in.

In the event that the SIA form was allocated to a patient in hospitals 1–5 but no consent was obtained before discharge, the researcher telephonically contacted the patient to obtain consent to use the information on their SIA form anonymously, for the purpose of this research project. This was followed up by a consent form being faxed to the patient. A copy of these consent forms was then, once again, used to obtain medical records and complete the structured form. Data from completed SIA forms were then captured onto a spreadsheet developed in consultation with the statistician.

3.10 STATISTICAL ANALYSIS

For descriptive analysis, pie charts and histograms were used for visual presentation. Means and standard deviations were calculated where applicable. To determine relationships between different variables, the following statistical techniques were used:

- ANOVA: To determine possible differences in average measurements between various groups. In cases where it appeared that the ANOVA assumptions were violated, non-parametric bootstrap techniques were employed.
- Correlations: To determine the relationships between pairs of measurements.
- Linear regression: To determine the combined relationships between measurements for e.g. age and pleural effusion and LOS.

- Logistic regression: To determine the combined effects of measurements on a categorical variable.
- A p-value of less than or equal to 0.05 was used to indicate statistical significance
- Probability calculations (odds ratios) were calculated and significant risk was identified by 95% confidence limits around odds ratios where neither 95% confidence limits encompass the value of 1.

3.11 ETHICAL CONSIDERATIONS

Approval for the study was obtained through the Ethical Committee of the University of Stellenbosch, and furnished with project number: N05/04/072 (see Addendum H). As this was an observational study of non-therapeutic and non-invasive nature, a proxy consent was obtained from superintendents of the two state hospitals to review the records of all patients admitted to the cardiothoracic unit during the period 15 August 2005–15 November 2005 (see Addendum F). At all the private hospitals patient consent was obtained before including their data in the study (see Addendum E). Only hospital 4 gave a formal letter of recognition of the study in their hospital (see Addendum I). However, verbal consent was obtained from hospitals 1–3, as they were satisfied that the patients would sign individual consent forms (see Addendum E).

The structured documentation form collected by the researcher had no identifiable information on them, which was achieved by allocating a study code to each form. Collected data was kept confidential by means of study codes and reporting the results of the study anonymously. A separate datasheet was used to document the

folder number and corresponding study code only as a measure to retrieve missing information, and was destroyed by the researcher at the end of the data collection period (see Addendum D).

All information obtained remained confidential. The data obtained was entered into a computer and was scrambled (hidden) so that no one, including the researcher, knew the identity of the patient. The results of the study will be made available to all parties who participated in the study, namely the private physiotherapy practices, the physiotherapy departments at the state hospitals and hospital superintendents/managers.

CHAPTER 4:

RESULTS

4.1 INTRODUCTION

This chapter will describe the profile as well as the outcomes obtained from the total population of both state and private hospitals. Demographic data will be reported on first, followed by the pre-operative medical status, health behaviour, the pulmonary status of patients prior to CABG surgery as well as the difference in profile of patients in each hospital type. Subsequently, the selected outcomes specific to the study namely intra-operative length of anaesthesia, length of intubation, incidence of PPCs, re-intubation rate and total length of stay will be presented.

During the data collection period, a total of 254 patients were admitted to both state and private hospitals 1–7. More than 75% of the data collected was from private hospitals with the remaining 25% from state hospitals. Nine patients were lost during the data collection period; written consent was not obtained from seven patients; the hospital records of one patient were not retrievable, and one patient refused to participate in the study. Eight patients died during the data collection period. However, their information was still used in the study as consent had been obtained prior to surgery. Thus, the data of 245 patients were analyzed.

For ease of reading and clarity, the results will be presented in a specific order. Firstly, results for the total sample will de described followed by the differences

between state and private hospitals. For continuity, the results for the total population will be displayed graphically by means of histograms followed by pie charts (where possible) which will depict the results of the private and state hospitals respectively.

4.2 **DEMOGRAPHICS**

The demographics of this population which included age, gender, race and body mass index (BMI) is depicted in Table 4.1. As shown in Table 4.1, more than 75% of subjects were male and 69% were Caucasian. The mean age for the total sample was 60.9 years ±10 years.

 Table 4.1
 Demographics of population

	Number	Percentage (%)
AGE		
> <70yrs	199	81
> >70yrs	46	19
GENDER		
> Male	191	78
> Female	54	22
RACE		
> Caucasian	169	69
> Coloured	63	26
> Black	9	4
> Indian	4	2
ВМІ		
> ≤30 (normal)	160	66
> ≥30 (increased)	85	35

Interesting to note, is that none of the abovementioned variables other than race varied between state and private hospitals as seen below in Figure 4.1.

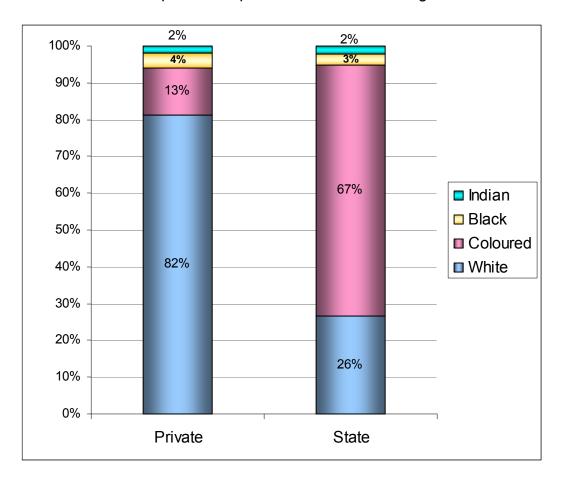


Figure 4.1 Race: Private vs State

Age and BMI between the hospital type(s) did not differ significantly as shown in Table 4.2. below.

 Table 4.2
 Differences in age and BMI per hospital type

Mean						
	Private (<i>n</i> = 187)	State (<i>n</i> = 58)				
Age	62.00 (±10.50)	59.00 (±9.70)				
ВМІ	28.44 (±4.40)	28.30 (±5.00)				

4.3 PRE-OPERATIVE MEDICAL STATUS

In the pre-operative medical status, patients' cardiac, diabetic, renal and pulmonary status prior to CABG surgery was recorded. These will be discussed in the following sections

4.3.1 Cardiac status

The incidence of unstable angina, hypertension and aortic stenosis for the sample is shown in Figure 4.2 below. Unstable angina was reported in 77% (n = 189) of the patients and hypertension was prevalent in 68% (n = 165) of the sample.

Both state and private hospitals had similar percentages of patients diagnosed with unstable angina. With regard to hypertension, the state sample n = 50 (86%) of subjects were diagnosed as hypertensive compared to n = 115 (62%) in the private institutions (Figure 4.3).

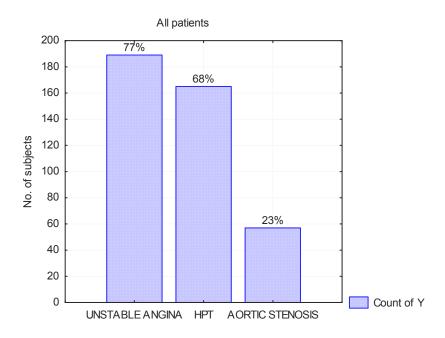


Figure 4.2 Pre-operative cardiac status

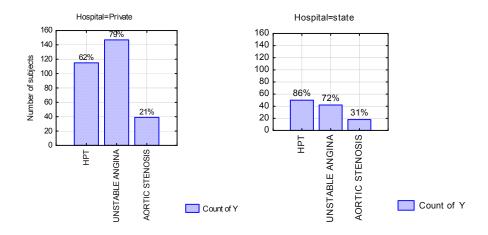


Figure 4.3 Pre-operative cardiac status: Private vs State hospital type

4.3.2 Diabetic and Renal status

Less than a third of this population (28%) was reported to have diabetes mellitus (Figure 4.4). There was no difference in patients' diabetic status in either of the institutions (Figure 4.5). Of the 245 patients, pre-operative creatinine levels were obtained in only n = 229 patients; the remaining 16 patients (5 state and 11 private) did not have pre-operative creatinine levels taken. The creatinine level for both the state and private hospitals patients were within the normal levels (mean = 98.0ul/mol).

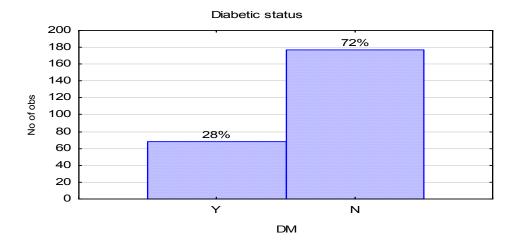


Figure 4.4 Pre-operative diabetic status

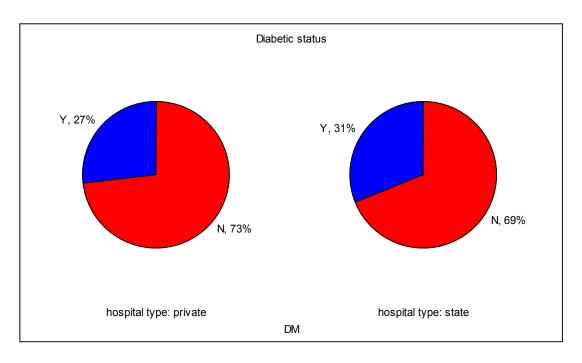


Figure 4.5 Diabetic status: Private vs State hospital

4.3.3 Pulmonary status

A description of the pulmonary status included the occurrence of asthma, COPD and a productive cough prior to surgery. Nearly half (45%) the population had an occurance of at least one of the aforementioned pulmonary status descriptors. Twenty four per cent of the population presented with a productive cough preoperatively, and only 14% presented with diagnosed COPD (Figure 4.6).

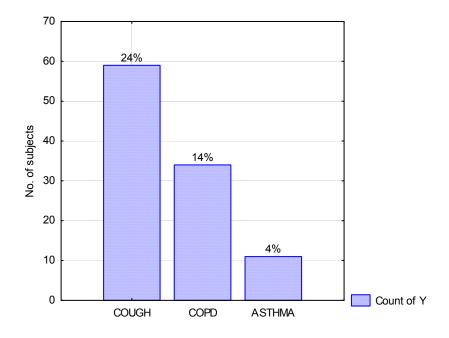


Figure 4.6 Pulmonary status pre-operatively

4.4 HEALTH BEHAVIOUR

Health behaviour describes the patients' physical activity level as well as smoking history prior to surgery.

4.4.1 Physical Activity

Patients were classified as having an either active or sedentary physical level. Active physical level was described as any structured or unstructured activities which were not part of daily activities such as housekeeping or gardening. Patients commonly described walking, cycling and gym as activities not part of their daily activities. Less common were swimming and sky-diving (Figure 4.7).

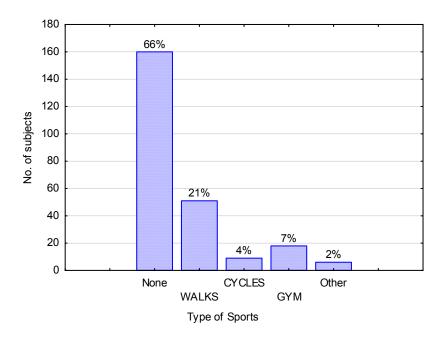


Figure 4.7 Type of physical activity

Only 35% of this sample participated in the abovementioned activities (Figure 4.8). Active participants tended to be private subjects (n = 77) with as little as nine subjects in the state hospitals as seen in Figure 4.9 below.

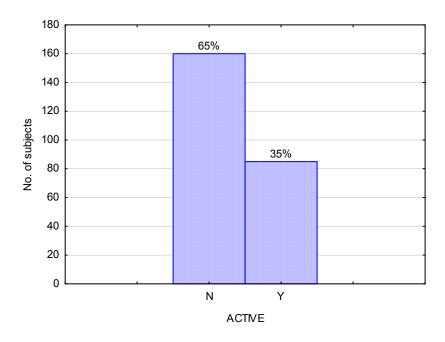


Figure 4.8 Physical activity

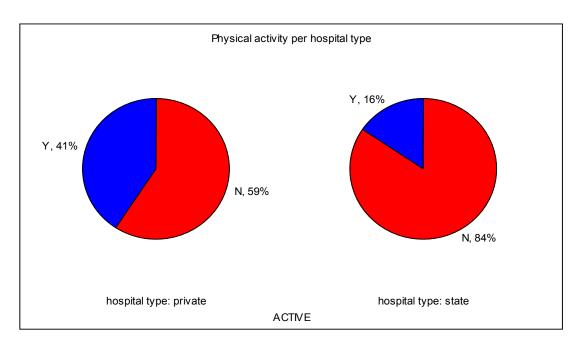


Figure 4.9 Physical activity: Private vs State hospital

4.4.2 Smoking History

Patients were classified as having a positive smoking history if they were currently smoking or had smoked in the past. Almost two thirds (64%) of the sample had a positive smoking history (Figure 4.10).

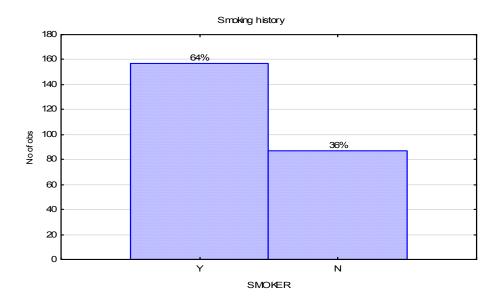


Figure 4.10 Smoking history

Although fewer subjects (n = 73) from the private hospitals smoked (Figure 4.11) than those from state hospitals, it is interesting that they had longer pack years (35.35 years) which means more intense smoking over a shorter period of time. The majority of subjects with a positive smoking history were male (n = 130).

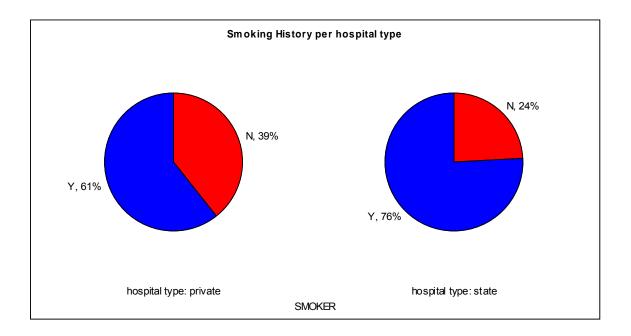


Figure 4.11 Smoking distribution: Private vs State hospital

Patients who presented with a smoking history (Figure 4.12) were more likely to have a productive cough pre-operatively (p<0.01).

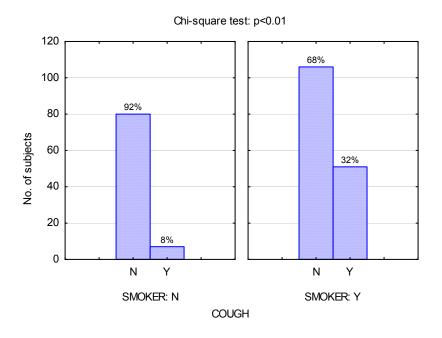


Figure 4.12 Relationship of productive cough and smoking history

Pack years, which is a way of measuring the number of cigarettes smoked over a long period of time, was also calculated for each patient. The formula used is as follows: **Pack years** = number of pack of cigarettes per day **X** number of years smoked. Although not significant, the private hospital patients s reported a longer pack year history (mean = 35 years) when compared to their state counterparts (mean = 23 years), as seen in Table 4.3 below.

Table 4.3 Pack years per hospital type

	Private	State
Pack years (mean)	35.35	23.04
Pack years (n)	117	45
Pack years (Std. dev)	±29.15	±19.30

4.5 INTRA-OPERATIVE LENGTH OF ANAESTHESIA

The mean anaesthetic time (AT) for the total sample was 4hrs 65minutes ± 1 hr 14minutes. In the state hospitals, the mean anaesthetic time tended to be longer when compared to the private hospitals p=0.01 (see Table 4.4)

Table 4.4 Intra-operative anaesthetic time

Hospital	AT (hours)	AT (hours)	AT (hours)	AT (hours)	Total
type	Mean	Std. dev	-95.00%	+95.00%	(<i>n</i>)
Private	4.50	±0.08	4.30	4.65	187
State	5.30	±0.14	5.00	5.56	58

None of the demographic variables described thus far had any influence on the duration of anaesthesia.

4.6 LENGTH OF INTUBATION

Length of intubation is defined in this study as the time from anaesthesia to time of extubation. The mean duration of intubation was 22hrs ±0.08. A Bootstrap analysis of means indicated that patients presenting with a positive smoking history tended to be intubated for a longer period of time (p=0.02) (see Figure 4.13 below). Patients with a positive smoking history were on average intubated for 24 hours compared to their non-smoking history counterparts who were only intubated for 19 hours.

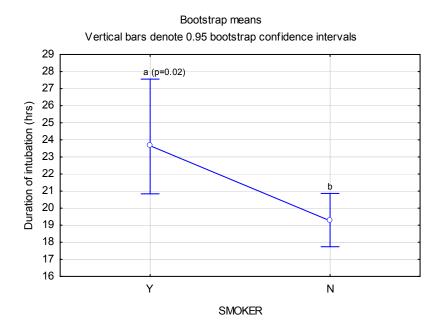


Figure 4.13 Duration of intubation and smoking

No relationship was found between gender, age, positive diabetic status, BMI, or pack years and duration of intubation. No significant differences (p>0.05) were found in the duration of intubation between private and state hospitals as can be seen in Figure 4.14.

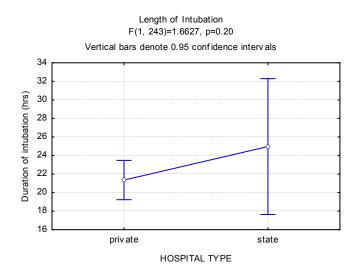


Figure 4.14 Length of intubation

4.7 RE-INTUBATION RATE

No correlation was found between any demographic variables and re-intubation rate (p>0.05). Only six patients were re-intubated during the study period: three females and three males. The profiles of these six patients were similar to the total population, namely: 80% were <70 years old, all had unstable angina and >80% had hypertension. Only one patient had the above co-morbidities as well as diabetes. With the exception of one, all patients who were re-intubated had elective surgery. All six patients were smokers and 70% had a productive cough as well. Duration of re-intubation varied greatly amongst these patients with a minimum of two days and a maximum of 13 days.

4.8 INCIDENCE OF PPCs

The study reported on the following PPCs after cardiac surgery: atelectasis, pleural effusion, pneumonia and pneumothorax (Figure 4.15). Only 86 patients (35%) did not develop any PPC after surgery. Almost half of the population (47%) presented with atelectasis (Figure 4.16).

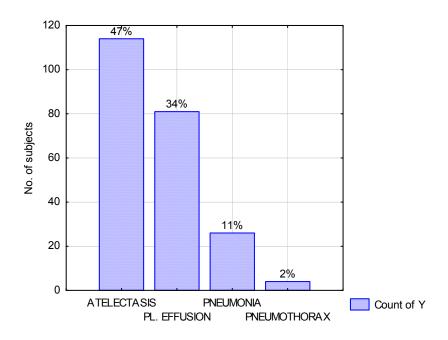


Figure 4.15 Incidence of PPCs

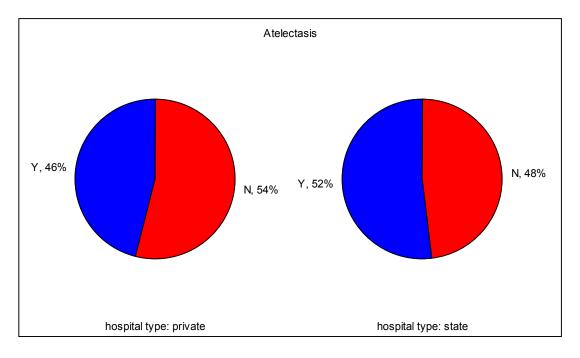


Figure 4.16 Incidence of atelectasis per hospital type

The development of pleural effusion was also prevalent in a third (34%) of the patients (Figure 4.17).

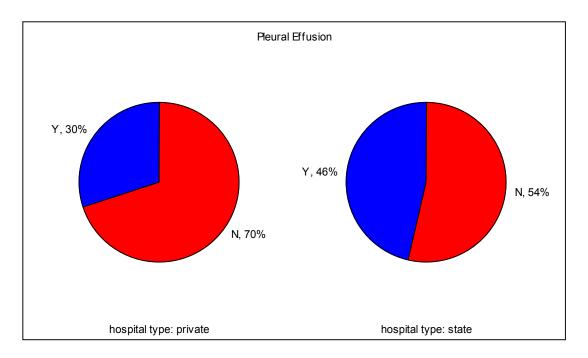


Figure 4.17 Incidence of pleural effusion per hospital type

Of the 11% of subjects who were reported to have pneumonia, more the three quarters of them were younger than 70 years and had a positive smoking history. More than two thirds had unstable angina as well as hypertension. Similar distributions for pneumonia were found in both institutions (Figure 4.18).

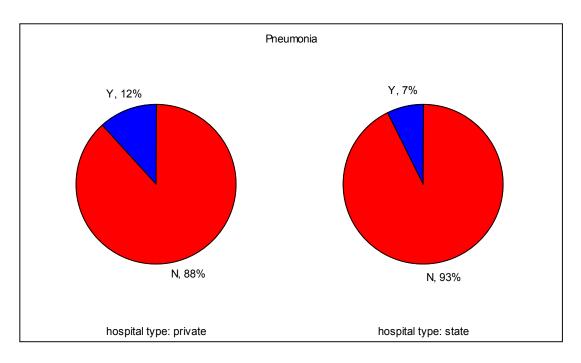


Figure 4.18 Incidence of pneumonia per hospital type

The incidence of pneumothorax (n = 4) was negligible in the current study. Patients could present with more than one PPC, however there was no statistical significance on the outcome of length of stay (Figure 4.19).

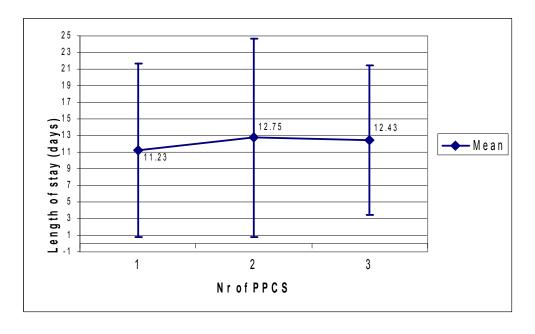


Figure 4.19 Relationship between LOS and Number of PPCs

PPCs were commonly reported within the first three days post surgery as shown in Table 4.5.

Table 4.5 Day of PPC developed

		POST	
PPC	NUMBER	SURGERY	STD. DEV
		MEAN DAY	
Pneumonia	26	2.80	± 2.62
Atelectasis	114	2.40	± 2.60
Pleural Effusion	81	3.10	± 3.15
Pneumothorax	4	1.50	± 1.30

No correlation was found between risk factors (age, gender, smoking history, anaesthetic time and length of intubation) and occurrence of any of the four post-operative pulmonary complications. However, non-linear regression indicated that duration of anaesthetic was indicative of development of atelectasis, and increased age was significant in prediction of pleural effusions.

4.9 LENGTH OF STAY (LOS)

The mean LOS for the total sample was 12.13 days (\pm 5.5). The results showed that patients in the state hospital stayed longer – 13.4 days (\pm 7.1) – compared to the private patients who stayed only 11.7 days (\pm 4.8).

The sample was divided into the group of subjects staying for longer or equal to 12 days and less than 12 days. The probability of whether subjects older than 60 years, female gender and at least one PPC's will predict a longer than the average 12 days length of hospital stay, 95% confidence intervals around odds ratios were determined.

 Table 4.6
 Odds ratio for LOS (* indicates significant values)

VARIABLE	ODDS RATIO	UPPER 95% CI	LOWER 95% CI
Female gender	1.34	0,67	2.69
Age >60	2.49*	1.33*	4.65*
PPC	1.35	0.73	2.49
Female gender	1.39	0.59	3.23
& PPC			

Although there was a significant relationship of age and L.O.S. in the private hospitals, the correlation (r = 0.23) was not strong (Figure 4.20).

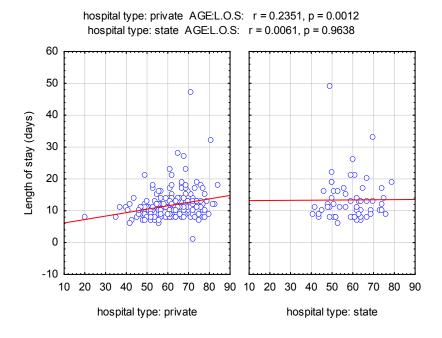


Figure 4.20 Relationship between age and LOS – Private vs State hospital

The development of a pneumothorax and/or a pleural effusion was identified as PPCs which increased hospital LOS, as shown in Figures 4.21 and 4.22 respectively.

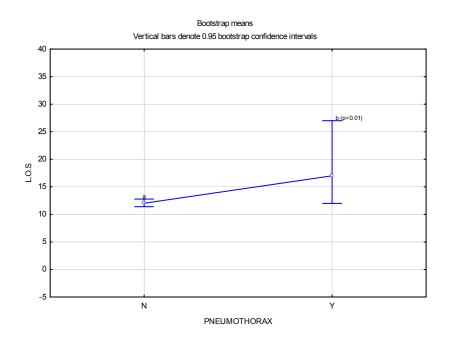


Figure 4.21 LOS and pneumothorax

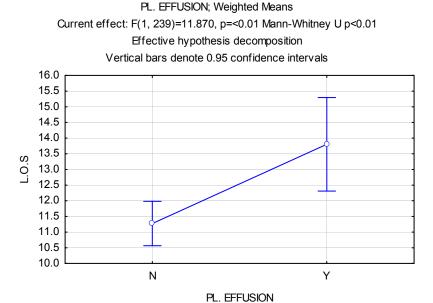


Figure 4.22 LOS and pleural effusions

4.10 CONCLUSION

Results of demographic data collected showed that the profile of patients in the Cape metropolitan area differed minimally between the two service providers. In both institutions, patients were more likely to be <70 years of age, Caucasian, male, have unstable angina, hypertension, currently smoke or have a positive smoking history. Mean LOS was 12.13 days (± 5.5) and patients who were older than 60 years old were twice as likely to have a LOS of more than 12 days. Patients in the state hospitals tended to have sedentary health behaviour (see Figure 4.9).

CHAPTER 5

DISCUSSION

5.1 INTRODUCTION

Recent studies conducted internationally have shown that the current profile of patients undergoing CABG surgery is: age ≥70years, male, Caucasian, and usually presents with multiple risk factors which include both cardiac and non-cardiac factors (Fuster *et al.*, 2005; Abramov *et al.*, 2000; Ferguson et al., 2002; Scott *et al.*, 2005; Engoren *et al.*, 2002).

This prospective observational study investigated the profile and selected outcomes of patients undergoing CABG surgery in the Cape Metropolitan Area. This chapter will discuss the findings of the study within the context of current literature with emphasis on the following:

- Demographics and pre-operative medical status of CABG patients
- Selected outcomes in CABG patients: Mortality, Incidence of Post-operative
 Pulmonary Complications (PPCs), and Length of stay (LOS)

5.2 Demographics of CABG patients in the Cape Metropolitan Area

The current cohort of 245 CABG surgery patients was obtained from both the private and public sector over a 3 month period. With respect to gender, pre-operative risk factors and health behaviour the current study sample was similar to that of

international studies conducted on CABG surgery patients and will be discussed later (Aggarwal *et al.*, 2006; Fuster *et al.*, 2005; Ferguson *et al.*, 2002; Engoren *et al.*, 2002; Abramov *et al.*, 2000; Aldea *et al.*, 1999; Estafanous *et al.*, 1998). However age was the one demographic which differed from international studies.

In the last decade, studies conducted in both America and Europe reported a mean age of 70 years and older for patients undergoing CABG surgery (Fuster *et al.*, 2005; Ferguson *et al.*, 2002; Engoren *et al.*, 2002; Aldea *et al.*, 1999; Estafanous *et al.*, 1998). This increase in the mean age has been attributed to the increase in the elderly population in westernized countries (Fuster *et al.*, 2005; Engoren *et al.*, 2002; Ferguson *et al.*, 2002). In the current study only 19.6% of the sample were in the similar age category of 70 years and older. The remainder of the sample (78.4%) were thus younger than 70 years of age, with 43% of this total falling into the 60 years and younger age group.

The variety of techniques developed over the past decade have included coronary angioplasty, stenting, and pharmacological medication to prolong the time of surgical intervention which could also have resulted in the older population found in other studies. However, in a recent randomized control trial conducted by Zhang *et al.* (2006), the impact of CABG surgery versus percutaneous coronary intervention (PCI), on functional limitation, frequency of angina and quality of life at 6 and 12 months post intervention, was investigated. In the aforementioned study patients undergoing isolated CABG surgery and PCI were divided into two groups namely: patients younger than 65 undergoing CABG and PCI compared to patients older than 65 years undergoing similar interventions. The results of the study showed that younger

patients undergoing CABG surgery had better outcomes in all three outcome measures at both 6 and 12 months compared the older population undergoing CABG. Furthermore, when compared to patients undergoing PCI, the younger population undergoing CABG surgery showed better outcomes than both the younger and older populations undergoing PCI (Zhang *et al.*, 2006; Borkon *et al.*, 2002).

Although the study conducted by Zhang *et al.* (2006), reported a better short-term outcome (1 year) for younger patients undergoing CABG surgery, long-term outcomes such as survival and health –related quality of life (HRQoL) for this group is yet to be established. Studies pertaining to the long –term survival of CABG surgery show an increased lifespan of 8-10 years after CABG surgery (Sabik *et al.*, 2006). However this time-frame is attributed to the use of arterial conduits for grafting, specifically if the left internal mammary artery (LIMA) is used (Sabik *et al.*, 2006). In both the current study and that conducted by Zhang *et al.*, (2006), the type of graft used for bypass was not documented. Future studies to establish the long term implications with regard to the incidence of re-operation in the same younger population of Zhang *et al.* (2006) as well as the current study population would be of interest.

5.2.1 Race

Numerous studies have been conducted to ascertain the pre-operative risk profile of the patient undergoing CABG surgery (Koch *et al.*, 2003; Aldea *et al.*, 1999; Higgins, 1998; Estafanous *et al.*, 1998). Pre-operative risk factors for CABG surgery commonly included age, gender, and comorbidities such as hypertension and

diabetes (Fuster *et al.*, 2005; Koch *et al.*, 2003; Ferguson *et al.*, 2002; Abramov *et al.*, 2000; Aldea *et al.*, 1999; Higgins, 1998; Estafanous *et al.*, 1998).

These studies have however commonly been conducted in first world countries such as America (Koch *et al.*, 2003; Ferguson *et al.*, 2002), Canada (Abramov *et al.*, 2000) and Spain (Fuster *et al.*, 2005). In the study by Koch *et al.* (2003), who investigated the risk profile of patients undergoing CABG surgery and their outcomes, only the percentage of Caucasian patients was reported. In the aforementioned study which had a sample size of 2,048 patients undergoing CABG surgery, 87.7% were Caucasian. As the Cape Metropolitan area is representative of all ethnic groups namely: Black, Coloured, Caucasian and Indian, the current study included ethnicity to see whether the incidence of risk factors for the development of CAD was different in these race groups.

Furthermore, according to statistics of mortality rates for chronic diseases of lifestyle, CVD (of which CAD is a subgroup of) is however projected to increase in the Black sector as there is an increase in the middle class Black population in South Africa (Bradshaw *et al.*, 2006, chapter 2:9-20). Contrary to the report on Chronic disease of Lifestyle however, the current study did not reflect similar results. In the current study only 4% and 2% of the sample were Black and Indian respectively. The majority (69%) of patients in the current study was Caucasian, with less than a third (26%) being Coloured. According to Bradshaw *et al.* (2006) possible explanation could be that mortality rates for blacks with CVD are attributed to ischeamic heart disease (IHD) such as stroke and hypertention rather than CAD.

The low percentage (2%) of Indian patients seen in the current study may not be a reflection of the incidence of CAD in this ethnic group. Due to all facilities not being fully operational at the only private hospital which was situated within a predominantly Indian community in the Cape Metropolitan Area, at the time of the study, the hospital was not included in the study. However, according to Ranjith et al. (2005), who investigated the demographic data and outcomes of acute CAD in the South African Asian Indian population in KwaZulu-Natal, a high incidence of risk factors for the development of severe CAD was reported. In his study, the cohort consisted of 2290 patients admitted to a single center between 1996 and 2002. Patients were divided into three age subgroups namely: young (≤45 years; 20%), middle age (>45 to ≤65 years; 59%), and old age (>65 years; 21%). Results of the study were that young patients had aggressive CAD, with risk factors such as smoking hypercholesterolaemia being more prevalent than diabetes and hypertension in this age group. The reasons for the aggressive nature of CAD seen in this ethnic group was attributed to familial history of CAD which was reported in all age groups, with the highest being in the younger group (60%).

The percentage (69%) of Caucasian patients seen in the current study is comparable to international studies conducted on the profile of CABG surgery patients which also reported an 87.7% Caucasian population (Koch *et al.*, 2003; Ferguson *et al.*, 2002). According to a recent South African study conducted by Ranjith *et al.* (2005), this higher incidence is due to the higher prevalence of familial history of CAD in this race group. Another possible reason could be attributed to the fact that most CABG surgery in the Cape Metropolitan area is provided by private hospitals (Department of

Health, 2002). In the current study 65% of the surgeries were performed in the private sector of which 82% of patients were of Caucasian race (refer figure 4.1).

Only 26% of the sample was Coloured, with the majority of these patients serviced by the public hospitals. Unlike the genetic predisposition given for the development of CAD in the Caucasian and Indian population, behavioural patterns (Type Apersonality) have been suggested in earlier studies as the reason for the development of risk factors for CAD in Coloured population of the Cape peninsula specifically (Steyn *et al.*, 1986). The fact that these patients were seen predominantly in the public sector is however not unexpected as only 16% of the South African population belong to a medical insurer, with the majority of them being Caucasian (Department of Health, 2002).

5.2.2 Gender

In the current study more than 75% of subjects were male. This finding is similar to several other international studies which also showed a predominantly male population undergoing CABG surgery (Aldea *et al.*, 1999; Abramov *et al.*, 2000; Zitser-Gurevich *et al.*, 2002; Koch *et al.*, 2003; Fuster *et al.*, 2005; Aggarwal *et al.*, 2006).

Studies in the last decade have largely focused on whether female gender was an independent risk factor for poor outcomes such as mortality and increased LOS after CABG surgery and are equivocal (Aldea *et al.*, 1999; Butterworth *et al.*, 2000; Zitser-Gurevich *et al.*, 2002; Koch *et al.*, 2003). However current research has now shifted focus as to whether the measurements to establish the extent of coronary disease as

well as the management of CAD in females differ to their male counterparts (Raine *et al.*, 2002; Anand *et al.*, 2005; Jacobs 2006). Recent studies conducted to answer this question found that females when presenting with acute coronary symptoms such as unstable angina, and myocardial infarction, were less likely to undergo coronary angiography and revascularization surgery such as CABG when compared to their male counterparts with similar acute symptoms (Guth *et al.*, 2005; Anand *et al.*, 2005; Jacobs 2006). According to Guth *et al.*, (2005), who looked at the influence of gender on surgical outcomes including CABG surgery, reported that women were being underdiagnosed and thus undertreated due to their atypical presentation of CAD.

In the current study 22% of the sample was female. This percentage falls within the range of 16-30% reported by international studies (Abramov *et al.*, 2000; Fuster *et al.*, 2005; Aggarwal *et al.*, 2006). According to a Spanish retrospective study conducted Fuster *et al.* (2005), which looked at the trend of patients undergoing CABG surgery over a 9 year period between 1993 and 2001, reported an increase in the percentage of females undergoing CABG surgery over time. The author attributed this increase in the female population over time from 17-21%, as a result of an ageing population. Data pertaining to the trend of females undergoing CABG surgery in the South African population is not available and future studies could investigate the trend of CABG surgery in the last decade to ascertain if this intervention is increasing amongst women.

5.2.3 Pre-operative medical status

The pre-operative medical status for the patients undergoing CABG surgery is routinely scrutinized to determine the level of risk for mortality (Higgins, 1998). The incidence of unstable angina (77%), hypertension (68%) and aortic stenosis (23%) in the current study is comparable to other international studies conducted on the pre-operative risk profile of CABG patients (Ferguson *et al.*, 2002; Abramov *et al.*, 2000; Fuster *et al.*, 2005; Koch *et al.*, 2003; Aldea *et al.*, 1999). A Canadian study conducted by Koch *et al.* (2003), which investigated the prevalence of risk factors to determine short and long term survival after CABG surgery, reported a similar incidence of hypertension (55.9%) and unstable angina (90.7%). Although the sample size (n=245) in the current study was much smaller than its Canadian counterpart (n=2,048), both studies only included patients undergoing isolated CABG surgery, making them comparable.

Retrospective studies conducted internationally on the trends of the pre-operative medical status of CABG surgery patients, have reported an increase in the prevalence of both cardiac and non-cardiac morbidities over the last ten years (Abramov *et al.*, 2000; Fuster *et al.*, 2005; Estafanous *et al.*, 1998). In the study conducted by Fuster *et al.* (2005) at a single center in Spain, between 1993 and 2001, a gradual increase in the non-cardiac comorbidities for patients undergoing CABG surgery was noted. In the aforementioned study, the sample population of 1360 patients was divided into three time cohorts namely; 1993-1995, 1996-1998 and 1999-2001. The study showed that there was a steady increase in the non-cardiac comorbidities namely; chronic renal failure (CRF), peripheral vascular disease (PVD), diabetes and chronic obstructive pulmonary disease (COPD). According to the

findings by Fuster *et al.* (2005), the prevalence of the aforementioned non-cardiac comorbidities was associated with older age (≥70 years old), which was greatest in the later period (1999-2001).

In the current study only 2% of the sample had CRF prior to surgery, which is contrary to the 8.5% and 14.2% reported by Abramov *et al.* (2000) and Aggarwal *et al.* (2006) respectively. In the Canadian study conducted by Abramov *et al.* (2000), which investigated the trend of the CABG surgery patient over a nine year period (1990-1998), an increase of CRF in patients in the later cohort of 1996-1998 was noted. Similar to Fuster *et al.* (2005), Abramov *et al.* (2000) also attributed this increase to a larger proportion (25.8%) of patients older than 70 years undergoing CABG surgery in the later cohort of 1996-1998. A possible reason for the lower CRF percentage seen in the current study could be attributed to the lower proportion of patients (19.6%) older than 70 years old.

With regard to diabetes, the current study results showed a 28% incidence. The 28% of patients with diabetes in the current study is comparable to that of international studies, which report a range of 18-42% for patients undergoing CABG surgery (Abramov *et al.*, 2000; Ferguson *et al.*, 2002; Estafanous *et al.*, 1998; Aggarwal *et al.*, 2006; Koch *et al.*, 2003; Choi *et al.*, 2005). Disregarding sample size, the demographics in the American study conducted by Ferguson *et al.* (2002) were similar to the current study, with respect to percentages for female gender (28.7%) and diabetic incidence (32.7%).

The incidence of emergency surgeries in the current study sample (24%) was also comparable to international studies which reported a range of 7-41.5% (Abramov *et al.*, 2000; Fuster *et al.*, 2005; Aggarwal *et al.*, 2006; Koch *et al.*, 2003). Factors which influenced this range was attributed to that of increased age coupled with increased comorbidities, as well as an increase in the proportion of females presenting for CABG surgery (Abramov *et al.*, 2000; Fuster *et al.*, 2005; Koch *et al.*, 2003). The subset of emergency patients in the current study sample did not reflect current international literature which reports a higher percentage of females undergoing emergency CABG surgery (Aldea *et al.*, 1999; Koch *et al.*, 2003). The dissimilar results regarding female gender and emergency surgery in the current study may either be attributed to the time period of the study (3 months) or the incidence of CAD in the South African female population. Studies to ascertain the prevalence of the disease (CAD) in South African females is proposed for further research.

The pre-operative medical status for both emergency and elective surgery patients was similar in both state and private institutions. This could be attributed to the fact that the current study did not document the severity and number of occlusions found on angiography, which distinguishes between emergency and elective CABG surgery (ref). Multivessel occlusions of the main stem coronary arteries (left anterior descending and proximal left circumflex arteries) with stenosis of ≥50% are always managed with CABG (Eagle *et al.*, 1999). Alternative management such as catheterization is performed for single vessel occlusion of arteries with less stenosis (Poyen *et al.*, 2003). The severity of symptoms on admission coupled with the aforementioned would thus result in an emergency surgery.

5.2.4 Smoking history

A positive smoking history in the current study was reported in 64% of the total sample. Studies conducted internationally have reported that a positive smoking history is a known risk factor for the development of PPCs, and increased mortality for patients with CAD (Hulzebos *et al.*, 2003; Critchley and Capewell, 2003; Nakagawa *et al.*, 2001).

The study by Hulzebos *et al.* (2003), investigated the use of pre-operative risk factors such as smoking, to predict the incidence of post-operative pulmonary complications (PPCs). The prospective study which consisted of 117 patients undergoing isolated CABG surgery during a 3 month period (December 1998-February 1999), was similar in demographics to the current study and reported that a positive smoking history within eight weeks prior to CABG surgery was a predictor (p=0.008) of a PPC. In the current study however, a positive smoking history was associated with a longer intubation period (refer 4.6). This longer intubation period although statistically significant (p=0.02) in the current study did not predict the incidence of a PPC nor did it result in a longer LOS. A possible reason for the dissimilar results could be due to a limitation of the current study which did not differentiate between current and previous smokers.

5.3 SELECTED OUTCOMES

Historically, outcome measures for CABG surgery were mainly for mortality (Parsonnet *et al.*, 1989; Nashef *et al.*, 1999; Geissler *et al.*, 2000; Kurki *et al.*, 2002). Studies conducted in the last ten years have, however, identified the need for outcome measures to be more specific, especially with regard to morbidity (Johnson

et al., 1996) and function (Barnason et al., 2000; Eales et al., 2005). Current outcome measures for CABG surgery include quality of life (Barnason et al., 2000), health-related quality of life (Eales et al., 2005), length of stay in hospital (Peterson et al., 2002) and the incidence of post-operative pulmonary complications (Hulzebos et al., 2003).

As the focus of the current study was to identify the profile of the patient undergoing CABG surgery in the Cape Metropolitan area, outcome measures which were measurable during the patients' hospital stay namely; mortality, incidence of PPCs and LOS were recorded. Factors which were found to be significant in influencing the aforementioned outcomes will be discussed appropriately. QoL and HRQoL of this population must be investigated in a separate study.

5.3.1 MORTALITY

As discussed in chapter 2, (refer 2.4.2) mortality can be measured at various time points. In the current study mortality was measured as in-hospital deaths. Only eight patients (3%) in the sample died during the study period. This finding is not unexpected as patients undergoing CABG surgery are selected for optimal outcome (Estafanous *et al.*, 1998). Studies conducted in America, Canada and Europe on the profile and mortality rates for CABG surgery patients report a mortality range of 1-3.7% (Aggarwal *et al.*, 2006; Fuster *et al.*, 2005; Scott *et al.*, 2005; Ferguson *et al.*, 2002; Engoren *et al.*, 2002; Abramov *et al.*, 2000; Aldea *et al.*, 1999; Estafanous *et al.*, 1998).

Two reasons for the relatively low in-hospital mortality have been noted in the literature. Firstly, the optimal screening tools such as the Euroscore which allow for identification of patients who are at low risk for mortality after CABG surgery (Geissler *et al.*, 2000). Secondly the advances made in terms of the surgery with regard to smaller incisions, routine use of arterial grafts and normothermia during on pump surgery (University of Southern California, 2005).

According to Ferguson et al. (2002) and Engoren et al. (2002) patients undergoing CABG surgery are not at an increased risk for mortality due to the surgical developments in cardiac surgery (refer 2.2.1). In the observational study conducted by Ferguson et al. (2002) which looked at the risk profiles and outcomes of isolated CABG surgery patients between 1990 and 1999, it was observed that despite higher risk profiles, the risk adjusted mortality rate decreased from 5% in 1990 to 3% in 1999. Similarly the Canadian study by Abramov et al. (2000), which also reported on the trends of CABG surgery showed that over a similar period (1990-1998) risk adjusted mortality reduced from 2.4% to 1.8% despite higher risk profiles of the study sample. However, in a recent Canadian study by Aggarwal et al. (2006), risk adjusted mortality rate was stable at 1% for the study period between 2000 and 2003. The author however concedes that the results could be reflective of the time period in which the study was conducted as the data collected were from a data base started in July 1999 only and thus they did not have an earlier time frame with which to compare their results.

In another South African study conducted by Klopper *et al.* (2005), a mortality rate of 0.2% was found in their sample of 38 CABG patients. In both the current study and

that of Klopper *et al.* (2005), a possible reason for the low mortality rate may be attributed to the fact that quality of care in specialized fields such as cardiothoracic surgery in South Africa is equivalent to that of first-world countries. Another reason for the low mortality rates may relate to patient selection with regard to level of operative risk, i.e. patients undergoing either emergency or elective surgery were not necessarily at high risk for mortality.

5.3.2 Incidence of Post-operative Pulmonary Complications (PPC)

The incidence of PPCs after abdominal or cardiothoracic surgery is commonly reported and managed (Hulzebos *et al.*, 2003). Several studies have shown that PPCs after CABG surgery contribute to longer hospital length of stay (O'Donohue *et al.*, 1992; Lawrence *et al.*, 1995) and an increase in healthcare cost and resources (Wynne, 2004).

Reporting of PPCs after CABG surgery varies greatly amongst studies, with an incidence ranging between 6–88% (Wynne, 2004). This large range can be attributed, in part, to the variability of the PPCs reported after CABG surgery as well as the variability in definition of these PPCs (Pasquina *et al.*, 2003; Wynne, 2004). The range of PPCs reported after CABG surgery includes prolonged ventilation, diaphragmatic dysfunction, phrenic nerve paralysis, atelectasis, pneumonia, pleural effusion and pneumothorax (Wynne, 2004). The current study reported on the latter four PPCs after CABG surgery, namely atelectasis, pneumonia, pleural effusion and pneumothorax, as they are the most commonly reported PPCs in the literature (Brooks-Brunn, 1997; Wynne, 2004; Hulzebos *et al.*, 2003).

The majority (65%) of the current sample presented with either one or more of the aforementioned PPCs. These findings are comparable to international studies, which report a prevalence of PPCs of up to 88% after CABG surgery (Wynne, 2004). In the review conducted by Wynne (2004) on the incidence of PPCs after CABG surgery, pleural effusion and atelectasis were most frequently reported.

Nearly half the sample (47%) in the current study presented with atelectasis. The incidences of pleural effusion, pneumonia and pneumothorax were less prevalent (see Figure 4.15). The selected PPCs in the current study were all reported within the first three days. This is in line with a study conducted by Cockram *et al.* (1999) who also reported the incidence of PPCs within the first two days after CABG surgery. In the study by Cockram *et al.* (1999), which looked at the cardiovascular and respiratory responses to early ambulation and stair climbing after CABG surgery, atelectasis was commonly reported within the first two days. According to Wynne (2004) the prevalence of atelectasis may be attributed to the unique surgical procedures such as cardiopulmonary bypass (Wynne, 2004).

The incidence of atelectasis in the current study was associated with longer anaesthetic time (p = 0.03). This finding differed to an international report on the predictors for the development of PPCs such as atelectasis (Hulzebos *et al.*, 2003). The study conducted by Hulzebos *et al.* (2003), which investigated the prediction of PPCs on the basis of pre-operative risk factors in CABG surgery patients, reported that an eight week smoking history prior to surgery, age older than 70 years, a productive cough and diabetes were predictors for the development of a PPC. The dissimilar results found in the current study can be attributed to the different

measuring tool used to report atelectasis than that of Hulzebos *et al.* (2003). In the study by Hulzebos *et al.* (2003) operational definitions were used for the classification of PPCs (see addendum J) which was done by an independent microbiologist. As the validity of this method has not been reported and it would have resulted in extra cost for the researcher, the researcher decided to utilize the CxR reports. The two reasons being that this method of reporting has been used in other studies (Gust *et al.*, 1999; Bonacchi *et al.*, 2001; Thomas *et al.*, 1997). As CXR are commonly taken daily for the first three days after surgery as well as on the 5th and discharge day it did not incur extra cost on the part of the researcher. However, use of CXR alone is noted by the researcher as a shortcoming of the current study as they do not differentiate between transient and clinically significant atelectasis but reported all patients with the diagnosis of atelectasis. Valid methods of diagnosing atelectasis need to be obtained.

Pneumonia was only reported in 11% of the current study. This finding is similar to international studies which report a range of 4.2–20% (Pasquina *et al.*, 2003; Wynne, 2004). The mean age and smoking history for the subset of pneumonia was similar to the entire cohort. Similar to that of atelectasis, known risk factors such as advanced age (70 years and older), diabetes and smoking history were, once again, not found to be predictive in the current study sample. This finding may be due to the small number (n = 26) of patients who developed pneumonia.

Another reason why the aforementioned risk factors were not associated with the incidence of pneumonia in the current study could be due to the absence of a definition given for pneumonia, as well as the measuring tool used. The presence of pneumonia was reported by CXR only, as patients routinely had CXR on the first,

third and fifth post-operative day as well as prior to discharge. Eventhough measuring tools such as the cardiopulmonary risk index (CPRI) and the clinical pulmonary infection score (refer to Section 2.5.2) are valid measuring tools for pneumonia, and ventilator associated pneumonia (VAP) respectively (Fartoukh *et al.*, 2003; Brooks-Brunn, 1997). However, these tools have not been validated in cardiothoracic surgery patients (Arslan *et al.*, 1996). According to Singh *et al.* (1998), different ICU patient populations may have different risk factors for the development of VAP.

The incidence of pleural effusion occurred in nearly a third of the sample and was associated with older patients within the study (p = 0.006). A large range (25–90%) of pleural effusions is also reported in internationally studies (Wynne, 2004). A possible reason for this can be attributed to transient volume overload, left lower lobe atelectasis, or heart failure (Johnson, 2000; Conti *et al.*, 2001). According to Johnson (2000), another possible reason may be that patients are immunologically mediated or that the incidence of pleural effusions is related to pericardial injury.

The problem encountered with the current reporting of PPCs is a matter of concern. This is due to the variability of the measurement tools, the definitions, as well as the end points reported for PCCs (Wynne, 2004). Variability in the aforementioned makes it difficult for clinicians such as physiotherapists to implement appropriate evidence-based treatment techniques into practice. However, a recent systematic review (Pasquina *et al.*, 2003), examined the literature for the efficacy of prophylactic respiratory physiotherapy after cardiac surgery and found the evidence to be inconclusive. These findings were attributed to size of the trials ($n \le 50$), the fact that

few studies had no intervention control groups, and variability in definitions of PPCs such as pneumonia.

As early as 1992, O'Donohue defined PPCs as "any pulmonary abnormality occurring in the post-operative period that produces identifiable disease **or** dysfunction that is clinically significant and that adversely affects clinical course". Wynne and Botti (2004) are one of the first to question the interchangeable use of post-operative dysfunction (PPD) with PPCs. According to these authors, the former is an expected physiological outcome and is usually transient in nature. Currently, transient pulmonary effects such as atelectasis as well as clinically significant complications such as pneumonia are grouped under the umbrella of PPCs.

Until consensus can be reached regarding the definitions and measuring tools for end points of PPCs, appropriate and effective management will remain inconsistent.

5.3.3 LENGTH OF STAY

A mean LOS prior to the implementation of fast-tracking (refer 2.5.3) was reported as 9 days (Engoren *et al.*, 2002). However, after the successful implementation of fast-tracking ten years ago, the current mean LOS of patients undergoing CABG has been reduced to 5.5 days (Lazar *et al.*, 2001; Petersen *et al.*, 2002; Fuster *et al.*, 2005). Age, female gender, PPCs and presence of multiple co-morbidities have been reported in international studies as predictors for longer LOS (Katz *et al.*, 1995; Butterworth *et al.*, 2000; Scott *et al.*, 2005; Toumpoulis *et al.*, 2005).

The mean LOS of the current sample was more than double of that reported in current international literature (Petersen *et al.*, 2002). Petersen et al. (2002), investigated the length of stay after CABG surgery, using the American Society of Thoracic Surgeon's National Cardiac Database, reported a mean LOS for CABG patients as 5 days. As the mean LOS in the current study was reported as 12.13 days, a prolonged LOS was defined as LOS more than 12 days. Patients older than 60 years of age in the current study sample were twice as likely to have a prolonged LOS (see Table 4.6) and mirrors findings reported in the USA (Butterworth *et al.*, 2000; Toumpoulis *et al.*, 2005).

A likely explanation for this could be that older patients stay in hospital for longer and require more assistance with attaining independence prior to safe discharge. A study conducted by Lazar et al. (2001), which looked at the discharge and LOS patterns of CABG patients in a pre (1990) and post (1998) fast-tracking environment also reported similar reasons for referral to step down facilities rather than home. According to Lazar et al. (2001), patients in the later cohort were older, had more comorbidities and were commonly sent to step down facilities due do difficulty in achieving independent ambulation.

The delayed independence of patients in the current study could be attributed to the increase incidence (p=0.01) of pleural effusions (a PPC) found in the older patients in the current study. Management of pleural effusions is treated by needle aspiration when small or insertion of an intercostal drain when large (Hough, 2001, page 79). The management of the effusion, or the underlying cause for development of the effusion could have prolonged the hospital stay.

Longer LOS in female patients older than 65 years of age undergoing CABG surgery has been reported internationally (Rosen *et al.*, 1999; Butterworth *et al.*, 2000; Watanabe *et al.*, 2001; Petersen *et al.*, 2002; Woods *et al.*, 2004). According to Butterworth *et al.* (2000), a higher incidence of non-cardiac co-morbidities such as diabetes, chronic renal failure and peripheral vascular disease in females is responsible for the longer LOS reported. However, contrary to studies conducted in USA, female gender in the current study was not a predictor of prolonged LOS. This can be ascribed to the younger aged small female sample (mean = 62 years old) as well as the lower non-cardiac co-morbidities such as chronic renal failure reported in the current study.

A study conducted by Klopper *et al.* (2005) which investigated the effect of a structured exercise program implemented within 24 hours after extubation of CABG surgery patients, showed a mean LOS of 9 ± 1.4 days. While the mean LOS in the aforementioned study is also longer than international studies, it is considerably less than the current study findings (12.13days ± 5.5 days). A possible reason for the lower LOS in the Klopper *et al.* (2005) study could be a reflection of patient selection, as only elective uncomplicated patients from a single surgeon, were included in their study sample of CABG patients. This is in contrast to the current study which included all patients undergoing CABG surgery. Thus, the findings by Klopper *et al.* (2005) must be viewed with caution as it cannot be inferred to other populations. Although the current study also collected a subgroup from the same private institutions as Klopper *et al.* (2005), similar LOS was not found. The difference in LOS may also be attributed to the fact that patients were also obtained from other cardiothoracic

surgeons in the same private hospital, which may have different post-operative management protocols.

When comparing the private and state hospitals, patients stayed longer in the state hospital (13.4 days vs. 11.7 days). It is possible that transport delays were a mitigating factor for the longer LOS observed in the public hospitals. A possible reason could be that patients treated in state hospitals may come from outlying or neighbouring provinces and thus rely on state transport before discharge to home can occur. A limitation of the current study is that this information, which would be obtainable in the patient folder, was not documented. Future prospective studies would have to take this into account. The shorter LOS in current international literature should, however, be viewed with caution as patients are more likely to be discharged to a step-down facility rather than home (Lazar et al., 2001; Engoren et al., 2002). According to Lazar et al. (2001), patients who were discharged early, within 5 days after CABG surgery, spent on average an additional 10 days in stepdown facilities. It must, however, be recognized that although step-down facilities allow for early discharge from acute care facilities, additional costs are still incurred. Data pertaining to the cost of step-down facilities compared to increased ward stay is not available and could be investigated in further research.

It could be speculated that all aspects for the successful implementation of fast track protocols (see section 2.5.3) are not being achieved in either state or private institutions, resulting in the longer LOS found in the current study.

However, the longer LOS seen in both state and private hospitals could be due to the lack of step-down facilities within the Cape Metropolitan area and specifically in the

communities to which patients are discharged to that has resulted in the LOS seen in the current study. Further studies could be conducted using the current sample to ascertain the cost of longer LOS of CABG patients in both state and private hospitals. From the abovementioned it is clear that the longer LOS in state hospitals may not necessarily be a true reflection of the average LOS of patients after CABG surgery. Thus it can be questioned whether LOS is a valid outcome measure for patients undergoing CABG surgery as variable factors such as transport, hospital protocol, and resources available may influence it (Petersen et al., 2002).

CHAPTER 6

CONCLUSION

6.1 CONCLUSION

The profile of CABG surgery patients in the Cape Metropolitan Area while comparable to those in the first world, nonetheless displayed two distinct differences namely: a younger population (<70 years) and an average longer hospital length of stay.

The question of whether younger patients benefits from early CABG surgery rather than delaying interventions like PCI or pharmacological treatment is still a dilemma. Studies up to now have always concentrated on the patients older than 70 years old. In this older patient population, research pertaining to short and long term outcome for CABG vs. PCI is well documented (Mullany et al., 1999; Pfisterer et al., 2003; Hoffman et al., 2003; The SoS investigators, 2002). However, research trials into how the younger population fare is still in its infancy. Thus far only 1 study; a matched RCT by Zhang et al. (2006) has shown that short term outcomes in a younger population (<65 years), undergoing CABG surgery is more effective than delaying interventions. According to Zhang et al. (2006), these patients do better than their older counterparts both at 6 and 12 months post surgery with respect to functional limitation, frequency of angina and QoL. However of greater value would be the long -term outcomes in this population. The question of cost effectiveness in a resource limited setting such as South Africa will have to be weighed against the risk of reoperation in this population. Only then can cost- benefit analysis be undertaken to see

whether early CABG surgery is the correct intervention for the younger cohort of patients seen in the current study.

In the current study age > 60 years was a predictor (OR 2.49, CI 1.33 – 4.65) of a prolonged LOS (> 12 days). While the implementation of fast tracking might decrease both the ICU and in-hospital LOS, this does not necessarily equate to an earlier discharge home or a decrease in overall cost (Lazar *et al.*, 2001). It is a known fact that the high cost associated with CABG surgery is related to the time spent in acute care facilities, primarily in the ICU (Doering *et al.*, 2001; Eisenberg *et al.*, 2005). However, according to Lazar *et al.* (2001), patients referred to step –down facilities after CABG surgery on average stay at least 10 days at such facilities. Thus, it is questionable whether the availability of such facilities actually results in a decrease in the total cost for the CABG surgery patient. The longer LOS found in the current study can therefore not be compared to their international counterparts as patients in the current study were discharged home and not to step-down facilities.

Prior to the commencement of the study the researcher met with private physiotherapy practitioners as well as state therapists and during the session was informed that patients were receiving routine physiotherapy after undergoing CABG surgery. Even though it was not the scope of the current study to look at the physiotherapy management, it was interesting to note that despite patients receiving physiotherapy routinely after CABG surgery, the incidence of PPCs was still reported in almost half (47%) of the population. While several studies have been conducted on the efficacy of prophylactic physiotherapy after CABG surgery, the evidence is inconclusive due to small sample size, variable definitions of PPCs as well as

different measuring tools being used (Gosselink *et al.*, 2000; Pasquina *et al.*, 2003; Wynne, 2004; Wynne & Botti, 2004).

This study highlights the need for the development of valid and reliable measuring tools, gold standard definitions for PPC and further discerning information on the incidence of CAD in our younger population.

6.2 LIMITATIONS

This is this first study documenting the profile and outcomes of patients, in the Cape Metropolitan Area, undergoing CABG surgery and therefore the researcher acknowledges the limitations below.

6.2.1 Data capture form (SIA form)

The SIA form was developed in consultation with private practitioners and hospital physiotherapists to replace their initial assessment documentation. The form was used to ensure that all relevant information pertaining to the profile of the CABG surgery patient was documented. However, the SIA form was limited by what information was routinely documented and available to all physiotherapists. As the study was conducted in several hospitals the researcher had to work within the confines of what was available to the attending therapists namely; only the current in hospital patient folder. The use of folder searches is problematic as documentation between doctors and centres are inconsistent. A possible solution to this problem could have been limited if the study trial was conducted in a single center.

6.2.1.1 Cardiac status

Even though the most common cardiac conditions were documented (refer addendum c) familial history of CAD could also have been included. This information could have shed light on the incidence of CAD in ethnic groups. According to the study by Ranjith *et al.* (2005) the incidence of familial history of CAD in both Indian and Caucasian reported are higher than their black counterparts. However, this information is not consistently available to the therapists and therefore had to be excluded.

6.2.1.2 Elective versus Emergency data

The current study had a similar profile for both elective and emergency surgery patients. Factors such as the number of diseased vessels prior to surgery may have provided better insight into the choice of surgery. Also the reporting of cardiac events such as myocardial infarction, and use of intra-aortic balloon pump prior to surgery could have led to better analysis of those patients undergoing emergency surgery.

6.2.1.3 Reporting on PPCs

The reporting of PPCs is acknowledged as a limitation of the current study. Other than radiological reports, the current study had no specific diagnostic parameters to identify PPCs. Although measuring tools such as the CPIS have been developed to report on the incidence of ventilator associated pneumonia (VAP), this tool has yet to be validated (Schurink *et al.*, 2004). According to Schurink *et al.* (2004), who looked at the accuracy and inter-observer variability of the CPIS for diagnosing VAP, the authors concluded that the CPIS had a high inter-observer variability and was no more sensitive than clinical prediction by the physician.

It was the researcher's initial intention to use the physician's clinical diagnosis to report the incidence of PPCs. However, during the pilot study the documentation of PPCs was not consistently documented by the physicians, which led to the use of radiological reports to diagnose the onset of PPCs. The domain of diagnosis is not within the scope of practice of the attending physiotherapists in the management of CABG patients. Physiotherapy in this environment is an adjunct to management once the diagnosis has been made by the physician.

Management of the reported PPCs is another aspect which should have been included in the SIA form. This information could have strengthened the argument for prolonged LOS in those patients who presented with pleural effusions and pneumothoraces.

6.2.1.4 LOS

LOS is still a widely used outcome measure for CABG surgery patients (Savino *et al.*, 2002; Petersen *et al.*, 2002; Johnston *et al.*, 2004). However, the use of LOS as an outcome measure is not reliable as it is influenced by many biases including transport delays, hospital protocols, surgeons and resources available (Petersen *et al.*, 2002). Data pertaining to LOS could have been better analyzed if duration of ICU length of stay was documented on the SIA form, allowing for better comparison between the current study and international studies pertaining to LOS (Petersen *et al.*, 2002; Doering *et al.*, 2001; London *et al.*, 2001; Lazar *et al.*, 2001; Rosen *et al.*, 1999). Date discharged from the attending physician could also in retrospect have been documented, so that prolonged LOS due to transport could have been noted.

6.3 RECOMMENDATIONS

- Although short term outcomes has shown promising results for younger patients undergoing CABG surgery, long term outcomes such as survival 10 years after, incidence of re-operation and HRQoL is yet to be established in a younger population.
- Current reporting of PPCs is a matter of concern due to the variability of definition as well as a lack of valid measuring tools to report the diagnosis of PPCs (Wynne, 2004; Wynne & Botti, 2004). Therefore it is strongly recommended that future research looks at the development of valid and cost effective measuring tools for the reporting of PPCs. The development of standardized definitions of PPC, which is currently lacking in research studies, will also aide in improving the reliability of comparison across studies. As mentioned in the discussion (refer 5.3.2) further investigation as to the predictive factors for the development of a PPD into a PPC is needed to improve the reporting of clinical significant complications.
- The establishment of a centralized, easily accessible database in South Africa would allow researches to follow trends of patients undergoing CABG surgery. The data captured will enable clinicians to perform analysis on whether CABG surgery and its concomitant outcomes are desirable with respect to HRQoL. Data pertaining to LOS can be extrapolated into monetary terms and together with the cost of step down facilities, a cost benefit analysis will be able to answer the question on whether the current study's increased ward stay was more cost effective. Furthermore a follow-up study of the current cohort must be conducted to establish whether the longer LOS found, ultimately was cost effective by leading to fewer readmissions.

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ADDENDUM A

EUROSCORE RISK TOOL

Patient Page 1 of 2



You can try the system for yourself with our interactive calculator (available in six languages) or download a calculator for use offline.

These scores are for the simple or "additive" EuroSCORE. Click here to find out how to calculate the "logistic euroSCORE".

Patient-related factors		Score
Age	(per 5 years or part thereof over 60 years)	1
Sex	female	1
Chronic pulmonary disease	longterm use of bronchodilators or steroids for lung disease	1
Extracardiac arteriopathy	any one or more of the following: claudication, carotid occlusion or >50% stenosis, previous or planned intervention on the abdominal aorta,limb arteries or carotids	2
Neurological dysfunction disease	severely affecting ambulation or day-to- day functioning	2
Previous cardiac surgery	requiring opening of the pericardium	3
Serum creatinine	>200m micromol/L preoperatively	2
Active endocarditis	patient still under antibiotic treatment for endocarditis at the time of surgery	3
Critical preoperative state	any one or more of the following: ventricular tachycardia or fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before arrival in the anaesthetic room, preoperative inotropic support, intraaortic balloon counterpulsation or preoperative acute renal failure (anuria or oliguria<10 ml/hour)	3

Cardiac-related factors		Score
Unstable angina	rest angina requiring iv nitrates until arrival in the anaesthetic room	2
LV dysfunction	moderate or LVEF30-50% poor or LVEF <30	1
Recent myocardial infarct	(<90 days)	3 2
Pulmonary hypertension	Systolic PA pressure>60 mmHg	2
Operation-related factors	5	Score
Emergency	carried out on referral before the beginning of the next working day	2
Other than isolated CABG	major cardiac procedure other than or in addition to CABG	2
Surgery on thoracic aorta	for disorder of ascending, arch or descending aorta	3
Postinfarct septal rupture		4

[home] [euroSCORE] [scoring] [calculator] [references] [contacts]

ADDENDUM B

DISTRICT HEALTH MAP

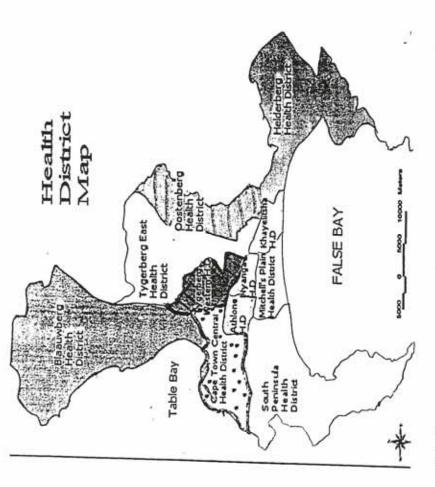


FIG. 1. HEALTH DISTRIC MAP FOR CAPE METROPOLITAN AREA 2004-2005

ADDENDUM C

STRUCTURED INITAIL ASSESSMENT FORM (SIA)

ADDENDUM D

DATASHEET

DATASHEET FOR CABG PATIENTS: 15 AUGUST -15 NOVEMBER 2005

STUDY NUMBER	FOLDER NUMBER

ADDENDUM E

PATIENT CONSENT FORM

RESEARCH INFORMATION

Research Topic:

THE PROFILE AND SELECTED OUTCOMES OF CORONARY ARTERY BYPASS GRAFT (CABG) PATIENTS IN THE CAPE METROPOLITAN AREA. A BASELINE STUDY.

Researcher: Mrs Shamila Manie (B Sc Physiotherapy, UWC)

(Project number: N05/04/072)

The goal of the project is to determine the profile of coronary artery bypass patients admitted to the Cardiothoracic Intensive Care Unit of this institution during the time period 15 August 2005 – 15 November 2005.

The objectives of the study are to describe and determine the:

- · demographics of CABG patients
- pre-operative medical status of the patient with respect to: cardiac, renal, diabetic and pulmonary status
- health behaviour of patients prior to CABG surgery with regard to: smoking and activity level
- following selected outcomes in CABG patients with regard to: intraoperative length of anesthesia, length of intubation, incidence of postoperative pulmonary complications (PPCs), re-intubation rate and length of hospital stay

The information obtained during this study will remain **confidential**. The results of this study will be published with no reference to any patient or staff member or institution involved. **Participation in this study will not result in any additional costs to the patient.**

CONSENT FORM

I HEREBY CONSENT TO DATA FROM MY HOSPITAL RECORDS BEING USED FOR RESEARCH PURPOSES. ALL DATA USED WILL BE ENTIRELY ANONYMOUS.

Date:	
Name:	
Signature:	

ADDENDUM F

PROXY CONSENT FORMS

Addendum F

INFORMATION AND PROXY CONSENT DOCUMENT

TITLE OF THE RESEARCH PRO.	JECT:	
The profile and selected outc	omes of Coronary Artery Bypass G	raft patients: A
baseline study.	ra rastrustera dun artis attis antare il truttur rastri recentristi promite dell'estre estre estre e	
REFERENCE NUMBER:		
PRINCIPAL INVESTIGATOR:	MRS SHAMILA MANIE	
ADDRESS:	DEPARTMENT OF PHYSIOTHERAPY	
	STELLENBOSCH UNIVERSITY	
	PO BOX 19063	
	TYGERBERG	
	7505	
TEL:	938 9300	
DECLARATION ON BEHALF O I, THE UNDERSIGNED,	San	(name)
TYGERRERE !		roi

A. HEREBY CONFIRM AS FOLLOWS:

- The data of all patients admitted to the cardiothoracic intensive care units of this institution during 1 August 2005 – 31 October 2005 are to be included in the abovementioned research project which is being undertaken by the Department of Physiotherapy, Faculty of Health Sciences, Stellenbosch University.
- The following aspects have been explained to me:
 - 2.1 The proposed study is of an observational, non-invasive, non-therapeutic nature
 - 2.2 The goal of the project is to determine:

- 2.2.1 the profile of coronary artery bypass patients admitted to the Cardiothoracic Intensive Care Unit of this institution during the time period 1 August 2005 – 31 October 2005.
- 2.2.2 pre-operative medical status of the patient with respect to: cardiac, renal, diabetic and pulmonary status
- 2.2.3 health behaviour of patients prior to CABG surgery with regard to: smoking and activity level
- 2.2.4 following selected outcomes in CABG patients with regard to: intraoperative length of anesthesia, length of intubation, incidence of postoperative pulmonary complications (PPCs), re-intubation rate and length of hospital stay

2.3 Data Collection:

Data will be collected weekly by the researcher in the following manner:

- A standardized structured documentation form will be completed daily by physiotherapists working in the unit. This form will be completed in duplicate and the original will constitute the physiotherapy notes.
- The copy will be collected by the researcher and stored in secure environment.

2.4 Confidentiality:

- · The information obtained will remain confidential.
- The structured documentation form will have no identifiable information on them. This will be achieved by allocating a code to each form.
- A separate datasheet will contain the folder number and corresponding code only as a measure to retrieve missing information, and will be destroyed by the researcher at the end of the data collecting period.
- Collected forms will be stored in a secure environment.
- The data obtained will be entered into a computer and will be scrambled (hidden) so that no one, not even the researcher will know the identity of the patient.

- The results of this study will be published with no reference to any patient or staff member or institution involved.
- The information above was explained to me by Mrs S. Manie in Afrikaans/*English and
 I am in command of this language. I was given the opportunity to ask questions and all
 these questions were answered satisfactorily.
- 4. Participation in this study will not result in any additional costs to this institution.

B. I HEREBY CONSENT THAT THE DATA OF ALL CORONARY ARTERY BYPASS GRAFT PATIENTS ADMITTED TO THE CARDIOTHORACIC INTENSIVE CARE UNIT AT TYGERBERG HOSPITAL (WARD A2W) DURING THE PERIOD 1ST AUGUST 2005 TO 31 OCTOBER 2005 MAY BE USED IN THE ABOVEMENTIONED STUDY.

Signed/confirmed at .	TYGERBERG HOSPIT	4L on 12 08 20 65
	(place)	(date)
Silu	Mes	
100		
Signature of Su	perintendent	Signature of witness

STATEMENT BY INVESTIGATOR:

I, Shamila Manie declare that		
I explained the information given in this docume	ent to J. P. MULLEK .	
 he/*she was encouraged and given ample time to ask me any questions; 		
this conversation was conducted in Afrikaans/*E	English and no translator was used.	
Signed at TYGERBERG HOSPITAL (place)	on	
Signature of investigator/*investigator's representative	Signature of witness (first)	
Signature of witness (second)		

ADDENDUM G

LETTER TO RADIOLOGY DEPARTMENT

Shamila Manie Department of Physiotherapy University of Stellenbosch Po Box 19063 Tygerberg 7505 26 September 2005

Prof. A Scher Department of Radiography Tygerberg Hospital

Dear Prof. Scher

Re: Request for radiological reports of post-operative Coronary Artery Bypass Graft patients for research purposes.

I, Shamila Manie, am currently enrolled in a masters degree program at the University of Stellenbosch (Department of Physiotherapy).

My research topic is: "The profile and selected outcomes of Coronary Artery Bypass Graft patients in the Cape Metropolitan Area. A baseline study."

One of the selected outcomes in this study is post-operative pulmonary complications(PPCs), which looks at the prevalence of four specific pulmonary complications, i.e. atelectasis, pleural effusion, pneumothorax and pneumonia. At present no written radiological report is available for these patients, and diagnosis of the abovementioned PPCs are done by the attending doctor.

For the purpose of my study it would be greatly appreciated if a written or verbal report be given to me regarding only the abovementioned PPCs, i.e. atelectasis, pleural effusion, pneumothorax and pneumonia.

Hoping that my request is considered favourably.

Yours Sincerely

Mrs. Shamila Manie

ADDENDUM H

RESEARCH APPROVAL



UNIVERSITEIT. STELLENBOSCH-UNIVERSITY jour kennisvennout. your knowledge partner

29 July 2005

Ms S Manie Dept of Physiotherapy

Dear Ms Manie

RESEARCH PROJECT: "THE PROFILE AND SELECTED OUTCOMES OF

CORONARY ARTERY BYPASS GRAFT PATIENTS IN THE

CAPE METROPOLITAN AREA: A BASELINE STUDY"

PROJECT NUMBER : N05/04/072

It is a pleasure to inform you that the Committee for Human Research has approved the abovementioned project, including the ethical aspects involved. This project is therefore now registered and you can proceed with the work.

Please quote the above-mentioned project number in all further correspondence.

Yours faithfully

CJ VAN TONDER

Gantardes

RESEARCH DEVELOPMENT AND SUPPORT (TYGERBERG)

CJVT/ev

C-DOCLMENTS AND SETTINGDEVIANCE CORMIT DOCLMENTSHIMMINGLEST EQUIPMENT AND DOC

ENQUIRIES NAVRAE

TELEPHONE TELEFOON

FAX FAKS

E-MAIL

REFERENCE VERWYSING

DATUM

Dr B Patel

(021) 404-4469

(021) 404-4304

Bpatel@pgwc.gov.za

16 August 2005

Mrs S Manie 72 Dale Street Rondebosch East 7780

Dear Mrs Manie

PROVINCIAL ADMINISTRATION: WESTERN CAPE

Department of Health

PROVINSIALE ADMINISTRASIE : WES-KAAP

Departement van Gesondheid

ULAWULO LWEPHONDO : INTSHONA KOLONI

Isebe Lezempilo

RE: RESEARCH STUDY FOR MASTER'S DEGREE

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

- Your research may not interfere with normal patient care.
- (b) Hospital staff may not be asked to assist in the research.
- (c) No hospital consumables and stationery may be used.
- (d) Please introduce yourselves to the person in charge of an area before commencing.

I would like to wish you every success with your project.

Yours truly,

DR B PATEL

For CHIEF EXECUTIVE OFFICER

BP/yw

Ref.c:l-researchManie

e.e Chair Research/Ethics Committee - Prof Zabow

Mrs Farquharson - Physiotherapy

Groote Schuur Hospital Private Bag, Observatory, 7935 Telephone: 404-9111



Groote Schuur Hospitaal Privaatsak, Observatory, 7935 Telefoon: 404-9111

UNIVERSITY OF CAPE TOWN



Research Ethics Committee E52 Room 24,0ld Main Building Groote Schuur Hospital, Observatory, 7925

Queries: Lamees Emjedi

Tel: (021) 406-6338 Fax: 406-6411 E-mail: lemjedi@curie.uct.ac.za

22 August 2005

REC REF: 316/2005

Ms 5 Manie Physiotherapy University of Stellenbosch PO Box 19063 Tygerberg 7505

Dear Ms Manie

THE PROFILE AND SELECTED OUTCOMES OF CORONARY ARTERY BYPASS GRAFT PATIENTS IN THE CAPE METROPOLIAN AREA: A BASELINE STUDY

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform that the Ethics Committee has formally approved the abovementioned study on the 18 August 2005.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROF T. ZABOW CHAIRPERSON

ADDENDUM I

APPROVAL BY PRIVATE HOSPITAL

N1 City Hospital

Iouwijie Rottertan Street, Goodwood, 7460, P.O. Box 12581, N1 Cth., 7463 TELEPHONE + 27 (21) 590-4444 FACSIMILE + 27 (21) 595-2304 E-MAIL ADDRESS n1hospiliothica.com

8 September 2005

WEB ADDRESS www.netcare.co.za

Ms S Manie 72 Dale Street RONDEBOSCH EAST 7780

Dear Ms Manie

RE: RESEARCH ON "THE PROFILE AND SELECTED OUTCOMES OF CORONARY ARTERY BYPASS GRAFT PATIENTS"

It is with pleasure that we inform you that your application to conduct research on the above mentioned at N1 City Hospital has been successful, subject to the following:

- All information with regards to Netcare will be treated as confidential.
- Netcare's name will not be mentioned without written consent from the Academic Board of Netcare.
- Where Netcare's name is mentioned, the research will not be published without written consent from the Academic Board of Netcare.
- A copy of the research will be provided to Netcare once it is finally approved by the tertiary institution, or once complete.
- All legal requirements with regards to patient rights and confidentiality will be complied with.

We wish you success in your research.

Yours faithfully

Dr E.A. Van Wyk

HOSPITAL MANAGER

Cc: Mr H. Laskey, Human Resources Manager

