
**AN INVESTIGATION INTO
NONBRONCHOSCOPIC BRONCHOALVEOLAR
LAVAGE AND ENDOTRACHEAL SUCTIONING IN
CRITICALLY ILL INFANTS AND CHILDREN**

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**Thesis presented for the degree of Doctor of Philosophy in the Division
of Physiotherapy, Faculty of Health Sciences, University of Cape Town**

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ABSTRACT

Introduction: This thesis investigated the effects on critically ill, mechanically ventilated paediatric patients of two related, frequently performed physiotherapy procedures: nonbronchoscopic bronchoalveolar lavage (NB-BAL) and endotracheal (ET) suctioning.

General aims: To investigate un- or poorly-documented complications of paediatric NB-BAL and ET suctioning, and to test a method for each procedure of reducing the incidence and/or severity of these complications.

Motivation: As a result of this research it is hoped that a better understanding of the risks of these so-called “routine procedures” be gained. It is also hoped that the improved techniques will be adopted within paediatric intensive care units nationally and internationally in order to improve the management of patients and minimise potentially avoidable complications. The published results of this thesis will substantially add to the body of knowledge presently available on this subject and will have direct practical application in improving patient care.

Methods: In order to pursue this line of investigation, a series of five related research studies were conducted and are presented in this thesis as separate chapters.

Chapter Two documented the clinical complications of NB-BAL in 35 mechanically ventilated paediatric patients, by means of a prospective observational clinical study. In this study NB-BAL was performed through an open system, allowing supplementary oxygen flow but not ongoing ventilation.

Chapter Three tested an original method of reducing the complications of NB-BAL, by means of a controlled clinical trial of 70 patients, using the initial study group as control. In this study NB-BAL was performed through a closed ventilatory system, allowing positive pressure ventilation to continue throughout the procedure.

Chapter Four presents an *in vitro* study recording the pressure changes occurring within a simple chest model during ET suctioning, using a range of suction catheter and

endotracheal tube (ETT) sizes, different vacuum pressures and different techniques. In addition the relationship between the amount of synthetic mucus suctioned and various aspects of suctioning were investigated.

Chapter Five presents a prospective before-after clinical study documenting the immediate effects on lung dynamics of ET suctioning in 30 paediatric patients, using a CO₂SMO Plus! Respiratory Profile Monitor. A single-catheter insertion, standardised ET suctioning procedure was used to ensure reproducibility and reliability.

Chapter Six presents a prospective single-blind randomised controlled clinical trial of 48 patients investigating whether recruitment manoeuvres were safe to perform in haemodynamically stable paediatric patients; whether the manoeuvre successfully reversed suction-induced decreases in dynamic compliance; and whether the manoeuvre improved oxygenation.

Results: In Chapter Two, NB-BAL was found to be associated with significant desaturation events, which were related to the patients' oxygen requirements.

The original adaptation of NB-BAL described in Chapter Three was successful in significantly reducing the severity of desaturation events.

Chapter Four's investigation recorded a decrease in pressure in the chest model associated with ET suctioning. The degree of pressure change was related to ETT and catheter sizes, suction pressure and technique.

The study described in Chapter Five observed that ET suctioning caused a significant decrease in dynamic compliance, which was particularly marked when suctioning infants intubated with small diameter ETT. There was no change in airway resistance following suctioning. There were no other clinically significant complications associated with ET suctioning.

The investigation into recruitment manoeuvres in Chapter Six showed that the manoeuvre appeared to improve arterial oxygenation whilst having no effect on post-suctioning dynamic compliance relative to the control group.

Discussion and conclusions: Hypoxia is a frequent complication of NB-BAL and is associated with the severity of the patient's lung disease. Maintaining airway pressure

during NB-BAL can reduce the severity of desaturation. Hypoxia occurs less frequently as a result of a single-insertion ET suctioning procedure. However, even this brief, minimally invasive procedure resulted in a significant decrease in dynamic compliance, attributable to lung volume loss. This was supported by the results of the *in vitro* study, which indicated that suctioning was likely to generate large pressure changes in the lung, particularly when using large suction catheters in relatively small diameter ETTs. It is likely that prolonged suction or repeated suction passes would exacerbate lung volume loss leading to hypoxia. Recurrent derecruitment associated with ET suctioning could result in lung injury. The routine use of post-suctioning recruitment manoeuvres does not appear to be beneficial, but further research is needed in this regard.

Recommendations: Evidence-based guidelines for NB-BAL and ET suctioning, developed from the results of this series of investigations and the available literature, are presented in Chapter Seven.

PREFACE

Primum non nocere

In this day of evidence-based healthcare practice it is essential to question all aspects of patient care. This includes those procedures that are performed and requested routinely, often without thought to the potential risks to the patients.

It is hoped that this thesis will contribute to the slowly expanding evidence base for physiotherapeutic intervention in paediatric respiratory disease. It presents an attempt to start addressing the consequences of the different modalities used by physiotherapists daily in the paediatric intensive care unit, in order to ensure that we, as health care providers, “first do no harm”.

CHAPTER ONE

INTRODUCTION

1.1 The role of chest physiotherapy in paediatric intensive care

For many years, chest physiotherapy (CPT) and endotracheal (ET) suctioning have been accepted as part of the routine care of critically ill children and infants being managed in paediatric intensive care units (PICU) throughout the world (Krause and Hoehn, 2000; Stiller, 2000).

CPT and ET suctioning procedures are regularly performed in mechanically ventilated infants and children in order to remove secretions from the airways thereby aiming to improve delivery of mechanical ventilation; improve gaseous exchange; reduce the work of breathing; prevent and resolve respiratory complications; and facilitate early weaning from the ventilator (Main et al, 2004; Ntoumenopoulos et al, 2002; Wallis and Prasad, 1999; Ciesla, 1996). The precise role of the physiotherapist in different intensive care units varies according to the country of location, local tradition, staffing levels, training and expertise (Stiller, 2000).

The respiratory physiotherapist is also frequently responsible for obtaining specimens of pulmonary secretions to enable microscopy, bacterial culture and identification of antibiotic sensitivity; viral culture; and histological investigation; in order to accurately identify and treat pulmonary disease. The most commonly requested specimens for intubated patients in the PICU of Red Cross War Memorial Children's Hospital (RCWMCH), Cape Town, South Africa, are tracheal aspirates (TA) and nonbronchoscopic bronchoalveolar lavage (NB-BAL).

Unfortunately, virtually every intervention in medical practice carries with it a risk to the patient, and sometimes to the practitioner. Many procedures are viewed as routine, and the risks attached to the practice are often not known, or taken into consideration. Procedures are often performed as they were taught to the practitioners as students (Wallis and Prasad, 1999). Practitioners frequently do not question the evidence upon which the procedures were based, or whether there might be a better or safer method of performing the technique.

The concept of evidence-based health care refers to “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al, 1996). This requires “integration of individual clinical expertise and patient preference with the best available external clinical evidence from systematic research” (Guyatt et al, 2002). Sackett’s hierarchy of evidence (taken from <http://www.wmin.ac.uk/sih/page-484>) is one method of categorising the level of evidence available:

1. A Systematic reviews/ meta-analyses
B Randomised controlled trials
C Experimental designs
2. A Cohort control studies
B Case-control studies
3. A Consensus conference
B Expert opinion
C Observational study
D Other types of study eg. interview based, local audit
E Quasi-experimental, qualitative design
4. Personal communication

CPT and ET suctioning have become accepted as part of the care of critically ill infants and children, despite a limited evidence-base (Krause and Hoehn, 2000; Stiller, 2000), largely because of the risks of endotracheal tube (ETT) obstruction.

When attempting to answer the question of what effects CPT and ET suctioning actually have on critically ill infants and children, the literature is not reassuring. Few studies of scientific merit have been performed on this group of patients. Those that have been published suggest that routine CPT and ET suctioning may do more harm than good (Chalumeau et al, 2002; Krause and Hoehn, 2000; Wallis and Prasad, 1999; Harding et al, 1998; Button et al, 1997; Cross et al, 1992; Reines et al, 1982).

Responses to CPT, ET suctioning and other techniques such as bronchoalveolar lavage (BAL) may affect the respiratory, cardiovascular and central nervous systems; and metabolic demand. It has been noted that CPT is associated with the most pronounced variation in vital signs and metabolic demand of any routine intensive care unit (ICU) intervention (Weissman et al, 1984).

CPT in the PICU environment is a broad term usually referring to any combination of positioning/postural drainage, chest manipulations (percussion, vibrations, shaking), manual hyperinflation and endotracheal suctioning (Main et al, 2004). Recently, other procedures such as the “saline lavage - simulated cough technique”, employing aspects of NB-BAL, have been suggested for use in acute lobar atelectasis not responsive to conventional CPT (Galvis et al, 1994).

Many studies evaluating the effects and efficacy of CPT and ET suctioning do not specify which individual or combinations of techniques were employed, their duration or the exact method of application. This makes reproducibility and generalisability difficult, if not impossible. In addition to this, the study designs are often flawed, with the resulting evidence being of a low level.

There are many anecdotal reports of CPT resulting in immediate radiological improvement in acute lobar atelectasis in children and infants and studies in adult patients support these observations (Marini et al, 1979; Stiller et al, 1990). However, this was not seen in an animal model, using anaesthetised dogs, where percussion applied to the chest

wall was shown to cause lung collapse under the area of percussion as well as an area of collapse on the opposite lung (Zidulka et al, 1989).

CPT has been associated with the development of severe brain damage and intracranial haemorrhage in very low birthweight infants (Harding et al, 1998; Raval et al, 1987), and potentially severe hypoxaemia in term neonates (Fox et al, 1978). Following paediatric cardiac surgery, routine four-hourly CPT was related to the development of atelectasis and prolonged hospital stay (Reines et al, 1982). CPT modalities can exacerbate bronchospasm, particularly in children recovering from an acute asthma attack (Asher et al, 1990).

There is no good evidence that CPT has any role to play in preventing postextubation atelectasis (Flenady and Gray, 2002; Bloomfield et al, 1998); nor does CPT hasten the resolution of paediatric viral bronchiolitis (Webb et al, 1985; Nicholas et al, 1999).

Although no randomised controlled trials have assessed the benefits of CPT in children with primary pneumonia, an adult study found that there was no difference in length of hospital stay or improvement in lung function between the CPT and placebo groups. In fact, the treated group had a longer duration of fever than the control group (Britton et al, 1985). Despite this evidence, it is generally accepted that, although CPT has no part to play whilst the lungs are consolidated, there may be some benefit once the pneumonia begins to resolve, especially in a child or infant who is unable to effectively clear secretions him/herself.

It is currently not known which aspects of CPT are responsible for the reported benefits and complications.

As blood culture results in acute childhood pneumonias are frequently negative (Grigg et al, 1993), it is important to have a sensitive tool for determining causative organisms. TA cultures have relatively low sensitivity and are unreliable in most intubated patients, due

to contamination by organisms colonising the upper respiratory tract (Jourdain et al, 1995).

Paediatric bronchoscopic BAL is a sensitive diagnostic technique, which samples lower respiratory tract secretions under direct visualisation. This procedure requires the child to be anaesthetised, an experienced operator is needed to perform the bronchoscopy and the equipment is expensive. In addition, flexible fiberoptic bronchoscopic BAL is limited by the ETT internal diameter, and is therefore difficult to perform in small infants.

NB-BAL is a blind method of obtaining a BAL specimen, frequently performed by physiotherapists. NB-BAL requires less expertise and is less expensive than bronchoscopic BAL; is not limited by ETT size and does not require the child to be anaesthetised. This technique has also been shown to specifically sample secretions from the lower respiratory tract. NB-BAL incorporates the instillation of three aliquots of saline into the distal airways through a suction catheter, thus washing out a portion of the alveolar lining fluid, and then suctioning as much of this fluid as possible from the lungs. The suction catheter is not removed from the airway in between the saline insertions and suctioning events.

At the time of performing the investigations described in this thesis, the risks and complications of NB-BAL had not been published, and the procedure was recommended for use in even the most critically ill neonates (Shields and Rielder, 2000; Dargaville et al, 1999; Kotecha, 1999; Koumbourlis and Kurland, 1993; Alpert et al, 1992; Minotuli et al, 1990). Considering the known risks of ET suctioning and the invasive nature of NB-BAL, it was felt that NB-BAL was likely to result in similar, but more severe complications than ET suctioning alone.

ET suctioning is performed by physiotherapists when obtaining TA specimens and in order to remove secretions mobilised by CPT manipulations in intubated patients or those who are unable to cough and clear secretions effectively themselves. ET suctioning is also performed routinely by nursing staff on intubated patients in order to maintain ETT

patency and prevent the accumulation of secretions in the proximal airways. It is recognised that severe adverse events may result from ET suctioning. These include hypoxia, bradycardia and other arrhythmias, raised intracranial pressure, bacteraemia, mucosal trauma, pneumothorax, loss of ciliary function and atelectasis (Carhuapoma and Williams, 1999; Kerr et al, 1999; Darlow et al, 1997; Barker and Rutter, 1995; Segar et al, 1993; Monaco and Meredith, 1992; Shah et al, 1992; Skov et al, 1992; Tarno-Mordi, 1991; Singh et al, 1991; Durand et al, 1989; Loubser et al, 1989; Bailey et al, 1988; Fanconi and Duc, 1987; Graff et al, 1987; Gunderson et al, 1986; Arai et al, 1985; Murdoch and Darlow, 1984; Ehrhart et al, 1981; Simbruner et al, 1981; Zmora and Merritt, 1980; Cabal et al, 1979; Kuzenski, 1978; Anderson and Chandra, 1976). However, the mechanisms for these reported complications have not been comprehensively addressed.

The literature pertaining to NB-BAL and ET suctioning will be reviewed in detail in Chapters Two to Six.

1.2 Paediatric respiratory anatomy and physiology

The specific anatomical and physiological differences between the paediatric and adult respiratory systems mean that directly applying results from adult studies to paediatric practice may be inappropriate and even potentially dangerous.

The average diameter of the infant's trachea is 5-6mm, compared to 14-15mm in the adult (Kendall, 1987). The narrowest point of the infant's airway is at the level of the cricoid cartilage, just below the vocal cords. The cricoid cartilage forms a complete cartilaginous ring, as compared to the tracheal cartilages, which are C-shaped (Myer et al, 1995). The cricoid region is lined with ciliated epithelium. Trauma to the epithelium may be caused by ET intubation, especially if the ETT is of too large a diameter. In order to minimise laryngeal injury, uncuffed ETTs, which allow a small air leak around the ETT during the application of positive pressure ventilation, are used in paediatric practice (McWilliams, 1993). ET suctioning can also cause epithelial damage in intubated children if the catheter is inserted beyond the distal ETT tip, and if the catheter adheres to

the airway mucosa during the application of suction pressure. This may cause oedema and narrowing of the airway leading to increased airway resistance and work of breathing (Kendall, 1987).

The absolute cross-sectional airway in infants and children is smaller than in adults and therefore the paediatric airway is more easily occluded by mucus, foreign bodies and other debris. The amount, strength and distribution of cartilage, other supporting structures and glandular tissue vary with growth. In the newborn, the trachea and bronchi have relatively little supporting tissue such as cartilage, elastic tissue, connective tissue or muscle. The lung develops by increasing the size and number of alveoli (Tooley, 1982).

The pattern of airway growth is age dependent. Under five months of age, proximal and distal airways enlarge proportionally. From one year of age, enlargement of the distal airways exceeds that of the proximal airways by up to 30%. This explains why resistance in the small peripheral airways accounts for a higher percentage of total airway resistance in children under the age of five years than in adults (Fisher et al, 1990).

Infants and children have a greater number of mucous glands than adults, which may hypertrophy rapidly in response to irritation, infection, or inflammation. This high density and large size of mucous glands, and the small airway diameter of these children all contribute to the susceptibility of infants and small children to severe respiratory disease (Fisher et al, 1990).

The ribs in infants and young children are angled more horizontally, and the diaphragm is flatter than the adult diaphragm. This results in a mechanical disadvantage for the infant's respiratory system, as the intercostal muscles cannot raise the rib cage further during inspiration. Thus the rib cage excursion contributes very little to inspiratory volume changes. The infant relies on his/her diaphragm for inspiration, but this is also at a disadvantage as the range of diaphragmatic excursion is limited. Infants have a high chest wall compliance which contributes to mechanical insufficiency by being easily deformed during diaphragm contraction, and this is especially so if the stabilising effect of intercostal muscle contraction is inhibited. In addition to these mechanical disadvantages,

the diaphragm and intercostal muscles of the term infant contain only about 30%, and preterm infants 10%, of slow-twitch, high oxidative, fatigue-resistant (Type 1) muscle fibres, compared with 55% in adults. They are thus more prone to respiratory muscle fatigue than the adult (Scarpelli, 1990).

The infant has a resting oxygen (O₂) consumption and carbon dioxide (CO₂) output per kilogram body weight of twice that of an adult. Therefore, hypoxaemia can develop rapidly (Kendall, 1987). The respiratory rate (RR) is determined by the alveolar ventilation:dead space ratio and the time constant of mechanical impedance to respiration. Thus infants have a much higher RR than adults, and this decreases as body size increases (Fisher et al, 1990).

In infants and young children, functional residual capacity is closer to the closing capacity (that volume of gas present in the lungs when the small conducting airways begin to collapse) than in adults; the chest wall compliance is much greater than lung compliance (Nunn, 1993), with stiffening of the chest wall occurring as the child gets older; bronchi and bronchioles lack structural support, with inadequate cartilaginous or smooth muscle support (Fisher et al, 1990) and the collateral ventilation channels between alveoli and bronchioles are poorly developed (Kendall, 1987). For these reasons, it is likely that infants and young children are more prone to developing atelectasis as a result of pulmonary pathology and, potentially, as a result of interventions such as CPT and ET suctioning.

1.3 Motivation for the study

Two techniques were chosen for investigation in this thesis: paediatric NB-BAL and ET suctioning. Detailed literature reviews for these procedures will be presented in the relevant chapters.

These techniques were chosen as they are performed on a daily basis by the PICU physiotherapist, and ET suctioning is also performed routinely by nursing staff. Published clinical guidelines for both techniques do not appear to be based on high-level evidence,

despite the potential for serious complications. It was felt that data from this study could be directly applied to clinical practice in the PICU and could be a starting point for analysis of the effects of all the respiratory therapeutic and investigative techniques performed by physiotherapists in the PICU.

The investigations that culminated in this thesis began in July 1998 when NB-BAL was first introduced as a common investigative procedure in the PICU at RCWMCH. NB-BAL was first introduced in this study site as part of a large research programme investigating HIV- related pneumonia and has since become part of the accepted diagnostic workup for all mechanically ventilated patients with known or suspected pulmonary pathology. The investigator, a physiotherapist, was charged with performing these procedures, according to a set protocol, which was unsupported by high-level scientific evidence. Soon after introducing the procedure it was observed that a number of patients appeared to experience immediate serious complications as a direct result of NB-BAL. All studies published prior to this time indicated that NB-BAL was completely safe for use in even the most critically ill infants (Alpert et al, 1992; Koumbourlis and Kurland, 1993). It was therefore decided to prospectively collect data on the adverse effects of this procedure, which at the time of investigation had not been reported elsewhere. Subsequent to these studies, the initial protocol has been revised.

After initiating research studies into NB-BAL, the infants' reactions to ET suctioning (performed by the investigator, nursing staff and other health care professionals) were observed. In one case a neonate with an intercostal drain *in situ* for pleural effusion drainage was observed during suctioning. This child had received muscle paralysis and was therefore not breathing during the suctioning procedure. The contents of the intercostal drain were drawn back into the chest during the application of suction pressure. The main question arising from this observation was whether the application of a negative pressure to the lungs could cause negative pulmonary pressures and what effect these would have on the patient's lung dynamics.

It was also observed that ET suctioning was often performed without thought by colleagues (physiotherapists, nurses and doctors alike), who appeared oblivious to the monitor alarms as significant cardiovascular changes occurred.

No suctioning protocol existed in the PICU at the start of this research process, and the techniques employed varied from using low suction pressure and single catheter insertion, to the use of the highest suction pressure and the largest catheters inserted into the ETT repeatedly without allowing the infant sufficient time to breathe in between suction catheter insertions.

After performing an extensive literature search it was surprising to note that more questions than answers existed about how and when to suction, as well as the mechanical and clinical effects of suctioning. The literature regarding the effects of ET suctioning on lung mechanics were particularly poor, with many papers merely citing poorly designed trials.

The results of the investigations presented in this thesis will contribute to the formulation of rational evidence-based protocols and improved, safer practice techniques. Subsequent investigations into all physiotherapy modalities used in PICU are planned for the future.

As a result of this research it is hoped that a better understanding of the risks of these so-called “routine procedures” will be gained. It is also hoped that new methods of performing these techniques be adopted within PICUs nationally and internationally in order to improve the management of patients and minimise potentially avoidable complications. Thus the results of this thesis will substantially add to the presently small body of knowledge on this subject as well as having direct practical application in improving patient care.

1.4 General aims

This thesis presented a series of studies investigating some of the physical effects of ET suctioning and NB-BAL when performed on critically ill infants and young children. It

also proposed and tested a method for each technique of reducing the negative effects of the procedures.

1.5 General objectives

The main objectives of this research were to:

- identify and measure the levels of severity of some of the respiratory and cardiovascular complications associated with NB-BAL;
- test the efficacy of a modified NB-BAL technique in reducing the severity and/or incidence of these complications;
- investigate the physical principles of pressure and gas flow dynamics associated with ET suctioning;
- measure the changes in lung dynamics before and after a standardised ET suctioning procedure in critically ill infants and children;
- determine risk factors for the complications of NB-BAL and ET suctioning;
- determine the effect of a standardised recruitment manoeuvre (RM) performed after a standardised ET suctioning procedure on lung dynamics and SaO₂; and
- assess the safety and practicality of performing the RM after suctioning.

1.6 Literature Search

Literature searches for articles published between January 1962 and December 2004 were conducted using PubMed, CINAHL (Cumulative Index of Nursing and Allied Health Literature), PEDro (Physiotherapy Evidence Database) and EBSCOhost research databases. In addition, hand searches through physiotherapy journals were performed and letters were sent to authors in the field and to South African universities in an attempt to obtain non-published data.

For ease of reading, the results of comprehensive reviews of the relevant literature are presented within the introduction and discussion sections of Chapters Two to Six.

1.7 Context and Study Site

This series of investigations was conducted by the primary investigator (BM), a physiotherapist working within the PICU of an academic tertiary paediatric hospital (Red Cross War Memorial Children's Hospital) in Cape Town, South Africa.

The first study described in Chapter Two of this thesis was conducted in a purely medical PICU, whilst the subsequent clinical studies described in Chapters Three, Five and Six were performed after combining the individual surgical, cardiac and medical units into a single 24-bed multidisciplinary PICU.

RCWMCH is the only dedicated tertiary level children's hospital in Africa, south of the Sahara. The PICU admits approximately 1400 patients per year, with a large variety of medical and surgical problems. Patient turnover is rapid, and there is approximately a 10% mortality rate (PICU database).

South Africa is a developing country, and the patients admitted to this PICU are generally of low to mid socio-economic circumstances. Their living environments reflect the social problems associated with poverty. These include inadequate housing, overcrowding, poor access to water and sanitation, malnutrition and lack of access to medical care. These poor living environments result in patients admitted here being more ill than might be experienced in First World PICUs. Many patients present with multi-organ disease. Lower respiratory tract infections, malnutrition and diarrhoeal disease are major contributors to morbidity and mortality in this population (Bradshaw et al, 2003). In addition, 10-15% of patients admitted to the PICU are infected with human immune deficiency virus (HIV)-related illness and/or serious opportunistic infections associated with the acquired immune deficiency syndrome (AIDS). HIV/AIDS is the leading cause of death among young South African children (Bradshaw et al, 2003). The importance of accurately identifying opportunistic, and other, pathogens in order to provide appropriate treatment for these children must be weighed up against the potential complications of the investigative procedures.

Resource constraints are not specific to patients and their families. Much of the equipment used in this hospital is outdated; the facility is short-staffed with poor remuneration of highly skilled health care professionals at all levels. Research funding is limited and research can only be conducted in the time available after completing a large clinical patient load. Thus this series of investigations was conducted in a resource-limited environment, without the technology commonly available in most first-world settings. A major challenge of this project was to conduct reproducible, scientifically sound research with minimal equipment, insufficient staff and limited funding.

1.8 Outline of research and thesis presentation

Five sequential research studies were conducted and are presented in this thesis as separate chapters. Detailed descriptions of the methodologies are provided in Chapters Two to Six. Specific limitations of the research will be discussed in the relevant sections. For all studies, $p < 0,05$ was considered statistically significant. Throughout this thesis, the South African convention of using commas for decimal points is used.

1.8.1 Equipment

The equipment used for the investigations of Chapters Two to Six is described in the methodology sections of the relevant chapters (Appendix E).

1.8.1 Patient sample

Patients studied were all intubated, mechanically ventilated paediatric patients with a range of pathologies. Specific inclusion and exclusion criteria are presented in each chapter. Patients with haemodynamic instability and coagulation defects, pulmonary haemorrhage or oedema, and premature neonates were excluded from all clinical studies. A total of 148 patients were studied during the course of these investigations.

1.8.2 Ethical considerations

Formal approval for clinical research was obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town, before commencement of any of the studies. Where specified as necessary, informed consent

was obtained from the child's parent or legal guardian in the language of their choice. Specific ethical considerations for each investigation are presented in the relevant chapter.

1.8.3 Thesis outline

Chapter Two describes a prospective observational clinical study documenting the immediate reactions to diagnostic NB-BAL in a convenience sample of 35 paediatric patients, from July to December 1998. At the time of the investigation, no published papers had identified any potentially serious complications of the procedure. Chapter Two also aimed to determine predictive factors for the most frequently occurring complications and to compare the diagnostic yield of the NB-BAL specimen to international standards.

In 2000, the study described in Chapter Three was proposed and was conducted in 2001 in order to identify a means of preventing or minimising the hypoxia identified as the main complication of NB-BAL in Chapter Two. A new NB-BAL technique, which seals the ventilatory system thus maintaining mean airway pressure throughout the procedure, was proposed and tested. A sample of 70 patients was studied by means of a non-randomised clinical trial using the initial study group as control.

A number of questions arose from the results of Chapters Two and Three regarding ET suctioning itself:

1. Does routine ET suctioning also result in hypoxia?
2. Is there the same incidence of hypoxia and other complications associated with ET suctioning as with NB-BAL?
3. What causes these complications?
 - a. Are they related to different aspects of ET suctioning, including catheter size:ETT size, suction technique and vacuum pressure?
 - b. Could they be due to lung volume loss as a direct result of the application of negative pressure to the lung?

4. What is the most efficient suctioning technique, vacuum pressure and catheter size to use with different mucus consistencies?
5. If ET suctioning causes a loss of lung volume, is there a safe and simple method of reversing or preventing this lung volume loss?

Owing to the paucity of data on the subject of suctioning, it was decided to first explore the physical gas flow/pressure dynamics related to ET suctioning before initiating clinical trials. This was demonstrated by means of *in vitro* experiments conducted using a simple “bag-in-a-box” chest model (Chapter Four). In addition, the relationships between catheter- and ETT size, suction pressure and the amount of synthetic mucus suctioned per second were also examined. This investigation was completed in December 2001. Specific interactions noted between catheter and ETT size and the negative pressures generated in the chest model, had not been reported previously.

Chapter Five describes the extension of the suctioning investigation into clinical practice. This investigation was a prospective before-after clinical trial (Guyatt et al, 2002) examining the effects of a standardised, single- catheter insertion ET suctioning procedure on lung mechanics in 30 patients enrolled over a six-month period from May to October 2002. A CO₂SMO Plus! portable respiratory profile monitor (Novamatrix Medical Systems Inc. USA) was used for measurement of lung dynamics. This study was unique in that the sample was heterogeneous in nature, the suctioning procedure was standardised and patients did not receive muscle paralysis prior to the procedure.

The final investigation presented in Chapter Six was a prospective randomised controlled clinical trial of 48 patients, conducted over an 18-month period from May 2003 to the end of October 2004. This study aimed to determine whether performing a standardised recruitment manoeuvre (RM) (30 cmH₂O sustained for 30 seconds) was safe to perform on critically ill infants and children and whether it was effective in reversing suctioning-induced decreases in dynamic respiratory system compliance, as recorded using a CO₂SMO Plus!. The effect of the RM on SaO₂, HR and blood pressure was also recorded. This was the first investigation of its kind involving paediatric patients. This

study also aimed to confirm the reliability and reproducibility of the investigation described in Chapter Five. The changes in lung dynamics of patients in both Chapter Five and Six's studies, recorded before and after a standardised ET suctioning procedure, were combined in order to increase the power of the results of the investigation in Chapter Five.

Chapter Seven presents a synthesis of the results and conclusions of the investigations conducted in this research. Recommendations for clinical practice; NB-BAL and ET suctioning guidelines; and recommendations for future research are provided.

University of Cape Town

CHAPTER TWO

THE RISKS AND COMPLICATIONS OF PAEDIATRIC NONBRONCHOSCOPIC BRONCHOALVEOLAR LAVAGE

2.1 Introduction and literature review

In order to obtain the most recent and relevant literature pertaining to paediatric NB-BAL, the search terms “bronchoalveolar lavage” and “nonbronchoscopic bronchoalveolar lavage” were used alone and in combination with “children” and “paediatric” (both American and UK spelling were used).

2.1.1 Historical review

BAL using a flexible fibreoptic bronchoscope was introduced in the early 1970's. This technique was shown to be a safe and effective way of establishing the aetiology of infectious pulmonary processes, in both adult and paediatric populations (Panero et al, 1995; Koumbourlis and Kurland, 1993; Alpert et al, 1992). BAL is a less invasive procedure than lung biopsy and appears to obtain comparable specimens from the lower respiratory tract (Bye et al, 1987). As *Pneumocystis carinii* cysts typically adhere to Type I alveolar cells, this tool has become increasingly important in the diagnosis of *Pneumocystis carinii* pneumonia in immunocompromised patients (Panero et al, 1995), a particular concern in patients infected with HIV.

Unfortunately, the HIV epidemic has resulted in many patients being admitted to PICUs with serious opportunistic infections associated with AIDS. It is, therefore, essential to be able to perform a sensitive diagnostic test to detect the presence of the causative organisms, using a safe procedure that is unlikely to cause complications in already critically ill children.

Flexible bronchoscopic BAL is not possible in infants with an ETT of internal diameter

(ID) < 4,5mm since the 3,5mm paediatric bronchoscope would largely obstruct the lumen of the artificial airway (Koumbourlis and Kurland, 1993; Alpert et al, 1992) and smaller bronchoscopes do not have a suction channel. Rigid bronchoscopy with BAL is possible but requires general anaesthesia and may cause airway trauma. In patients with small ID ETTs and diffuse pulmonary disease, BAL performed by the blind insertion of a suction catheter via the ETT (Panero et al, 1995) is preferable.

NB-BAL was first described by Green in 1847 (Alpert et al, 1992). In adults it is considered to be a simple, safe, effective, less time-consuming procedure that requires less expertise and is cheaper than bronchoscopic BAL (Prokop et al, 1996; Pugin et al, 1991; Minotuli et al, 1990; Mann et al, 1987; Caughey et al, 1985). Results from NB-BAL sampling has also compared favourably with that of open lung biopsy (Gaussorgues et al, 1989). NB-BAL was first used in patients suffering from AIDS where it was found to safely and accurately detect the presence of *Pneumocystis carinii* (Caughey et al, 1985). It has since been used in intubated adults with other medical conditions, being managed in intensive care units (Henderson, 1994; Koumbourlis and Kurland, 1993; Pugin et al, 1991).

NB-BAL was first described in a paediatric population by Alpert et al (1992). As blood culture results in acute childhood pneumonias are frequently negative (Grigg et al, 1993), it is important to have a sensitive tool for determining causative organisms. TA cultures have relatively low sensitivity and are unreliable in most intubated patients, due to contamination by organisms colonising the upper respiratory tract (Jourdain et al, 1995). NB-BAL is able to specifically sample fluid from the lower respiratory tract, as demonstrated by the presence of alveolar macrophages in the lavage fluid. Diagnostic yields from 42% to 85% have been reported (Koumbourlis and Kurland 1993; Alpert et al, 1992; Minotuli et al, 1990; Piperno et al, 1988).

In addition to the diagnostic benefits, therapeutic benefits of NB-BAL have been described. It was found to be effective in improving lung expansion in 84% of infants with radiological evidence of lobar collapse, which had not responded to conventional

CPT (Galvis et al, 1994). Dargaville et al (1999) noted that in three infants with meconium aspiration NB-BAL appeared to have a beneficial effect by removing meconium debris. Two patients with atelectasis showed radiological evidence of improvement following NB-BAL (Koumbourlis and Kurland, 1993). In the PICU where this study was conducted, therapeutic NB-BAL is occasionally used to reinflate lung segments when lobar or lung collapse does not respond to conventional CPT and suctioning. This technique appears to have been effective in these cases in removing the mucus plug with radiological and clinical resolution of the atelectasis, but has not been prospectively objectively investigated. Although therapeutic NB-BAL is beyond the scope of this study, it is an aspect worthy of further investigation.

2.1.2 Complications and described NB-BAL techniques

In initial studies of NB-BAL in paediatric patients, no significant complications of the procedure were noted (Schindler and Cox, 1994; Koumbourlis and Kurland 1993; Alpert et al, 1992; Minotuli et al, 1990, Piperno et al, 1988).

Numerous complications of routine ET suctioning have been described. These include hypoxaemia; arrhythmias including bradycardia; airway trauma causing mucosal damage; pneumothoraces; increased intracranial pressure; increased blood pressure; and bacteraemia (Darlow et al, 1997, Alpert et al, 1992, Singh et al, 1991; Perlman and Volpe, 1983; Anderson and Chandra, 1976).

During NB-BAL the catheter is inserted via the ETT into the tracheobronchial tree, partially obstructing the airway and markedly increasing airway resistance, for longer periods than during normal ET suctioning; repeated suction manoeuvres are performed without allowing recovery time; and a large amount of saline is instilled into the lungs. These factors suggest that NB-BAL could result in more adverse events than would occur during ET suctioning (Koumbourlis and Kurland, 1993). The added airway obstruction caused by the suction catheter could also cause CO₂ retention.

Wagener et al (1987) reported significant desaturation and cardiac arrhythmia followed by death in a child undergoing bronchoscopic BAL. This child had pulmonary hypertension and congestive cardiac failure secondary to upper airway obstruction. These authors postulated that increased pulmonary vascular resistance induced by hypoxia could worsen heart failure. In addition, in the presence of high pulmonary vascular pressure, markedly negative intrapleural pressures during aspiration may result in fluid transudation from the pulmonary vessels thereby precipitating acute pulmonary oedema (Wagener et al, 1987).

Bye et al (1987) reported two serious incidents of complications of bronchoscopic BAL. One child had an episode of seizures and another child experienced increased tachypnoea, low BAL fluid return and died 30 hours after the procedure. These authors mention the potential risk of fluid overload from poor recovery of BAL fluid. The unretrieved saline could also interfere with alveolocapillary O₂ exchange (Ridling et al, 2003).

There is also a potential risk of pneumothorax being caused by bronchial perforation by means of the suction catheter, which is inserted far beyond the distal tip of the ETT (Anderson and Chandra, 1976).

It has been shown that diagnostic BAL in patients with pneumonia may cause intravascular translocation of toxins or mediators producing pyrogenic and hypotensive effects (Pugin and Suter, 1992).

There is concern about the potential washing out of surfactant, which may exacerbate existing respiratory disease, particularly in infants with neonatal Respiratory Distress Syndrome. Although this has been disputed in a controlled trial, which found that repeated NB-BAL in newborn infants did not appear to be associated with radiological changes (Kotecha, 1999), it is noteworthy that in many experimental animal models of acute lung injury, the injury is induced by means of saline lavage (Allen et al, 2002; Rimensberger et al, 1999; Neumann et al, 1998).

Alpert and others (1992) performed paediatric NB-BAL using a balloon wedge pressure catheter passed through a swivel adaptor. The balloon was inflated once wedged to achieve airway occlusion. These investigators used five aliquots of 0,75 ml/kg normal saline for the procedure. NB-BAL was performed on 20 patients with an age range of 1 month to 6½ years. Fluid was aspirated manually using a syringe. They did not observe any complications of NB-BAL: SaO₂ remained > 90%, electrocardiography (ECG) trace was stable and there was no change in O₂ requirement or ventilatory support in any patient following the procedure. Dargaville et al (1999), using the same technique, observed an unacceptably high number of significantly bloodstained specimens, attributed to the balloon-wedge catheters. This was improved by changing to a straight, snub-nosed, end-hole suction catheter.

Koumbourlis and Kurland (1993) performed NB-BAL in 15 patients ranging in age from two weeks to 18 months. They also inserted the catheter through a swivel adaptor, thus allowing mechanical ventilation to continue during the procedure; although it is unclear from this paper exactly how the system allowed on-going ventilation. All patients tolerated the procedure without experiencing any complications and did not require increased ventilatory support after the procedure. Some patients had a transient decrease in SaO₂ during NB-BAL, but these returned to pre-lavage levels as soon as the suction catheter was removed from the airway.

Schindler and Cox (1994) reported that NB-BAL did not result in any significant complications in 28 paediatric patients with a mean age of 4,1 ± 4 years. Their levels of oxygenation and ventilation requirements were not altered by the technique

Dargaville et al (1999) reported a decrease in SaO₂ during NB-BAL of 5% (range -5% to 31%). Twenty-three percent of the patients experienced desaturation lasting > 1 minute, with only two patients experiencing episodes of desaturation lasting > 5 minutes during NB-BAL. These authors concluded that NB-BAL could be conducted safely in a population of infants with significant lung disease. Despite being associated with transient desaturation there was no prolonged compromise of gas exchange. They

performed NB-BAL by inserting the suction catheter into the ETT by means of a suction “bullet” in a swivel Y-connector, allowing ventilation to continue throughout the procedure. Dargaville et al (1999)’s investigation was published after data for the research described in this chapter had already been collected.

Labenne et al (1999) reported frequent, minor complications following nonbronchoscopic protected brush specimens and bronchoalveolar lavage. In a study of 103 paediatric patients ranging in age from 7 days to 8.8 years, 11% experienced mild self-limited bronchial haemorrhage; 10% required a moderate, but persistent increase in FiO₂ or ventilatory requirements; and 6% experienced transient fever. Three neonates developed pneumothoraces after the procedure.

Burmester and Mok (2001) conducted a retrospective study of 60 patients who had undergone NB-BAL over a two-year period and reviewed the following data: paediatric risk of mortality (PRISM) score before NB-BAL; clinical observations at the time of NB-BAL; arterial blood gases; oxygenation index (OI); ventilator settings; haemodynamic variables; and temperature taken at one hour before and one and six hours after the procedure. This NB-BAL protocol deviated from those of others in that the lungs were inflated and the chest wall vibrated during expiration while mechanical suction was applied. The catheter was then removed and the procedure repeated three times. This paper was published after completing the study described in this chapter.

Burmester and Mok (2001) reported that most of the immediate complications of NB-BAL were transient and easily treatable but in 7% of the patients the complications were significant and necessitated increased respiratory or haemodynamic support. Two patients experienced prolonged arterial oxygen desaturation. Another two patients needed significant escalation of inotropic support, with it taking up to 36 hours for the blood pressure to return to baseline values. There was only one episode of transient bradycardia. Haemodynamic variables and temperature remained stable at one and six hour- intervals after the procedure for all patients. Arterial oxygenation, as expressed by median OI, showed no significant change at one- or six- hour intervals after the NB-BAL

procedure. It was noted, however, that 12% of the patients experienced a clinically significant increase in OI one hour after the procedure.

Burmester and Mok (2001) could not identify factors which could predict a deterioration in OI at one-hour post-NB-BAL. There was no correlation between the number or severity of complications and baseline OI or PRISM score. It was noted, however, that >50% of the patients with OI > 20 experienced a significant number of immediate or late complications associated with the procedure. They concluded that NB-BAL was generally well tolerated in critically ill infants and children, but that a small proportion of paediatric patients experienced significant cardiorespiratory compromise as a result of the procedure. As this was a retrospective study, no continuous changes in cardiorespiratory parameters during and immediately after the procedure were observed, and acute effects of NB-BAL might have been missed (Burmester and Mok, 2001).

In the RCWMCH PICU the method for performing NB-BAL involved inserting the suction catheter directly through a port in the ETT connector, thus maintaining O₂ flow but not ventilation during the procedure (Darlow et al, 1997).

Although physiotherapists generally perform NB-BAL procedures, (Burmester and Mok, 2001), there are no published studies in the Physiotherapy literature on this subject. After performing a number of NB-BAL procedures, the researcher became aware of the occurrence of complications in a number of patients. It became obvious to her that it was essential to investigate the procedure, in order to objectively assess the impact of NB-BAL on the patients' clinical condition.

2.2 Aims

The aims of the study in this chapter were to investigate the immediate reactions to and the complications associated with diagnostic NB-BAL in critically ill infants and children in a PICU; and to determine the number of diagnoses made from NB-BAL samples (diagnostic yield).

2.3 Objectives

The objectives of this study were to:

1. investigate the changes in HR and level of SaO₂ in mechanically ventilated infants and children in response to paediatric NB-BAL;
2. record any other observed clinical complications associated with the procedure;
3. determine predictive factors for hypoxia by measuring the following respiratory severity indices: OI, ventilation index (VI) and the arterial partial pressure of O₂ (PaO₂) / fraction of inspired O₂ (FiO₂) ratio;
4. measure NB-BAL fluid return; and
5. make clinical recommendations, if necessary, for improving the safety and efficacy of the NB-BAL procedure.

2.4 Materials and Methods

Approval for conducting this study was obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town, as part of a larger study investigating the aetiology and outcome of paediatric pneumonia (Zar et al, 2001). As NB-BAL was routine practice in the PICU, the need for informed consent from parents or guardians was waived.

2.4.1 Study design

This study design was a prospective observational clinical study.

2.4.2 Patient Sample

Data was collected from a convenience sample of 35 consecutive patients over a six-month period, from July to December 1998.

Inclusion criteria:

- bilateral opacification on chest x-ray;
- NB-BAL requested by attending physician; and
- intubated and mechanically ventilated.

Exclusion criteria:

- haemodynamic instability over preceding three hours (fluctuations of > 20% in HR, MABP or SaO₂);
- pulmonary haemorrhage;
- pulmonary oedema;
- cor pulmonale with pulmonary hypertension;
- premature neonates; and
- clinical signs of raised intracranial pressure (observed clinically by decreased level of consciousness, raised fontanelle or, if measured, >15mmHg).

2.4.3 Technique and Apparatus

Prior to the NB-BAL procedure, patients received an intravenous bolus of 0,1 mg/kg morphine or midazolam and were preoxygenated with 100% O₂ for approximately one minute. 100% FiO₂ was delivered during the procedure and was continued until the patient's SaO₂ returned to prelavage levels.

Throughout the procedure there was continuous ECG and pulse oximetry monitoring. Levels of SaO₂ and HR were recorded one minute before; during the procedure; and after the NB-BAL at one-, five- and, where necessary, ten-minute intervals. The patient was positioned supine with his/her head turned away from the therapist in order to prevent mucus from being splashed into her face. All patients had been positioned in supine for at least one hour prior to the NB-BAL procedure.

Suction catheters of French Gauge (FG) sizes 6 to 8 were used, according to availability and the ETT size. Where possible, the external diameter (ED) of the catheter did not exceed half the internal diameter (ID) of the ETT. The catheter was introduced into the ETT directly through a port in the ETT connector so that oxygenation could continue during the procedure. The port was not sealed; therefore airway pressure was not maintained during the procedure.

Three lavages of 1 ml/kg, 0,9% saline at room temperature were performed (Ratjen and Bruch, 1996). The suction catheter was inserted into the ETT and wedged as far distally as possible (Schindler and Cox, 1994; Koumbourlis and Kurland, 1993). After withdrawing the catheter slightly (< 5mm) to remove the catheter tip from the mucus membrane, the lavage volume was introduced and the suction catheter was then attached to a mucus extractor with continuous mechanical suction applied. The suction pressure gauge was set to “medium”, corresponding to a vacuum pressure, with tubing occluded, of \pm -360 mmHg.

Movement of the suction catheter of < 0,5cm was permissible to maximise fluid extraction. Subsequent lavages were done through the same catheter in the same position. The first aliquot was discarded and the subsequent two were combined and sent for analysis (Ratjen and Bruch, 1996; Grigg et al, 1993).

The amount of fluid extracted was measured directly in 14 cases using markings on the mucus extractor container. The entire procedure, from pre-oxygenation to catheter withdrawal lasted between one and three minutes. All NB-BAL procedures were performed by the same person (BM).

The NB-BAL fluid was sent for gram stain, bacterial culture and, where clinically indicated, for immunofluorescence for *Pneumocystis carinii*, fungal or viral cultures, culture for *Mycobacterium tuberculosis* and staining for fat or haemosiderin laden macrophages.

If a patient's SaO₂ decreased to \leq 80% at any stage during the procedure, the catheter was withdrawn and if immediate improvement did not occur, the patient was manually ventilated with 100% O₂ until the SaO₂ level returned to pre-lavage levels. NB-BAL was also aborted as soon as the HR dropped to < 90 BPM. An intention-to-treat principle was adhered to for this study in order to accurately assess the incidence of all complications associated with NB-BAL. Therefore, patients who required the procedure to be abandoned were included in data analysis.

2.4.4 Analysis

Respiratory severity indices of OI ($\text{MAP}(\text{FiO}_2(100)/\text{PaO}_2)$) and VI ($\text{RR}(\text{PaCO}_2(\text{PIP}/1000))$) were calculated for each patient as well as $\text{PaO}_2/\text{FiO}_2$ (Peters et al, 1998). PIP is positive inspiratory pressure. The most recent blood gas values (taken the morning of the NB-BAL) of PaO_2 and PCO_2 were used to calculate the above respiratory severity indices.

The following statistical analyses were performed:

- Data were tested for normality using the Levene's Test.
- Descriptive statistics were used to obtain the median, mean, range, standard errors and/or interquartile ranges for all variables studied;
- normally distributed between-group data were analysed using the Student's *t* – test for independent variables;
- between-group independent nonparametric variables were compared using the Mann-Whitney U test;
- Spearman's rank order non-parametric correlation tests were used to assess relationships between variables;
- The chi-square test was used as well as the Yates-corrected chi-square test when some cells contained data values <10.

Statistica for Windows (release 5.1 Statsoft Inc) was used for all analyses.

Table 2.1: Patient data.

Patient	Age (months)	Primary Diagnosis (Indication for BAL)	Secondary Diagnosis (Underlying Condition)	MAP (cmH ₂ O)	FiO ₂
1	1	Pneumonia + Lower airway obstruction		5	0.3
2	26	Pneumonia	Meningococcaemia	6	0.3
3	5	Pneumonia	Obstructive emphysema	21	0.8
4	36	Bronchopneumonia		8	0.8
5	11	Pneumonia	Atrioventricular septal defect + Gastro-oesophageal reflux	8	1
6	5	Pneumonia	Diarrhoeal disease + seizures	7	0.21
7	108	Diffuse Interstitial Pneumonia	Bilateral pneumothorax + right ventricular failure	15	0.7
8	1	Pneumonia + apnoea		8	0.3
9	1.5	Bronchopneumonia	Pneumothorax + Septicaemia	14	0.3
10	1	Pneumonia + Apnoea	Septicaemia	10	0.55
11	3	Diffuse Interstitial Pneumonia	HIV infection	23	0.95
12	1	Pneumonia	HIV infection	15	0.8
13	48	Desquamating Interstitial Pneumonitis		49	0.8
14	4.5	Pneumonia	Congestive Cardiac Failure	12	0.8
15	23	Pneumonia + Upper Airways Obstruction	Acute Myeloid Leukaemia + Febrile Neutropaenia	8	0.8
16	12	Pneumonia		14	0.8
17	60	Pneumonia and Haemothorax	HIV infection	11	0.5
18	19	Pneumonia + Muscle Weakness	Septicaemia	9	0.3
19	1	Pneumonia	Septicaemia	3	0.3
20	108	Cystic Fibrosis Post-Laparotomy	Chronic Lung Disease	5	0.4
21	3	Bronchopneumonia		7	0.4
22	12	Diffuse Pneumonia	Chronic Lung Disease	14	0.5
23	2	Bronchiolitis	Lower airway obstruction	5	0.35
24	1	Pneumonia + Apnoea		7	0.4
25	3	Pneumonia	Atrioventricular septal defect + Coarctation of the Aorta	12.5	0.5
26	3	Pneumonia	Renal Failure	12	0.55
27	4	Pneumonia		15	0.8
28	7	Desquamating Interstitial Pneumonitis		10	0.6
29	1	Pneumonia + Apnoea		13	0.35
30	6	Bronchopneumonia	Chronic lung disease + gastro-oesophageal reflux + Tetralogy of Fallot + HIV infection	15	1
31	3	Bronchopneumonia	HIV infection	14	0.45
32	2	Interstitial Pneumonia		24	0.3
33	28	? Pulmonary Tuberculosis	Septicaemia + Kwashiorkor	7	0.35
34	1	Interstitial Pneumonia	Ventricular septal defect	15	0.9
35	1	Bronchopneumonia	Bacterial Meningitis	19	0.25

2.5 Results

The age of patients ranged from three weeks to nine years (median 4 months). Median weight was 4,9 kg (range 2,1 - 20,0kg). The underlying diagnoses for which children were admitted included diffuse pneumonia (n=31, with 6 of those having interstitial pneumonia), meningococcaemia (n=1), other septicaemias (n=3), bronchiolitis (n=1), cardiac defects (n=3), congestive cardiac failure (n=1), cystic fibrosis (n=1), chronic lung disease (n=3), pneumothorax (n=2) and haemothorax (n=1). Some patients had more than one diagnosis. Six patients were known to be immunocompromised at the time of BAL; five of whom were HIV positive and one had acute myeloid leukaemia (Table 2.1).

Thirty-three patients received conventional mechanical ventilation (Newport Ventilators model E100m) with a respiratory rate of $39,7 \pm 4,0$ (mean \pm standard error) breaths per minute (bpm); FiO_2 of $0,55 \pm 0,04$; PIP of $26,2 \pm 1,4$ cmH₂O; positive end-expiratory pressure (PEEP) of $6,7 \pm 1,2$ cmH₂O; and mean airway pressure (MAP) at the time of NB-BAL of $12,6 \pm 1,4$ cmH₂O. Two patients received modified high-frequency positive pressure ventilation (HFOV) using a BIRD[®] ventilator (Bird Products, Palm Springs, California) oscillating at MAPs of 23 and 49 cmH₂O respectively. At the time of this investigation, no oscillatory ventilators were available. When HFOV was indicated, therefore, BIRD[®] ventilators were set to deliver a high respiratory rate (RR) of >120 bpm, at the required MAP.

Thirty-four patients were intubated with an ETT of median ID of 3,5 mm (range 2,5 to 6 mm). One patient had a tracheostomy with ID of 3,4 mm.

The OI, VI and PaO_2/FiO_2 were calculated in 34 of the 35 patients, as arterial blood gases had not been taken on one patient. The median OI was 6,2 (range 1,4 to 44,0); median VI was 26,5 (range 5,0 to 154,1); and the median PaO_2/FiO_2 ratio was 139,7 mmHg (range 36,6 to 333,0 mmHg).

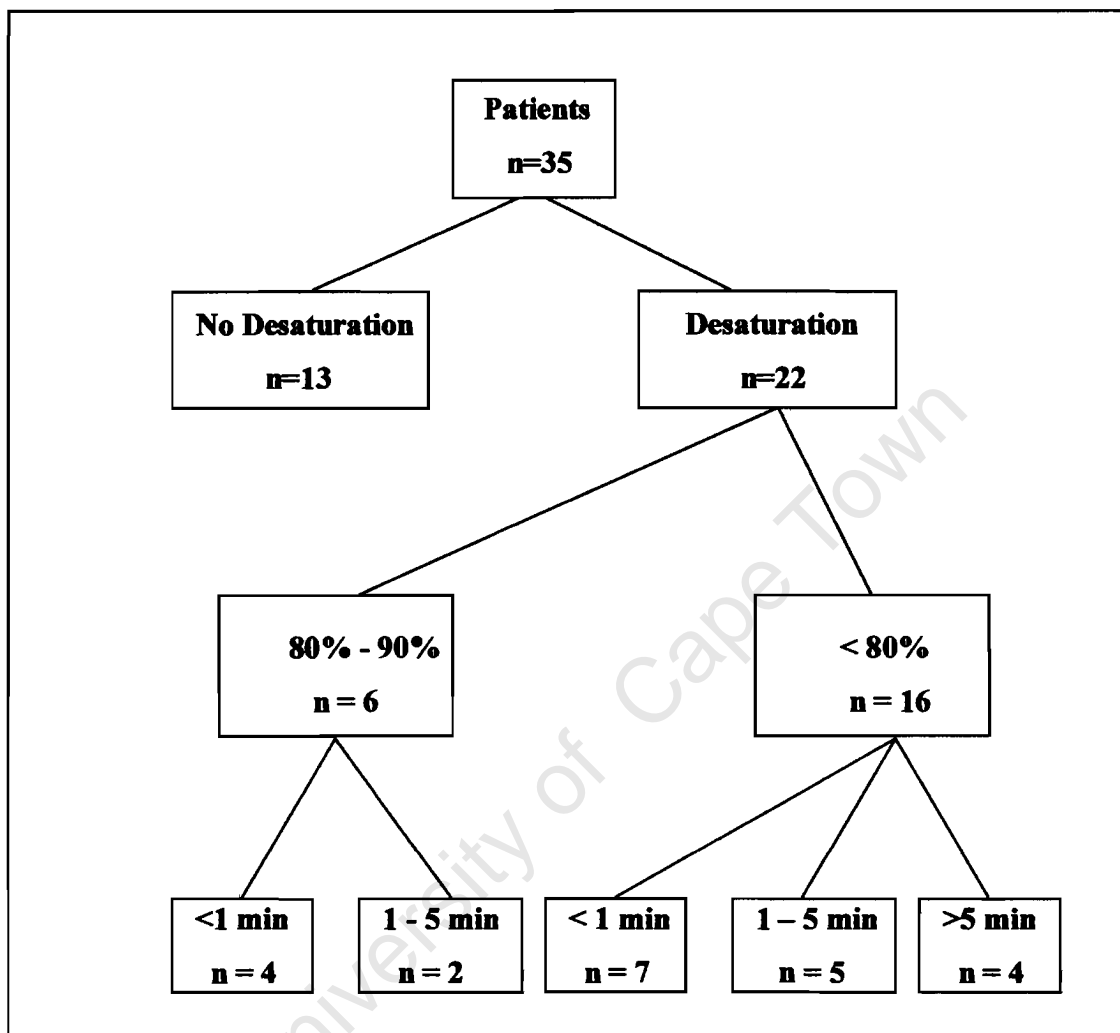


Figure 2.1: Number and duration of desaturation events during or immediately after NB-BAL.

Twenty-two patients (62,9%) experienced a decrease in SaO₂ to < 90% during or immediately after NB-BAL (Figure 2.1). Eleven of these (50%) experienced transient episodes of desaturation of < one minute. Seven of them experienced transient episodes of desaturation to < 80% during the procedure. In all these cases the procedure was immediately terminated, ensuring that as much fluid as possible was suctioned out on withdrawal of the catheter. Their SaO₂ levels rapidly rose to pre-lavage levels.

Seven patients maintained low levels of SaO₂ for between one and five minutes before improvement. Of these two desaturated to < 80% and three to < 70%.

Four patients experienced periods of desaturation continuing for > 10 minutes, despite manual ventilation with 100% O₂. All of these patients had SaO₂ levels of < 80% and were clinically cyanosed. However, three of them had poor SaO₂ levels prior to the procedure. Two had readings in the low 80's and one had pre-lavage SaO₂ level of 70%. The SaO₂ levels of these patients decreased even further during the NB-BAL procedure.

The SaO₂ levels decreased to < 70% in both patients on high-frequency positive pressure ventilation.

One patient experienced a mild bronchial haemorrhage during NB-BAL. This child had recently been intubated and no siderophages were found on iron staining. The bleeding stopped soon after withdrawing the catheter.

Six patients (17,1%) experienced bradycardia with a HR < 85 beats per minute (BPM) with a desaturation event during NB-BAL. The bradycardias were transient and resolved by discontinuing the procedure. HR increased by ≥ 10 BPM during the BAL in 16 patients (45,7%).

Figures 2.2 and 2.3 illustrate the inverse relationship between OI and VI and the level of desaturation during or immediately after NB-BAL. Figure 2.4 illustrates the positive correlation between PaO_2/FiO_2 and the level of desaturation. Solid red lines indicate the best-fit linear curve and dotted red lines indicate 95% confidence interval.

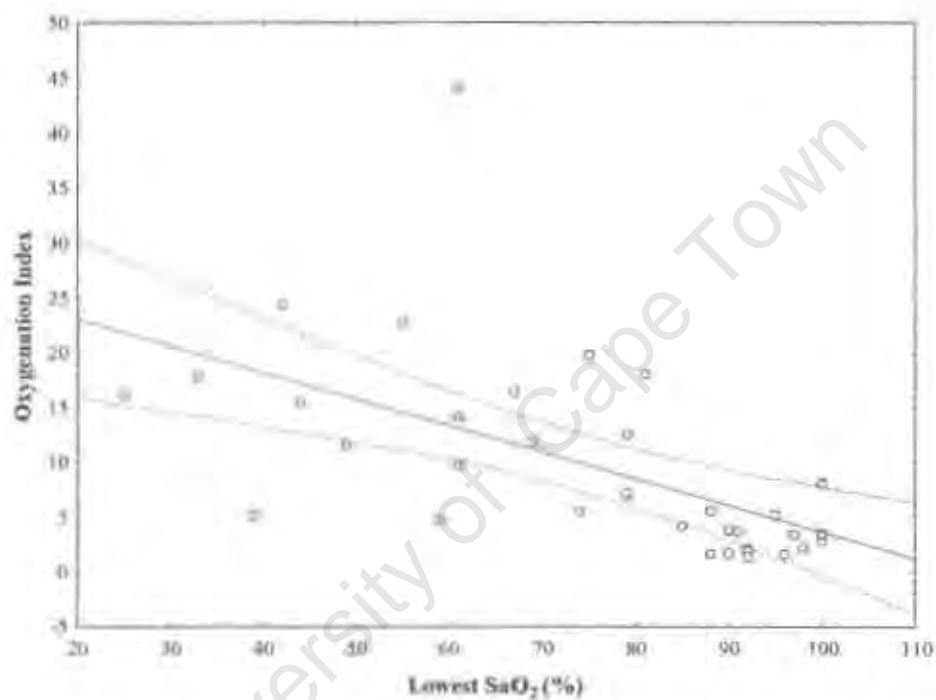


Figure 2.2: Correlation between OI and the level of desaturation during or immediately after NB-BAL. (Spearman's $R = -0,71$; $p < 0,0001$).

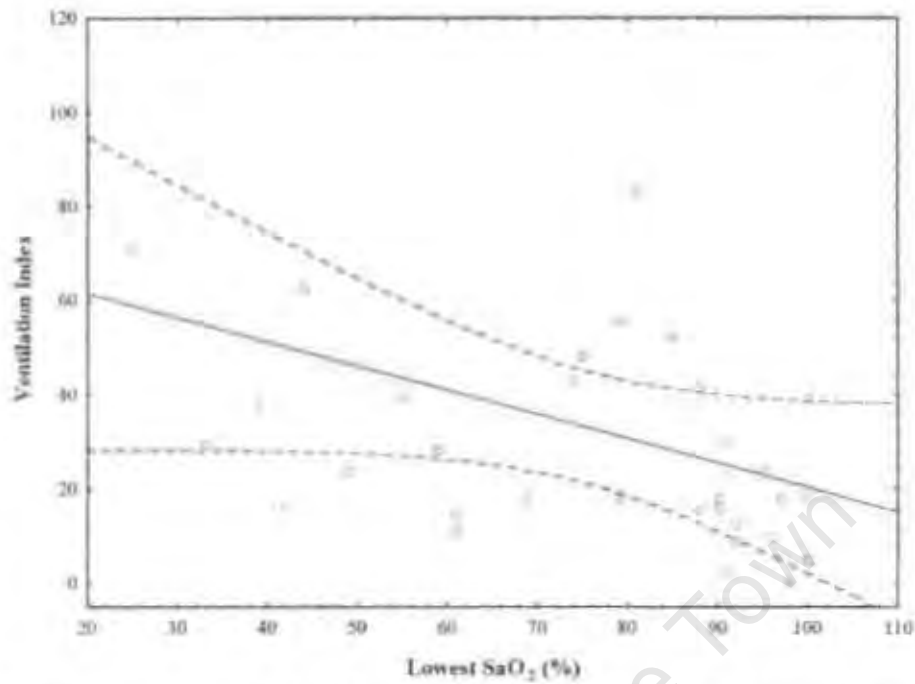


Figure 2.3: Correlation between VI and level of desaturation during or immediately after NB-BAL (Spearman's $R = -0,45$; $p = 0,007$).

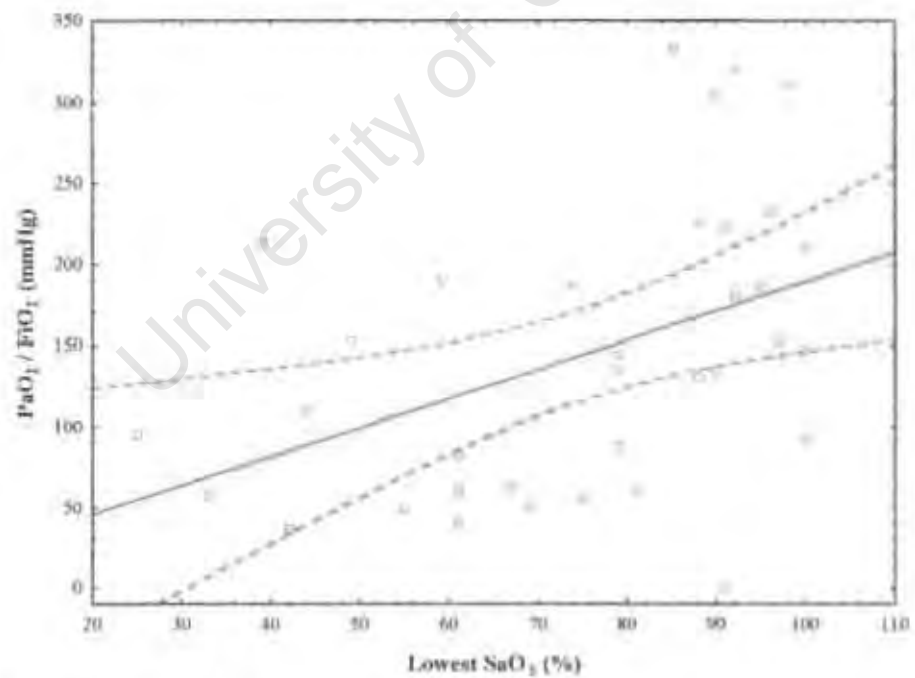


Figure 2.4: Correlation between PaO₂/FiO₂ and degree of desaturation during or immediately after NB-BAL (Spearman's $R = 0,45$; $p = 0,006$).

The relationship between OI and the severity of desaturation can be seen in Table 2.2. Ten of the 13 patients (76,9%) with OI < 5 maintained their SaO₂ levels ≥ 90%. Two patients (15,4%) desaturated to < 90% and only one (7,7%) desaturated to < 80%. All three patients recovered within one minute. In contrast, all 13 patients (100%) with OIs ≥ 10 desaturated as a result of the BAL. Twelve (92,3%) of the 13 desaturated to < 80%, and ten of them desaturated for ≥ three minutes.

Table 2.2: Relationship between baseline OI and severity of desaturation.

OI	No. of Patients	SaO ₂ ≥ 90%	SaO ₂ < 90%	SaO ₂ < 80%
0 to 5	13	10	2	1
5 to 10	8	2	4	5
>10	13	0	1	12

There was a significant difference in OI ($p < 0,01$) and PaO₂/FiO₂ ($p < 0,05$) between those patients who desaturated for > 1 minute compared to those who desaturated for < 1 minute. There were no statistically significant differences in gender, age, mortality or VI (Table 2.3)

Table 2.3: Length of desaturation during or after NB-BAL.

	Desaturation < 1 min	Desaturation > 1 min	<i>p</i>
Age (months)	17,32 ± 9,67	18,86 ± 9,78	0,91
Gender	7 male 4 female	8 male 3 female	0,72
OI	8,11 ± 1,54	22,33 ± 3,56	0,002
VI	40,83 ± 12,48	43,10 ± 8,27	0,88
PaO ₂ / FiO ₂ (mmHg)	155,18 ± 25,88	78,18 ± 11,42	0,02
Mortality	4	2	0,47

Age, OI, VI, and PaO₂/FiO₂ are expressed as mean ± standard error.

Eleven patients had a baseline $\text{FiO}_2 \geq 0,8$. All of them desaturated: four experienced transient periods of desaturation; four had sustained periods of desaturation lasting between one minute and five minutes; and the remaining three experienced sustained periods of desaturation of $< 80\%$, lasting > 10 minutes.

Of the 13 patients who maintained $\text{SaO}_2 \geq 90\%$, 10 (76,9%) had OIs < 5 , two had OIs between 5 and 10. The remaining one OI was unable to be calculated due to missing PaO_2 results. All 13 patients had baseline FiO_2 set at $< 0,6$. Similarly, of the twelve calculable values for $\text{PaO}_2/\text{FiO}_2$; of those who maintained $\text{SaO}_2 > 90\%$, only one was below 100; five were between 150 and 200; and six were above 200.

There were no pneumothoraces caused by the NB-BAL procedure.

Of the patients who underwent NB-BAL, 27 survived, four with neurological sequelae. One patient displayed athetoid movements of unknown aetiology on admission, which worsened during her stay in PICU; two developed hypertonia, probably as a result of metabolic derangement due to severe diarrhoeal disease; and one was severely affected with brain atrophy attributable to hypoxic events in the PICU. One patient survived, but after a year was still dependent on supplementary O_2 . One patient was lost to follow-up and the neurological status outcome is unknown. Of the eight patients who died, ventilatory support was withdrawn from one patient before NB-BAL results were known; one patient died the day after NB-BAL as a result of neurological complications; and the remaining six died as a result of cardiac and/or respiratory arrest. There was no evidence to consider that the NB-BAL procedure was the cause of any of these deaths.

2.5.1 Diagnostic Yield of NB-BAL

The mean recovery of NB-BAL fluid was $58,8\% \pm 5,9\%$ (range 45% - 75%). Differential cytology was performed on 16 specimens, all of which demonstrated the presence of alveolar macrophages confirming sampling of the alveolar lining fluid (Ratjen and Bruch, 1996).

The bacterial cultures were positive in 20 patients (57.1%). A single organism was cultured in 17 patients (48.6%), while in the remaining three, multiple organisms were cultured. The cultured organisms are listed in Table 2.4. Immunofluorescence examination of the lavage fluid documented the presence of *Pneumocystis carinii* in two patients. The culture of one patient's specimen was positive for *Mycobacterium tuberculosis*.

Table 2.4: Bacterial and fungal cultures from NB-BAL.

Culture result	n
<i>Acinetobacter baumannii</i>	6
<i>Pseudomonas aeruginosa</i>	5
<i>Staphylococcus aureus</i> ,	3
<i>Sphingomonas (pseud.) paucimobilis</i>	2
<i>Haemophilus influenzae</i>	1
<i>Serratia marcescens</i>	1
unspecified gram-positive species	1
<i>Streptococcus viridans</i>	1

Viral cultures were requested in 13 patients, two of whom yielded positive cultures of parvovirus IgG type 1 and Parainfluenzae Type 3. Yeasts were found in six patients. Fat laden macrophages, which may indicate lipid aspiration (Knauer-Fischer and Ratjen, 1999; Columbo and Hallberg, 1987), were seen in six specimens; and siderophages, indicating pulmonary haemorrhage / haemosiderosis, were found in three specimens.

Thirty-two of the 35 (91.4%) blood cultures taken coincidentally within a day of NB-BAL were negative except for contaminants. Three blood cultures were positive (8.6%); the first cultured *Staph. aureus*, which was also cultured from cerebrospinal fluid and pus swab whilst the NB-BAL culture was negative. The second blood culture grew *Serratia marcescens* whilst the NB-BAL culture yielded *Sphingomonas (Pseud.) paucimobilis* and Parainfluenzae virus (type 3). The third blood culture grew *Candida albicans*, which was

also cultured from a pus swab whilst the NB-BAL culture was negative.

A specific aetiology was established and treatment given on the basis of the cytology and/or culture result in 24 of the 35 patients (68,6 %). A diagnosis was made on NB-BAL findings based on the microbiological or cytological findings in nine (81,8%) of the 11 patients who desaturated for longer than a minute.

2.6 Discussion

Few reports on the use of NB-BAL in a paediatric population have been published. The information regarding the safety of this technique with different population groups is, therefore, still inconclusive.

Three lavages of saline were performed for the NB-BAL as it has been suggested that by adjusting saline solution volume to body weight a constant fraction of epithelial lining can be obtained (Ratjen and Bruch, 1996). Continuous mechanical suction was used as it has been shown that one obtains a better fluid return with continuous suction than with interrupted manual aspiration (Caughey et al, 1985). The cell profile of the first NB-BAL aliquot differs from the subsequent two, containing mainly bronchial cellular material and epithelial cells. The first portion of the aspirated fluid was, therefore, separated and discarded, in order to improve information gained about lower respiratory tract pathology (Pohunek et al, 1996).

The results of this chapter's investigation show that mild desaturation that readily resolves is a frequent occurrence during NB-BAL. This has been confirmed by other authors in studies conducted after the completion of this study (Burmester and Mok, 2001; Dargaville et al, 1999). Of more concern are the episodes of severe oxyhaemoglobin desaturation, which lasted for more than one minute. Burmester and Mok (2001) did not record acute changes in saturation during and immediately after NB-BAL, as the data in this study show. However, the results of this chapter's study support their contention that NB-BAL may result in significant adverse effects.

Burmester and Mok (2001) were unable to identify predictive factors for the complications associated with NB-BAL and Dargaville et al (1999) could not demonstrate a propensity to desaturation based on the severity of lung disease. In contrast to these findings, the results of this study show that there is a significantly greater risk of more marked and more prolonged desaturation in patients with high OI and low PaO₂/FiO₂ ratios. Patients with high VI tended to desaturate to lower levels, but there was no significant correlation between VI and duration of desaturation. This is the first time that these risk factors and their relationships have been analysed and documented.

A PaO₂/FiO₂ ratio < 200 mmHg is accepted as being indicative of a severe oxygenation defect in the lungs (Peters et al, 1998). In this study all the patients who experienced sustained desaturations had a PaO₂/FiO₂ ratio of < 150 mmHg, conforming to the definition of acute respiratory distress syndrome (ARDS) (Bernard et al, 1994).

It was decided to perform NB-BAL despite low pre-lavage SaO₂ levels in four patients as no pathogens had been isolated and their clinical conditions were deteriorating. Three of these patients experienced a further decrease in SaO₂, which took more than ten minutes to return to pre-lavage levels. Two of the four patients died, one of cardio-respiratory arrest the day after NB-BAL and the other child was extubated and died the day after NB-BAL before the results were obtained. The remaining two survived with no neurological sequelae. NB-BAL results of both these children yielded pathogens, resulting in a change of treatment being implemented.

Other complications found to be associated with NB-BAL were transient episodes of bradycardia and tachyarrhythmia and a single case of bronchial haemorrhage. The haemorrhage was mild and was probably as a result of traumatic intubation. The bradycardias, which occurred in six patients, were most likely caused by vagal nerve stimulation, which can be caused by routine endotracheal suctioning (Darlow et al, 1997), and were not clinically significant. The tachyarrhythmias recorded generally occurred with signs of patient discomfort or distress. This occurred despite sedation, which in 86% of the cases, was given in addition to the routine morphine infusion. It is possible that the

sedative dose given may have been insufficient or it may have been given too soon before the procedure to be effective.

It has previously been shown that routine suctioning causes an increase in intracranial pressure (Perlam and Volpe, 1983). None of the patients in this study had clinical signs of raised intracranial pressure, despite the diagnosis in one patient of meningococcal meningitis; and another with possible bacterial meningitis as well as diffuse pneumonia. The latter patient died the day after NB-BAL, but this was considered unlikely to be related to the procedure.

The results of the study in this chapter may differ from those of previous authors due to a variation of NB-BAL technique. The ventilatory system was not sealed during the procedure and therefore O_2 flow, but not MAP, was maintained. In response to the results of this study, attention was drawn to the fact that previous investigators had introduced the suction catheter through a hole in a diaphragm on an ETT swivel adaptor, thus enabling mechanical ventilation with pressure support to continue during NB-BAL (O'Sullivan, 2002). These details were not clear in the published studies and the difference in technique may explain the higher number of complications reported in the study in this chapter. For this reason, a further study (Chapter Three) was conducted to investigate the effect on NB-BAL complications of using a different NB-BAL technique where the O_2 flow as well as the MAP were maintained.

It is also possible that patients in this study were sicker than those studied by other authors who did not include OI, VI, or PaO_2/FiO_2 values (Alpert et al, 1992; Koumbourlis and Kurland, 1993). Dargaville et al (1999) reported a median OI of 11,3 (range 3,2 - 33), which was higher than that of patients in this study, whose median OI was 6,2 (range 1,4 to 44,0). Dargaville et al (1999) did not report PaO_2/FiO_2 or VI parameters.

There is minimal literature regarding the frequency of desaturation with routine ET suctioning. It is possible, therefore, that similar results would be obtained when taking routine TA specimens, although Dargaville et al (1999) reported that there was no

hours. Where possible, it is recommended that this be extended to haemodynamic stability for the preceding 12 hours.

- In hypoxic children, special care should be taken with regard to preoxygenation, sedation and lavage technique. Hypoxia cannot be considered an absolute contraindication to NB-BAL, but care should be taken in selecting patients for the procedure. Consideration should be given to the relevance of performing the procedure; the potential risks and benefits to the child; the financial cost of the investigations; and whether NB-BAL findings would affect the management of the patient in any way.
- In children with pulmonary tuberculosis (TB) or other highly infectious pathogens, there are potential risks to the therapist performing the procedure. There are reports of nursing staff having acquired tuberculosis from children requiring ET suctioning (Curtis et al, 1999; Rabalais et al, 1991).
- All of the patients described in this chapter had diffuse pulmonary disease. Where there is localised lung disease, and ETT > 4,5mm ID, bronchoscopic BAL, which allows direct visualisation of the airways, is indicated. In this situation, bronchoscopic BAL would be the technique of choice as specific sampling from the area of pathology could be obtained. In infants with unilateral lung disease and ETT ID < 4,5mm; bronchoscopic BAL is difficult to perform. In such patients a directed, blind NB-BAL technique could be performed by positioning the patients so that their heads are turned away from the abnormal lung (Kotecha, 1999). This position enables the catheter to be directed into the bronchus of choice.

Based on the results of this chapter's study, the following recommendations are made:

- It is recommended that special precautions be taken during NB-BAL with regard to sedation, preoxygenation and technique. This is especially important in patients with high oxygenation and ventilation requirements, specifically those with

OI > 10, VI > 20 and with PaO₂/ FiO₂ < 150.

- The patients' level of consciousness and anxiety should be assessed prior to performing the procedure and the appropriate sedative given accordingly, with enough time to take effect.
- Considering the number of complications associated with the procedure, the researcher recommends that NB-BAL should not be used as a routine investigative procedure for all patients, but should rather be reserved for patients who are haemodynamically stable. It should be carried out as soon after intubation as possible before bacterial ETT colonisation has occurred and/or in the event of a changing clinical picture with signs of infection and unknown pathogen. Frequent TA specimens obtained by ET suctioning may be sufficient in detecting potential respiratory tract pathogens (Prokop et al, 1996), in order to commence correct antibiotic therapy in the event of raised septic markers.
- Due to a shortage of staff, only one person performed the NB-BAL procedures in the study reported in this chapter. The technique would be facilitated by the presence of two people, one to perform the procedure and the other to monitor the patient. Unfortunately, in the current climate of public health care in South Africa, there are insufficient staffing levels to allow this and, therefore, another technique needs to be found to make NB-BAL a safer procedure.

The potential complications of NB-BAL should not be minimised; all patients should be carefully monitored throughout the procedure (Pattishall et al, 1988), and resuscitation equipment should be available at all times.

Chapter Three describes a prospective study that was conducted as a direct consequence of the findings reported in this chapter, in an attempt to reduce the incidence and/or severity of complications associated with NB-BAL.

CHAPTER THREE

A SIMPLE METHOD OF REDUCING THE COMPLICATIONS OF PAEDIATRIC NONBRONCHOSCOPIC BRONCHOALVEOLAR LAVAGE.

3.1 Introduction

As demonstrated in Chapter Two, paediatric NB-BAL is an effective diagnostic procedure in determining the aetiology of pulmonary pathology (Kotecha, 1999; Prokop et al, 1996; Panero et al, 1995; Koumbourlis and Kurland, 1993; Minotuli et al, 1990; Piperno et al, 1988). It is less expensive, less time-consuming and requires less expertise than bronchoscopic BAL (Baughman and Conrado, 1998; Minotuli et al, 1990; Pugin et al, 1991) and has the advantage that it can be easily used in infants with ETT ID < 3,5mm through which flexible bronchoscopes with suction ports cannot be passed (Kotecha, 1999; Koumbourlis and Kurland, 1993; Alpert et al, 1992).

Until recently, NB-BAL in mechanically ventilated infants and children has been considered to be a safe procedure, suitable for use even in the sickest term and preterm infants (Shields and Rielder, 2000; Dargaville et al, 1999; Kotecha, 1999; Koumbourlis and Kurland, 1993; Alpert et al, 1992; Minotuli et al, 1990). The results of the previous chapter, along with recently published literature, suggest that NB-BAL may cause significant immediate and later complications (Burmester and Mok, 2001; Baughman and Conrado, 1998).

Chapter Two described the most notable immediate complication of NB-BAL as that of oxyhaemoglobin desaturation. This is corroborated by the findings of Baughman and Conrado (1998). In Chapter Two, desaturation was shown to be most severe and prolonged in patients with high O₂ and ventilatory requirements. A substantial increase in OI at one hour after NB-BAL has been described in some patients and the negative

effects of NB-BAL have at times necessitated an increase in the level of respiratory or haemodynamic support (Burmester and Mok, 2001).

It was recommended at the end of the previous chapter, and suggested by O' Sullivan (2002), that maintaining ventilation and oxygenation during NB-BAL may substantially reduce the complications associated with the procedure. Previous investigators have ensured ongoing ventilation during NB-BAL (Dargaville et al, 1999; Koumbourlis and Kurland, 1993), although in the study by Koumbourlis and Kurland (1993) the exact method of maintaining ventilation is unclear.

As a result of the findings reported in Chapter Two, a new method of performing NB-BAL was adopted in the PICU of RCWMCH in an attempt to reduce the number of complications associated with the procedure.

3.2 Aim

This study aimed to determine whether a simple method of maintaining positive pressure ventilation during NB-BAL would reduce the incidence and/or severity of desaturation events associated with the procedure.

3.3 Objectives:

The objectives of this study were to:

1. assess the feasibility and practicality of a simple adaptation of the NB-BAL technique, which would allow ongoing ventilation during the procedure;
2. compare the incidence and level of severity of the complications associated with this new NB-BAL technique, with those recorded using the NB-BAL technique described in Chapter Two; and
3. confirm the risk factors for hypoxia by means of correlations between respiratory severity indices (OI, VI, PaO₂/FiO₂) and the degree of desaturation for both patient groups.

3.4 Materials and Methods

During the period from 1998 to 1999 NB-BAL was performed using an “unsealed” technique as part of the prospective study described in Chapter Two. Subsequently, from 2000, a modified (“sealed”) NB-BAL technique was introduced in an attempt to minimise the side-effects of NB-BAL. Data using this method were collected prospectively from September 2001 to February 2002 and compared to the data reported in Chapter Two.

The Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town formally approved this study (REC REF 306 / 2001) and waived the need for informed consent.

3.4.1 Study design

The study design was a non-randomised clinical trial using an historical control.

3.4.2 Patient Sample:

All intubated and mechanically ventilated patients being managed in the PICU for whom a diagnostic NB-BAL was clinically indicated were eligible for participation in this study, subject to the inclusion and exclusion factors listed below.

A convenience sample of 35 consecutive patients who underwent investigative NB-BAL between September 2001 and February 2002 was studied. These data were compared with the sample of 35 patients described in Chapter Two.

Inclusion and exclusion criteria for the control group, using an “unsealed” NB-BAL technique, were presented in Chapter Two. Inclusion and exclusion criteria for the “sealed” NB-BAL group were the same, except that the period of haemodynamic stability required for inclusion was extended to 12 hours; patients with meningitis were excluded from the study as a result of concerns about intracranial pressure; and patients with low platelet counts were excluded owing to concerns about iatrogenic pulmonary haemorrhage. These may have introduced minor confounding variables.

Inclusion criteria:

- pulmonary disease diagnosed radiologically and/or clinically; and
- intubation and mechanical ventilation.

Exclusion criteria:

- haemodynamic instability over preceding twelve hours (fluctuations in HR, MABP or SaO₂ of > 20%);
- pulmonary haemorrhage;
- pulmonary oedema;
- cor pulmonale with pulmonary hypertension;
- meningitis;
- raised intracranial pressure (observed clinically by raised fontanelle or decreased level of consciousness or, if measured, >15mmHg);
- congestive cardiac failure;
- platelet count <50 x 10⁹ /l; and
- premature neonates.

3.4.3 Technique and apparatus

Briefly, the “unsealed” NB-BAL technique (as described fully in Chapter Two) was performed as follows:

- Patients were positioned in supine at least one hour prior to the procedure.
- Patients, on continuous ECG and pulse oximetry monitoring, received 0,1 mg/kg additional sedation of intravenous morphine or midazolam 10 to 15 minutes prior to the procedure and were ventilated for one minute with 100% O₂.
- The suction catheter, of FG sizes 5-8, was passed directly into the ETT through a 7mm port in the ETT connector until it wedged distally. This ensured that oxygenation, but not airway pressure, was maintained during the procedure. The Shann (1998) guidelines were used as the basis for catheter selection.
- After wedging, the catheter was withdrawn slightly (< 5mm) and three

lavages of 1 ml/kg of 0.9% saline at room temperature were performed in rapid sequence without displacing the catheter. After introduction of each lavage volume, the suction catheter was attached to a mucus extractor with vacuum pressure applied.

The new “sealed” technique was identical to the “unsealed” technique described above except that the suction catheter was passed through a diaphragm consisting of two layers of *Tegaderm* transparent dressing (3M Health Care, USA) placed over the ETT connector port in such a way that positive pressure ventilation could be maintained throughout the procedure (Figure 3.1).



Figure 3.1: “Sealed” NB-BAL, during saline instillation through *Tegaderm*. The arrow indicates the site of catheter insertion. Photograph with parental consent.

Patients receiving HFOV were manually ventilated using an anaesthetic bag during the procedure and the catheter was passed through a diaphragm in the same way.

If a patient’s SaO₂ level decreased to $\leq 80\%$ at any stage during both methods of NB-BAL, the catheter was withdrawn. If immediate improvement did not occur, the patient was manually ventilated with 100% inspired O₂ until the SaO₂ returned to the pre-lavage levels. The procedure was not continued after stabilisation. This was an intention-to-treat analysis therefore patients who required the procedure to be abandoned were still

included in data analysis.

Levels of SaO₂ and HR were recorded before, during and up to 15 minutes after NB-BAL. Personal data were recorded for patients in each group as well as their FiO₂ and ventilation requirements.

3.4.4 Analysis

OI ($MAP(FiO_2(100)/PaO_2)$), VI ($RR(PaCO_2(PIP/1000))$) (Peters et al, 1998) and PaO₂/FiO₂ were calculated for each patient.

The following statistical analyses were performed:

- Data were tested for normality with Levene's Test of Homogeneity of Variances.
- Descriptive statistics were used to obtain the median, mean, range, standard errors and/or interquartile ranges for all variables studied,
- normally distributed between-group data were analysed using the Student's *t* – test for independent variables;
- between-group independent nonparametric variables were compared using the Mann-Whitney U test;
- Spearman's rank order non-parametric correlation tests were used to assess relationships between variables; and
- Chi-square or Fisher's exact tests were also used

- (*Statistica* for Windows, Kernel Release 5.5, StatSoft Inc, USA)

3.5 Results

NB-BAL was performed on 35 patients using the "unsealed" method (Chapter Two), and two years later on 35 patients using the "sealed" technique. All patients were diagnosed with diffuse pneumonia, with or without secondary or underlying diagnoses and underwent NB-BAL for diagnostic purposes.

Table 3.1: Summary of patient data

	"SEALED"	"UNSEALED"	<i>p</i>
Age (months)	3 (1 - 73)	4 (1 - 108)	0,63
Weight (kg)	4,0 (1,6 - 15,0)	4,9 (2,1 - 20,0)	0,2
FiO ₂	0,4 (0,21 - 0,85)	0,5 (0,21 - 1,0)	0,33
ETT (mm ID)	3,5 (2,5 - 5,0)	3,5 (2,5 - 6,0)	0,47
MAP (mmHg)	10,36 (4,4 - 18,8)	8,88 (2,2 - 36,3)	0,10
OI	5,76 (1,6 - 27,7)	6,24 (1,4 - 44,0)	0,99
VI	20,1 (5,0 - 154,9)	23,5 (2,02 - 199,8)	0,53
PaO ₂ /FiO ₂ (mmHg)	169,3 (42,7 - 390,8)	144,4 (36,6 - 333)	0,3
Lowest SaO ₂ (%)	88 (37 - 100)	79 (25 - 100)	0,14
Decrease in SaO ₂ (%)	6,0 (-6 - 44)	13,0 (-2 - 61)	0,03

Results are expressed as median (range).

Results are summarised in Table 3.1. Using the Mann-Whitney U test, there were no differences between the two groups with regard to patient data or oxygenation and ventilatory requirements.

In the "unsealed" group, 33 patients received conventional mechanical ventilation and two patients received HFOV using a BIRD[®] ventilator (Bird Products, Palm Springs, California). In the "sealed" group, 32 patients were on conventional ventilation (Newport Ventilators models E100i and E100m) and three received HFOV (SensorMedics Model 3100A Oscillatory Ventilator).

The decrease in SaO₂ from baseline (Δ SaO₂) was significantly smaller in the “sealed” group of patients ($p < 0,05$) (Table 3.1). This is also shown in Figure 3.2.

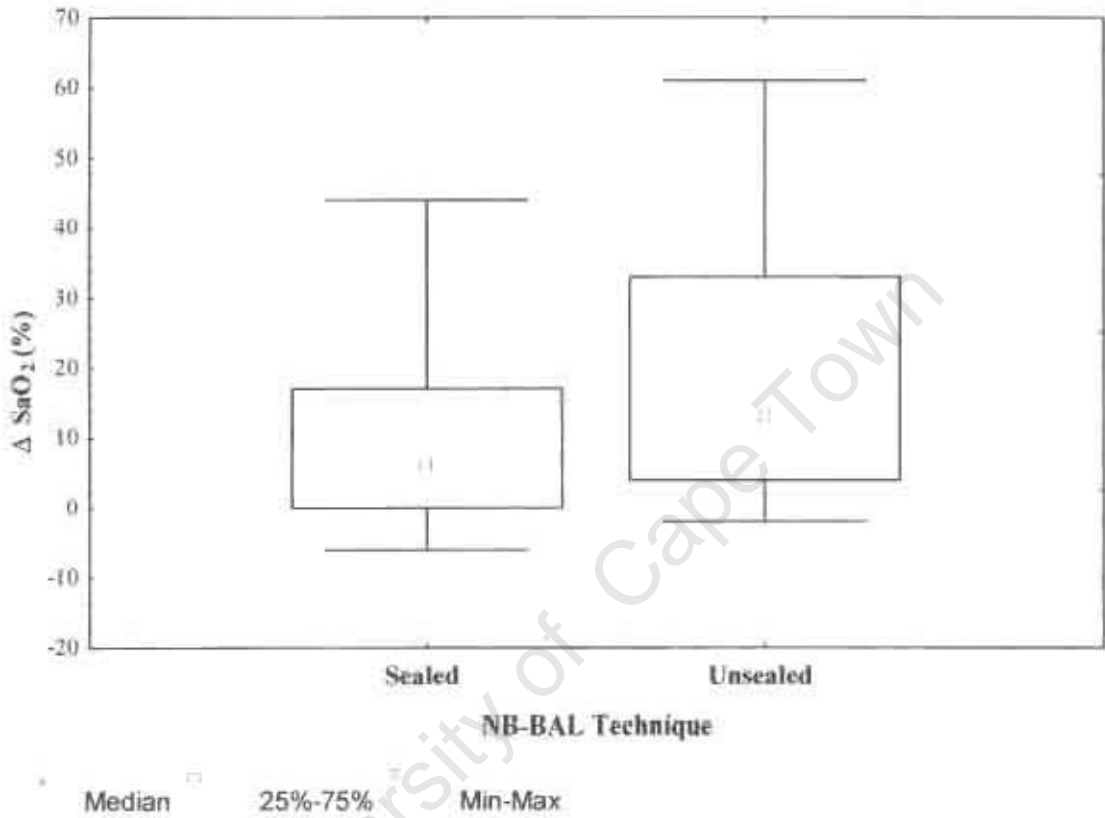


Figure 3.2: The decrease in saturation (Δ SaO₂) recorded using the two NB-BAL techniques.

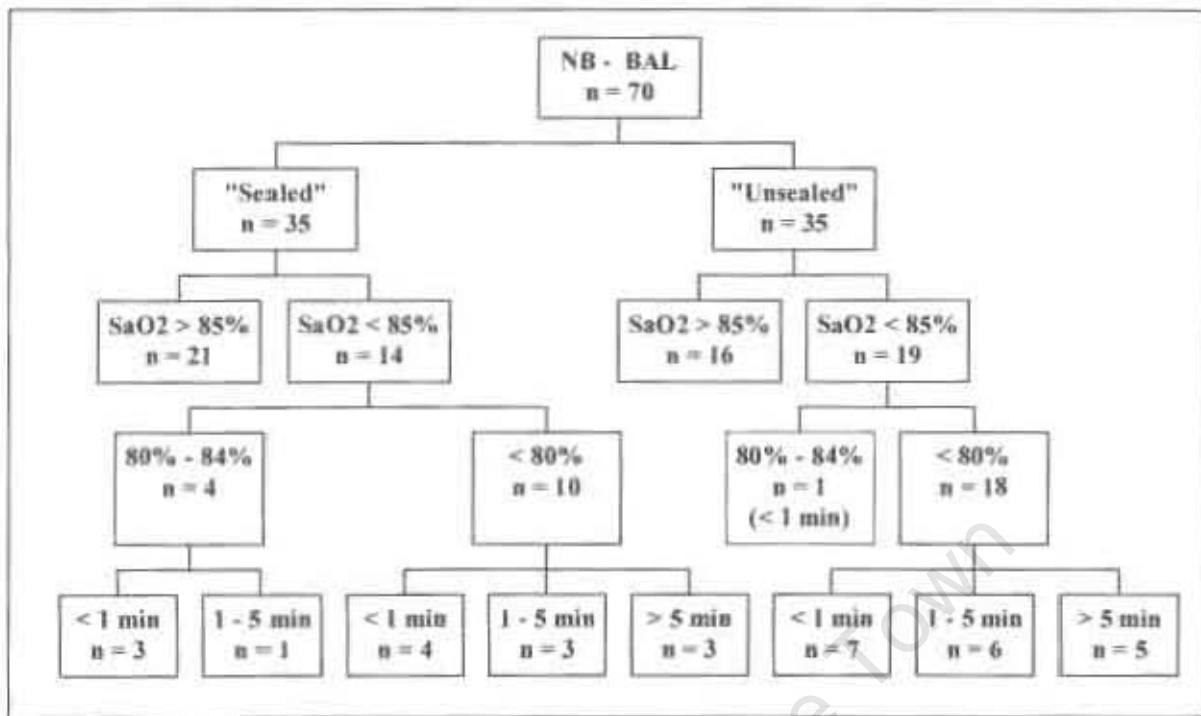


Figure 3.3: Desaturation events and their duration.

Figure 3.3 illustrates the desaturation events occurring in patients in the “sealed” and “unsealed” groups and the times taken for SaO₂ to return to pre-lavage levels when desaturation occurred. Of those who desaturated to < 85%, the recovery time was 5,1 ± 5,8 minutes in the “unsealed” group and 4,2 ± 5,3 minutes (mean ± standard deviation) in the “sealed” group ($p = 0,65$).

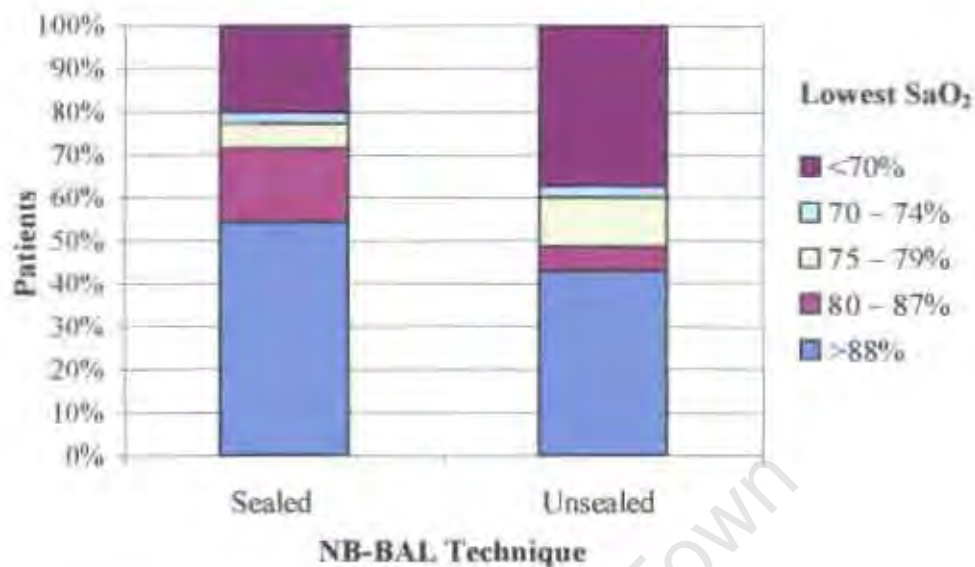


Figure 3.4: Lowest recorded SaO₂ during or following NB-BAL.

Figure 3.4 and Table 3.2 show the level of desaturation episodes in each group. Thirteen (68,4%) of the 19 patients in the “unsealed” group who desaturated to < 85% experienced desaturation levels of < 70 % as opposed to seven (50%) of 14 in the “sealed” group ($p = 0,3$).

Table 3.2: Number of patients in each group experiencing desaturation events during NB-BAL.

Lowest SaO ₂ (%)	“Sealed” (n = 35)	“Unsealed” (n = 35)
>85	21	16
80 – 84	4	1
75 – 79	2	4
70 – 74	1	1
<70	7	13

In the "sealed" group, 54,2% (19/35) maintained SaO₂ ≥ 88% with 28,6% (10/35) desaturating severely to < 80%. Of the "unsealed" group, 42,9% (15/35) maintained SaO₂ ≥ 88% whilst 51,4% (18/35) desaturated to < 80%. Significantly more patients desaturated to < 80% in the "unsealed" group ($p = 0,04$) (Table 3.3). Thirteen (65%) of the 20 patients in the "unsealed" group who desaturated during NB-BAL, experienced desaturation to < 70 % compared to seven (43,8%) of 16 in the "sealed" group ($p = 0,2$).

Table 3.3: Lowest SaO₂ during or immediately after NB-BAL for patients in each group.

SaO ₂ (%)	"Sealed" (n = 35)	"Unsealed" (n = 35)
≥ 80	25 (71,4%)	17 (48,6%)
< 80	10 (28,6%)	18 (51,4%)

There was a significant positive correlation between OI and Δ SaO₂ during NB – BAL, for both "sealed" (Spearman $R = 0,47$; $p < 0,001$) and "unsealed" groups ($R = 0,63$; $p < 0,0001$). For both groups, there was a significant negative correlation between PaO₂/FiO₂ and Δ SaO₂ ("unsealed" group $R = -0,38$; $p < 0,05$; "sealed" group $R = -0,47$; $p < 0,01$). There was also a significant positive correlation between VI and Δ SaO₂ ($R = 0,43$ for "unsealed", $R = 0,41$ for "sealed"; $p = 0,01$ for both groups).

Table 3.4: Baseline OI and lowest recorded SaO₂ during or after NB-BAL.

OI	n		SaO ₂ > 85%		SaO ₂ 80 - 84 %		SaO ₂ < 80%	
	"sealed"	"unsealed"	"sealed"	"unsealed"	"sealed"	"unsealed"	"sealed"	"unsealed"
0 to 5	16	13	13	12	2	0	1	1
5 to 10	6	9	4	3	0	0	2	6
> 10	13	12	4	0	2	1	7	11

Table 3.4 shows the desaturation events in patients with different OI. In the "sealed" group three (19%) of 16 patients with OI < 5 desaturated; two of these patients desaturated to between 80% and 84% and one desaturated to < 80%. In the "unsealed" group, one (8%) of the 13 patients with OI < 5 desaturated to < 80%. Significantly more patients, in both groups, with OI > 10 desaturated than those with OI < 10 ($p \leq 0,0001$). Four (30,8%) of 13 patients with OI > 10 in the "sealed" group maintained SaO₂ ≥ 85% whilst in the "unsealed" group, 100% of the patients desaturated.

Table 3.5: Lowest SaO₂ of patients in each group with OI > 10. Fisher's Exact test, $p = 0,046$.

Lowest SaO ₂ (%)	"Sealed" n (%)	"Unsealed" n (%)
≥ 80	6 (46,2)	1 (8,3)
< 80	7 (53,8)	11 (91,7)

There were 53,8% of patients in the "sealed" group with OI > 10 who experienced severe desaturation events to < 80% and 91,7% in the "unsealed" group ($p = 0,046$) (Table 3.5). There was no significant difference between NB-BAL groups for severity of desaturation at other OI levels.

Table 3.6: Baseline PaO₂/FiO₂ and lowest recorded SaO₂.

PaO ₂ /FiO ₂ (mmHg)	n		SaO ₂ ≥ 85%		SaO ₂ 80 - 84%		SaO ₂ < 80%	
	"sealed"	"unsealed"	"sealed"	"unsealed"	"sealed"	"unsealed"	"sealed"	"unsealed"
>250	7	4	7	4	0	0	0	0
200-250	9	5	7	4	1	0	1	1
150-200	2	6	1	3	1	0	0	3
<150	17	19	6	4	2	1	9	14

Table 3.6 shows the desaturation events in patients with different PaO₂/FiO₂ ratios. In both groups all patients with PaO₂/FiO₂ ratios > 250 mmHg maintained SaO₂ ≥ 88% during and immediately after NB-BAL. For both patient groups there were significantly more severe desaturation events in those with PaO₂/FiO₂ ratios < 150 mmHg than in patients with higher PaO₂/FiO₂ ($p \leq 0,0001$). 73,7% of patients in the "unsealed" group and 52,9% of patients in the "sealed" group with PaO₂/FiO₂ ratio < 150 mmHg experienced severe desaturation events to < 80% during or immediately after NB-BAL ($p = 0,17$). There were no significant differences in desaturation levels between the two groups for other PaO₂/FiO₂ levels (> 250, 200-250, 150-200; $p > 0,1$).

There was no difference in severity of desaturation at various VI levels between the two NB-BAL groups (< 20, 20-40, > 40; $p > 0,1$).

Six patients in the "unsealed" group (17%) experienced transient, self-limiting bradycardia to < 85 BPM during NB-BAL. The procedure was abandoned and their HR returned to prelavage levels immediately on reconnecting the ventilator. No patients in the "sealed" group experienced this complication. One patient in the "sealed" group experienced prolonged, severe desaturation to < 50% following NB-BAL despite manual ventilation with 100% O₂. This necessitated changing the mode of ventilation from conventional ventilation to HFOV. Following this change, SaO₂ rapidly improved. One patient in the "unsealed" group experienced a mild haemorrhage during NB-BAL. Bleeding ceased soon after discontinuing the procedure.

3.6 Discussion

Chapter Two and other recent reports have documented adverse effects of NB-BAL (Burmester and Mok, 2001; Baughman and Contrado, 1998). The results of this chapter confirm that desaturation is a frequent complication of NB-BAL and is more severe in patients with markers of severe respiratory disease, as seen by high OI and VI and low PaO₂/FiO₂.

The adaptation of the NB-BAL technique was cost-effective, as it did not require expensive adaptations to the ETT. It was simple to perform, required minimal operator training, and appeared to effectively seal the ventilatory system, allowing mechanical ventilation to continue throughout the procedure. This method is therefore practical to use in all patients undergoing NB-BAL.

During routine ET suctioning, hypoxia has been well described and has been attributed to a combination of O₂ deprivation, interruption of ventilation and airway occlusion (Kohlhauser et al, 2000; Skov et al, 1992; Graff et al, 1987; Ehrhart et al, 1981; Simbruner et al, 1981; Fox et al, 1978; Rosen and Hillard, 1962). Aspiration of intrapulmonic gas during suctioning may reduce the total volume of O₂ in the lungs and also cause hypoxia (Simbruner et al, 1981; Rosen and Hillard, 1962).

Hyperoxygenating before suctioning prevents hypoxaemia (Branson et al, 1993; Skov et al, 1992; Shah et al, 1992; Rosen and Hillard, 1962). In this study, however, despite adequate pre-oxygenation and the provision of 100% O₂ during the procedure, episodes of hypoxia were reported during both "sealed" and "unsealed" NB-BAL techniques. Hypoxia was usually transient, but in some cases the episodes were severe and prolonged, with the possibility of neurological sequelae developing as a consequence.

Possible explanations for the number and severity of the hypoxic events that occurred with NB-BAL, despite adequate provision of 100% O₂, are suggested below:

1. The patients had severe lung pathology, as shown by their respiratory severity indices (Table 3.1). The median PaO₂/FiO₂ ratio was < 200 in both groups,

indicative of a severe oxygenation defect (Peters et al, 1998). The majority of patients met the criteria for ARDS (Bernard et al, 1994).

2. During NB-BAL the suction catheter remained in the airway for longer than the time usually taken to suction a child and repeated suction events were performed without removing the catheter in between suctioning events. This would greatly increase airway resistance. In addition, negative intrapulmonary pressure may have accumulated, particularly with the "unsealed" method, leading to loss of lung volume.
3. The volume of saline solution introduced into the lungs during NB-BAL may decrease the surface area available for gaseous exchange. Ridling et al (2003) suggest that unretrieved saline could interfere with alveolocapillary O₂ exchange.
4. When negative suction pressure is applied, most of the instilled saline would be removed together with some of the alveolar lining fluid, which contains surfactant necessary for the patency and stability of the alveoli (Burmester and Mok, 2001). This may have further contributed to atelectasis with resulting hypoxia.
5. Gases in the distal airways may be aspirated during suctioning resulting in alveolar collapse with subsequent hypoxia (Simbruner et al, 1981).

Patients were sedated, but were not paralysed, during NB-BAL. There is a possibility, therefore, that the babies' responses to the unpleasant and possibly painful suctioning experience, could have brought about some of the cardiorespiratory changes reported here (Simbruner et al, 1981). This may have occurred despite sedation, if the doses given were insufficient or had not been given sufficiently in advance of the procedure.

This study demonstrates that a small modification of the NB-BAL technique, which allows positive pressure ventilation to continue during the procedure, makes a significant difference to the severity of the adverse effects and is clearly a safer technique. The "sealed" technique is likely to have minimised lung volume loss during suctioning, thus enabling better O₂ transfer at an alveolar level and subsequently better O₂ delivery to the tissues. This is supported by Choong et al (2003) who reported that suctioning through a closed system reduced suctioning-induced lung volume loss.

The use of an historical control is a limitation of this study, but was necessary for ethical reasons. This was due to the fact that a high number of complications were noted to occur when using the original NB-BAL technique. It should be noted that the same person (BM) performed the lavages for both groups of patients and both data sets were collected prospectively. The patients were well matched with regard to personal data and severity of lung disease and it is unlikely that any other medical management would have differed greatly between the groups. Therefore, the results of this study are likely to be valid.

Dargaville et al (1999) found that severity of lung disease did not predict whether desaturation would occur during a lavage procedure. Burmester and Mok (2001) were unable to predict complications of NB-BAL with OI or PRISM scores. In contrast to these findings, patients in this study with OI > 10 desaturated significantly more frequently and more severely than patients with lower OI in both groups. Desaturation episodes were also significantly more frequent and more severe in patients with PaO₂/FiO₂ ratios < 150 in both groups.

Similarly, there was a significant correlation between OI, VI and PaO₂/FiO₂ and the change in SaO₂ during or immediately after NB-BAL. These results indicate that the severity of lung disease may predict the likelihood of arterial desaturation occurring during NB-BAL. This has not been reported previously.

Although patients with OI > 10 are at risk of developing complications with NB-BAL, regardless of the technique used, these results show that sealing the system reduces this risk significantly.

Other complications recorded resolved spontaneously. The bradycardic episodes could have been caused by direct vasovagal stimulation by the catheter. It is unclear why this complication did not occur in patients undergoing "sealed" NB-BAL. It may be due to the fact that ventilation continued during the procedure resulting in decreased anxiety, thereby reducing some of the cardiovascular effects associated with pain and discomfort.

The catheters used did not have side-holes, both in order to facilitate saline delivery to the distal airspaces beyond the point of wedging (Dargaville et al, 1999) and in an attempt to minimise mucosal trauma caused by adherence of the side-holes to the bronchial walls. One episode of haemorrhage was reported, which may have been caused by trauma during a recent intubation or by trauma caused by the suction catheter itself. Bleeding ceased soon after discontinuing the procedure with no further intervention being required.

In both groups there were patients who experienced severe desaturation episodes to <80%, for more than five minutes duration. As a direct result of NB-BAL, one patient required marked escalation of ventilation and oxygenation support. These results support the contention that NB-BAL should not be underestimated with regard to its potential deleterious effects (Burmester and Mok, 2001).

3.7 Conclusion and recommendations

This study aimed to determine whether a novel method of maintaining positive pressure ventilation during NB-BAL would reduce the incidence and/or severity of desaturation events associated with the procedure.

These data confirm that there are risks associated with NB-BAL, but that the severity of desaturation can be significantly reduced by a simple modification of the technique that enables ongoing ventilation and maintenance of airway pressure during the procedure. Based on these results, it is recommended that this or a similar technique be adopted in other PICUs in order to improve the safety of paediatric NB-BAL.

Considering that paediatric NB-BAL, a procedure largely consisting of prolonged ET suctioning, caused such notable complications; the results of the investigations reported in Chapters Two and Three raised numerous questions regarding the haemodynamic and physiological responses to ET suctioning alone (page 1-14). In order to investigate the effects of paediatric ET suctioning, a series of investigations was conducted, beginning with an *in vitro* study described in Chapter Four.

CHAPTER FOUR

ENDOTRACHEAL SUCTIONING: MOVING FROM PRINCIPLES TO PRACTICE

4.1 Introduction

The investigations reported in Chapters Two and Three raised numerous questions regarding the mechanisms underlying the haemodynamic and physiological changes that occur during paediatric ET suctioning (page 1-14).

An extensive literature search was conducted around ET suctioning, in an attempt to determine the effects of suctioning on the lung itself. The search terms used were "suctioning", "suction", "tracheal suction", "endotracheal suction", in various combinations with modifiers such as "children", "paediatric", "complications" and "effects".

ET suctioning is a routine procedure performed by nursing and medical staff on all patients with artificial airways in the PICU. Suctioning is performed by physiotherapists after CPT to remove mobilised secretions and to obtain TA specimens for microscopy, sensitivity and bacterial culture.

Although considered essential to prevent airway obstruction from accumulation of secretions, it is recognised that severe adverse events may result from suctioning. These include hypoxia; bradycardia and other arrhythmias; raised intracranial pressure; bacteraemia; mucosal trauma; pneumothorax; loss of ciliary function; and atelectasis (Carhuapoma and Williams, 1999; Kerr et al, 1999; Darlow et al, 1997; Barker and Rutter, 1995; Segar et al, 1993; Monaco and Meredith, 1992; Shah et al, 1992; Skov et al, 1992; Tarnow-Mordi, 1991; Singh et al, 1991; Durand et al, 1989; Loubser et al, 1989; Bailey et al, 1988; Fanconi and Duc, 1987; Graff et al, 1987; Gunderson et al, 1986; Arai

et al, 1985; Murdoch and Darlow, 1984; Ehrhart et al, 1981; Simbruner et al, 1981; Zmora and Merritt, 1980; Cabal et al, 1979; Kuzenski, 1978; Anderson and Chandra, 1976). Some of these events may be due to vagal nerve stimulation (Zmora and Merritt, 1980), coughing or catheter trauma (Hodge, 1991; Bailey et al, 1988; Anderson and Chandra, 1976) and others may be directly related to the physical effects of suctioning on the lungs (Maggiore et al, 2003; Lu et al, 2000; Ehrhart et al, 1981; Hipenbecker and Guthrie, 1981; Polacek and Guthrie, 1981; Brandstater and Muallem, 1969; Rosen and Hillard, 1962).

It has been suggested that atelectasis may be caused by the aspiration of intrapulmonic gas during suctioning (Ehrhart et al, 1981). It has also been hypothesized that if a catheter largely or completely occludes an artificial airway or bronchus, greater negative pressures are created in the lung leading to massive atelectasis (Rosen and Hillard, 1962). This has led to the recommendation that the suction catheter size should be no more than half the ID of the ETT (Boothroyd et al, 1996; Young, 1984). This is clearly not possible when suctioning infants with very small ID ETTs.

Recommendations have been made regarding appropriate, safe suction pressures, depth of insertion of the suction catheter and catheter size (Boothroyd et al, 1996; Shann, 1998; Branson et al, 1993; Young, 1984). Few of these recommendations are evidence-based, nor do they address any dimensions of the suction catheters other than the cross sectional diameter. They do not appear to make allowances for variation in mucus viscosity nor do they appear to consider the relationships between ETT size, catheter length and diameter and suction pressures; and the potential effects these may have on the lung. Neither do they address specific suctioning techniques or intrathoracic pressure changes during ET suctioning of intubated infants and children.

Owing to the paucity of data related to ET suctioning, it was important to first investigate some of its effects by means of an *in vitro* study in order to obtain baseline data before initiating clinical trials.

4.2 Aims

The aims of the study in this chapter were to:

- investigate the physical principles of pressure and gas flow dynamics associated with ET suctioning;
- to demonstrate these on a simple illustrative model; and
- to discuss the clinical implications of applying these principles to paediatric practice.

4.3 Theoretical Discussion

During ET suctioning, it is postulated that the pressure changes within the thorax would be related to the balance between the volume of gas suctioned out through the suction catheter; the volume of gas that replaces this by means of the gas flow between the ETT and the suction catheter; and the compliance of the respiratory system.

The volume of gas suctioned from the lungs through the suction catheter would be related to the resistance of the catheter, the pressure gradient applied across the length of the catheter, the presence of laminar or turbulent flow through the suction catheter and the presence of gas flow limitation within the suction catheter. According to Poiseuille's law (Black-Payne, 1993), in the presence of laminar flow, the resistance provided by the catheter would be proportional to its length and the 4th power of its radius (or the square of the cross-sectional area).

The walls of a collapsible tube approach each other as the external pressure increases relative to internal pressure. The cross-sectional area is therefore a function of the pressure difference across the wall of the tube and the elastic properties of that wall. As this airway collapse occurs, resistance to flow increases and the pressure increases upstream from the narrowed airway segment. In spite of increasing driving pressure the speed of gas flowing through a narrow tube never exceeds the speed with which a pressure wave propagates through the wall of the tube (gas flow limitation) (Dawson and Elliot, 1977).

The volume of gas suctioned would be greater with higher pressure gradients, shorter and wider ID catheters. If turbulence occurs the resistance may be higher than predicted for laminar flow; and if gas flow limitation occurs the resistance may be considerably higher.

With high flow rates it is likely that flow limitation would occur within a catheter, and thereafter changes in pressure gradients would not affect the gas flow through the catheter. Secretions within the catheter would limit gas flow to a variable degree, and may also completely obstruct flow. The volume of gas withdrawn through the catheter during suctioning would also likely be affected by the duration of the suctioning manoeuvre.

The pressure gradient across the length of the catheter depends on the suction pressure applied to the catheter and the pressure developed within the chest. It is likely that the level of intrathoracic pressure developing during suctioning would be related to the compliance of the respiratory system, gas flow through the suction catheter; and the extent to which gas flowing into the chest through the ETT and around the catheter can replace the gas being extracted through the suction catheter lumen. Considering the compliance of the respiratory system in small infants, it is unlikely that intrathoracic pressure would significantly affect the rate of gas flow through the lumen of the catheter.

Gas flow between the ETT and the suction catheter would be determined by the pressure gradient between the internal to external openings of the ETT and the square of the cross-sectional area of the ETT available for gas flow (Poiseuille's Law). The maximum cross sectional area available for this flow is represented by the difference between the internal cross sectional area of the ETT and the external area of the catheter (Area Difference (AD)). In reality the cross-sectional area available for flow would be even less than this, as secretions would obstruct some of the area and there may also be constrictions at certain points such as the point of insertion of the connecting tube. It is also likely that the thickness of the catheter tubing substantially influences the relationship between the

maximal flow possible through the catheter and the maximal flow between the ETT and the suction catheter.

Gas flow out of the thorax, through the catheter, is determined largely by the cross-sectional area of the catheter (CA), and gas flow into the chest by the AD. It was therefore predicted that in a rigid chest model the pressure changes developed in the model during suctioning would be related to the Catheter Area: Area Difference (CA:AD) ratio.

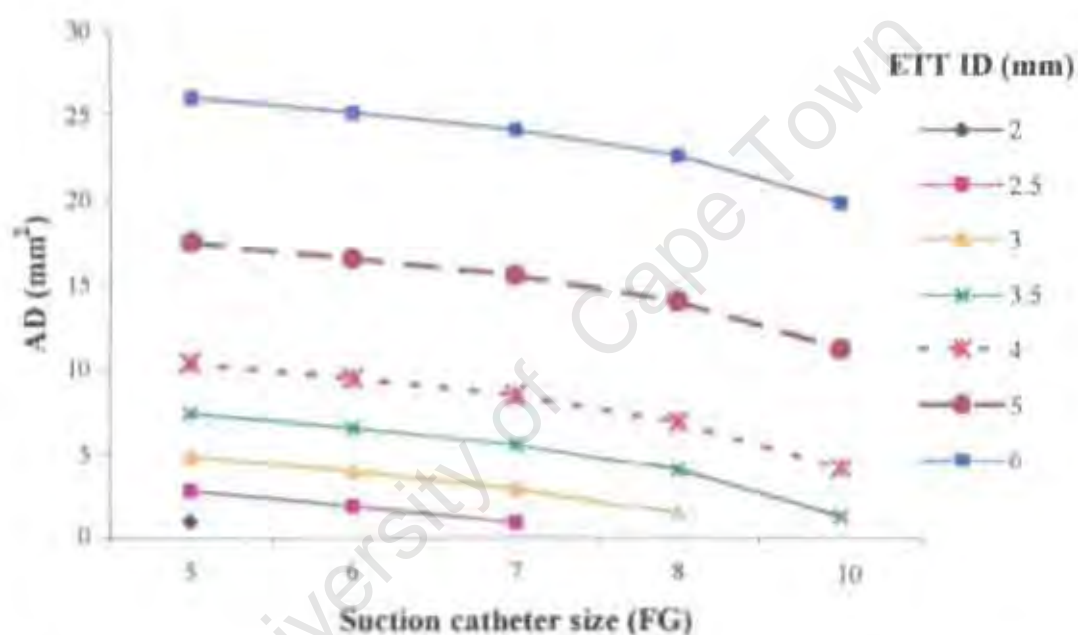


Figure 4.1: The relationship between suction catheter size and Area Difference.

In Figure 4.1, the AD has been plotted for a range of ETT and suction catheter sizes available commercially in South Africa. As can be seen, changes in ETT size have a considerably larger effect on AD than changes in the suction catheter sizes. With large diameter ETTs, differences in catheter sizes make relatively little difference to the AD. However, in the infant ETT size range, the AD is small with all commercially available catheter sizes and increases in catheter size dramatically decrease the AD. Small volumes of secretions in the ETT would also have a much higher impact in the smaller ETT.

The objective of ET suctioning is to remove secretions that accumulate within the large airways and ETT, thereby preventing occlusion of the ETT. To some extent the suction catheter may clear the ETT by “brushing” or physically dislodging the secretions in the airway. One would predict that the smaller the AD, the more effective the catheter would act as a “brush” to dislodge the secretions.

It is suggested that the amount of secretions that can be removed through the catheter would depend on the amount of secretions present in the ETT, on the viscosity of the secretions, the suction pressure applied and the resistance provided by the suction catheter to the secretions.

In order to demonstrate the nature of these relationships, pressure was measured during ET suctioning using a simple “bag in a box” model. Gelatine solutions were used to demonstrate some of the physical principles of secretion clearance.

4.4 Objectives

The objectives of this study were to:

1. examine the relationships of different ETT and suction catheter sizes to peak pressure changes (ΔP) occurring within a simple chest model;
2. record the effect of using different vacuum pressures on ΔP in the model;
3. assess the effect of two different suctioning techniques on ΔP in the model;
4. measure ΔP occurring during suctioning using catheters of different lengths;
5. determine the relationship between catheter size, mucus density, suctioning pressure and the mass of mucus aspirated during suctioning.
6. apply the above to principles of suctioning in paediatric clinical practice.

4.5 Materials and Methods

4.5.1 Pressure changes in the lung model

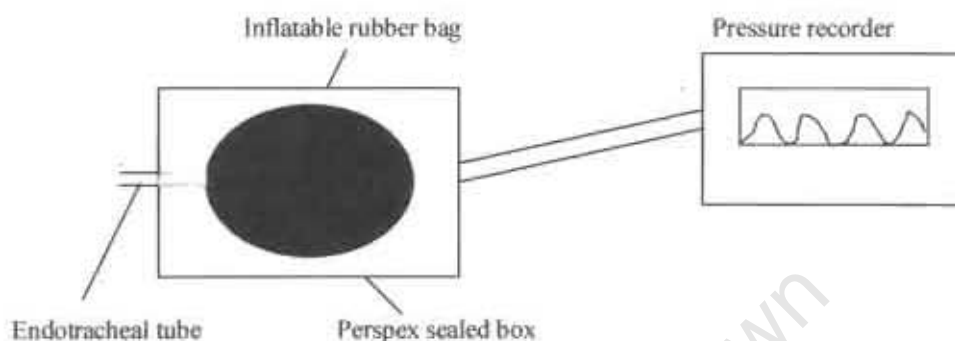


Figure 4.2: Diagram of equipment

A simple paediatric sized model was used (Figure 4.2) consisting of a partially inflated one-litre rubber bag within a 4700ml sealed perspex box. ETTs with ID of 2mm to 7mm were inserted into the inflatable rubber bag and the area around the ETT was sealed with *Prestik* (an oil-based polybutene sealant, Genkem (Pty) Ltd under license from Bostik Ltd, England). The interior of the perspex box was linked to a patient pressure monitor (Marquettehellige Eagle 3000 patient monitor) and chart recorder.

Before each suction event, the pressure recorder was set to zero. ΔP obtained in the box was recorded for each occasion of suctioning.

Suction catheters of FG sizes 5 to 12 were used. The catheters were inserted into the ETTs to immediately beyond the distal tip of the tube; suction was applied by means of a patient suction control apparatus attached to a central vacuum unit, and the catheters were withdrawn whilst rotating them. Five catheters of each size were used to ensure reliability. The same suction apparatus was used throughout.

4.5.2 Relationships of ETT and suction catheter sizes on ΔP

The above suction procedure was performed using ETTs with ID of 2mm; 2,5mm; 3,0mm; 3,5mm; 4,0mm; 4,5mm; 5,0mm; 5,5mm; 6,0mm; 6,5mm and 7,0mm on a single "high" suction pressure. The same suction pressure was used for all suctioning manoeuvres.

4.5.3 Effect of suction pressure on ΔP

The above suction procedure was repeated using 2,5mm; 3,5mm; 4,5mm; 5,5mm and 6,5mm ID ETTs at three different suction pressure settings - "low", "medium" and "high".

The "low", "medium" and "high" suction settings corresponded to readings on the pressure gauge of the suction apparatus of approximately -200 mmHg, -360 mmHg and -500 mmHg respectively. Pressure measurements were recorded with the suction tubing occluded.

4.5.4 Suction technique and ΔP

The effect on ΔP of inserting an unclamped catheter with the suction applied on both catheter insertion and withdrawal, and the technique of clamping the catheter on insertion such that suction is only applied on catheter withdrawal was tested using FG 7 and FG 8 catheters inserted into an ETT with ID of 3,5mm.

The volume of gas withdrawn from the system was calculated using Boyle's Law (Stocks et al, 1996).

4.5.5 Catheter length and ΔP

The effect on ΔP of using 30cm and 50cm-long suction catheters was tested using FG 6 catheters of both lengths into a 3,5mm ID ETT and FG 8 catheters of both lengths inserted into a 6mm ID ETT. A single "high" suction pressure was used.

4.5.6 Amount of material suctioned

Gelatine was mixed with water to three different volume to volume (v:v) concentrations (1:100, 1:75, 1:50), and left in room air for 12 hours to set to approximate the viscosities of thin to thick mucus. For each concentration of gelatine, catheters sized FG 5 to FG 12 were inserted 5mm into the gelatine and suction was applied for five seconds. This was performed at "low", "medium" and "high" suction pressures. Three repetitions of the procedure with each catheter were performed to assess variability and reliability.

The above procedure was performed comparing the mass suctioned using 30cm- and 50cm-long FG 8 catheters.

Each gelatine sample was weighed using an analytical balance (Ohaus[®] Analytical Standard AS 200 Electronic Scale) before and after suction and the amount of gelatine mixture suctioned in one second was calculated.

4.5.7 Analysis

- Data were tested for normality using the Kolmogorov-Smirnov test;
- descriptive statistics were used to obtain means (standard error / standard deviation);
- between-group data were analysed using the Student's *t* – test for independent variables;
- Pearson-Product Moment Correlation tests were used to assess relationships between variables.
- *Statistica* for Windows (Release 5.1, Statsoft, Inc.) was used for all analyses.

4.6 Results

4.6.1 ΔP in the lung model

4.6.1.1 Relationship of ETT and suction catheter sizes

Using a single, "high" suction pressure and all ETT and catheter sizes, the mean ΔP recorded was $-5,17 \pm 0,403$ mmHg (mean \pm standard error) with a range of -31,5mmHg using size 2,5mm ID ETT and FG 7 catheter to -0,25 mmHg with 6mm ID ETT and FG 8 catheter.

The relationship between the AD and the pressure change within the chest model is shown in Figure 4.3 and Table 4.1. As the difference between cross-sectional areas increases there is a corresponding decrease in ΔP . Again it was noted that with all large ID ETTs the corresponding AD was also large relating to a smaller ΔP .

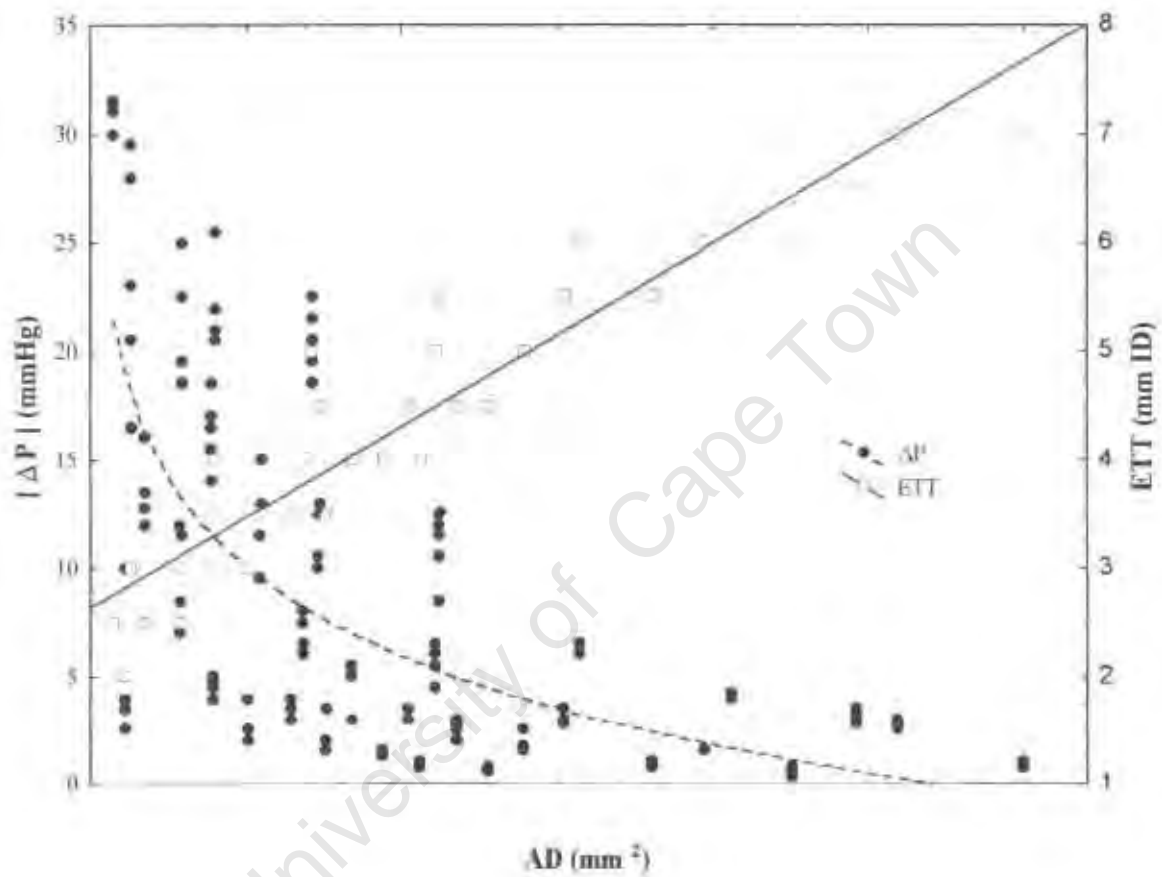


Figure 4.3: The relationship between the AD, ETT ID and ΔP within the model.

As predicted, there was a clear linear relationship between ΔP and the ratio of CA:AD (Figure 4.4). The correlation coefficient, $r = 0,8$ ($p < 0,05$).

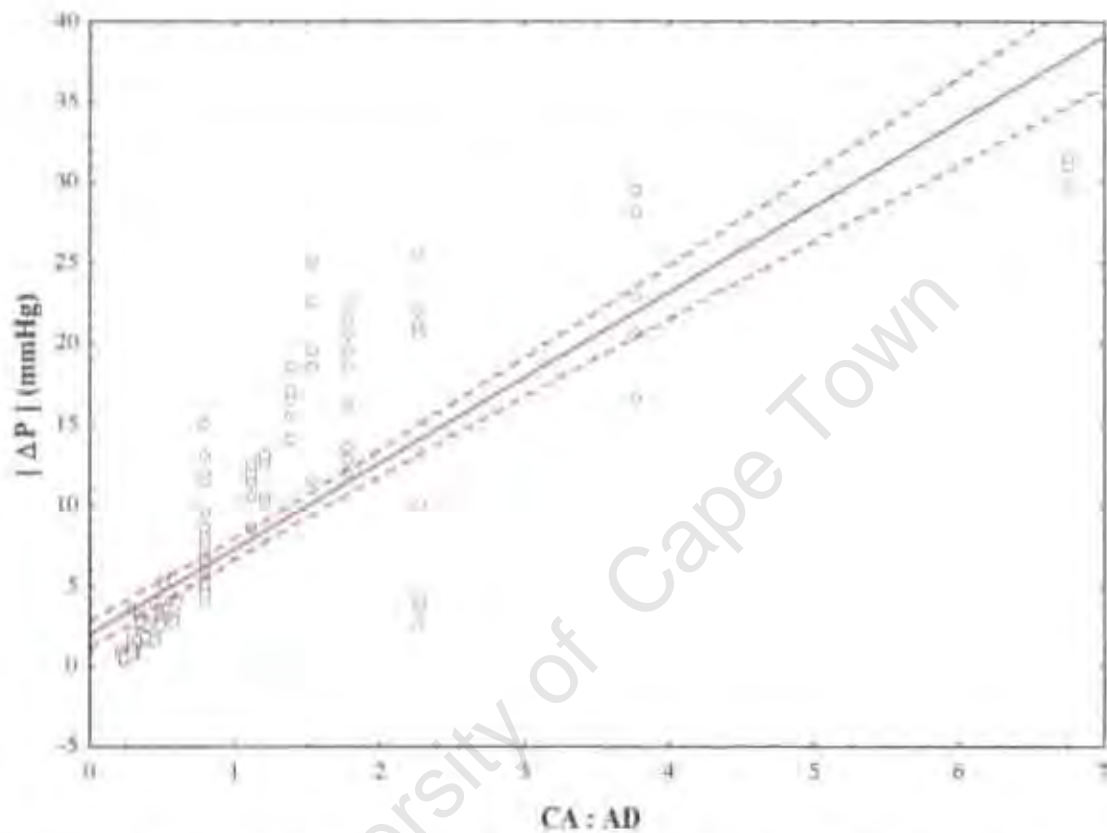


Figure 4.4: The relationship between the absolute ΔP and the CA:AD ratio

Table 4.1 indicates ΔP recorded using the ETT and catheter sizes recommended by Shann (1998) as well as ΔP recorded with varying combinations of ETT and suction catheter sizes. The calculated volume of gas extracted from the model is also shown. Considering the small lung volumes of neonates who may be intubated with similar sized ETTs, it is notable that the calculated volume change that resulted from the interaction of 2,5mm ETT and FG 7 suction catheter was approximately 200ml.

Table 4.1: Relationship between recorded ΔP and the interaction between catheter and ETT sizes. The volume of gas removed from the model was calculated using Boyle's Law.

ETT (mm ID)	Catheter Size (FG)	Catheter Size (mm ID)	AD (mm ²)	ΔP (mmHg)	Volume extracted (ml)
2,0	5	1,7	0,87	-4,8 ± 3,0	29,7 ± 18,4
	6*	2	0	Unable to insert catheter	
2,5	5	1,7	2,64	-8,4 ± 2,1	51,9 ± 13
	6*	2	1,77	-13,6 ± 1,5	83,8 ± 9,3
3,0	7	2,3	0,75	-30,5 ± 0	191,1 ± 3,4
	5	1,7	4,80	-2,7 ± 0,8	16,7 ± 4,7
	6	2	3,93	-4,7 ± 0,4	28,8 ± 2,6
	7*	2,3	2,91	-19,4 ± 5,4	120,0 ± 31,6
3,5	8	2,7	1,34	-23,5 ± 5,4	145,3 ± 33,1
	5	1,7	7,35	-2,2 ± 0,8	13,6 ± 4,7
	6	2	6,48	-3,7 ± 0,4	22,9 ± 2,8
	7	2,3	5,47	-12,1 ± 2,0	74,8 ± 12,6
	8*	2,7	3,90	-16,3 ± 1,7	100,8 ± 10,4
4,0	10	3,3	1,07	Unable to insert catheter	
	6	2	9,43	-1,5 ± 0,1	9,0 ± 0,7
	7	2,3	8,41	-4,7 ± 1,0	29,1 ± 6,0
	8*	2,7	6,84	-7,1 ± 0,8	43,9 ± 5,1
4,5	10	3,3	4,01	-22,2 ± 2,1	137,3 ± 12,1
	6	2	12,76	-0,7 ± 0,1	4,3 ± 0,7
	7	2,3	11,75	-2,5 ± 0,4	15,2 ± 2,8
	8*	2,7	10,18	-3,3 ± 0,3	20,4 ± 1,7
5,0	10	3,3	7,35	-11,2 ± 1,4	69,3 ± 8,9
	8	2,7	13,91	-1,9 ± 0,4	11,4 ± 2,3
	10*	3,3	11,08	-5,6 ± 0,7	34,6 ± 4,6
5,5	12	4	7,07	-20,5 ± 1,6	126,8 ± 9,8
	8	2,7	18,03	-0,9 ± 0,1	5,6 ± 0,8
6,0	10*	3,3	15,21	-3,2 ± 0,3	19,5 ± 2,1
	12	4	11,19	-11 ± 1,6	68,0 ± 9,8
6,0	8	2,7	22,56	-0,5 ± 0,2	3,1 ± 1,1
	10*	3,3	19,72	-1,5 ± 0,0	9,3 ± 0,0
6,0	12	4	15,71	-6,3 ± 0,3	39,0 ± 1,7

* and bold print indicates the catheters recommended by Shann (1998). Mean values ± standard deviation.

4.6.1.2 Effect of suction pressure on ΔP

ΔP (mean \pm standard error), using a range of ETT and catheter sizes, obtained at "high", "medium" and "low" suction pressure were $-6,18 \pm 0,56$ mmHg, $-5,99 \pm 0,55$ mmHg and $-4,37 \pm 0,40$ mmHg respectively. Significantly greater ΔP was obtained at "high" compared to "low" suction pressures ($p < 0,01$) and at "medium" compared to "low" pressures ($p < 0,05$), but there was no significant difference between ΔP at "medium" and "high" suction pressures ($p > 0,1$).

4.6.1.3 Effect of catheter length on ΔP

Suctioning with a 30cm FG 6 catheter and 3,5mm ID ETT at a "high" suction pressure yielded a mean ΔP of $-2,55 \pm 0,05$ mmHg, whilst with a 50cm FG 6 catheter with the same suction pressure and ETT size, ΔP was $-1,65 \pm 0,06$ mmHg (mean \pm standard error) ($p < 0,001$). Similarly, when using a 30cm FG 8 catheter inserted into a 6mm ID ETT at a "high" suction pressure, a ΔP of $-2,55 \pm 0,11$ mmHg (mean \pm standard deviation) was yielded. Using a 50cm FG 8 catheter at the same set pressure and ETT, ΔP was $-1,65 \pm 0,14$ mmHg ($p < 0,0001$) (Figure 4.5).

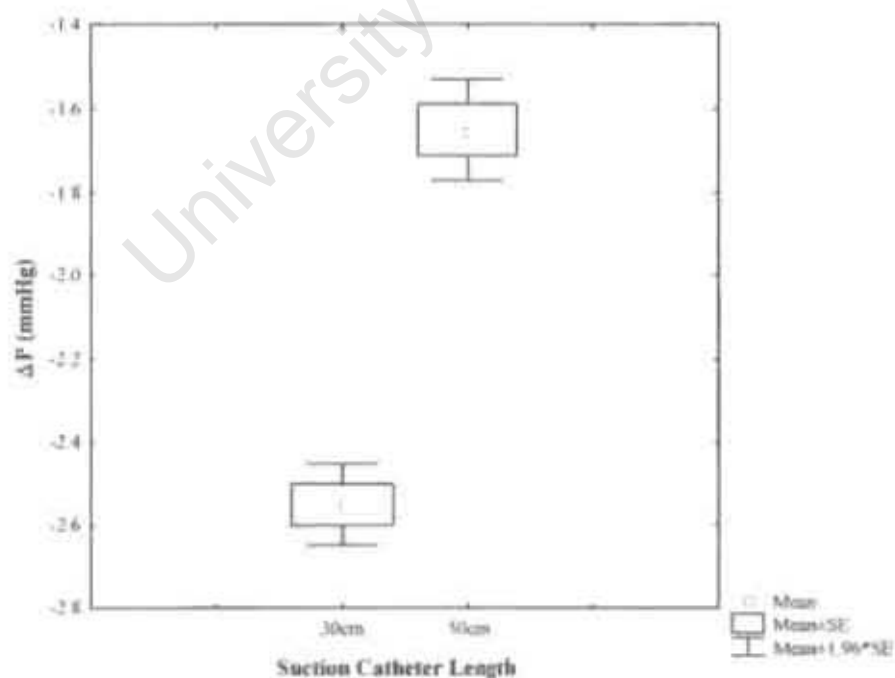


Figure 4.5: The effect of suction catheter length on ΔP .

4.6.1.4 Suctioning technique and ΔP

Using a FG 7 catheter and 3,5mm ID ETT, ΔP when a clamped catheter was inserted was $-12,0 \pm 0,27\text{mmHg}$ (mean \pm standard error) compared to $-20,1 \pm 0,27\text{mmHg}$ with unclamped catheter insertion ($p < 0,0001$). Similarly, using a FG 8 catheter and 3.5mm ID ETT, inserting a clamped catheter resulted in ΔP of $-17,5 \pm 0,35\text{mmHg}$ (mean \pm standard error) and $-33,7 \pm 1,46\text{mmHg}$ ($p < 0,0001$) with unclamped catheter insertion (Figure 4.6).

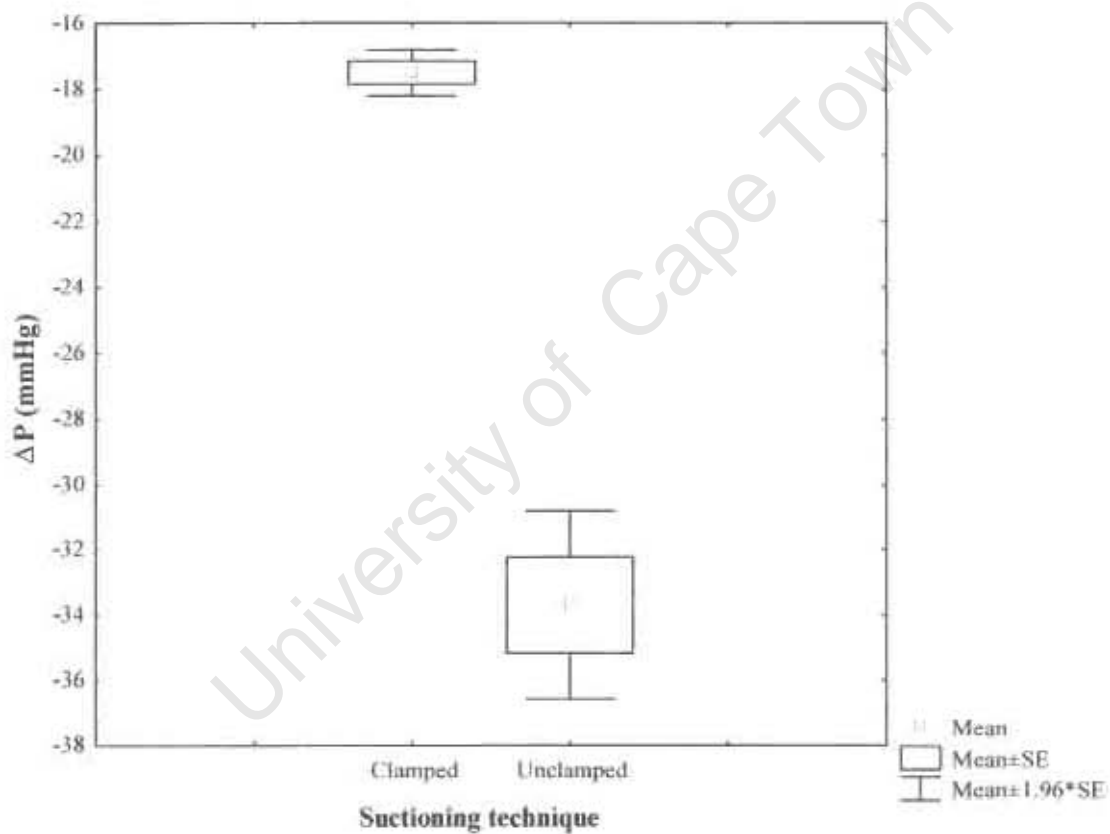


Figure 4.6: ΔP when inserting a clamped and unclamped catheter, using 3,5mm ID ETT and FG 8 suction catheter.

4.6.2 Amount of material suctioned

When using FG 10 and FG 12 catheters with 1:100 and 1:75 gelatine, all the gelatine was suctioned up in less than 5 seconds, making accurate measurement beyond that impossible. Therefore, for these consistencies of gelatine, only the results with catheter sizes FG 5 to FG 8 were recorded.

There was a significant positive correlation between the amount (g/sec) of all the gelatine consistencies suctioned and catheter diameters at all suction pressures ($p < 0,05$) (Table 4.2).

Table 4.2: The correlation between catheter ED and the amount of gelatine of different consistencies extracted, at different suction pressure levels.

Gelatine v/v	1:100	1:75	1:50	1:100	1:75	1:50	1:100	1:75	1:50
Suction pressure	low	low	low	medium	medium	medium	high	high	high
Correlation coefficient (r)	0,88*	0,92*	0,91*	0,72*	0,85*	0,71*	0,80*	0,92*	0,91*

* indicates correlations significant at $p < 0,05$.

For all of the different gelatine consistencies, a significantly greater gelatine mass was suctioned per second at "high" compared to "low" suction pressures and at "medium" compared to "low" pressures ($p < 0,05$). There was no significant difference between the amount suctioned at "medium" and "high" suction pressures (Table 4.3 and Figures 4.7 to 4.9).

Table 4.3: Amount of gelatine suctioned (g/sec) for different gelatine consistencies at different suction pressures

GELATINE CONSISTENCY	SUCTION PRESSURE		
	"LOW"	"MEDIUM"	"HIGH"
1:100	0,624 ± 0,267	1,031 ± 0,355	1,063 ± 0,531
1:75	0,184 ± 0,067	0,584 ± 0,294	0,527 ± 0,367
1:50	0,027 ± 0,155	0,076 ± 0,075	0,061 ± 0,038

Mean values ± standard deviation

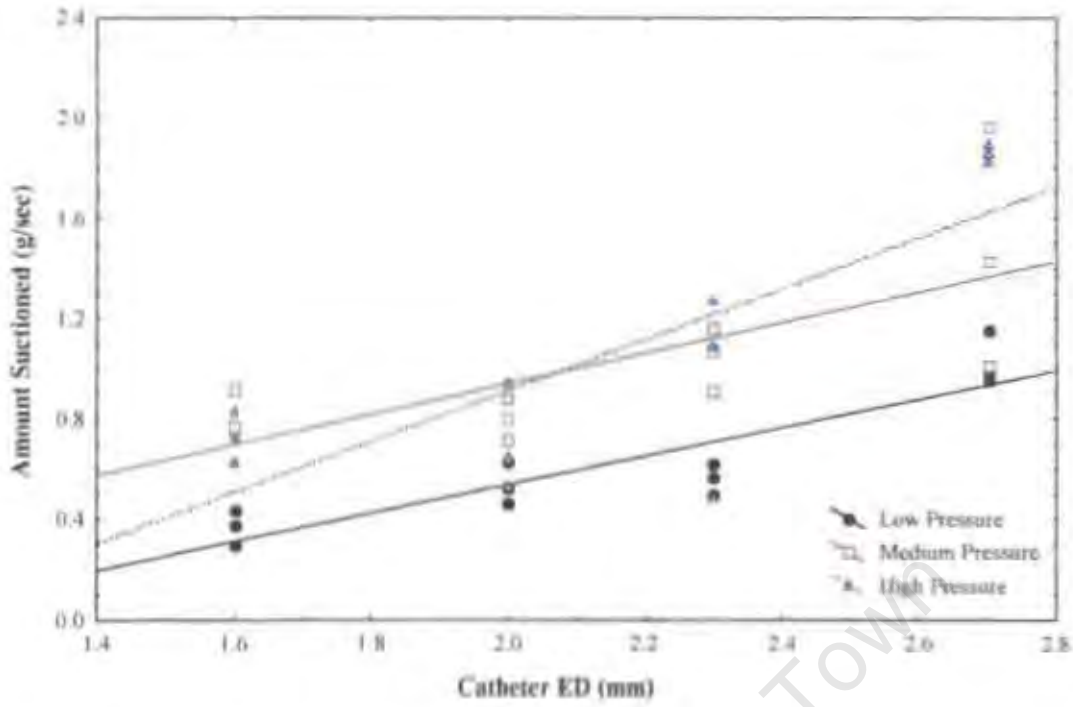


Figure 4.7: Mass of 1:100 gelatine suctioned per second at different suction pressures.

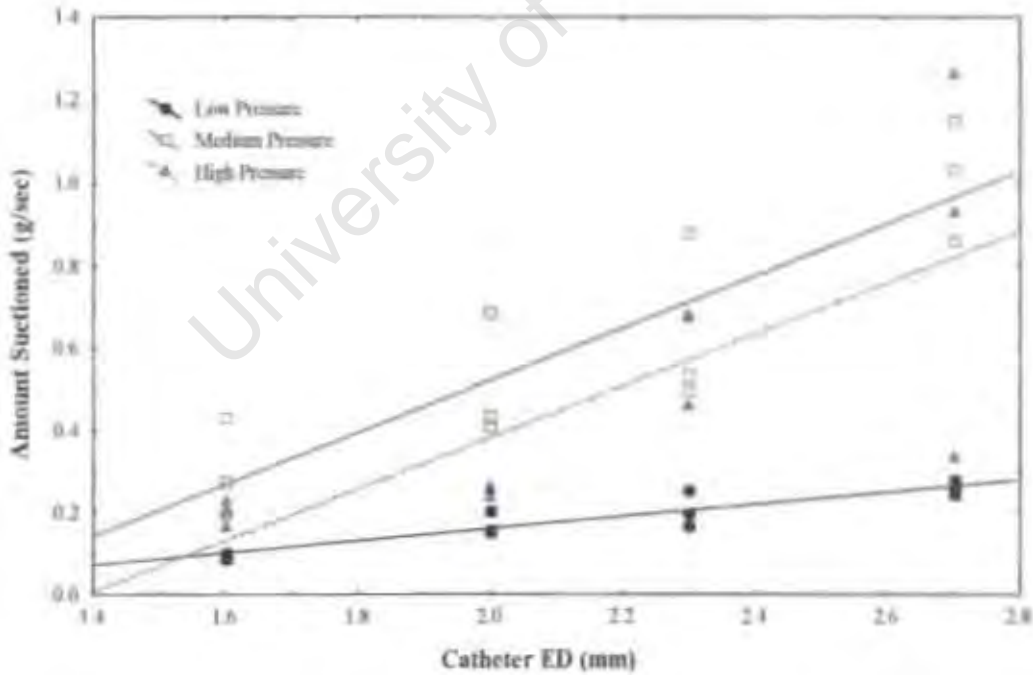


Figure 4.8: Mass of 1:75 gelatine suctioned per second at different suction pressure settings.

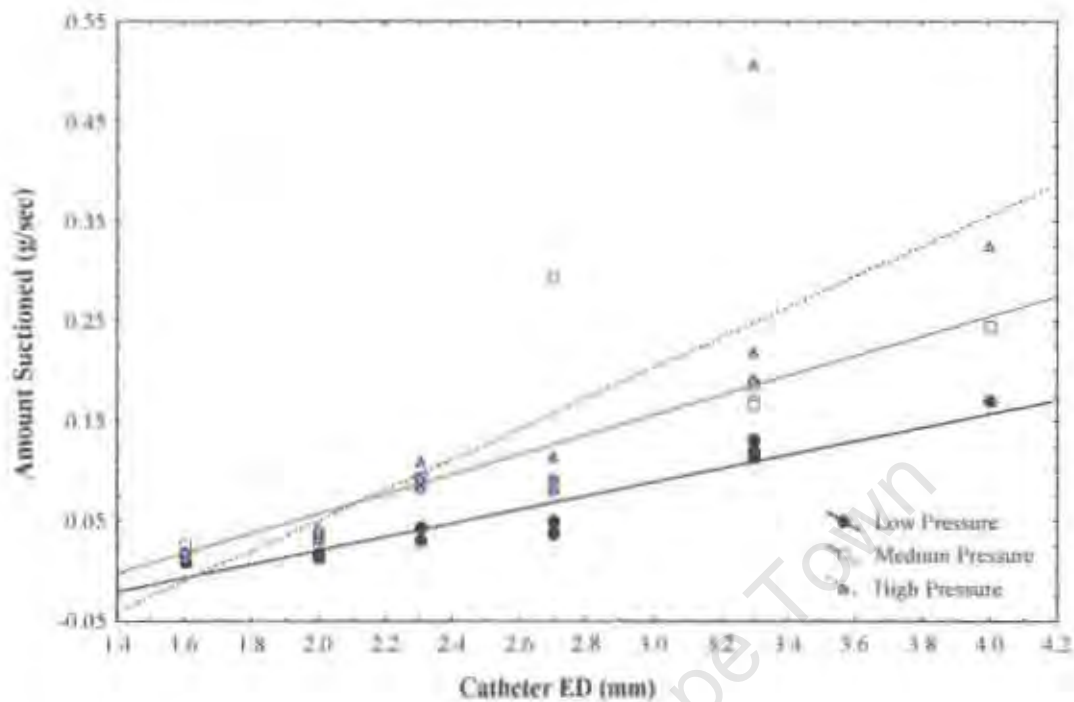


Figure 4.9: Mass of 1:50 gelatine suctioned per second using different suction pressures.

Significantly more 1:100 gelatine was suctioned using a 30cm than a 50cm FG 8 catheter. The differences were not significant for 1:75 or 1:50 gelatine (Table 4.4).

Table 4.4: The mass of gelatine suctioned per second using 35cm and 50cm long FG 8 catheters.

GELATINE CONSISTENCY			
Catheter length	1:100 gelatine	1:75 gelatine	1:50 gelatine
30cm	1,45 ± 0,436	0,775 ± 0,404	0,097 ± 0,078
50cm	1,146 ± 0,33	0,463 ± 0,204	0,095 ± 0,054
<i>p</i>	0,02	0,14	0,95

Mean values ± standard deviation.

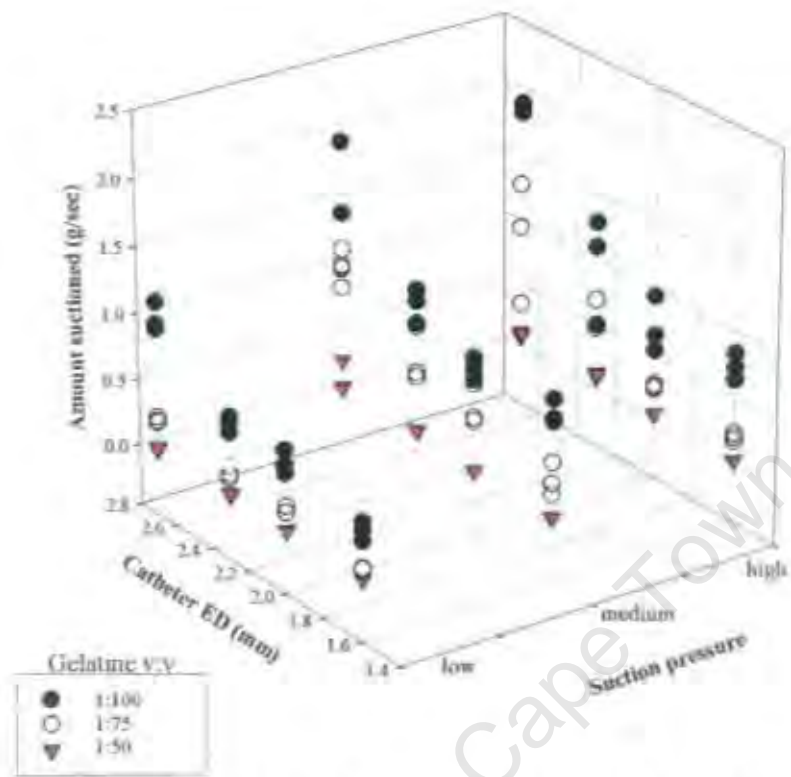


Figure 4.10: The mass of gelatine of different consistencies suctioned per second using different suction catheter sizes, and varying suction pressures

Figure 4.10 illustrates the amount of gelatine extraction related to catheter size and suction pressure levels. With the exception of FG 7 (2,3mm ED) catheter at "high" suction pressure, significantly more 1:100 gelatine was suctioned than 1:50 gelatine ($p < 0,05$) for all catheters at all suction pressures. With FG 7 catheter using "high" suction pressure, there was no statistically significant difference between the amount of 1:100 gelatine and 1:50 gelatine suctioned ($p > 0,05$).

4.7 Discussion

ET suctioning is a routine PICU procedure, although it can cause significant negative complications (Carhuapoma and Williams, 1999; Kerr et al, 1999; Darlow et al, 1997; Barker and Rutter, 1995; Segar et al, 1993; Monaco and Meredith, 1992; Shah et al, 1992; Skov et al, 1992; Tamo-Mordi, 1991; Durand et al, 1989; Loubser et al, 1989;

Bailey et al, 1988; Fanconi and Duc, 1987; Graff et al, 1987; Gunderson et al, 1986; Arai et al, 1985; Murdoch and Darlow, 1984; Ehrhart et al, 1981; Simbruner et al, 1981; Zmora and Merritt, 1980; Cabal et al, 1979; Kuzenski, 1978; Anderson and Chandra, 1976).

This chapter has described how some theoretical pressure/flow principles apply to ET suctioning, using commercially available ETTs and suction catheters.

The actual ΔP obtained within the model are unlikely to apply directly to the clinical situation for the following reasons: the volume of the model was 4700ml whereas total lung capacity is normally between ± 52 ml/kg (Thorsteinsson et al, 1994) and ± 66 ml/kg (Hammer et al, 1998) for infants; the absence of a “lung” with different airway generations in the system, the non-compliance of the “chest wall”; the lack of secretions in the system; and the use of gelatine instead of respiratory mucus. However, the study does demonstrate the potential importance of the suction pressure applied to the suction catheter during ET suctioning; suction catheter dimensions (both cross-sectional area and length); and the duration and technique of ET suctioning.

The suction pressures used were higher than that recommended by some authors (Kacmarek and Stoller, 1995; Hodge, 1991) but were within the range used in clinical practice worldwide (Dyhr et al, 2003; Bethune et al, 1971). The suction pressures used were the only options on the suction units used in the PICU of RCWMCH. Although not measured, much lower suction pressures would actually have been delivered at the distal end of the catheter than were indicated on the gauge due to the resistance offered by the suction tubing and suction catheter.

Even with small catheters, the data in this chapter demonstrated that changes in suction pressure in the range of -200 to -360 mmHg might be transmitted through the ETT. Beyond that range there was no significant increase in ΔP and it is likely that gas flow limitation occurred within the catheters. These data suggest that with large ETTs, high suction pressures could safely be used as these may not be transmitted into the thorax,

probably because the area around the suction catheter allows gas suctioned through the catheter to be readily replaced by gas flow between the ETT and the suction catheter. This may not be true if a “closed” suction system is used. However, with small ETTs, (as are used with neonates) considerably more care is necessary to prevent large intrathoracic pressure changes.

It was hypothesised at the beginning of this chapter that during ET suctioning the amount of gas that could be removed from the model would depend on the CA:AD ratio. The correlation between ΔP and CA:AD suggests that this hypothesis was correct. This finding has not been reported previously as other authors have focused on direct ratios of cross-sectional areas and other similar measures (Monaco and Meredith, 1992; Hipenbecker and Guthrie, 1981; Polacek and Guthrie, 1981; Rosen and Hillard, 1962). This implies that the larger the suction catheter is, relative to the difference in sizes of the ETT and catheter, the higher the pressure effects exerted on the lungs are likely to be. This may explain the finding that the effects of suctioning on the lungs with a FG 8 catheter were greater than when a FG 5 catheter was used in a size 3,0mm ID ETT (Brandstater and Muallem, 1969).

It has also been shown that the length of the catheter had a significant effect on ΔP . This is most likely to be due to the fact that less negative suction pressures were transmitted to the model as a result of the increased catheter length (Poiseuille’s law). This effect was not as great as the difference between clamped and unclamped catheter insertion.

It has been suggested that clamping the catheter before insertion into the trachea allows maximal negative pressure build-up in the suction system, which is then directly applied to the lungs on release (Rosen and Hillard, 1962). This was not found to be the case in this study. Significantly greater ΔP was obtained when an unclamped catheter was inserted, thus applying suction on catheter insertion as well as withdrawal, as opposed to applying suction on catheter withdrawal only. This is most likely due to the increased duration of suction application (Rosen and Hillard, 1962), and thus a longer period of gas removal. This is supported clinically by the finding that the effects of suctioning on the

lungs of neonates were also greater when suction was prolonged (Brandstater and Muallem, 1969) and lends support to Young (1984), who suggested that hypoxia occurring after prolonged suctioning may be due to atelectasis. This finding supports the generally recommended practice of clamping the catheter on insertion and only applying suction when it is withdrawn.

In the clinical situation there are likely to be secretions in the ETT and in the suction catheter. Negative pressure in the lungs produced during suctioning would only occur while air was flowing through the suction catheter. As soon as secretions are drawn into the catheter, the pressure in the lungs would return to that of the atmosphere (Rosen and Hillard, 1962). In clinical situations it is likely that the presence of secretions on the wall of the ETT would exacerbate the ETT obstruction caused by the suction catheter, thereby reducing the amount of gas that could replace that removed during the suctioning process.

The issue of selecting suction pressures relates to the balance between effective suctioning of secretions and potential risk to the patient. The data on suctioning of gelatine show that increased suction pressure (from “low” to “medium”) increased the mass of gelatine suctioned per second (regardless of the viscosity of the gelatine mixture), although above this point there was no further increase in the gelatine suctioned. However, increasing the suction pressures from “low” to “medium” was also associated with increased ΔP . At this point, there are insufficient experimental data to recommend an appropriate, safe maximum suction pressure level (Branson et al, 1993), but high suction pressures should be avoided in small patients with narrow ETTs as this model suggests that large intrathoracic or intrapulmonary ΔP could be induced. When copious secretions are present it may be justifiable to increase suction pressures, to allow more effective secretion removal. If there were secretions in the catheter, there would be very little ΔP transmitted down the ETT.

The “chest wall” in this model was rigid whereas that of an infant is very compliant. The pressure changes in the lung of an infant during ET suctioning depends on the pressures transmitted down the ETT-suction catheter system, the extent to which the airways

collapse and obstruct airflow, the compliance of the lung itself as well as factors external to the lung. If the chest wall were not compliant the intrapulmonary ΔP would be transmitted into the intrathoracic space. However, if the chest wall is very compliant, as is the case with neonates, the intrapulmonary ΔP is likely to result in loss of lung volume and atelectasis. This may explain the sharp fall in pulmonary compliance reported in a small sample of neonates following ET suctioning (Brandstater and Muallem, 1969) and supports the suggestion that ET suctioning causes atelectasis in mechanically ventilated children as a result, partly, of the high negative intrapulmonary pressures generated during the suctioning procedure (Boothroyd et al, 1996; Rosen and Hillard, 1962).

In the model used in this study, the opening of the rubber bag was sealed around the ETT. In the clinical situation there is usually a leak around the ETT during the application of positive intrapulmonary pressure. There is unlikely to be a leak around the ETT while negative pressure is applied to the ETT, and thus it is not a feature of this model that would invalidate the findings.

The only literature available on the efficiency of ET suctioning is a series of experiments conducted by Rosen and Hillard (1962). They graded several suction catheters according to the efficiency with which they were able to remove a fixed volume of egg mixture. The smallest diameter catheter received the lowest efficiency grade and changing the average negative pressure did not improve the efficiency of suctioning. With larger catheters suctioning efficiency was improved by increasing the average negative suction pressure. The most efficient use of any suction catheter occurred while using a high suction pressure. These studies used only one mixture of egg, which would probably have been similar to viscous mucus, but did not investigate results with material of varying viscosity.

There may be considerable differences between the characteristics of pulmonary secretions and gelatine, however the nature of secretions in the clinical situation also varies considerably. The results of this study show that the masses of gelatine of all consistencies suctioned in a given time were directly proportional to the diameter of the

catheter. More 1:100 gelatine (equivalent to mucus of low viscosity) was suctioned in a set time than 1:50 gelatine (equivalent to mucus of higher viscosity), regardless of catheter diameter or suction pressure. More concentrated gelatine required larger diameter catheters and higher pressures for more effective removal of secretions although it appeared that "medium" suction pressure was as effective at clearing secretions as "high" suction pressure.

The above findings potentially have important clinical implications. If secretions are kept thin or more liquid, which may be done by adequate humidification of inspired gas (Branson et al, 1992), then more mucus may be suctioned using smaller diameter catheters with lower suction pressures, for a shorter duration and with fewer repetitions of the procedure. This is desirable, as less negative pressure is likely to be produced in the lungs and the risk of all the potential complications of suctioning would be reduced.

The catheter sizes recommended in Shann's guidelines (1998) ranged from 55% to 100% of the corresponding ETT's ID. In this chapter it was shown that for ETTs $\leq 3,5\text{mm ID}$, the catheters recommended by Shann (1998) all occluded the ETT by more than 75% and that the negative pressures generated all exceeded -12mmHg . For a $2,0\text{mm ETT}$, the catheter recommended in the Shann Guidelines (1998) could not be inserted into the ETT, as the catheter ED was equivalent to the ETT ID.

Although there is no evidence of the levels of pressure which result in lung damage, it would appear that, where possible, smaller diameter catheters than recommended by Shann (1998) should be used in order to generate the lowest possible intrathoracic pressures. In the Shann guidelines (1998), only one catheter was suggested for use with each ETT size and no differentiation was made for sputum of different viscosities. Similarly, recommendations for specific suction pressures were not made. As liquid mucus is suctioned effectively at low suction pressures and with small diameter catheters, one should theoretically be able to suction effectively using much smaller catheters than those recommended in his guidelines. For thicker secretions, where larger diameter

catheters are needed at higher pressures to effectively clear mucus, the Shann guidelines (1998) are satisfactory.

4.8 Conclusion and recommendations

The aims of the study in this chapter were to investigate the physical principles of pressure and gas flow dynamics associated with ET suctioning by means of a simple illustrative model; and to discuss the clinical implications of applying these principles to paediatric practice.

It is clear from the model data that the intrapulmonary pressure changes generated by ET suctioning can be considerable, particularly with neonates intubated with small ETTs. This needs to be evaluated in the clinical situation.

It is still not clear which aspect of suctioning is actually responsible for clearing the ETT. It may be the physical removal of secretions by suctioning in which case adequate humidification is essential in order to keep secretions liquid thereby avoiding the use of larger diameter catheters and higher suction pressures required to remove more viscous secretions. If, however, the ETT clearance is due to the mechanical “brushing” effect of the catheter then suctioning with larger catheters using very low suction pressures for a short duration may be more effective. The optimal point of interaction between applied suction pressure; catheter size and mucus removal is still unclear and requires further investigation.

This chapter demonstrates that if clinical studies of ET suctioning are to be adequately evaluated it is essential that the details of the suctioning technique should be standardized and comprehensively documented as the data obtained from the chest model show that there are a number of factors and interrelationships related to the procedure that may have a profound impact on the patient.

The following proposed guideline for suction catheter size selection was made on the basis of the findings of this chapter (Table 4.5).

Table 4.5: A proposed guideline for suction catheter selection.

Age	Shann Guidelines (1998)			Proposed Guidelines		
	Weight (kg)	ETT (mmID)	Catheter (FG)	Catheter (FG)		
				Liquid mucus	Medium viscosity	Thick mucus
Newborn	<1	2,0	6	5	5	5
Newborn	1	2,5	6	5	5	6
Newborn	2	3,0	7	5	6	6
Newborn	3,5	3,5	8	5	6	7
3 months	6	3,5	8	5	6	7
1 year	10	4,0	8	6	7	7
2 years	12	4,5	8	6	7	8
3 years	14	4,5	8	6	7	8
4 years	16	5,0	10	7	8	8
6 years	20	5,5	10	7	8	8
8 years	24	6,0	10	8	10	10
10 years	30	6,5	12	8	10	12
12 years		7,0	12	8	10	12

Chapter Five extends this investigation into clinical practice, by presenting a prospective clinical study on the effects of ET suctioning on lung dynamics in ventilated paediatric patients.

CHAPTER FIVE

AN INVESTIGATION INTO THE EFFECTS OF ENDOTRACHEAL SUCTIONING ON LUNG DYNAMICS IN MECHANICALLY VENTILATED PAEDIATRIC PATIENTS

5.1 Introduction

ET suctioning is a routine procedure in all patients with an artificial airway in the PICU. The primary purpose of ET suctioning is to remove secretions and prevent airway obstruction, thereby preventing atelectasis; optimising oxygenation and ventilation; and decreasing the work of breathing (Guglielminotti et al, 1998; Young, 1995).

In addition to the regular tracheal toilette performed by nursing staff, ET suctioning is an integral component of CPT, in order to remove secretions mobilised during positioning and chest manipulations. Physiotherapists also suction intubated patients in order to obtain TA specimens for microbiological testing.

Suctioning is known to have many adverse consequences including hypoxia (Kohlhauser et al, 2000; Skov et al, 1992; Singh et al, 1991; Graff et al, 1987; Simbruner et al, 1981; Fox et al, 1978; Rosen and Hillard, 1962), bradycardia (Kohlhauser et al, 2000; Segar et al, 1993; McCauley and Boller, 1988; Simbruner et al, 1981; Ehrhart et al, 1981; Cabal et al, 1979) and other arrhythmias (Simbruner et al, 1981; Ehrhart et al, 1981), raised intracranial pressure (Kerr et al, 1999; Durand et al, 1989; Fanconi and Duc, 1987), bacteraemia (Bailey et al, 1988), pneumothorax (Loubser et al, 1989; Anderson and Chandra, 1976), mucosal trauma (Loubser et al, 1989; Bailey et al, 1988; Nagaraj et al, 1980; Kuzenski, 1978) and loss of ciliary function (Bailey et al, 1988).

Atelectasis has been observed following ET suctioning (Boothroyd et al, 1996; Ehrhart et al, 1981; Hippenbecker and Guthrie, 1981; Polacek and Guthrie, 1981; Nagaraj et al, 1980;

Brandstater and Muallem, 1969; Rosen and Hillard, 1962), and has been attributed to aspiration of intrapulmonic gas (Ehrhart et al, 1981), mucosal oedema caused by the suction catheter itself (Boothroyd et al, 1996), or bronchial obstruction by granulation and fibrous tissue formed as a result of mucosal trauma (Nagaraj et al, 1980).

Changes in lung compliance have been considered to be evidence of atelectasis, however the results of published studies are contradictory. Brandstater et al (1969) reported a decrease in dynamic compliance following suctioning in a very small sample (n = 6) of neonates with normal lungs. By contrast Fox et al (1978) found no change in lung compliance after suctioning in 13 neonates recovering from respiratory disease. Animal studies have shown a decrease in static lung compliance following suctioning (Hipenbecker and Guthrie, 1981; Polacek and Guthrie, 1981).

More recently, after completion of the investigation described in this chapter, Main et al (2004) found that there were no significant changes in tidal volume (TV) or compliance after ET suctioning in a large sample of 100 paediatric patients with variable lung disease. The focus of this study (Main et al, 2004) differed from the aims of this investigation in that they attempted to approximate actual clinical practice and therefore did not standardise the suctioning procedure. Patients received different repetitions of suctioning; catheter size and suction pressures were not reported; variable amounts of saline were instilled prior to suctioning; and some patients received hyperinflation manoeuvres after the procedure. The duration, method and amount of positive pressure applied during these manoeuvres were not documented. This lack of standardisation of the suctioning technique between patients resulted in their study having limitations in interpretation, application, reliability and reproducibility.

After completion of this study, Maggiore et al (2003) reported the effects of ET suctioning on adults (n = 9) with acute lung injury. They found that end-expiratory lung volume decreased during ET suctioning, regardless of the suctioning technique performed: open suction, through swivel adaptor or through a closed suction system.

In another publication after this study had been completed, Choong et al (2003) showed that ET suctioning resulted in loss of lung volume in paediatric patients (n = 14; aged 6 days to 13 years). The loss of lung volume was significantly greater in patients undergoing open suction in which they were disconnected from the ventilator as opposed to closed-system suctioning which allowed ongoing ventilation throughout the procedure.

There is still no clear evidence that ET suctioning improves respiratory mechanics (Guglielminotti et al, 1998). Despite this, the procedure is considered essential to physiotherapeutic intervention and nursing care.

5.2 Aims

The aim of the study in this chapter was to determine the immediate effects of open ET suctioning on lung mechanics, specifically dynamic respiratory system compliance (C_{dyn}) and airway resistance, in mechanically ventilated paediatric patients in the PICU.

5.3 Objectives

The objectives of this study were to:

1. determine the immediate change in various pulmonary function parameters, specifically C_{dyn}, and dynamic inspiratory (R_i) and expiratory (R_e) airway resistance, following a standardised suctioning procedure;
2. determine whether the relationship between ETT ID and catheter ED affected the above changes;
3. record any predictive or correlative factors using OI, PaO₂/FiO₂ and VI for the changes in C_{dyn} after suctioning; and
4. record any complications associated with the ET suctioning procedure.

5.4 Materials and Methods

This study was formally approved by the Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town (Rec/ Ref. 162 / 2001). Written informed consent (Appendix C) was obtained from the patient's parent or legal guardian prior to enrolment, in their language of choice.

5.4.1 Study Design

The study design was a prospective before-after clinical study.

5.4.2 Patient Sample

All mechanically ventilated patients, intubated with ETT \leq 4,0mm ID, in the PICU of RCWMCH were eligible for participation in this study. A sample of convenience of 30 patients, over a six-month period from May to October 2002, was chosen subject to the following criteria:

Inclusion criteria:

- Intubated and mechanically ventilated; and
- ETT \leq 4,0mm ID.

Exclusion Criteria:

- Haemodynamic instability over preceding twelve hours (change of \geq 20% in HR, MABP or SaO₂);
- pulmonary haemorrhage or pulmonary oedema;
- previous intracranial surgery;
- clinical concern about or documented raised intracranial pressure (as seen by raised fontanel or measured intracranial pressure $>$ 15 mmHg);
- previous cardiac surgery; and
- previous inclusion in this investigation.

5.4.3 Technique and apparatus

The following data were recorded for each patient:

- age, gender, weight and medical condition;
- oxygenation and ventilatory settings; and
- ETT size and the catheter size used for suctioning.

The time of the suctioning procedures for this study were arranged to coincide with that of the nursing staff so that no additional patient discomfort was experienced as a result of

the research programme. All patients received intravenous morphine infusions as part of routine PICU practice.

Patients were placed in the supine position at least one hour prior to the study intervention. Patients were positioned in supine with their head turned away from the therapist in order to prevent pulmonary secretions splashing into the therapist's face. All patients underwent the study intervention between 09h30 and 12h00. No patients received CPT prior to the study intervention.

Patients were connected to a CO₂SMO Plus! Model 8000 Respiratory Profile Monitor by means of a neonatal flow sensor with <1ml deadspace (CO₂SMO Plus! Respiratory Profile User Manual, 1998) for five minutes before and five minutes after a single-catheter insertion suctioning procedure (page 5-6).

The CO₂SMO Plus! continuously measures pressure and flow by means of a fixed orifice differential pressure pneumotachometer. Gas flowing through the flow sensor causes a small pressure gradient across the two tubes connected to the sensor. This is transmitted to a differential pressure transducer where it is correlated to gas flow according to manufacturer-stored calibration (CO₂SMO Plus! Respiratory Profile Monitor: User Manual, 1998). Measurement of capnography was beyond the scope of this study. Arterial blood samples were not taken before and after suctioning, as would be necessary if accurate interpretation of changes in expired CO₂ were to be made (Main and Stocks, 2004).

The CO₂SMO Plus! was selected for this study as it had previously been validated *in vitro* as a sensitive, accurate tool capable of measuring applied volume changes within 0,9% (2,3% SD) accuracy (Main et al, 2001). Similarly, pressure recordings had been found to be within 2% of those displayed by an electric manometer. The least squares algorithm used by the CO₂SMO Plus! to calculate compliance and resistance were found to be accurate to within 5% (Main et al, 2001). Recordings of respiratory parameters were

found to be highly reproducible in a sample of fully ventilated paediatric patients with pulmonary pathology (Main et al, 2004).

The CO₂SMO Plus! was calibrated manually according to the manufacturer's guidelines before each measurement period. In addition, it was returned to the manufacturing company after four months of use for formal calibration and mechanical service. A new flow sensor was used for each patient to prevent cross-infection between patients.

Data were downloaded from the CO₂SMO Plus! using *Analysis Plus* for Windows Version 5.0. The following parameters were automatically computed during the procedure: C_{dyn}; R_e and R_i; inspiratory (V_{ti}^{spont}) and expiratory (V_{te}^{spont}) spontaneous tidal volume; inspiratory (V_{ti}^{mech}) and expiratory mechanical tidal volume (V_{te}^{mech}); peak expiratory flow; MAP; total, mechanical and spontaneous minute volume (MV); and total RR. Breath- by -breath values were averaged over each minute of recording and these values were used for analysis. The parameters were corrected for patient weight where appropriate.

The suctioning procedure was performed as follows: The patient received 100% inspired oxygen for less than one minute prior to suctioning. He / she was given a machine breath and was then disconnected from the ventilator. A sterile, clamped suction catheter was inserted into the ETT to just beyond its distal end, suction was applied and the catheter was withdrawn whilst rotating it slightly. The length of catheter insertion was measured against the known ETT length. The patient was then immediately reconnected to the ventilator circuit. The suction catheter was discarded. Any adverse effects were documented.

A range of catheter sizes was used. Where possible, the proposed guidelines developed from the findings in Chapter 4 (Table 4.5) were used as a basis for suction catheter selection, but at times during the study period this was not possible as certain catheter sizes were not available. The suction pressure was approximately -360mmHg measured at the source with the tubing clamped. The suction catheter remained in the ETT for ≤ 10 seconds.

After suctioning was completed, the FiO_2 was immediately changed to presuction settings unless desaturation had occurred, in which case the FiO_2 was gradually decreased as the SaO_2 improved. Throughout the observation and suctioning period, there was continuous ECG and pulse oximetry monitoring.

5.4.4 Analysis

OI and VI were calculated for each patient (Peters et al, 1998) as well as the $\text{PaO}_2/\text{FiO}_2$ ratio.

The percentage leak around the ETT was calculated for each patient using each minute's averaged values of $V_{\text{ti}}^{\text{mech}}$ and $V_{\text{te}}^{\text{mech}}$ according to the equation: $\% \text{ Leak} = [(V_{\text{ti}}^{\text{mech}} - V_{\text{te}}^{\text{mech}}) / V_{\text{ti}}^{\text{mech}}] \times 100$ (Main et al, 2001).

The following statistical analyses were performed:

- Data were tested for normality using the Kolmogorov – Smirnov Test;
- descriptive statistics were used to determine means, medians, ranges and standard deviation / standard error;
- Friedman's Analysis of Variance (ANOVA) was used as the non-parametric alternative to the One-Way Repeated Measures ANOVA;
- Kendall Tau or Spearman's rank order correlation tests were used to assess relationships between nonparametric variables.

- *Statistica* (Kernel Release 5.5, StatSoft Inc 1984 - 2000) was used for all statistical analyses.

5.5 Results

The sample size for this study comprised 30 patients (Table 5.1). They were intubated with ETTs of sizes 2,5 (n = 1); 3,0 (n = 13); 3,5 (n = 14) and 4,0 (n = 2) mm ID and were all receiving conventional mechanical ventilation using Newport Ventilators (models E100I and E100m). The gender distribution was coincidentally equal, with 15 males and 15 females.

Table 5.1: Summary of baseline patient data (n = 30).

VARIABLE	MEDIAN	RANGE
Age	2,75 months	10 days – 29 months
Weight (kg)	3,55	1,65 – 11,8
ETT size (mm ID)	3,5	2,5 – 4,0
FiO ₂	0,4	0,21 – 0,7
RR (bpm)	20,0	11 – 46
PIP (cmH ₂ O)	22,0	14,0 – 32,0
PEEP (cmH ₂ O)	6,0	2,0 – 11,0
MAP (cmH ₂ O)	11,0	4,0 – 24,4
OI	4,48	0,8 – 18,83
VI	13,19	4,64 – 157,89
PaO ₂ / FiO ₂ (mmHg)	178,47	76,48 – 747,9

The patients were not paralysed, as it was not considered ethically acceptable to deliver such medication purely for the purposes of this research. It is not routine practice to paralyse patients in this PICU. Therefore, some patients were able to breathe spontaneously between mechanically-delivered breaths. There was no deviation from the standardised suctioning procedure in any of the subjects.

The patients studied had a variety of medical conditions including congenital heart defects (n = 8), pneumonia of unspecified aetiology (n = 19), pneumothoraces (n = 3),

diarrhoeal disease (n = 4), septicaemia (n = 3), post laparotomy (n = 3), hydrocephalus (n = 1), empyema (n = 1), ischaemic brain injury (n = 1), seizures (n = 1) and apnoea (n = 2). Some patients had more than one medical condition.

Eighteen patients (60%) fulfilled the criteria for ARDS with acute onset of respiratory disease, bilateral infiltrates on chest X-ray and $\text{PaO}_2/\text{FiO}_2 \leq 200$ mmHg (Bernard et al, 1994). Fifteen of these patients (83%) had primary pulmonary disease with two (11%) having secondary or nonpulmonary ARDS as a result of sepsis. Five patients (17%) fulfilled the criteria for acute lung injury (ALI) with bilateral infiltrates on chest X-ray and $\text{PaO}_2/\text{FiO}_2 \leq 300$ mmHg.

The changes in pulmonary function parameters after suctioning are presented in Table 5.2. There was a significant overall decrease in median Cdyn following suctioning ($p < 0,0001$). The change in mean Cdyn is also shown in Figure 5.1. There was no statistical difference between pre- and post-suctioning R_c or R_s ($p > 0,1$). There was a non-significant increase in the ETT leak following suctioning ($p > 0,05$).

Table 5.2: The difference between pre- and post- suctioning lung function parameters for all patients (n = 30).

	Before suction	After suction	<i>p</i>
Cdyn (ml/cmH₂O/kg)	0,76 (0,57 – 1,02)	0,64 (0,51 – 0,91)	< 0,00001
R _i (cmH ₂ O/l/s)	70,0 (44,0 – 99,6)	66,6 (39,4 – 98,5)	0,3
R _e (cmH ₂ O/l/s)	93,5 (60,4 – 122,1)	90,45 (63,7 – 115,7)	0,2
V _{ti} ^{mech} (ml/kg)	8,37 (6,75 – 10,95)	8,48 (6,69 – 10,48)	0,7
V _{te} ^{mech} (ml/kg)	7,01 (5,5 – 8,75)	6,97 (5,5 – 8,25)	0,25
V _{te} ^{total} (ml/kg)	2,33 (0,2 – 3,9)	2,25 (0,5 – 3,8)	<1
ETT leak (%)	10,14 (0 – 25)	11,11 (2,53 – 25,76)	0,06
Peak expiratory flow (l/min)	4,0 (3,1 – 6,8)	4,3 (3,1 – 6,4)	0,35
Total RR (bpm)	51,5 (35 – 69)	54,0 (39 – 72)	0,01
Mechanical MV (l/kg)	0,17(0,12-0,25)	0,16 (0,12-0,26)	0,02
Total MV (l/kg)	0,28 (0,22 – 0,34)	0,35 (0,22 – 0,5)	<0,00001
MAP (cmH ₂ O)	9,4 (7,2 – 12,5)	9,25 (7,1 – 12,4)	0,55

Bold type indicates statistical significance, using Friedman's ANOVA. Results are expressed as median (quartile range).



Figure 5.1: Overall change in Cdyn following suctioning (*p* < 0,0001)

Figure 5.2 indicates the variable response to suctioning on Cdyn amongst individual patients. The majority (23/30; 76,7%) of patients experienced a decrease in Cdyn following suctioning. Six of the 30 (20%) had an increase in Cdyn following suctioning. One patient (3,3%) experienced no change in Cdyn. Of the 23 patients who experienced a decrease in Cdyn following suction, the Cdyn changed by >20% in seven (30,4%) and decreased by >15% in 11 (47,8%) patients. Two (33,3%) of the six patients who experienced an increase in Cdyn after suctioning had a change of >20%. One of the two patients whose Cdyn increased by >20% had a large ETT leak of >20%, implying that the recorded increase in Cdyn was likely to have been artefactual.

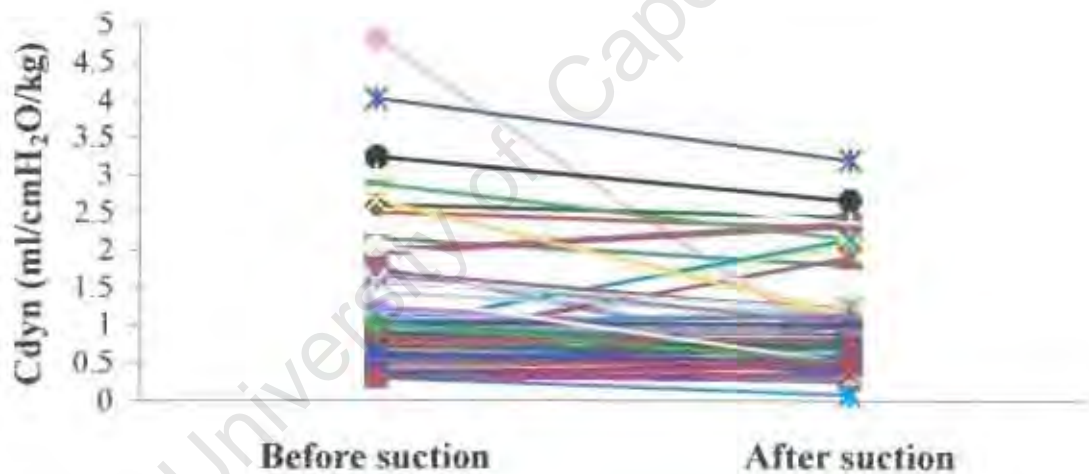


Figure 5.2: Mean Cdyn before and after suctioning for each patient.

Table 5.3 presents pre- and post-suctioning data for patients after excluding the 10 patients with ETT leaks $\geq 20\%$. After excluding patients with ETT leaks $\geq 20\%$, the decrease in C_{dyn} was still highly significant ($p < 0,001$)

Table 5.3: The difference between pre- and post-suctioning lung function parameters for patients with ETT leaks $< 20\%$ ($n = 20$).

	Before suction	After suction	<i>p</i>
C_{dyn} (ml/cmH ₂ O/kg)	0,67(0,53 – 0,81)	0,62 (0,49 – 0,76)	< 0,0009
R_i (cmH ₂ O/l/s)	60,25 (39,1 – 88,9)	54,55 (31,2 – 94,65)	0,32
R_e (cmH ₂ O/l/s)	84,7 (54,55 – 113,75)	80,55 (55,65 – 110,6)	0,07
V_{ti}^{mech} (ml/kg)	7,47 (6,1 – 9,7)	7,5 (6,06 – 9,6)	0,75
V_{te}^{mech} (ml/kg)	7,12 (5,71 – 9,59)	7,12 (5,91 – 8,93)	0,83
V_{te}^{pneum} (ml/kg)	2,74 (0,87 – 4,0)	2,38 (0,87 – 4,0)	0,1
ETT leak (%)	2,95 (0 – 10,14)	6,07 (0 – 11,32)	0,24
Peak expiratory flow (l/min)	4,0 (3,2 – 5,8)	4,25 (3,2 – 6,15)	0,75
Total RR (bpm)	56,5 (34,5 – 70)	60,5,0 (42 – 75)	0,008
Mechanical MV (l/kg)	0,17 (0,12-0,28)	0,18 (0,12-0,27)	0,18
Total MV (l/kg)	0,30 (0,24 – 0,34)	0,44 (0,30 – 0,61)	0,0001
MAP (cmH ₂ O)	8,55 (6,95 – 10,9)	8,1 (6,0 – 10,95)	0,9

Median (quartile range)

Individual patients had remarkably little variability in Cdyn readings for each five-minute period of observation, with no difference in variability before and after the suctioning procedure, as seen by the 95% confidence intervals in Figure 5.3

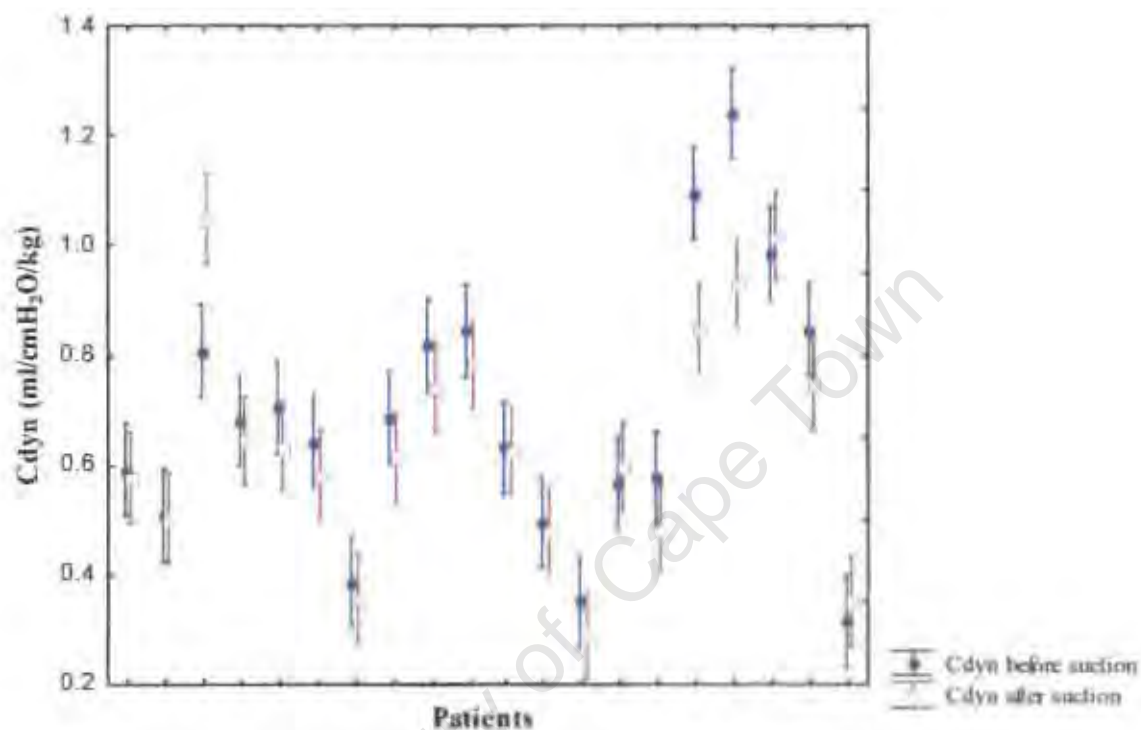


Figure 5.3: The mean Cdyn for patients with ETT leaks < 20% before and after ET suctioning. Vertical bars denote 95% confidence intervals.

There was no difference in Cdyn change between patients with ARDS ($\text{PaO}_2/\text{FiO}_2 < 200$ mmHg) and without ARDS ($\text{PaO}_2/\text{FiO}_2 > 200$ mmHg) ($p > 0,1$).

There was a significant correlation between Cdyn before suctioning and the percentage leak prior to suctioning (Spearman's $R = 0,5$; $p < 0,0001$), as expected. There was no correlation between the change in Cdyn (difference between pre- and post-suction Cdyn) and the change in the percentage leak (Spearman's $R = 0,14$, $p = 0,08$).

There was a significant correlation between the change in Cdyn and the CA:AD ratio (Kendall Tau = 0,12; $p = 0,03$).

There was a significant correlation between baseline Cdyn and the decrease in Cdyn following suctioning (Spearman's $R = 0,5$; $p < 0,0001$) (Figure 5.4). In other words, patients with higher baseline compliance tended to experience a larger decrease in Cdyn following suctioning.

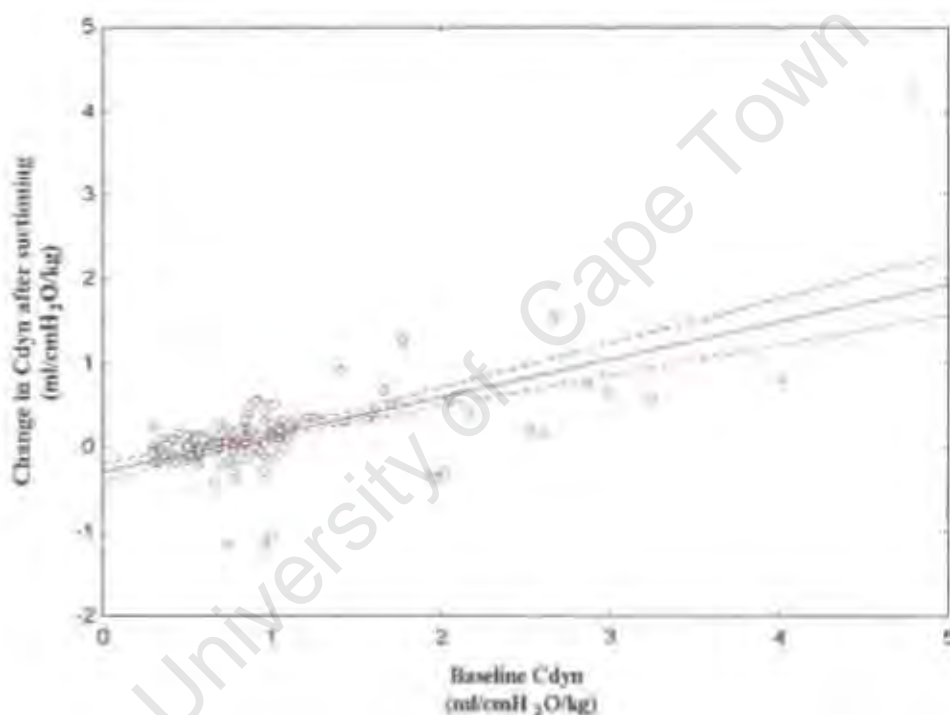


Figure 5.4: The correlation between baseline Cdyn and the subsequent change in compliance following ET suctioning.

There was no correlation between OI and the change in Cdyn (Spearman's $R = 0,09$; $p = 0,3$), or between PaO₂/FiO₂ and the change in Cdyn (Spearman $R = 0,09$, $p = 0,28$). There was, however, a significant correlation between VI and the decrease in Cdyn (Spearman's $R = 0,2$; $p < 0,005$).

Of the six patients who experienced an increase in Cdyn following suctioning, four had primary ARDS (two with pneumonia and underlying congenital heart defects, one premature baby with pneumonia as a complication of surgery for necrotising enterocolitis and one patient with pneumonia as a result of *Pneumocystis carinii* and *Respiratory Syncytial Virus* infection). One patient with pneumonia and underlying acyanotic heart defect fulfilled the criteria for ALI. The remaining patient with apnoea resulting from hydrocephalus, did not have lung disease and had a PaO₂/FiO₂ ratio > 300 mmHg. Detailed patient data are presented in Table 5.4.

Table 5.4: Summary of data for those patients who experienced an increase in Cdyn following suctioning (n = 6).

VARIABLE	MEDIAN	RANGE
Age (months)	3,25	0,5 - 25
Weight (kg)	4,5	1,65 - 10,0
ETT size (mm ID)	3,5	3,0 - 4,0
FiO ₂	0,4	0,21 - 0,5
RR (bpm)	15	14 - 35
PIP (cmH ₂ O)	21	14 - 26
PEEP (cmH ₂ O)	5	2 - 6
MAP (cmH ₂ O)	9,0	4,0 - 21,5
OI	4,98	0,8 - 15,99
VI	10,52	7,23 - 25,6
PaO ₂ / FiO ₂	139,8	81,0 - 367,9

Table 5.5 presents the change in selected parameters following suctioning in the patients whose Cdyn increased after suctioning, after excluding the two patients with ETT leaks $\geq 20\%$. These patients experienced a significant increase in Vt_i^{mch} ($p = 0,03$) following suctioning. There was a non-significant decrease in R_i ($p < 0,07$) and a non-significant increase in the percentage leak in these patients ($p = 0,8$). There was no correlation between the change in Vt_i^{mch} and the change in ETT leak (Spearman's $R = -0,09$; $p = 0,7$).

Table 5.5: The difference between pre- and post-suctioning lung function parameters for patients with ETT leaks $< 20\%$ who experienced an increase in Cdyn following suctioning ($n = 4$).

	Before suction	After suction	<i>p</i>
Cdyn (ml/cmH₂O/kg)	0,72 (0,42 – 0,94)	0,78 (0,48 – 1,0)	0,007
Vt_i^{mch} (ml/kg)	22,0 (14,5 – 85,0)	24,0 (13,5 – 87,5)	0,03
Vt _e ^{mch} (ml/kg)	22,5 (15,0 – 81,5)	24,0 (11,5 – 79,0)	0,13
R _i (cmH ₂ O/l/s)	44,8,15 (32,4 – 64,9)	27,7 (23,65 – 97,1)	0,07
R _e (cmH ₂ O/l/s)	87,25 (39,0 – 105,7)	78,45 (32,95 – 122,5)	0,18
ETT leak (%)	0,0 (-4,34 – 10,72)	5,98 (0,0 – 11,11)	0,8
Total RR (bpm)	63 (40,5 – 76,5)	66,5 (41,0 – 78,0)	0,16
Total MV (l/kg)	0,78 (0,53 – 1,74)	0,76 (0,58 – 1,54)	0,65

Bold type indicates statistical significance, using Friedman's ANOVA. Results are expressed as median (quartile range).

The SaO₂ level of one patient decreased from 95% to 78% during suctioning, but this returned to baseline < 30 seconds after reconnecting the ventilator. This patient's OI was 12,8 and PaO₂/FiO₂ was 103,3 mmHg. The SaO₂ level of another patient, with a cyanotic heart lesion, (OI = 14,5; PaO₂/FiO₂ = 91,6 mmHg) decreased from 74% to 66% during suctioning. The desaturation was considered by the consultant paediatrician to be within an acceptable range considering his pathology. All other patients maintained SaO₂ levels $\geq 88\%$ throughout the suctioning procedure, except for one patient with a cyanotic heart

lesion whose SaO₂ level was 83% before suctioning and it was maintained at ≥ 82% throughout the suctioning procedure. One patient experienced a transient relative bradycardia during suctioning with his HR decreasing from 135 to 95 BPM. The bradycardia was self-limiting and no added intervention was needed. In all cases the FiO₂ was returned to presuction settings within a minute after suctioning, with no further desaturation episodes occurring.

5.6 Discussion

This is the first study, that the investigator is aware of, that prospectively investigated the effects of a standardised single-insertion ET suctioning procedure in a heterogeneous group of critically ill paediatric patients.

As mentioned on page 5-10, patients did not receive muscle paralysis or extra sedation prior to the study intervention, both for ethical reasons and in an attempt to reflect the changes that would occur in the normal clinical situation. This may constitute a limitation of this study, as it has been suggested that in patients making spontaneous respiratory efforts, oesophageal manometry would be necessary to differentiate between chest wall and lung mechanics (Sly et al, 1996). This has been considered in the interpretation of the results discussed in this section.

There was a significant increase in total minute volume following suctioning. This can be explained by the increase in spontaneous RR seen as a significant increase in total RR following suctioning. This was most likely due to the distress or discomfort caused by the suctioning procedure, and may have also influenced other measured parameters.

In contrast to research by Brandstater et al (1969) and Fox et al (1978), patients in this study had a wide range of respiratory pathology and reacted to the suctioning procedure in a variety of ways. It is notable that the majority (77%) of patients experienced a decrease in C_{dyn} following suctioning and half of those had a decrease in C_{dyn} of > 15%. This degree of change is likely to have clinical implications for the patient.

Twenty percent of patients experienced an increase in Cdyn following suctioning, with a third of those changing by >20%.

The results of this chapter support the findings of Brandstater et al (1969) who documented a consistent decrease in pulmonary compliance, interpreted as atelectasis, produced by ET suctioning in a small group of paralysed neonates.

An artefactual change in compliance may be caused by a change in the percentage leak around the ETT (Main et al, 2001). Real changes in compliance may be caused by loss of lung volume (Ingimarsson et al, 2000; Davis et al, 1996) as a result of loss of airway pressure, suctioning or other factors such as position change (Main et al, 2001), or by overdistension of the lung. These possibilities are discussed below.

In order to minimise laryngeal injury, uncuffed ETTs are used in paediatric practice. There should always be a small air leak around the ETT during the application of positive pressure ventilation (McWilliams, 1993). When a large leak is present, there is evidence that values of compliance and resistance are overestimated (Main et al, 2001; Kondo et al, 1997; Kuo et al, 1996). Main et al (2001) emphasise that in the presence of a leak, apparent changes in compliance or resistance may not in fact reflect real clinical changes, but simply a change in the magnitude of the leak. They report that measurement of compliance appears to be more robust, but any attempt to use resistance as an outcome variable would require a negligible leak throughout the period of study.

Patients in this study did tend to have large baseline ETT leaks (median of 10,14%). Despite this, the median Cdyn recorded before and after suctioning was lower than the range expected for healthy term and preterm infants (1,1 – 2,0 ml/cmH₂O/kg) (Main et al, 2001) as opposed to being overestimated as expected (Main et al, 2001; Kondo et al, 1997; Kuo et al, 1996).

There was a significant correlation between Cdyn and the percentage leak before suctioning as expected (Main et al, 2001). If the change in ETT leak were responsible for

the overall decrease in C_{dyn}, one would have expected a similar, significant decrease in the percentage leak following suctioning. However, these results showed a nonsignificant increase in the magnitude of the leak around the ETT following suctioning ($p > 0,05$), indicating that the decrease in C_{dyn} following suctioning was real. This contention is supported by the fact that when patients with large leaks of $\geq 20\%$ were excluded from the analysis, there was still a significant overall decrease in C_{dyn} ($p < 0,001$) with no decrease in the ETT leak ($p = 0,2$).

During suctioning there was no change in patient position and there was no reason for a change in chest wall compliance. The changes in C_{dyn} must, therefore, relate to changes in lung characteristics (Nunn, 1993). Although there was a range of respiratory pathology represented in this study sample, the majority of patients had low to normal C_{dyn}, and there were no patients with severe air-trapping included in the sample. Ventilatory pressures were low, and no hyper- or re-inflation manoeuvres were performed. Thus overinflation is unlikely to explain the decrease in C_{dyn} and atelectasis is a more likely explanation. It is, however, difficult to explain the fact that tidal volume did not decrease significantly following ET suctioning, considering that the applied airway pressure was constant before and after suctioning. Although the sample size of 30 patients was larger than that of similar studies (Fox et al, 1987; Brandstater et al, 1969), a Type II statistical error may have occurred. Increasing the sample size and thus the power of the study could yield a statistically detectable change in tidal volume.

A study by Colgan (1968), reviewed by Young (1984), in which atelectasis was induced in dogs, recorded that changes in compliance were closely related to the amount of lung collapse seen later at post-mortem examination. Considering that pulmonary compliance is closely related to lung volume (Ingimarsson et al, 2000; Davis et al, 1996), the decrease in C_{dyn} reported here could also reflect a measure of lung collapse, particularly after excluding the effect of percentage leak change and other potential contributing factors.

A small number of patients (6/30) experienced an increase in C_{dyn} following suctioning. This increase in C_{dyn} may have been artefactual in two patients due to ETT leaks > 20%. It was not possible to identify predictive factors for the increase in C_{dyn} in the other four patients, but it is hypothesised that in these patients, suctioning secretions from the lungs opened up a significant area of lung to gas exchange thus increasing lung volume and improving C_{dyn}. The amount of secretions suctioned was not measured, but this hypothesis is supported by the increase in V_t^{mech} ($p = 0,03$) and the trend towards an increase in V_e^{mech} along with a decrease in R_i, which approached significance ($p = 0,07$), in this group of patients following suctioning. Other parameters were statistically unchanged after suctioning.

If secretions were drawn into the catheter during suctioning, the suction flow would have been blocked and the lung would not have been exposed to negative pressure. As a result of this, loss of lung volume was unlikely to occur, and a decrease in C_{dyn} would not have been recorded. These findings imply that suctioning in the presence of ETT secretions may not result in loss of lung volume. However, routine suctioning, which often occurs in the absence of secretions, is likely to cause significant atelectasis. Repeating suctioning manoeuvres after mucus has been removed is also likely to cause loss of lung volume.

It has been shown in Chapter Four that ΔP recorded in a lung model was linearly related to CA:AD. It has now been shown that a significant correlation also exists between the decrease in C_{dyn} following suctioning and the CA:AD ratio. As the catheter increased in size relative to the ETT ID, a larger decrease in C_{dyn} occurred. This relationship has not previously been described.

The addition of a control group receiving brief disconnection from the ventilator without suctioning would have improved this study design, as it has been shown that after discontinuation of PEEP lung collapse may occur rapidly (Neumann et al, 1998). However, the relationship between the change in C_{dyn} and the catheter size relative to ETT ID reported in this study suggests that the C_{dyn} changes recorded were, at least partly, due to the actual suctioning procedure as opposed to only being caused by the loss of airway pressure when disconnecting from the ventilator. This supports the findings of

Maggiore et al (2003) who found that the decrease in lung volume observed during ET suctioning of adults resulted from both the loss of PEEP and the application of negative pressure.

The relationship between CA:AD and the decrease in C_{dyn} following suctioning can be explained by the fact that when a catheter is inserted into a relatively large ID ETT, air is able to flow freely down the ETT around the catheter and into the lung during suctioning. Thus the air removed during suctioning is replaced and lung volume can be maintained. Conversely, when a catheter with large ED is inserted into a relatively small ETT, air is not able to flow through the ETT resulting in a larger loss of lung volume, which is reflected as a decrease in C_{dyn}.

This finding confirms that of previous authors who found a similar direct relationship between the amount of negative airway pressure produced during suctioning and the ratio of ETT ID : catheter ED using lung models or anaesthetised dogs (Chapter Four; Monaco and Meredith, 1992; Hippenbecker and Guthrie, 1981; Polacek and Guthrie, 1981; Bethune et al, 1971; Rosen and Hillard, 1962).

A high FiO₂ may augment lung collapse by causing absorption atelectasis (Rothen et al, 1995). All patients in this study were ventilated with 100% O₂ for less than one minute prior to suctioning according to accepted protocols (Branson et al, 1993) in order to minimise hypoxia (Skov et al, 1992; Shah et al, 1992). It appears unlikely that this brief period of hyperoxia could have affected C_{dyn} to such an extent. The significant relationship between the change in C_{dyn} and the CA:AD ratio, suggests that this was not the primary mechanism for the decrease in lung volume.

In contrast to the findings of Main et al (2004), patients with more compliant lungs experienced a greater decrease in C_{dyn} following suctioning than those with poor baseline C_{dyn} or “stiff” lungs. This is difficult to explain but considering that this was not due to the effect of ETT leak, it is possible that the latter group of patients had existing atelectasis and were, therefore, not further affected by suctioning.

The extent of C_{dyn} change could not be predicted using OI or PaO_2/FiO_2 . However, patients with high ventilation support requirements, including airway pressures and mandatory respiration rate, experienced greater decreases in C_{dyn} than those on low levels of ventilatory support. It is likely that more rapid derecruitment occurred in patients who were more dependent on higher PIP and mechanical RR for adequate ventilation.

Airway resistance was within the range previously reported in ventilated infants (70-150 $cmH_2O/l/s$) (Main et al, 2001; Sly et al, 1996), and as expected, R_e was consistently higher than R_i due to the dynamic narrowing of the airways on expiration. There was no overall change in R_e or R_i as a result of suctioning, although after excluding patients with ETT leaks > 20%, there was a trend towards a decrease in R_e following suctioning ($p = 0,07$). Although these results must be interpreted with caution, considering the effect of ETT leak on airway resistance (Main et al, 2001), it is worth discussing possible mechanisms for the above finding.

The results of this study differ from those of Fox et al (1978) who demonstrated a significant decrease in R_i and a trend towards a decrease in R_e after suctioning. They attributed the decrease in resistance to mucus being removed from the airways, thus reducing airway obstruction. It is likely that resistance would only decrease significantly if large amounts of mucus were removed from the airways during suctioning. Suctioning, for this study, was performed on patients who were undergoing routine, regular airway clearance and who did not necessarily have secretions in the airways at the time of the study intervention, a suggestion supported by the fact that baseline airway resistance was not high.

If loss of lung volume did occur as a result of suctioning, this would increase airway resistance (Young, 1984) thus negating the effect of clearing proximal airway obstruction. Thus, the effect of clearing secretions on airway resistance may have been offset by atelectasis occurring as a result of the suctioning procedure.

The fact that resistance did not decrease significantly following suctioning may also be explained by the fact that suctioning only clears the proximal airways, whereas medium and small bronchi are the main sites of respiratory resistance (Guglielminotti, 1998). It has also been suggested that a change in C_{dyn} , such as that recorded in this study, could be considered a more sensitive test of increased peripheral airway resistance than the measurement of resistance itself (West, 1981).

Few other complications of ET suctioning occurred in this study. The only adverse events were two episodes of transient desaturation and a single episode of relative bradycardia. These complications have been reported by other researchers (Kohlhauser et al, 2000; Segar et al, 1993; Skov et al, 1992; McCauley and Boller, 1988; Graff et al, 1987; Simbruner et al, 1981; Ehrhart et al, 1981; Cabal et al, 1979; Fox et al, 1978; Rosen and Hillard, 1962). The episodes of hypoxia occurred despite adequate pre-oxygenation in patients with $OI > 10$ and $PaO_2/FiO_2 < 120$ mmHg, indicating severe lung pathology with oxygenation defects and ARDS (Bernard et al, 1994). The bradycardia was most likely due to vagal nerve stimulation by the suction catheter (McCauley and Boller, 1988). Hypoxia may have been limited by hyperoxygenating the patients before and immediately after suctioning.

Dargaville et al (1999) reported that there was no difference in the level of desaturation between patients undergoing NB-BAL compared to TA. In contrast, the results of this chapter clearly showed that a single- catheter insertion- suctioning procedure, as performed when obtaining a TA for bacterial culture, resulted in far fewer episodes of desaturation or arrhythmias than those which occurred with NB-BAL (Chapters Two and Three). A Chi-square test comparing the number of desaturation events to $< 80\%$ during NB-BAL and ET suctioning was highly significant ($p < 0,0001$). This reinforces the contention that NB-BAL should not be used repeatedly on patients as part of routine monitoring of emerging pathogens. NB-BAL should probably be used as a routine investigative procedure only on stable patients as soon after intubation as possible and/or in the event of a negatively changing clinical picture with signs of infection and unknown pathogens. Frequent TA specimens may be sufficient in detecting potential respiratory

tract pathogens in order to start appropriate antibiotic therapy in the event of raised septic markers.

Shearing forces created by repetitive alveolar collapse and reopening can be injurious to the lung (Marraro, 2003; Suh et al, 2002; Matthews and Noviski, 2001; Neumann et al, 1998). The application of a negative pressure could further increase shearing forces resulting in lung damage (Taskar et al, 1997). This injury may stimulate a cascade of biological responses leading to further lung injury and eventually may lead to multiorgan failure (Suh et al, 2002; Ranieri et al, 1999). Suh et al (2002) also showed that repeated derecruitments may further aggravate lung injury and that sudden loss of recruitment may aggravate ventilation inhomogeneity and cause further closing of small airways, making the lung more vulnerable to injury.

Other factors which may contribute to lung injury include pre-existing lung damage and/or inflammation; high FiO_2 , the level of blood flow; and the local production and systemic release of inflammatory mediators (Marraro, 2003).

The goals of recently proposed ventilatory strategies to protect the lungs from injury are to prevent alveolar overdistension and derecruitment. In this context, the periodic derecruitment induced by ET suctioning and confirmed in this chapter by a decrease in C_{dyn} could be harmful to patients with ALI or ARDS (Maggiore et al, 2003; Suh et al, 2002; Taskar et al, 1997), despite there being few immediate clinical effects.

5.7 Conclusion

This study aimed to determine the immediate effects of open ET suctioning on lung mechanics in mechanically ventilated paediatric patients in the PICU.

The results of this research demonstrated that ET suctioning frequently causes a decrease in C_{dyn} in some mechanically ventilated children with variable lung pathology, who are intubated with small diameter ETTs. This decrease in C_{dyn} was related to both ETT and catheter diameter and may indicate loss of lung volume caused by the suctioning

procedure. There was no clear evidence that suctioning reduced airway resistance. These results require confirmation with further investigations.

In the clinical situation patients usually undergo repeated suction catheter passes during airway clearance. In this study only one catheter insertion was performed. It is likely that more complications and greater loss of lung volume would have been noted if repeated catheter insertions had been performed.

5.8 Recommendations for clinical practice and future research

Further investigations would have to be conducted to determine the clinical implications for the patient of these changes in lung mechanics. These future studies would have to measure other parameters such as blood gas values to establish clinical significance. This was beyond the scope of this investigation. The changes recorded in this study would, however, suggest that loss of lung volume occurs after suctioning. It is, therefore, recommended to limit this by suctioning only when there are clinical indications, such as the presence of secretions, as opposed to routine suctioning and then to use only the smallest effective catheters.

Lung mechanics were not recorded beyond five minutes after suctioning and it is, therefore, a matter of conjecture as to what would happen in the hours after suctioning. The lungs may remain partially collapsed as was found by Brandstater et al (1969), in which case the patient would be predisposed to infection and prolonged stay in the PICU; or the lungs may slowly reinflate unless suctioning is again performed in the interim. Therefore, further investigation is needed to determine the mid- and long- term effects of ET suctioning on lung mechanics.

In order to prevent lung injury (page 5-28 to 5-29) it is important to identify a means of preventing or reversing the alveolar derecruitment caused by ET suctioning. Therefore, the investigation described in Chapter Six was proposed and conducted to investigate the efficacy of performing a post-suctioning recruitment manoeuvre in order to reverse ET suctioning-induced atelectasis.

CHAPTER SIX

AN INVESTIGATION INTO THE EFFECTS ON LUNG DYNAMICS OF PERFORMING A LUNG RECRUITMENT MANOEUVRE AFTER ENDOTRACHEAL SUCTIONING IN VENTILATED PAEDIATRIC PATIENTS

6.1 Introduction

Intubated patients need regular suctioning of airway secretions, as they are unable to clear secretions spontaneously. Commonly, ET suctioning involves disconnecting the patient from the ventilator and then suctioning the ETT (open ET suctioning). In infants and young children where functional residual capacity is close to the closing volume, glottic closure is used as a natural mechanism to maintain lung volume. The presence of an ETT prevents glottic closure, predisposing the patient to atelectasis. Therefore, even in intubated children with normal lungs, PEEP is necessary to maintain lung volume and patients with lung disease are more at risk of developing atelectasis. Disconnection from the ventilator, therefore, results in a decrease in airway pressure with loss of lung volume, and further lung volume loss occurs with the application of a negative pressure during suctioning (Maggiore et al, 2003; Taskar et al, 1997). This loss of lung volume was also described in Chapter Five in terms of a decrease in C_{dyn} as a direct result of suctioning. As mentioned in Chapter Five, it is important to optimise alveolar recruitment and maintain lung volume in order to prevent lung injury (Amato et al, 1998).

Various techniques have been suggested to prevent hypoxia during suctioning, or to hasten the return to pre-procedure levels. These include administration of high levels of FiO₂; hyperinflation/reinflation techniques; and avoidance of disconnection from the ventilator by using a closed-system suction apparatus to maintain ventilation throughout the suctioning procedure.

In an attempt to identify a safe, inexpensive technique for preventing or reversing suction-induced lung volume loss, an extensive literature search was performed. Search terms used were “endotracheal suctioning” or “suction” and “tracheal suctioning” or “suction”, with modifiers such as “paediatric”, “children”, “complications”, “lung volume”, “recruitment”, “recruitment manoeuvres”, “closed system” and “in-line”.

6.1.1 Closed-system suctioning

It has recently been suggested that use of a closed-suction system may prevent ET suctioning-induced hypoxia and decreases in lung volume in paediatric (Choong et al, 2003) and adult (Cereda et al, 2001) patients. Closed-system suctioning can be performed through an adaptor inserted at the ETT-ventilator circuitry interface. The catheter is encased in a plastic sleeve on insertion, providing a seal that maintains a closed system (Taggart et al, 1988). Another potential benefit of using closed-system suctioning may be the limitation of aerosolisation of infectious mucus particles; thereby preventing the spread of infection between patients and from patients to staff.

The drawbacks of closed-system suctioning include the risk of producing high negative pressures (Stenqvist et al, 2001) if the amount of air suctioned exceeds the gas flow delivered to the patient by the ventilator (Strindlund, 2002); reduced efficiency in clearing thick secretions from the airways (Lindgren et al, 2001); and the high financial cost of the system which has to be replaced daily in order to avoid microbial lower respiratory tract colonisation (Freytag et al, 2003). Practically, based on personal observation, there is also a risk of not withdrawing the catheter completely after the suctioning event, thus partially occluding the ETT and markedly increasing airway resistance.

In a bench test evaluation of a neonatal closed-suction system, Monaco and Meredith (1992) found that the closed-suction system did not preserve continuity of volume or pressure delivery during suctioning; therefore this was unlikely to be the reason for the reported reduction in suctioning-related hypoxia (Cabal et al, 1979; Graff 1987; Zmora, 1980).

Choong et al (2003) compared the degree of lung volume loss resulting from open and closed-system ET suctioning in 14 paralysed paediatric patients ranging in age from six days to 13 years. They concluded that total lung volume loss was significantly greater with open- than closed-system suctioning. In addition, patients suctioned with the open method experienced greater levels of desaturation. These authors suggest that closed-system suctioning is preferable to the open technique, especially in patients with significant lung disease requiring high levels of PEEP, in order to avoid alveolar derecruitment and hypoxia during ET suctioning.

In an *in vitro* study using adult-sized ETT and suction catheters (Lindgren et al, 2004) it was found that open suctioning was significantly more efficient than closed-system suctioning during three different ventilation modes. Auto-triggering of the ventilator was observed during all closed-system suction procedures. In addition, during closed-system suctioning with positive pressure ventilation, the triggered inspiratory gas flow actually forced secretions away from the catheter tip. It appeared that pulmonary secretions could not be effectively removed without causing lung collapse and affecting gaseous exchange. Open suctioning was presented as the system of choice, in the presence of clear indications for suctioning.

In a recent *Cochrane* Review (Woodgate and Flenady, 2003), it was concluded that there was insufficient evidence to decide between ET suctioning with or without disconnection, despite some potential short-term benefits associated with closed-system suctioning. The authors suggested that it would seem wise for clinicians to continue with existing suctioning techniques where proficiency had been gained.

These reported benefits and complications of closed-system suctioning were considered in relation to the financial implications to a resource-constrained facility. On evaluating the available evidence it was decided that due to the high financial cost of closed suction systems, the potential drawbacks, as well as the lack of clear evidence supporting their use; it was not considered feasible to introduce the system into the PICU of RCWMCH.

6.1.2 Constant flow insufflation

Brochard et al (1991) showed that lung volume and PaO₂ could be maintained during open ET suctioning by using constant flow insufflation. Constant flow insufflation was administered via a modified ETT in which high-velocity jet flow was delivered through small capillaries near the tracheal end of the tube during disconnection from the ventilator. This was effective in reducing hypoxia in adults but necessitated the use of a special adapted ETT making it impractical in most developing countries, due to the financial costs involved. This technique may not be possible in infants and children, due to their small ETT size.

6.1.3 Recruitment manoeuvres

A suggested method to avoid derecruitment-associated lung injury (Chapter Five) may be to limit ventilator disconnections and, when disconnections do occur, to use a recruitment manoeuvre (RM) to reinflate the collapsed lung segments before resuming ventilation (Lindgren et al, 2004; Suh et al, 2002). It was suggested that, because the lungs of patients with ALI/ARDS may be difficult to expand, recruitment manoeuvres should be considered following ET suctioning.

A RM refers to the application of a sustained inflation pressure to the lungs for a specified duration, in order to return the lung to normal volumes and distribution of air. RMs have been proposed as a means of reversing suctioning-induced lung volume loss by recruiting atelectatic regions of the lung, thereby improving arterial oxygenation (Matthews and Noviski, 2001).

6.1.3.1 Animal studies

The effects of RM were initially tested in animal models of ALI, induced by repeated saline lavage, which leads to surfactant depletion with no damage to alveolar or perivascular cells; oleic acid injection, which produces acute endothelial and alveolar epithelial cell necrosis resulting in alveolar proteinaceous oedema with no initial inflammatory response; and intravenous infusion or intratracheal instillation of

endotoxin, which causes an inflammatory response and damage to pulmonary endothelial cells leading to proteinaceous oedema (Van der Kloot et al, 2000; Neumann et al, 1998). The nature of lung injury induced in these models is likely to be that of generalised atelectasis and low compliance. Paediatric ARDS/ALI, may present differently and therefore results from these studies cannot be directly extrapolated to clinical practice.

Rimensberger et al (1999) studied the effects of RMs in lung-injured rabbits. The RM resulted in a significant increase in end-expiratory lung volume, PaO₂ and C_{dyn} despite equal PEEP levels used before and after the manoeuvre. After RM, PaO₂ remained high over four hours of ventilation when optimal PEEP was used. These authors applied an inflation pressure of 30 cmH₂O for thirty seconds.

In anaesthetised sheep, hyperoxygenation and a post-suction RM completely reversed airway narrowing and atelectasis, measured by computed tomography (Lu et al, 2000).

In an animal study, using dogs, Cakar et al (2000) reported that a RM (60 cmH₂O for 30 seconds) improved arterial oxygenation, and was more effective in the prone than supine position.

Van der Kloot et al (2000) concluded that responses to RMs differed amongst different models of ALI, using dogs as experimental subjects. It was suggested that when a RM is used, a brief, 30-second, single application of a high airway pressure (60 cmH₂O) may be optimal and well tolerated.

Russell et al (2002) reported that a timed re-expansion inspiratory manoeuvre successfully reversed apnoea-induced decreases in C_{dyn} in anaesthetised lambs.

6.1.3.2 Adult data

Lapinsky et al (1999) performed a RM (sustained inflation using a pressure of 30–45 cmH₂O applied for 20 seconds) on 14 adults with hypoxia and bilateral pulmonary infiltrates on chest X-ray. Significant improvements in SaO₂ occurred in the majority of patients within 10 minutes. No significant adverse effects were noted and there were no

occurrences of barotraumas. They concluded that a sustained inflation is a safe, clinically applicable method of lung volume recruitment, which improves oxygenation in selected patients and may have a role in ventilatory management.

In 20 adults with ARDS, Lim et al (2001) showed that an “extended sigh” as a RM (a stepwise change in TV-PEEP values to 2-25, after which continuous positive airway pressure (CPAP) of 30 cmH₂O for 30 seconds was applied) resulted in a sustained increase in both PaO₂ and static respiratory compliance. In addition, no major haemodynamic or respiratory complications were noted.

Richards et al (2001) performed RM on 19 adults with severe ARDS. The RM consisted of patients first being turned prone and then applying a positive pressure of 40 cmH₂O for 90 seconds. There were significant, sustained improvements in OI, PaO₂/FiO₂ and alveolar-arterial O₂ difference as a result of the RM.

Physiotherapists working in adult intensive care units often use manual hyperinflation techniques as part of physiotherapy respiratory regimens (Patman et al, 2000; McCarren and Chow, 1996) in order to expand the lung and loosen secretions, in conjunction with other manipulations. These manoeuvres are usually repeated, short manual inflations reaching a predetermined set pressure or volume with a brief inspiratory hold. Patman et al (2000) conducted a randomised controlled trial on 100 medically stable patients who had undergone coronary artery bypass surgery. Manual hyperinflation was performed with an inspiratory pause of two to three seconds, inspiratory: expiratory ratio of approximately 1:2 at a rate of 10-12 bpm for a period of four minutes. Lung compliance improved markedly immediately post-intervention in the manual hyperinflation group and remained above baseline at one-hour post intervention, while varying very little over time in the control group. PaO₂/FiO₂ also improved immediately after intervention in the hyperinflation group

Barker and Adams (2002) randomly assigned 17 adults to one of three groups: Group One were placed head up in supine and were preoxygenated with 100% O₂ for three

minutes. This group receives ET suctioning only. Group Two were positioned and preoxygenated in the same manner as for Group One. The patients were then positioned in left and right decubitus positions with the bed at 0° elevation. They received ET suctioning in these positions. Group Three received the same intervention as Group Two but with the addition of six manual hyperinflation breaths before suctioning (delivered at 1.5 times the set tidal volume with a two second inspiratory hold). Procedures were repeated until the patient was clinically clear of secretions.

Barker and Adams (2002) observed a significant decrease in C_{dyn} for all patient groups, which was not significantly different between groups. They also observed an initial fall in systemic blood pressure, followed by an increase in blood pressure to above baseline values. Hyperinflation did not seem to improve C_{dyn}. These authors suggested that a tradeoff existed between disconnection and suctioning with the resultant loss of recruitment; and attempting to achieve recruitment with manual hyperinflation. One of the questions that arise from this research is whether a difference would have been noted had the hyperinflation manoeuvre been performed after (instead of before) suctioning the patient. Another possible reason for the lack of improvement following the hyperinflation manoeuvre could be that it was not sustained for long enough to adequately recruit alveoli. Statistical power may have not been sufficient to detect an actual change in C_{dyn}. Although not discussed in this paper, no change or a deterioration in C_{dyn} may reflect overinflation of the lung; whereas optimal recruitment to normal lung volumes would be reflected by an improvement in C_{dyn}.

Care should be taken when applying the above studies to paediatric practice. In infants and children, performing hyperinflation manoeuvres (as opposed to recruitment/inflation manoeuvres to normalise lung volumes) may be dangerous due to the high risk of barotrauma.

Lim et al (2003) found that patients with extrapulmonary ARDS showed a greater increase in PaO₂ after RM than those with pulmonary ARDS. The increase in PaO₂ induced by the recruitment manoeuvre was greater for patients in the supine than prone

position. Conceivably, some recruitable lung units had already been recruited by positioning the patient in the prone position.

The ARDS Clinical Trials Network (2003) performed RMs (a gradual increase in CPAP over 5-10 seconds to 35 cmH₂O with this pressure maintained for 30 seconds) or sham RM on adults with ARDS or ALI ventilated with high PEEP. Changes in SaO₂ were measured with pulse oximetry. They found a variable response to the RM, with some patients experiencing a drop in SaO₂ whilst others' increased markedly. Decreases in systolic blood pressure were significantly greater after RM than sham RM. RMs were terminated early in a few cases because of hypotension or desaturation. Respiratory system compliance did not increase more after RMs than after sham RMs. There were no apparent sequelae from the RM. This group of researchers concluded that more information regarding efficacy and safety is needed from clinical studies before RMs can be recommended as part of standard ventilator management in patients with ALI or ARDS.

Dhyr et al (2003) performed a prospective randomised controlled study using eight adults with ALI or ARDS. Patients received ET suctioning with or without a RM performed after the suctioning procedure. The RM consisted of two hyperinflations, using the CPAP function of the ventilator, to an airway pressure of 45 cmH₂O for 20 seconds, with an interval of one minute in between hyperinflations. This study suggested that open ET suctioning might result in a significant decrease in PaO₂ and lung volume, that the RM was well tolerated and produced a rapid recovery in end-expiratory lung volume, respiratory system compliance and PaO₂. The study was limited by the small sample size.

6.1.3.3 Paediatric experience

Marcus et al (2002) randomised 20 anaesthetised children less than two years of age with normal lungs, to receive either a timed RM (30 cmH₂O for 10 seconds using 33% O₂ in nitrous oxide followed by a return to the same ventilatory parameters) or three minutes of 100% inspired O₂ at the same ventilatory parameters, and then returned to 33% O₂ in nitrous oxide. This does not appear to be a well matched control group, as breathing

100% O₂ is known to cause absorption atelectasis by displacing inert pulmonary gases (Rothen et al 1995). The study design could have been improved by delivering the same FiO₂ to both patient groups.

Not surprisingly, therefore, the group receiving 100% inspired O₂ experienced a 9% decrease in C_{dyn} at three minutes, whilst the RM caused a 30% increase in C_{dyn} at one minute after RM. The changes in airway resistance were not significant. After the study intervention, the RM group showed significantly higher C_{dyn} and lower airway resistance than the 100% O₂ group. The beneficial effects of the RM reduced over time, with the increase in C_{dyn} only remaining statistically significant for seven minutes after RM. These authors believe that the reduced C_{dyn} was due to atelectasis and the correction of this based on the principle of the RM as an alveolar volume recruitment manoeuvre (Marcus et al, 2002).

Tusman et al (2003) performed RMs (CPAP progressively increased in steps of 5 cmH₂O every four breaths up to 15 cmH₂O; then increased further to 37-40 cmH₂O PIP for 10 breaths) on anaesthetized children under seven years of age, with healthy lungs. Compared with other groups, treatment with the alveolar recruitment strategy resulted in a lower frequency of atelectasis. The RM increased arterial oxygenation and respiratory compliance.

There are no published studies investigating the effect of RMs performed in ventilated paediatric patients with pulmonary disease. No research has been published assessing the effects of a RM performed after ET suctioning in infants and children. Clearly there is a need for research into this field, as RMs are being performed in many PICUs worldwide (Waggie, 2003; Cox, 2002 - personal communications), but there is no standardisation of technique and no objective evidence that RMs are beneficial at all.

6.1.3.4 Recruitment Manoeuvre Technique

The timing, optimal pressure, duration and method of performing RMs have not yet been determined (Villagr a et al, 2002; Matthews and Noviski, 2001). Matthews and Noviski

(2001) noted that the RM has not yet been validated for efficacy and should be used with a defined clinical protocol to learn more about its strengths and weaknesses.

Many techniques of performing RMs have been described, as mentioned previously. RMs typically consist of an application of CPAP of 30-50 cmH₂O for 30-45 seconds (Tusman et al, 2003; ARDS Clinical Trials Network, 2003; Neligan, 2002; Dyhr et al 2003; Villagr a et al, 2002; Marcus et al, 2002; Lim et al, 2001; Matthews and Noviski, 2001; Lapinsky et al, 1999). In healthy anaesthetised adults, the PIP needed to recruit alveoli is 40cmH₂O (Rothen et al, 1993).

Although paediatric literature in this area is scarce, it appears that pulmonary disease in children tends to be heterogeneous. From the adult literature, it is known that ARDS lungs may have areas of atelectasis and interstitial oedema which are potentially recruitable; areas of aerated normal lung or overdistended segments, which are susceptible to barotrauma; and air spaces that are filled with exudate and are therefore not recruitable (Richards et al, 2001).

In children and infants there is a balance between high chest wall compliance and low pulmonary compliance related to underdeveloped lung parenchyma, small airway diameter and small alveoli (Tusman et al, 2003). The optimal PIP required to safely recruit alveoli in this group of patients is not yet known. Physiologically, lung inflation depends on transpulmonary pressure, which is related to respiratory compliance. In children with very high chest wall compliance, large transpulmonary pressure could be caused by the application of a positive inflation pressure. This may result in effective alveolar recruitment of atelectatic areas, but also holds the risk of barotrauma, including pneumothorax.

In one of the few paediatric studies of RM performed on children with healthy lungs, a sustained inflation pressure of 30 cmH₂O applied for 10 seconds was found to be safe and effective (Marcus et al, 2002). Tusman et al (2003) used a stepwise increase in CPAP to

15 cmH₂O followed by a further increase to 37-40 cmH₂O PIP, maintained for 10 breaths.

Recruitment/derecruitment is not instantaneous, but rather has a timescale associated with it. Airway recruitment should thus be determined by time as well as by pressure. Opening and closing of flexible fluid-lined conduits occurs progressively over the time required for a liquid bridge across the lumen first to break and then reform (Bates et al, 2002). Collapsed alveoli are subject to Laplace's Law and a high inspiratory pressure is required to expand these atelectatic lung units. This pressure has to be maintained for long enough for the slow alveoli with prolonged time constants to reexpand (Marcus et al, 2002). Laplace's law, however, also implies that, in the presence of normally aerated or hyperinflated alveoli together with collapsed alveoli, there is a risk that the RM would preferentially overdistend the aerated units before expanding collapsed areas.

It was suggested by Cox (2002), that RMs on ventilated paediatric patients be performed by applying a sustained pressure of 30 cmH₂O for 30 seconds. This was based on animal models of diffuse lung injury and on personal clinical practice. This could be achieved either by using an anaesthetic bag attached to a manometer or by changing the ventilator mode to CPAP, increasing the pressure to 30 cmH₂O for the set time and then readjusting the ventilator mode and pressures.

For this study the investigator felt it was important to test a RM which, if found to be effective and safe, could be easily and safely used after ET suctioning by all nursing, physiotherapy and other medical staff. It was felt that changing ventilator settings could be hazardous if these were not returned to pre-suction settings after the RM.

Cox (2002) suggested that the ETT should be occluded after performing the RM in order to prevent loss of pressure and subsequent derecruitment. The method of securing the ETT in this PICU does not allow the ETT to be clamped, as the ETT is flush with the nose. Therefore it was decided to attempt to perform a RM using manually applied

30cmH₂O for 30 seconds by means of an anaesthetic resuscitation bag and then reconnecting the ventilator tubing as quickly as possible thereafter.

6.1.3.5 Potential side effects of RM

The magnitude and duration of the RM may be limited by its potentially deleterious effect on cardiac output (Matthews and Noviski, 2001). As a result of this concern, all children with heart disease, poor cardiac function or anatomical cardiac anomalies were excluded from this study.

There is clearly a risk of barotrauma and pneumothorax from the application of a high inflation pressure to the lungs. The possibility of lung injury resulting from high airway pressures has to be balanced against the potential benefit of the RM. It is possible that by applying high positive pressure to lungs that are partly atelectatic, alveolar recruitment of collapsed lung segments could occur with simultaneous over-distension of noncollapsed areas (Tusman et al, 2003).

6.2 Aims

This study aimed to investigate the effects of a post-suctioning RM on lung dynamics and SaO₂ in mechanically ventilated, non-paralysed paediatric patients.

6.3 Objectives

The objectives of this study were to:

1. confirm the reliability and reproducibility of the results of Chapter Five by comparing changes in C_{dyn}, R_e, R_i, V_{te}, total MV and total RR following a standardised ET suctioning procedure;
2. to combine the above data with that of Chapter Five to increase the power of the previous chapter's study;
3. determine the immediate and mid-term (25 minutes) effects of a standardised RM performed after a single- catheter insertion open ET suctioning procedure on C_{dyn}, V_{te}, R_e and R_i, MV, and RR;

4. determine the immediate and mid-term (25 minutes) effect of a standardised RM performed after a single- catheter insertion open ET suctioning procedure on SaO₂;
5. determine whether the child's position (specifically prone and supine) influences the efficacy of the RM with regards to Cdyn; and
6. assess the safety and practicality of performing the RM after suctioning, by clinical observation and by recording SaO₂, HR and BP throughout the study period.

6.4 Materials and Methods

Full approval was obtained from the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (Rec/Ref: 041/2003). Patient confidentiality was maintained throughout; patient details were kept by the primary investigator in case of any adverse events. Written, informed consent in the language of their choice was obtained from the patients' parent or legal guardian (Appendix D) before starting measurement using the CO₂SMO Plus!.

In addition to adhering to the strict inclusion/ exclusion and withdrawal criteria listed below, a Safety Monitoring Committee comprising PICU staff not involved in this study reviewed any adverse haemodynamic events after every five patients enrolled.

6.4.1 Study design

The study design was a prospective randomised controlled single-blind clinical trial.

6.4.2 Patient Sample

A sample population of 48 mechanically ventilated patients were assessed as being required in order to detect a difference between the groups of one standard deviation, with a power level of 80%, $\alpha = 0,05$. All patients admitted to the PICU of RCWMCH during the period from May 2003 to the end of October 2004, with ETT \leq 4mm ID, were eligible for participation in this study.

Once consent was obtained, eligible patients were randomly assigned to a recruitment or non-recruitment (control) group by means of concealed, opaque envelopes selected by the therapists performing the study intervention. The primary researcher was blinded to this allocation.

Exclusion criteria:

- cardiac abnormality or disease, either congenital or acquired;
- raised intracranial pressure, or increased potential to develop pathologically raised intracranial pressure (including patients with meningitis, post head injuries, intracranial tumours, hydrocephalus etc);
- haemodynamic instability for the preceding 24 hours (changes $\geq 20\%$ in MABP, HR or SaO₂);
- average baseline SaO₂ of $< 85\%$;
- pneumothorax, or a history of pneumothorax;
- post thoracic surgery;
- coagulopathy, with a platelet count $< 100 \times 10^9 /l$; and
- premature or small for gestational age neonates.

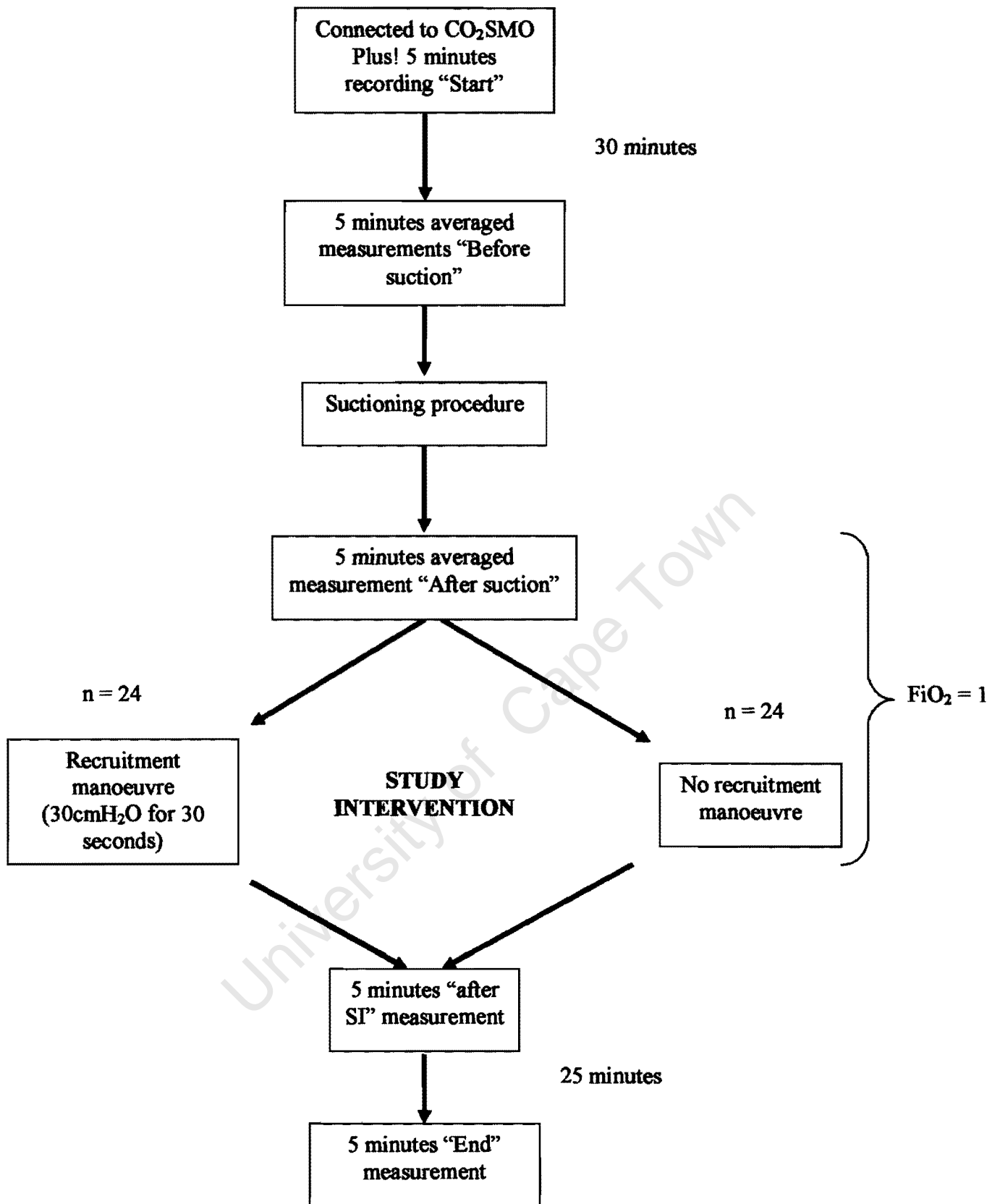


Figure 6.1 Timeline of research process

6.4.4 Technique

A flowchart of the study timeline is presented in Figure 6.1.

1. The following data were recorded for each patient: age; gender; weight; medical condition; FiO_2 and ventilation settings; PaO_2 and PaCO_2 ; ETT ID; the catheter size used for suctioning; patient position (prone or supine); and the number of days the child had been mechanically ventilated.
2. All patients were connected to a CO₂SMO Plus! Model 8000 Respiratory Profile Monitor using neonatal flow sensors (<1ml deadspace), for 30 minutes before and 30 minutes after a single- catheter insertion- suctioning procedure (page 6-17).
3. The CO₂SMO Plus! was calibrated manually before each recording event and was serviced and calibrated by the manufacturing company every six months.
4. A new flow sensor was used for each patient to ensure infection control.
5. Patients' body positions were not changed for research purposes. The patient had remained in the same position for more than an hour prior to the start of the monitoring period, and was not moved for the duration of the measurement time.
6. FiO_2 was increased to one for 30 seconds before the suctioning procedure and remained at this level for the duration of the suctioning manoeuvre and SI, after which FiO_2 was reduced to pre-suction levels. Apart from this, ventilation settings were constant during the measurement period.
7. The SI was performed five minutes after the suctioning procedure.
8. The FiO_2 was decreased to pre-suction values immediately after the SI.

The 30 minutes of measurement prior to the suctioning procedure was deemed necessary in order to standardise a period of non-intervention for all patients. In addition, this was done in an attempt to minimise the possible derecruitment effect of disconnecting the ventilator briefly in order to connect the flow sensor. It was not practical to extend the entire measurement period, and thus limit intervention procedures by other health professionals, to beyond an hour.

Study Intervention (SI): In the “recruitment” group: five minutes after the suctioning procedure, a sustained inflation pressure of 30 cmH₂O was applied manually by means of

a one-litre anaesthetic bag, with 10 l/min^{-1} gas flow of 100% O_2 , connected to a pressure manometer, for 30 seconds. Thereafter, the ventilator was immediately reconnected on its original settings. The CO₂SMO Plus! continued recording for a further 25 minutes.

The “non-recruitment” (control) group underwent an identical suctioning procedure. Patients were reconnected to the ventilator immediately after withdrawing the suction catheter and remained attached to the CO₂SMO Plus! for a further 25 minutes.

Patients did not receive additional sedation, muscle paralysis or analgesia for the purposes of this research. All patients received continuous morphine infusions as part of standard practice.

The suctioning technique used was standard practice in the RCWMCH PICU and was performed as follows:

- Patients were preoxygenated with 100% O_2 for 30 seconds prior to suctioning, whilst receiving intermittent positive pressure ventilation (IPPV).
- He / she was disconnected from the ventilator at the end of inspiration.
- A clamped suction catheter was inserted into the ETT to just beyond the distal ETT tip, suction was applied and the catheter withdrawn whilst rotating it slightly.
- The patient was then immediately reconnected to the ventilator circuit.
- A range of catheter sizes was used, depending on availability and based on the guidelines presented in Chapter Four.
- A vacuum pressure of approximately -360 mmHg was used, measured at the source with tubing clamped.
- The suction catheter was inserted in the ETT for ≤ 10 seconds, with vacuum pressure being applied for ≤ 5 seconds.

Throughout the observation and suctioning period, there was continuous ECG, blood pressure and pulse oximetry monitoring. The following criteria were set for termination of the procedure:

- a 20 % change in MABP;

- a decrease in SaO₂ to < 80%;
- a decrease in HR of more than 20 BPM (bradycardia);
- an increase in HR to > 160 BPM (tachycardia); or
- any other cardiac arrhythmia.

6.4.5 Allocation Concealment:

The suctioning procedures and RMs were performed by trained paediatric physiotherapists working in RCWMCH. These therapists randomly selected the envelopes containing a concealed code, representing assignment to either the recruitment or control group. The primary investigator left the PICU during study interventions. She performed the data analysis using the above codes and was only unblinded to allocation at the end of patient enrolment, after data analysis was completed.

6.4.6 Analysis

The following data were downloaded from the CO₂SMO Plus! using *Analysis Plus* for Windows Version 5.0: C_{dyn}; R_e, R_i, V_{te}, total MV; and total RR. The CO₂SMO Plus automatically averages breath- by -breath values for each minute of recording. For each patient, five of these readings at each measurement point were used for analysis. The parameters were corrected for patient weight where applicable. Expired tidal volume was used rather than inspired tidal volume to minimise errors due to ETT leak in children with uncuffed ETTs (Kuo et al, 1996; Main et al, 2001).

Respiratory severity indices of OI and VI (Peters et al, 1998) were calculated for each patient as well as PaO₂/FiO₂.

6.4.6.1 Statistical analysis

Direct comparisons of the changes in lung function parameters at each measurement point were made between the two treatment groups and, after unblinding, the effects of the RM were determined.

Data were tested for normality using the Kolmogorov- Smirnov and Lilliefors's tests. Data were not normally distributed and therefore the following nonparametric tests were used:

- descriptive statistics to obtain the median, mean, range, 95% confidence intervals and interquartile ranges for all variables studied;
- between-group independent variables were compared using the Mann-Whitney U test;
- within-group dependent variables were compared using the Wilcoxon matched pairs test or Friedman's ANOVA;
- Spearman's rank order non-parametric correlation tests were used to assess relationships between variables;
- where the residuals were normally distributed, Two-Way ANOVA was used to assess differences in effect between groups (between- and within- group design);
- multiple independent variables were analysed using the Kruskal-Wallis ANOVA and Median Test; and
- Yates-corrected Chi-square tests were used when some cells contained data values <10.

Statistica (Kernel Release 6.1, StatSoft Inc 1984 - 2003) was used for all statistical analyses.

6.5 Results

6.5.1 Patient data

The sample size for this study comprised 48 patients, with equal numbers randomly assigned to intervention and control groups. No patients were withdrawn from the study. Baseline patient data are summarised in Table 6.1. Patients were all receiving conventional pressure-limited time-cycled mechanical ventilation using Newport Ventilators (models E100) and E100m).

Table 6.1 Baseline patient data (n = 48).

VARIABLE	Control Group	Recruitment Group	<i>P</i>
Age (months)	4 (0,25 – 18)	3,25 (0,3 – 19)	0,7
Gender (M:F)	10:14	16:8	0,08
Weight (kg)	5,25 (1,7 – 9,8)	4,7 (2,3 – 11,0)	0,7
Ventilated days	2 (1 – 14)	2,5 (1 – 23)	0,9
ETT size (mm ID)	3,5 (3 – 4)	3,5 (2,5 – 4)	0,5
FiO ₂	0,4 (0,25 – 0,7)	0,4 (0,21 – 0,8)	0,7
RR (bpm)	20 (13 – 33)	25 (12 – 45)	0,2
PIP (cmH ₂ O)	22 (17 – 34)	23,5 (16 – 31)	0,4
PEEP (cmH ₂ O)	5 (3 – 11)	6 (3 – 12)	0,2
MAP (cmH ₂ O)	10 (6 – 18)	10,5 (5 – 18)	0,3
OI	3,15 (0,88 – 15,16)	5,46 (0,82 – 22,81)	0,4
VI	14,27 (5,56 – 80,37)	14,41 (0 – 45,63)	0,8
PaO ₂ / FiO ₂ (mmHg)	245,2 (68,75 – 690,0)	170,9 (58,4 – 769,3)	0,5

Median (range)

Primary medical conditions for which the patients were admitted to the PICU are listed in Table 6.2. The child with inhalational burns was included in the analysis, as his chest was not burnt and constrictive dressings were therefore not applied.

In the control group, eight patients with ETT leaks < 20% fulfilled the criteria for ARDS (47%), and four for ALI (23.5%). In the recruitment group 12 patients had ARDS (70.6%) and one patient had ALI (5.8%) ($p = 0,3$). These were all cases of primary ARDS.

Table 6.2 Primary medical conditions (n = 48).

DIAGNOSIS	Control Group n (%)	Recruitment Group n (%)	<i>p</i>
Pneumonia	20 (83,3)	22 (91,7)	0,7
Sepsis	5 (20,8)	1 (4,2)	0,2
Shocked gastroenteritis	4 (16,7)	0	0,1
Near drowning	0	1 (4,2)	1
Paraffin ingestion	0	2 (8,3)	0,5
Myasthaenia gravis variant (respiratory muscle weakness)	0	1 (4,2)	1
Upper airway obstruction	0	2 (8,3)	0,5
Apnoea	0	1 (4,2)	1
Inhalational thermic injury	1 (4,2)	0	1

6.5.2 Combined data: changes in lung dynamics occurring with ET suctioning

Recorded lung dynamics pre- and post- ET suctioning of the 30 patients from the study in Chapter Five were combined with the 48 patients' data from this study. After excluding 24 patients with leaks $\geq 20\%$, the remaining 54 patients' data were pooled and analysed (Table 6.3)

Table 6.3 Combined patient data pre- and post- ET suctioning. (n = 54)

	Before suction	After suction	<i>p</i>
Cdyn (ml/cmH ₂ O/kg)	0.60 (0.45-0.82)	0.56 (0.41 – 0.75)	< 0.000001
R _i (cmH ₂ O/l/s)	49.95 (32.3 – 84.3)	51.2 (29.0 – 76.7)	0.09
R _e (cmH ₂ O/l/s)	72.35 (49 – 111)	73.8 (42.9 – 111.4)	0.1
ETT leak (%)	2.47 (-2.9 – 9.52)	3.45 (-2.63 – 10.2)	0.4
Vt ^{mech} (ml/kg)	7.00 (5.45 – 8.24)	6.70 (5.38 – 8.18)	0.03
Total RR (bpm)	49.5 (34 – 68)	52.5 (36 – 72)	0.006
Total MV (l/kg)	0.25 (0.21 – 0.31)	0.28 (0.22 – 0.40)	0.00006

Median (interquartile range).

There was a significant correlation between the change in Cdyn after suctioning and CA:AD ratio (Spearman's R = 0,2; *p* = 0,005).

There was a significant correlation for both groups combined between the baseline Cdyn and the number of days receiving IPPV; and between PaO₂/FiO₂ and the number of ventilator days. There were also positive correlations between OI and VI and the number of ventilator days (Table 6.4).

Table 6.4 Correlations between number of days receiving IPPV and Cdyn as well as respiratory severity indicators.

	Cdyn	PaO ₂ / FiO ₂	OI	VI
Number of ventilator days	R = -0,2 <i>p</i> = 0,006	R = -0,16 <i>p</i> = 0,006	R = 0,19 <i>p</i> = 0,01	R = 0,23 <i>p</i> = 0,002

R refers to Spearman's R

6.5.3 Effect of ET suctioning and RM on lung mechanics

Seven patients in each group had mean ETT leaks $\geq 20\%$. In order to accurately assess changes in lung mechanics, these patients were excluded from the subsequent analyses (Main et al, 2001). Table 6.5 presents the changes in lung function parameters during the study period. There was no change in the percentage leak in either group following suctioning or the SI and the difference between groups was also not significant ($p = 0,4$).

For all the trend graphs presented in this section, markers are the median and the vertical bars denote interquartile range, unless otherwise indicated. All changes between measurements were not significant unless so marked. * indicates significance at $p \leq 0,05$; ** indicates significance at $p \leq 0,001$. The colour of the star represents changes within the respective patient group (red – recruitment group, blue – control group).

Table 6.5 Changes in lung function parameters at different measurement points.

	Start	<i>p</i>	Before suction	<i>p</i>	After suction	<i>p</i>	After SI	<i>p</i>	End
Cdyn	0,57 (0,45-0,73)	0,5	0,59 (0,48-0,76)	0,02	0,57 (0,41-0,75)	0,0004	0,64 (0,51-0,79)	0,6	0,62 (0,48-0,75)
(ml/cmH ₂ O/kg)	0,51 (0,39-1,0)	0,2	0,5 (0,39-0,97)	0,0002	0,49 (0,34-0,64)	0,0007	0,55 (0,44-1,2)	0,08	0,51 (0,42-0,97)
R_i (cmH₂O/l/s)	47,4 (22,9-73,4)	0,03	54,2 (27,8-87,1)	0,1	48,3 (24,4-76,1)	0,7	31,3 (20,9-87,1)	0,01	43,8 (25,8-78,7)
	52,8 (25-78,1)	0,06	46,8 (23,8-81)	0,4	49,5 (28,1-71,5)	0,03	40,2 (16,5-61,6)	0,2	43,1 (17,3-74,1)
R_e cmH₂O/l/s)	61,9 (31,7-101,0)	0,2	58,2 (32,7-111,8)	0,6	64,1 (31,2-97,5)	0,03	46,3 (29,1-96,4)	0,01	49,8 (29,0-102,9)
	78 (56,3-105,6)	0,07	68,3 (49,4-105,8)	0,5	81,5 (48,2-115,6)	0,009	65 (39,8-94,1)	0,6	64,7 (44,3-108,8)
V_{Te}^{max} (ml/kg)	7,08 (6,0-8,06)	0,02	7,33 (6,06-8,24)	0,12	6,92 (5,93-8,27)	0,0003	7,65 (6,29-9,0)	0,2	7,41 (5,66-8,82)
	5,0 (3,92-6,42)	0,005	5,91 (4,48-7,71)	0,05	5,68 (4,29-7,37)	0,2	5,56 (4,64-7,34)	0,01	6,36 (4,85-7,57)
V_{Te}^{min} (ml/kg)	2,59 (0,0-4,46)	0,9	2,0 (0,0-4,46)	0,009	2,59 (0,77-4,3)	0,8	2,17 (0,0-5,08)	0,8	2,45 (0,0-4,3)
	2,0 (0-3,04)	0,2	2,14 (0-3,57)	0,3	2,29 (0,4-3,44)	0,03	2,38 (0,36-3,7)	0,1	2,38 (0-3,48)
ETT leak (%)	2,4 (-3,0-12,1)	0,1	1,96 (-2,4-9,5)	0,2	1,9 (-5,6-7,9)	0,2	1,9 (-2,1-8,3)	0,5	2,0 (0-10,2)
	0 (-6,7-6,7)	0,6	2,6 (-6,5-8,8)	0,1	3,3 (-2,6-9,5)	0,99	3,0 (-2,4-9,4)	0,007	2,4 (-7,9-7,7)
Total RR (bpm)	48 (34-58)	0,001	42 (32-57)	0,3	47 (35-60)	0,2	44 (33-58)	0,99	43 (30-51)
	43 (35-81)	0,97	46 (32-75)	0,4	49 (34-77)	0,0008	53 (38-77)	0,07	45 (34-78)
Total MV (l/kg)	0,25 (0,2-0,29)	0,6	0,24 (0,21-0,3)	0,6	0,25 (0,21-0,33)	0,004	0,26 (0,23-0,32)	0,5	0,26 (0,2-0,29)
	0,216 (0,18-0,26)	0,01	0,22 (0,2-0,27)	0,93	0,24 (0,19-0,28)	0,0001	0,25 (0,2-0,3)	0,3	0,24 (0,21-0,31)

Median (quartile range). Blue shaded rows are control patients, unshaded rows are recruitment patients. *P* values refer to the change between the adjacent measurements.

6.5.3.1 Dynamic compliance

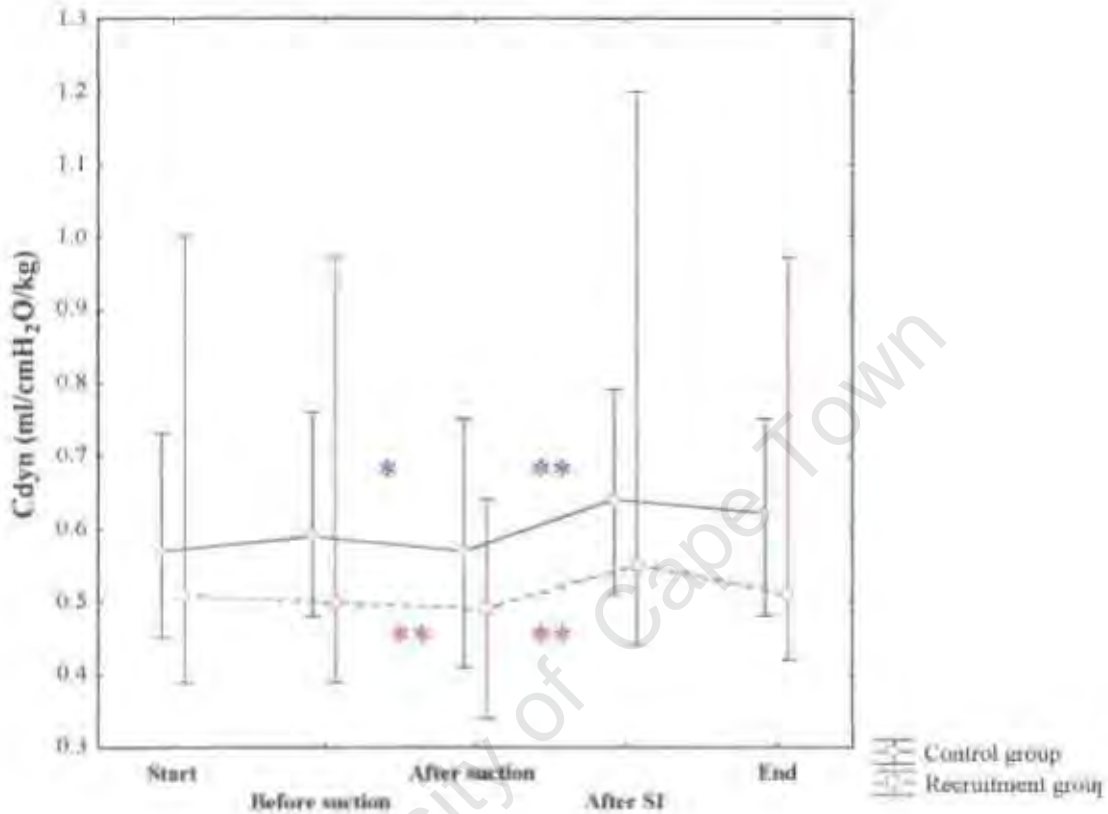


Figure 6.2 Changes in Cdyn throughout the study period.

Figure 6.2 illustrates Cdyn at all the measurement times. Cdyn in both groups decreased significantly following ET suctioning (control $p = 0,02$; recruitment $p = 0002$), with no difference in this Cdyn change between the two groups ($p = 0,4$).

Both groups increased Cdyn at the post-SI measurement (control $p = 0,0004$; recruitment $p = 0007$) with no statistical difference in the change in Cdyn between the two groups ($p = 0,7$). Despite the lack of statistically discernible differences in response to the SI for the groups, it is apparent from Figure 6.2 that the RM may have had a clinical effect on some

patients

Eight patients in the recruitment group and seven in the control group experienced an increase in C_{dyn} following the SI of >20%. Two patients in the recruitment group increased C_{dyn} by >100% (Figure 6.3). No patients in the control group increased C_{dyn} by >40%. Both children who responded to the RM were infants (1,5 and 3,5 months respectively) with ARDS due to *Respiratory syncytial virus* in one patient and *Pneumocystis carinii* pneumonia in the other.

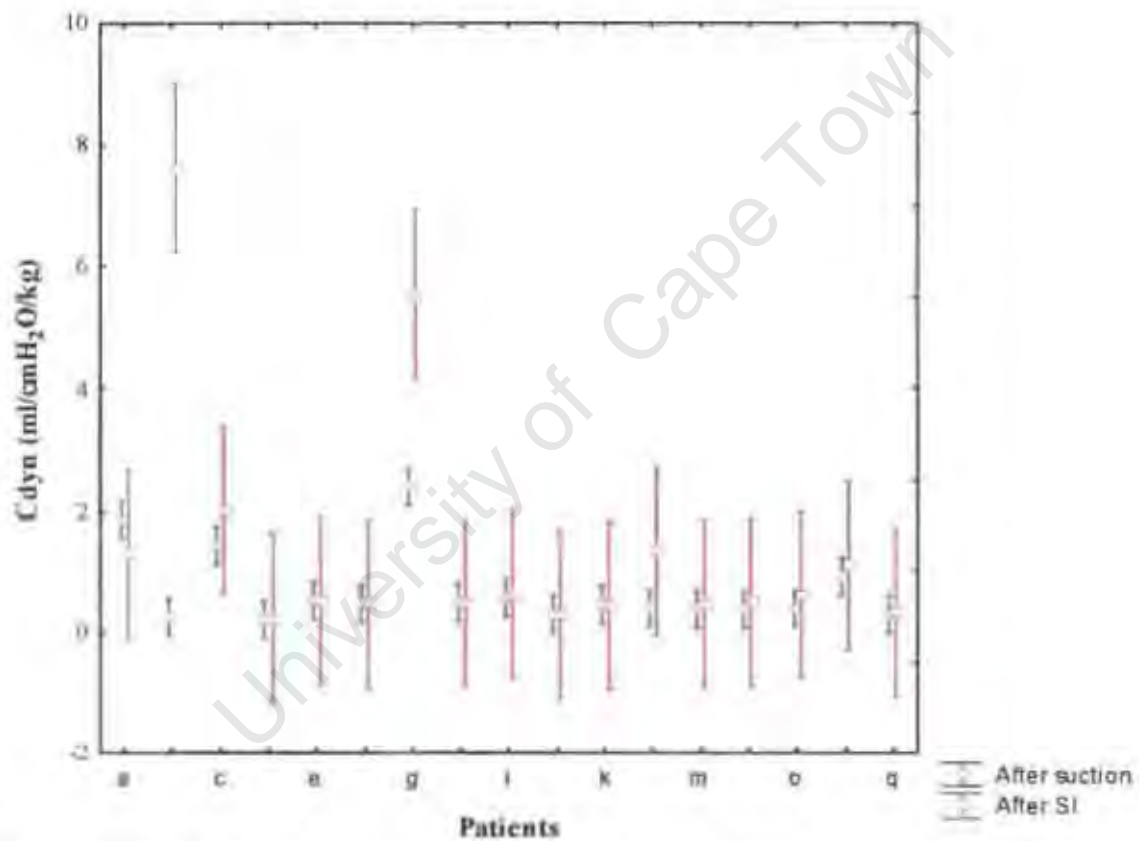


Figure 6.3 Individual responses to the SI in the recruitment group. Data points are means and vertical bars denote 95% confidence intervals.

C_{dyn} remained at the post-SI levels over the last 25 minutes of recording in both groups (control $p = 0,6$, recruitment $p = 0,08$) with no difference between groups ($p = 0,5$).

Both groups experienced a statistically significant increase in Cdyn from the start to the end of the study period (control $p = 0,01$; recruitment $p = 0,05$); with no difference in this change between the two groups ($p = 0,7$). Individual patient Cdyn readings did not change in variability after the suctioning procedure or the SI, as demonstrated by the constant confidence intervals ($p = 0,5$).

There were no correlations between age, weight, OI, VI or PaO₂/FiO₂ and the Cdyn change after the SI in either group ($p \geq 0,05$). As seen in Chapter Five, there was a significant correlation between baseline Cdyn and the change in Cdyn after ET suctioning (Spearman's R = 0,4, $p = 0,0009$). There was no correlation between baseline Cdyn and the change in Cdyn following the SI in either group (control Spearman's R = -0,1; $p = 0,9$; recruitment Spearman's R = 0,2; $p = 0,1$).

There was no difference between patients with and without ARDS for Cdyn change post SI in the recruitment ($p = 0,5$) or in the control group ($p = 0,7$).

Patient position

Patients were investigated in the positions they had occupied for the hour prior to the study intervention. Nine patients in the recruitment group were positioned in supine and eight in prone during the entire study period. In the control group six were supine and 11 prone ($p = 0,5$).

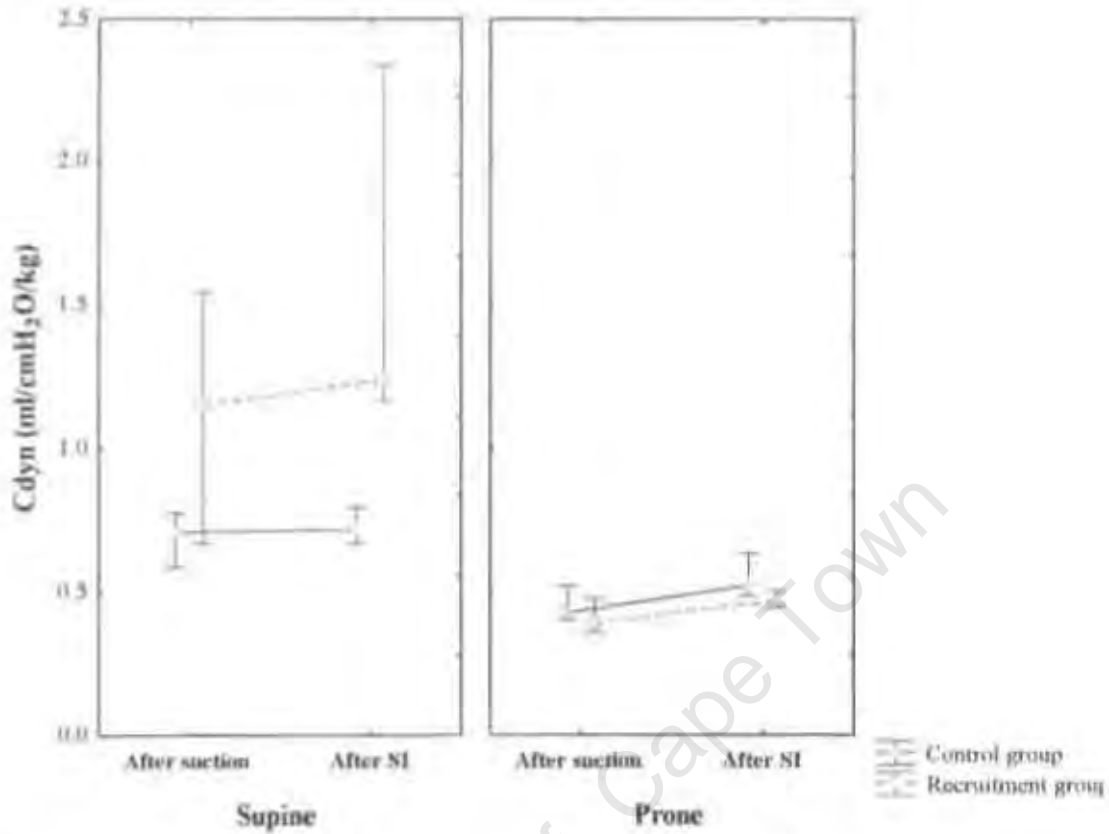


Figure 6.4 Effect of position on post-SI change in Cdyn. Data points show median (95% confidence interval of the median).

Patients positioned in prone had a significantly lower baseline Cdyn than those positioned in supine ($p < 0,0001$). There was no difference in the change in Cdyn after the SI between patients positioned in prone compared to supine ($p = 0,7$) (Figure 6.4).

6.5.3.2 Airway resistance

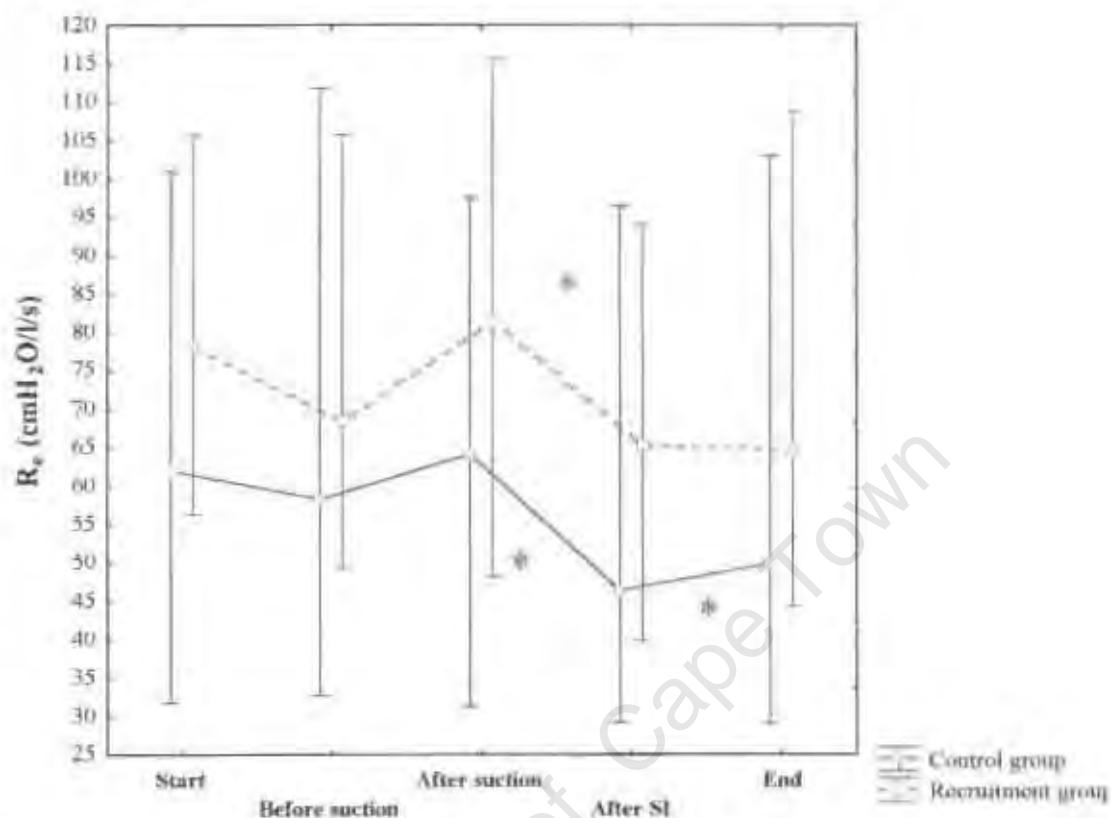


Figure 6.5 R_e at different measurement points.

Figure 6.5 illustrates the changes in R_e at all the recording times. Following ET suctioning, neither group experienced a significant change in R_e (control $p = 0,6$; recruitment $p = 0,5$), with no difference in effect between groups ($p = 0,3$).

Both groups experienced a significant decrease in R_e at the post-SI measurement (control $p = 0,03$; recruitment $p = 0,009$) with no difference in effect between the two groups ($p = 0,9$). The control group experienced a decrease in median R_e between the post-SI measurement and the end of recording ($p = 0,01$). This did not occur in the recruitment group ($p = 0,6$) but the difference in effect between the two groups did not reach significant levels ($p = 0,2$).

There was no change in the control group's R_e from the start to the end of the study period ($p = 0,9$); however the recruitment group experienced a decrease in R_e over this time ($p = 0,03$), with the difference between the two groups approaching significance ($p = 0,06$).

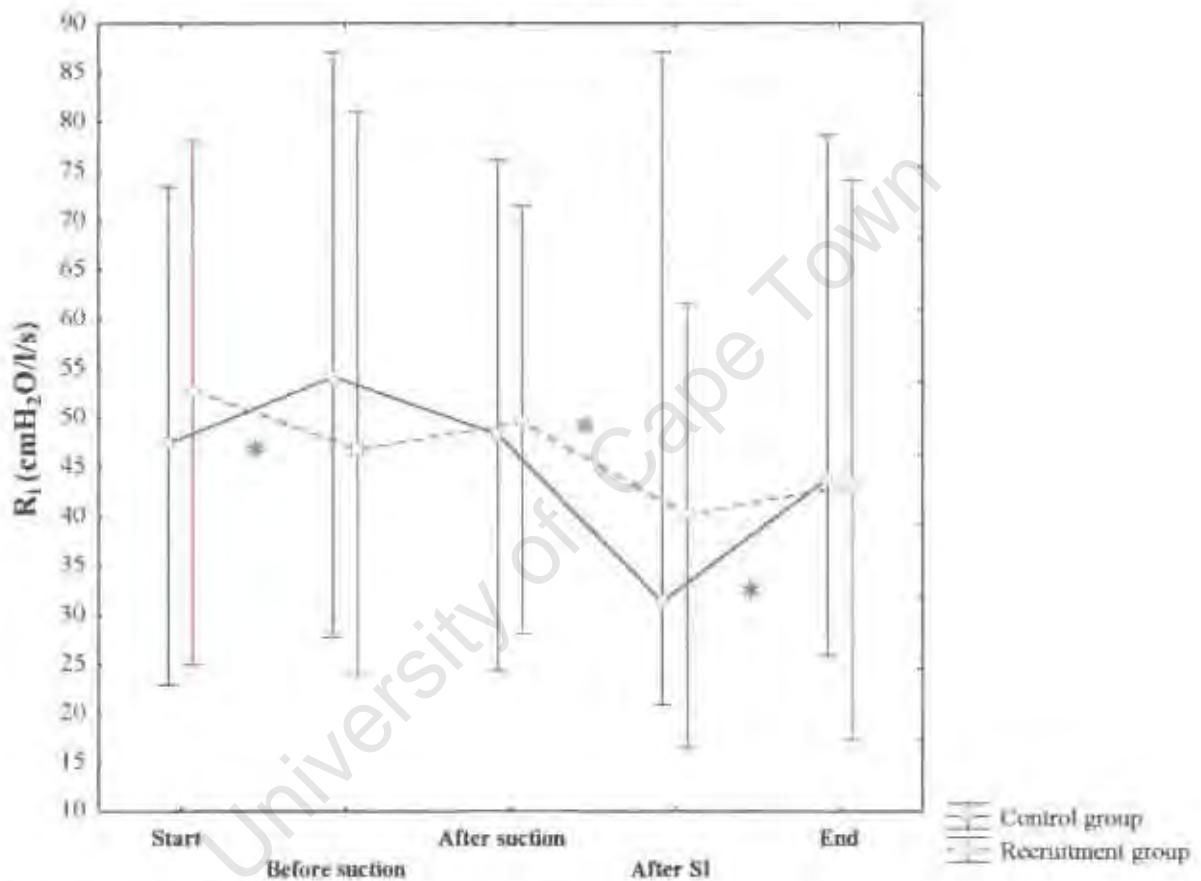


Figure 6.6 R_i at different measurement points.

Figure 6.6 presents the changes in R_i at all the recording times. Median R_i decreased following the SI in the recruitment group ($p = 0,03$), with no change in the control group ($p = 0,7$), however the difference between the two groups did not reach significance ($p = 0,3$).

There was an increase in R_i between the post-SI measurement and the end of recording.

which reached significance in the control group only (control $p = 0,01$ recruitment $p = 0,2$). The difference between the two groups was not significant ($p = 0,2$).

There was no change in R_i from the start to the end of measurement in the control group ($p = 0,2$), but the recruitment group's R_i decreased from the start to the end of measurement ($p = 0,001$), with a significant difference in the change of R_i over the entire study period between the two groups ($p = 0,001$).

6.5.3.3 Tidal volume

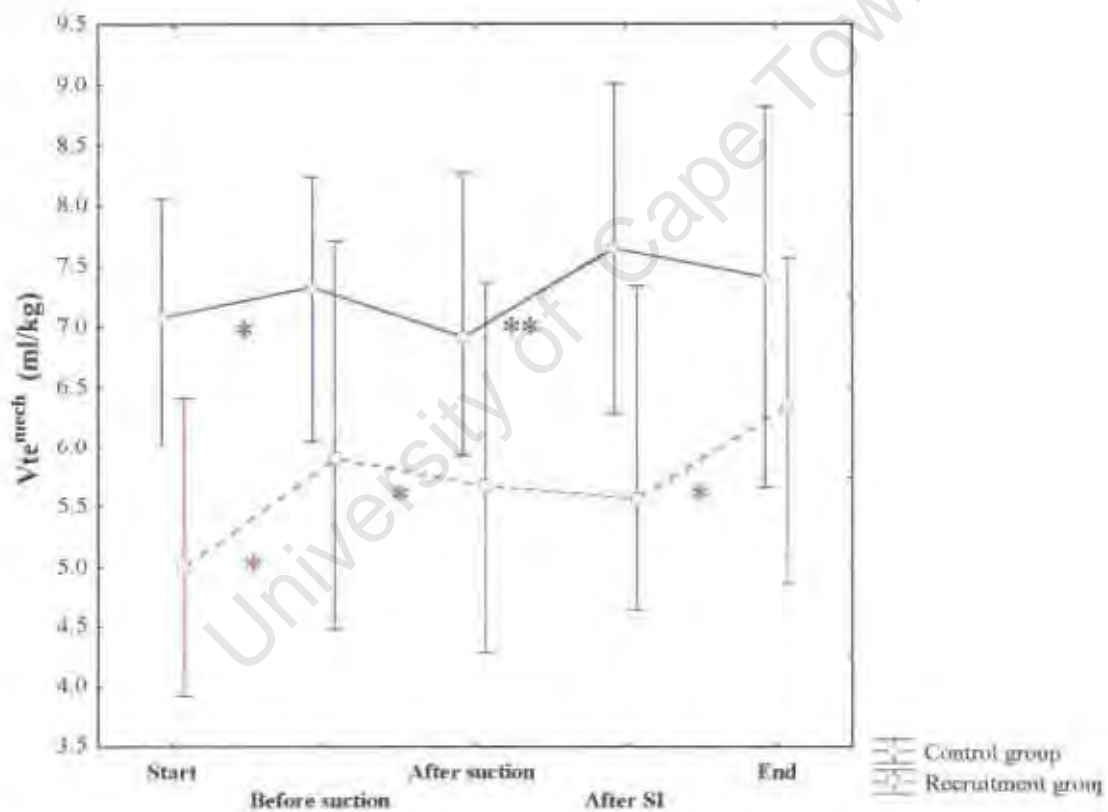


Figure 6.7 V_{te}^{mech} at different measurement points.

V_{te}^{mech} was higher ($p < 0,0001$) at the start of measurement in the control group, but this was purely due to chance as their selection was based on randomisation. Changes in median V_{te}^{mech} are presented in Figure 6.7.

Following the SI, patients in the control group experienced an increase in Vt_e^{mech} ($p = 0,0003$), which was not seen in the recruitment group ($p = 0,2$). The difference between the two groups was significant ($p = 0,03$). Between the post-SI measurement and the end of recording, the recruitment group alone experienced an increase in Vt_e^{mech} ($p = 0,01$; control $p = 0,2$), with a significant difference between the two groups ($p = 0,006$).

Both groups experienced a significant increase in Vt_e^{mech} from the start to the end of measurement (control $p = 0,01$; recruitment $p = 0,000009$). There was no difference between the two groups ($p = 0,5$).

The recruitment group had no greater response in Vt_e^{mech} to the RM in the prone compared to the supine position ($p = 0,14$).

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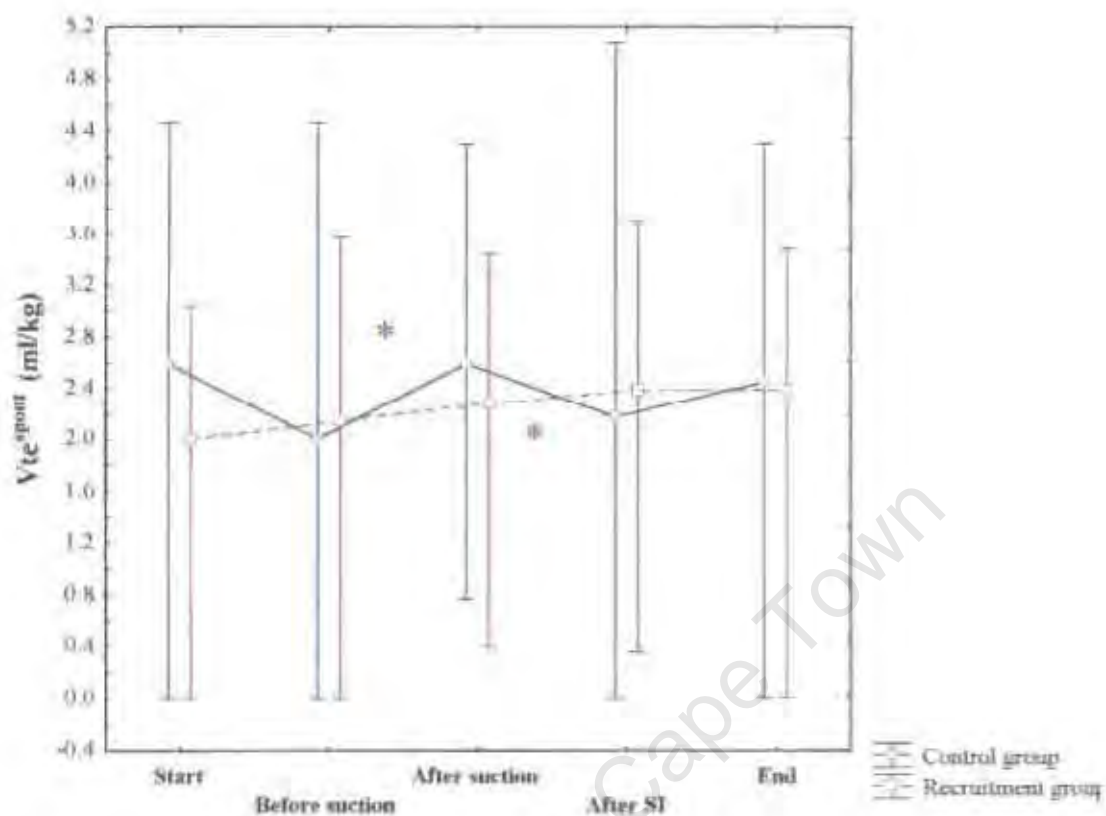


Figure 6.8 Changes in Vte^{spont} at different measurement points.

Changes in Vte^{spont} throughout the measurement period are presented in Figure 6.8. There was no difference in Vte^{spont} between the two groups at the start of measurement ($p = 0,09$).

Patients in the recruitment group alone experienced an increase in Vte^{spont} following the SI ($p = 0,03$; control $p = 0,8$). There was a significant difference between the two groups ($p = 0,049$). There was no change within either group in Vte^{spont} from the start to the end of measurement (control $p = 0,2$; recruitment $p = 0,1$).

6.5.3.4 Minute volume

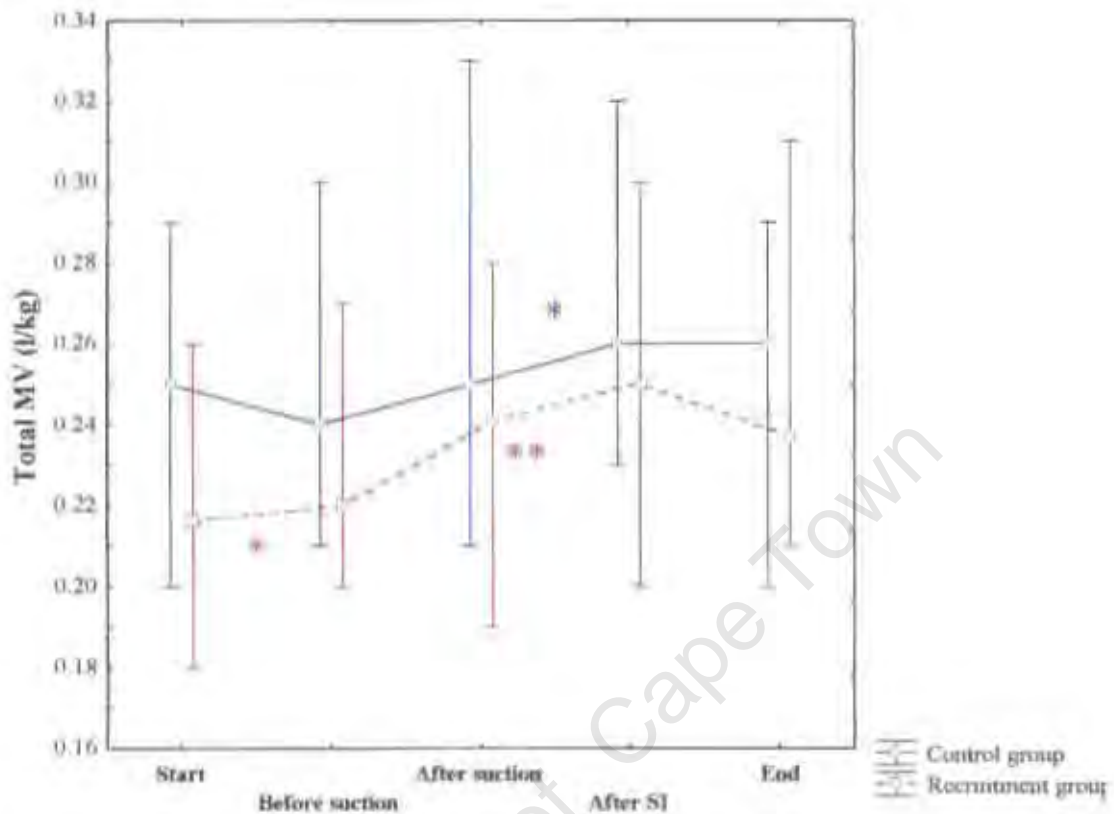


Figure 6.9 Total MV at different measurement points.

MV at the start of measurement was significantly lower in the recruitment group ($p = 0,003$) but was purely due to chance as a result of the randomisation process. By the end of the measurement period, the values were almost identical ($p = 0,9$).

Both groups experienced an increase in MV after the SI (control $p = 0,004$; recruitment $p = 0,0001$), with no difference in the change between the two groups ($p = 0,3$). There was a highly significant increase in MV from the start compared to the end of recording in the recruitment group ($p = 0,000007$) but not the control group ($p = 0,5$). The difference between the two groups was significant ($p = 0,01$) (Figure 6.9).

6.5.3.5 Respiratory rate

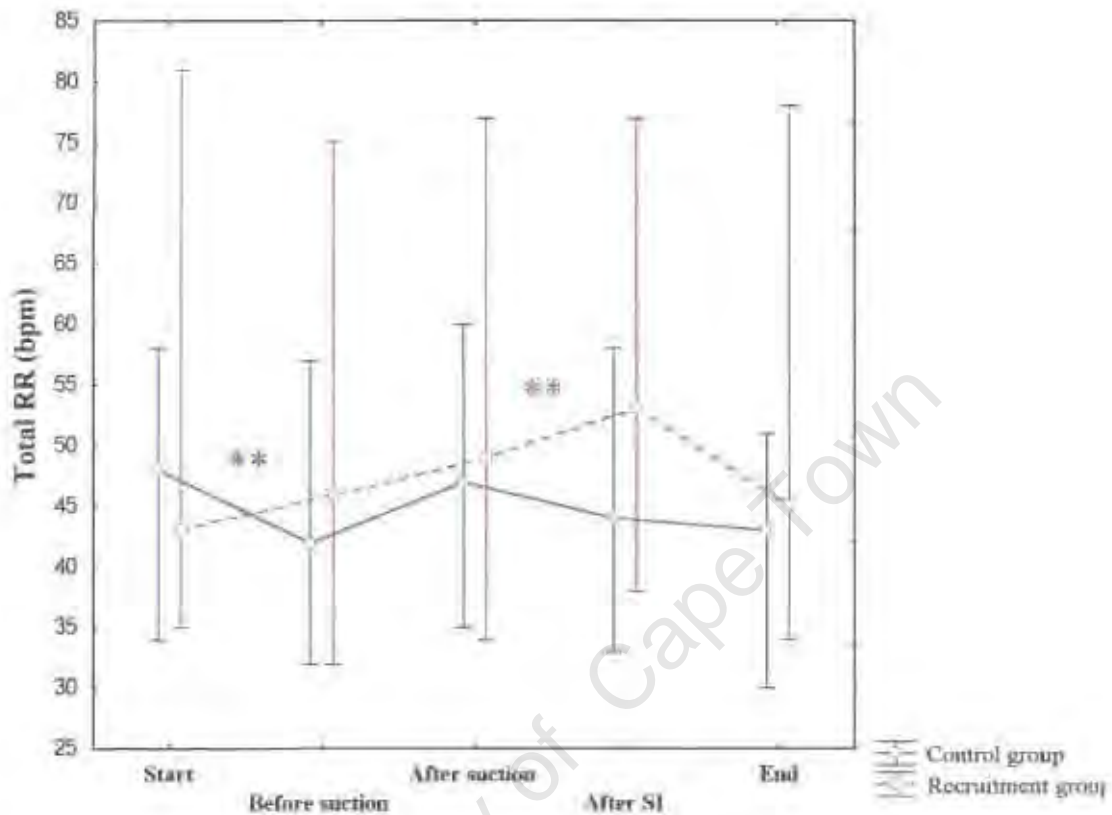


Figure 6.10 Total RR at different measurement points.

Changes in total RR are presented in Figure 6.10. There was no difference in baseline RR between the two groups ($p = 0,5$).

The recruitment group experienced a significant increase in RR following the SI ($p = 0,0008$), which was not observed in the control group ($p = 0,2$). The difference in effect between the two groups was significant ($p = 0,0004$). RR in the control group decreased significantly between the start and end of the study period ($p = 0,0001$), which was not observed in the recruitment group ($p = 0,2$). The between-group difference was significant ($p = 0,0005$).

6.5.4 Changes in SaO₂ occurring during the study period

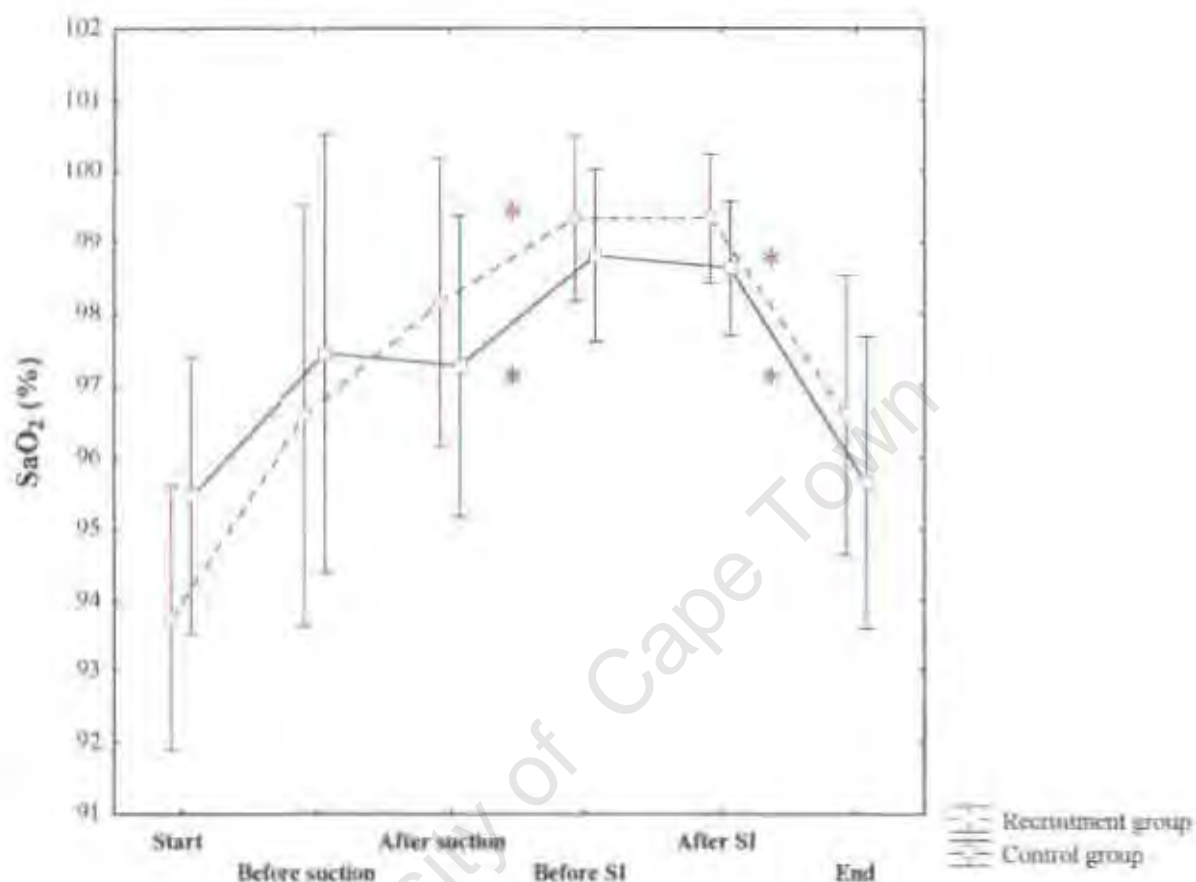


Figure 6.11 Changes in SaO₂. These data points represent the means and the vertical bars denote the 95% confidence intervals of the mean.

The changes in SaO₂ are presented in Figure 6.11. An extra reading was taken immediately prior to the SI ("Before SI"). Both groups experienced a significant increase in SaO₂ between the end of the suctioning event and the SI ($p < 0,05$), with no difference between patient groups ($p = 0,36$). There was no difference between groups for the trend in SaO₂ change throughout the study period ($p = 0,3$). Neither group experienced a change in SaO₂ after either the suctioning procedure or the SI ($p > 0,1$). There was no difference in the change in SaO₂ after the SI between the two groups ($p = 0,5$).

The recruitment group experienced an increase in SaO₂ from the start to the end of the

study period ($p = 0,002$), which was not seen in the control group ($p = 0,7$). This difference between the two groups was significant ($p = 0,02$) (Figure 6.12).

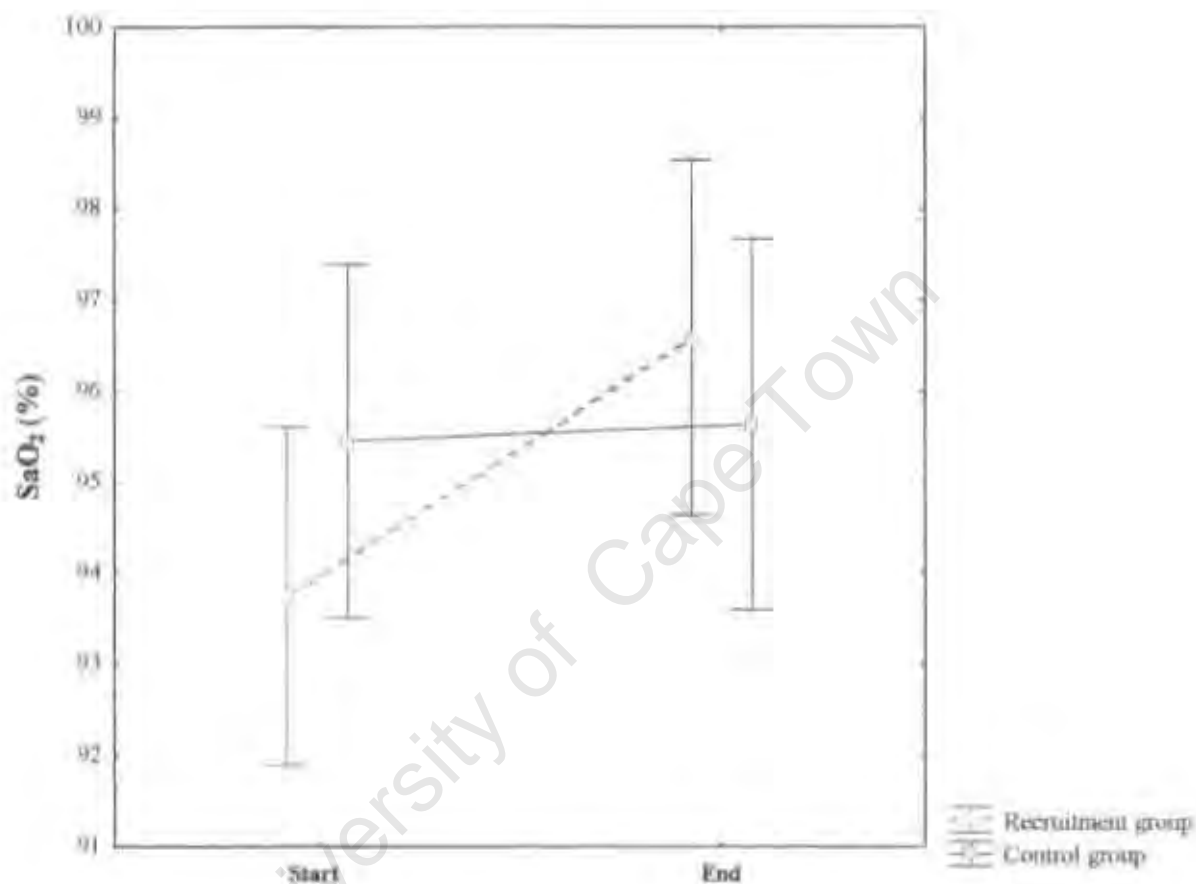


Figure 6.12 Changes in SaO₂ between the start and the end of measurement. Data points represent the means and the vertical bars denote 95% confidence intervals of the mean.

6.5.5 Safety and practicality of the recruitment manoeuvre

No adverse events occurred during or after the RM in any patients, HR and MABP remained stable during the RM for all patients and SaO₂ remained >85%. No pneumothoraces occurred.

6.6 Discussion

The research described in this chapter was the first to investigate the effects of a post-suctioning RM on lung dynamics in a representative group of stable ventilated infants and children, with variable lung disease. The RM was found to be safe in this group of patients.

Patients studied had a wide range of primary medical conditions, with the majority having pneumonia (>80%). Owing to the ethical criteria for patient inclusion, none of the patients studied had coexisting cardiac or neurological morbidity; all had been haemodynamically stable for the preceding 24 hours, with average baseline SaO₂ > 85%. No conclusions could therefore be made on the effect of the suctioning and RM on hypoxic patients, or their influence on cardiac or neurological function.

There was a deterioration in the OI, Cdyn, VI and PaO₂/FiO₂ levels in patients who had received IPPV for longer duration ($p \leq 0,01$). This could reflect that patients with more severe lung disease required longer periods of mechanical ventilatory support, or it could indicate that patients receiving IPPV for extended periods sustained ventilator-induced lung injury (Marraro, 2003; Suh et al, 2003; Matthews and Noviski, 2001; Schiller et al, 2001).

6.6.1 Reliability of Cdyn measurement

Cdyn did not change in either group over the 30 minutes preceding the suctioning procedure ($p = 0,2$ for both patient groups combined). This indicates that the Cdyn remained constant over a 30-minute period in the absence of any intervention, change of body position or change of ventilation parameters.

Variability of measurement for individual patients did not change after suctioning or after the SI, as seen by the constant confidence intervals ($p = 0,5$).

6.6.2 Combined data: changes in lung dynamics occurring with ET suctioning

On combining data of patients from the study in Chapter Five with those in this study,

thus increasing the power of Chapter Five's investigation, a significant decrease in V_{te}^{mech} was observed ($p = 0,03$). Considering that applied pressure was constant, there was no change in patient position, and no reason to consider that there were any changes in chest wall compliance (Ingimarsson et al, 2000; Davis et al, 1996; Nunn, 1993), the significant decrease in C_{dyn} ($p < 0,000001$; Table 6.3) is most likely to reflect a loss of lung volume.

All patients with ETT leaks $\geq 20\%$ were excluded from this analysis with the resulting median leak being small at 2,47%. There was also no change in leak following ET suctioning ($p = 0,4$). This confirms that the decrease in C_{dyn} was not artefactual due to a change in the percentage leak around the ETT (Main et al, 2001), and is more likely to reflect real changes.

This combined data analysis confirms the previous observation that the change in C_{dyn} following ET suctioning is directly related to the CA:AD ratio ($p = 0,005$). This implies that the most severe lung volume changes are likely to occur during suctioning in patients intubated with small ID ETT; and supports the suggestion presented in Chapter Four, that the larger the suction catheter is, relative to the difference in sizes of the ETT and catheter, the higher the pressure effects exerted on the lungs are likely to be.

The combined data confirm that ET suctioning does not have an effect on dynamic airway resistance ($p > 0,05$). These findings are likely to be valid as the median ETT leak was low (Main et al, 2001). Again, it must be noted that patients in these studies underwent ET suctioning at specified times and secretions were not necessarily present in the ETT at the time of suctioning. It is also possible, as mentioned in Chapter Five, that suctioning-induced lung volume loss may have increased the airway resistance (Young, 1984), thus negating the effect of clearing the large airways.

Total MV and total RR both increased following ET suctioning ($p < 0,01$). This may be attributed to the discomfort or distress caused to the patient by the suctioning procedure. A median increase of three bpm (Table 6.3), however, was unlikely to be clinically

significant and the increase in these parameters was not accompanied by any noticeable changes in HR or MABP. The increased RR and MV may reflect a compensation for the disruption of ventilation during the suctioning procedure.

6.6.3 Effects of the RM on lung dynamics and SaO₂

V_{te}^{mech} increased in both patient groups over the first thirty minutes of the study period. This may reflect a gradual reexpansion after the initial derecruitment caused by briefly disconnecting the ventilator in order to attach the flow sensor. This occurred again in both groups with disconnection and ET suctioning, but reached significance in the recruitment group only. Future studies may be improved by taking the first measurements 10-15 minutes after connecting the respiratory profile monitor.

V_{te}^{mech} increased following the SI in the control group ($p = 0,0003$) but not in the patients who received a RM ($p = 0,2$). This may be explained by the fact that the recruitment group were briefly disconnected from the ventilator twice, before and after the RM; whilst the control group received continuous IPPV, with the potential to reexpand areas of lung which may have collapsed with ET suctioning. It was noted, however, that between the post-SI measurement and the end of recording, the recruitment group experienced a significant increase in V_{te}^{mech} ($p = 0,01$), which was not observed in the control group (between-groups difference $p = 0,006$). It is possible that the increase in tidal volume caused by lung recruitment was delayed. Patients who received a RM had a significant increase in V_{te}^{spont} after the SI ($p = 0,03$). This was not observed in the control group ($p = 0,8$) and the between-groups difference was significant ($p = 0,049$).

The median baseline C_{dyn} in these patients was low; therefore it was expected that they would respond positively to the RM. However, after the SI both the control and the recruitment groups experienced an increase in C_{dyn} at the post-SI measurement ($p < 0,001$). The change in C_{dyn} was not statistically greater in the recruitment group ($p = 0,7$), indicating that the ET-suctioning induced decrease in C_{dyn} resolved spontaneously in most patients, with unchanged ventilator settings; and that the RM was generally not more effective in improving C_{dyn} than replacing the child on the ventilator

alone.

These results are contrary to the findings of Dhyr et al (2003) in their study of RMs performed after open- ET suctioning in adults. They found that after ET suctioning with no RM, maximal respiratory system compliance had not recovered at 25 minutes post-suctioning, whereas with the RM, compliance was rapidly regained. Their study, however, was very different to the one described in this chapter as their subjects were adults in the early stages of lung disease, and they were also deeply sedated during the procedures.

In this study, there was a variable change in Cdyn in response to the RM amongst different patients, with two patients with severe lung disease experiencing an increase in Cdyn >100% following the RM. No patients in the control group experienced such a large Cdyn change following the SI, indicating that the RM may be effective under certain conditions. However, it was not possible to identify predictive factors, such as OI, VI, PaO₂/FiO₂, number of days receiving IPPV or age, for this response ($p > 0,05$). This observation is consistent with the findings of Main et al (2004), who noted a variable response in lung mechanics to CPT and ET suctioning, with some patients receiving manual hyperinflation/reinflation manoeuvres. Even in retrospect, these authors were not able to identify groups of patients who were more or less likely to respond positively or negatively to the procedures.

There are several possible explanations as to why the RM did not result in greater improvement in Cdyn than the control group:

- Changes in Cdyn could be influenced by changes in thoracic compliance. However, this is unlikely to have occurred in these patients as there were no factors that could have influenced the chest wall and there was no change in patients' body positions throughout the study period.
- Immediately before and after applying the RM, patients were briefly disconnected from the ventilator, thereby losing PEEP. After discontinuation of PEEP lung

collapse may occur rapidly (Neumann et al 1998). This derecruitment may have negated the positive effect of the RM. This was also reported by Barker and Adams (2002) who noted that hyperinflation did not seem to improve Cdyn in adults following positioning and ET suctioning. They suggested that a balance exists between disconnection from the ventilator, with resulting loss of recruitment, and attempting to achieve recruitment with manual hyperinflation. Future studies should investigate alternative, safe methods of performing the RM without the need for ventilator disconnection.

- The two patients who responded positively to the RM both had primary ARDS with $\text{PaO}_2/\text{FiO}_2 < 200$ mmHg. It may be that other patients had more heterogeneous pathology, with areas of atelectasis, areas of normal lung and hyperinflated areas. If patent alveolar units are overdistended or hyperinflated during the RM, which can occur at the same time as recruitment of atelectatic lung segments (Tusman et al, 2003), Cdyn may not improve or may even decrease (Foti et al, 2000). It is possible that this phenomenon may have occurred in some patients.
- It is possible that the patients were receiving optimal ventilation with appropriate PEEP levels; thus reducing the potential for lung recruitment.
- Patients in this study did not receive paralysing agents prior to the SI, in order to best approximate the clinical situation. A variable amount of motor activity occurred which could account for the different responses to the RM. Patients coughing, in particular, could rapidly reverse RM effects (ARDS Clinical Trials Network, 2003).
- Seventy-one percent of patients assigned to the recruitment group had primary ARDS, mostly due to pneumonia; none had extrapulmonary or secondary ARDS. It has been suggested that responses to the RM may differ according to whether ARDS was associated with direct (primary) or indirect (extrapulmonary) lung

injury (Lim et al, 2003). It is possible that patients with secondary ARDS related to sepsis or trauma (Pelosi et al, 2003) would have shown a greater response to the RM than patients in this study, but clearly no conclusions in this regard can be made. This study may have been biased against RM efficacy by including patients with inherently low recruitment potential (ARDS Clinical Trials Network, 2003), and a study involving larger numbers over an extended period of time is recommended in order to assess the effect of RM in patients with nonpulmonary causes of ALI/ARDS.

- The RM technique was standardised for the purposes of reproducibility and validity of experimental methodology. It is possible that the optimal pressure or duration of application was not achieved. Future studies would need to investigate whether individualising the RM by applying different inspiratory pressures, possibly according to body weight, affects the recruitment achieved. In this study the inflation pressure was applied for 30 seconds, which should be adequate as most airways open within a few seconds when transmural pressures are raised to high enough levels (Neumann et al, 1998), but this aspect warrants further investigation. Turning patients prone prior to the RM may have improved the efficacy of the RM, by removing pressure and applying a high recruiting force to the dorsal regions that are compressed in the supine position (Barbas, 2003).

There was no difference in effect of the RM on Cdyn between patients with ARDS and patients without ARDS ($p = 0,5$).

In the RCWMCH PICU, patients with severe lung disease requiring high levels of FiO₂ and MAP are frequently positioned in prone in an attempt to improve their SaO₂ and PaO₂ and facilitate quicker weaning from the ventilator. It has been suggested that prone positioning recruits atelectatic dorsal regions of the lung, limits anterior chest wall movement and reduces the effects of abdominal pressure on the thoracic cavity, thereby promoting more uniform alveolar ventilation (Matthews and Noviski, 2001). This may not be true of the positioning method employed at RCWMCH, where the abdomen is not

freely suspended. Along with redistribution of perfusion away from the previously dependent lung region (Pelosi et al, 1998), there may be improved oxygenation of the blood and ventilation/perfusion matching with a reduction in intrapulmonary shunt (Marraro, 2003). Kornecki et al (2001) showed that prone positioning of children with acute respiratory failure showed a sustained improvement in OI over a 12-hour period, independent of changes in lung mechanics.

The fact that patients positioned in prone had significantly lower C_{dyn} throughout the measurement period than those positioned in supine ($p = 0,0001$) has also been reported by Cox et al (2001) in a study of infants with normal lungs. The lower C_{dyn} in prone patients may reflect that these patients were correctly selected on clinical grounds as potentially benefiting from the position, due to low lung compliance, hypoxia and basal consolidation. It is also possible that the position itself caused the resulting discrepancy in C_{dyn} between the positions. The weight of the patient on the anterior chest wall, as well as limitation of abdominal movement, could have reduced the amount of chest wall and diaphragmatic excursion (Cox et al, 2001), thereby affecting total respiratory system compliance.

There was no difference in effect of the RM on C_{dyn} or V_{te}^{mech} between patients positioned prone compared to supine ($p > 0,1$). This observation may be explained by the fact that patients positioned in prone might have already been optimally recruited by being turned into this position. C_{dyn} may, however, be an inappropriate parameter with which to measure recruitment in the prone compared to supine positions, as the position itself will affect the measurement of C_{dyn}, by limiting anterior or posterior chest wall movement. Direct lung volume measurements and arterial blood gas values would be more appropriate outcome measures for such a study design.

The increase in SaO₂ occurring in both groups from the suctioning procedure to the end of the SI may be explained by the fact that patients were receiving 100% O₂ during this time. Acute changes in SaO₂ did not, therefore, occur after the RM. However, the recruitment group did experience an increase in SaO₂ from the start to the end of the

measurement period, which was not seen in the control group ($p = 0,02$). The ARDS Clinical Trials Network (2003) paper on the effect of RM on adults with ALI/ARDS also reported that SaO_2 increased significantly more within ten minutes of the RM than after the sham RM, with respiratory system compliance not increasing more after RM than after sham RM. In this chapter's study, the FiO_2 was maintained at the same level in both patient groups, and the only difference between the two groups was the application of the RM. It is therefore likely that the RM resulted in this improved oxygenation. All patients studied had levels of baseline SaO_2 above 85%. RM performed on patients with low SaO_2 levels may result in a greater improvement in SaO_2 , which would then be more clinically significant. However, this suggestion warrants further investigation.

The majority of patients studied had ARDS or ALI (74%). ARDS is characterised by hypoxaemia and intrapulmonary shunting related to perfused but nonventilated alveoli. By recruiting these alveoli, intrapulmonary shunting should be reduced, with subsequent improvement in arterial oxygenation (Maggiore et al, 2001). Changes in SaO_2 may also be affected by changes in variables such as cardiac output. However, in previous studies cardiac output was not shown to change following RM in adults with ARDS (Villagra et al, 2002). If this holds true for the paediatric age group, RM-induced recruitment may have been the cause of this improved oxygenation. Furthermore, at 30 minutes post RM, when the final SaO_2 level was recorded, the haemodynamic effects of the RM were unlikely still to be present.

Following the SI, patients in both groups experienced a decrease in R_e ($p < 0,05$) and although this decrease was greater in the recruitment group, the difference in effect between the groups was not significant ($p = 0,9$). Median R_i decreased following the SI in the recruitment group only ($p = 0,03$) but again the difference between groups did not reach significance. Patients in the recruitment group experienced a significant decrease in both inspiratory and expiratory airway resistance between the start and the end of the study period ($p < 0,05$), which was not observed in the control group ($p > 0,1$). The difference between the two groups was significant for R_i ($p = 0,001$) and approached significance for R_e ($p = 0,06$). Considering that both groups experienced a nonsignificant

increase in R_e and R_i following the suctioning procedure, the reduction in resistance must have been due to the RM. The application of a sustained inflation pressure may have resulted in previously occluded bronchi or bronchioles being opened, with alveolar recruitment, which would be reflected by a decrease in airway resistance (Young, 1984). This, along with the improvement in SaO_2 , suggests that the RM was, at least partly, successful in recruiting alveoli.

Total MV increased significantly after the SI in both groups ($p < 0,01$). This is related to both the increase in RR seen in the recruitment group after the SI ($p = 0,008$) and the increased TV as a result of either the RM or the reconnection of the ventilator. Changes in RR may be compensatory following cessation of ventilation during suctioning or the RM; or due to increased agitation of the subjects during the manual inflation procedure.

6.7 Conclusions

This study investigated the effects of a post-suctioning RM on lung dynamics and SaO_2 in mechanically ventilated, non-paralysed paediatric patients.

It confirmed the results of Chapter Five, namely, that routine ET suctioning often results in a decrease in C_{dyn} , with no change in airway resistance. This change in C_{dyn} is directly related to the CA:AD ratio, implying that the greatest potential for suctioning-induced derecruitment lies with young infants and children, intubated with small ID ETTs. Larger children and adults are less likely to sustain clinically significant C_{dyn} changes after suctioning. C_{dyn} improved spontaneously within ten minutes of an ET suctioning procedure, on reconnecting the ventilator at the pre-suction settings. This implies that repeated suctioning manoeuvres usually result in derecruitment with subsequent spontaneous rerecruitment, and this could result in ventilator-induced lung injury (Maggiore et al, 2003; Marraro 2003; Suh et al, 2002; Matthew and Noviski 2001; Neumann et al 1998; Taskar et al, 1997).

There are currently no published studies investigating the use of RMs on ventilated infants and children with lung disease. Similarly, no research has been published

regarding the routine use of RM performed after ET suctioning in the paediatric population. This chapter, therefore, presents the first study aimed at investigating both the above aspects. The pitfalls identified here will help to design future studies on this subject.

As the subjects did not experience any adverse sequelae of the RM, one can conclude that a 30 cmH₂O x 30 second RM performed after ET suctioning is safe to use in this patient group of haemodynamically stable, ventilated infants. Patients with risk factors for complications, such as cardiac or central nervous system pathology, and small-for-age, premature infants, were not included in this study. Therefore, the safety of the RM was not assessed in these patient categories.

The RM appeared to improve SaO₂ and TV, whilst having no effect on C_{dyn}, as compared to a control group. The response to the RM was not influenced by patient position.

6.8 Recommendations for future research and clinical practice

- Further investigations need to be conducted to determine the clinical implications for the patient of the changes in SaO₂ and tidal volume, which occurred after RMs. These future studies would need to measure other parameters such as blood gases to establish clinical significance. This was beyond the scope of this investigation.
- The effects of RMs may be larger in patients with a greater potential for recruitment (ARDS Clinical Trials Network, 2003). Large randomised controlled trials are warranted to identify patients likely to respond to the RM.
- The possibility of lung injury resulting from high airway pressures has to be balanced with the potential benefits of the RM (Tusman et al, 2003). Future studies would need to investigate whether individualising the RM by applying different inspiratory pressures, possibly according to body weight, affects the

recruitment achieved. The inflation pressure in this study was applied for 30 seconds, which should be adequate as most airways open within a few seconds when transmural pressures are raised to high enough levels (Neumann et al, 1998). Whether a prolonged or shorter duration of application would improve recruitment warrants further clinical investigation. It is unclear whether a measured volume or an applied pressure would be more effective in recruiting the lung.

- Future studies should investigate alternative methods of performing the RM without the need for ventilator disconnection. If ventilator settings are changed for this purpose, however, there is a danger of staff forgetting to return the pressure settings to their original levels, with the subsequent risk of barotrauma. This risk should be taken into account when designing the study protocol.
- It is essential to assess the effects of RM in hypoxic children. These patients should, therefore, be included in future studies, as anecdotal reports and personal observations have indicated that such patients may benefit substantially from the RM.
- It would be interesting to investigate whether patients who require HFOV benefit from receiving a RM prior to being placed on, or during HFOV.
- Further investigation is recommended to assess whether patients who are clinically identified as requiring prone positioning improve oxygenation parameters better if no RM is performed or if a RM is performed prior to, or after turning the patient.
- The prevention of ET suctioning-related lung volume loss, by performing RMs during suctioning and minimising periods of disconnection from the ventilator, could be more clinically relevant than reversing it (Maggiore et al, 2003). This requires investigation in the paediatric population.

- Identifying patients who respond to a RM may have diagnostic benefits in identifying the type of lung pathology. This may provide useful information regarding optimization of ventilatory strategies.
- This study did not investigate the long-term effects of RM, and whether performing RMs has any impact on patient mortality (Matthews and Noviski, 2001), length of ventilator dependency, or length of PICU stay. Further research is required to investigate this.
- More information regarding efficacy, indications, and technique is needed from paediatric clinical studies before RMs can be recommended as part of standard management in ventilated infants and children.

Chapter Seven presents an overview of the investigations comprising this thesis and the findings reported in the published literature; recommendations for clinical practice; and recommendations for further research.

CHAPTER SEVEN

SUMMARY

7.1 Introduction

Lower respiratory tract infections (LRTI) constitute major contributors to morbidity and mortality in the South African paediatric population (Bradshaw et al, 2003). Infants and children with life-threatening LRTI frequently require admission to the PICU, where they may be intubated and mechanically ventilated. These patients require numerous interventions during their stay in the PICU. Some of these are necessary for investigative purposes to determine disease aetiology; some are therapeutic; and others are required in order to maintain optimal levels of patient comfort.

Diagnostic NB-BAL is performed on many ventilated patients in the PICU in order to determine the aetiology of their lung pathology by obtaining a specimen of pulmonary secretions specifically from the lower respiratory tract. Therapeutic NB-BAL has also been described as being an effective treatment modality in the reexpansion of atelectatic areas of the lung, which have not responded to “conventional” chest physiotherapy (Galvis et al, 1994).

Patients ventilated through ETT are unable to clear secretions effectively as glottic closure is compromised and normal mucociliary function is impaired (Bailey et al, 1988). Inadequately humidified inspired gas and the presence of the ETT may cause irritation of the airways with a resulting increase in secretion production (Fisher et al, 1990). Therefore, artificially ventilated infants and children require ET suctioning to remove secretions in order to maintain an optimal level of ventilation.

ET suctioning is performed after mobilising secretions with CPT, for routine tracheal toilette, and to obtain respiratory secretions from the proximal airways for microbiological analysis in patients with lung infections in order to determine the causative pathogen.

This thesis presented a series of studies aimed at addressing some of the physical effects of ET suctioning and NB-BAL when performed on infants and young children. It also proposed and tested a method for each technique of reducing the negative effects of the procedures.

This chapter presents an overview of the results of these investigations and the findings reported in the published literature; recommendations for clinical practice; and recommendations for further research.

7.2 NB-BAL

Diagnostic NB-BAL is a procedure frequently performed by physiotherapists in PICUs. Despite this, there are currently no published NB-BAL clinical guidelines in physiotherapy journals.

This synthesis, based on the findings reported in Chapters Two and Three of this thesis as well as the published literature, aims to summarise the rationale behind paediatric NB-BAL; the complications associated with the procedure; and recommends a NB-BAL guideline, based on the best currently available evidence, including indications, contraindications and technique for use in the PICU.

7.2.1 Rationale

Diagnosis of aetiological agents in childhood pneumonia is difficult as blood culture results are frequently negative (Grigg et al 1993). TA cultures have relatively low sensitivity and are unreliable in most intubated patients due to contamination with organisms colonising the upper respiratory tract (Jourdain et al 1995).

BAL is an effective and reliable way of establishing the aetiology of pulmonary disease processes (Chapter Two; Panero et al 1995, Koumbourlis and Kurland 1993, Alpert et al 1992). This technique has become extremely important in the diagnosis of opportunistic infections in immunocompromised patients (Panero et al 1995). This is a particular concern in HIV-infected patients, who comprise approximately 10-15% of the patients admitted to the RCWMCH PICU (PICU Database).

Bronchoscopic BAL requires expensive equipment and a large amount of operator training and expertise. Bronchoscopic BAL in infants is limited by small ETT size (Koumbourlis and Kurland 1993, Alpert et al 1992). In addition, where there is diffuse disease, direct visualisation by bronchoscopy is not necessary.

NB-BAL is a simple, effective, less time-consuming procedure that requires less expertise and is less expensive than bronchoscopic BAL (Prokop et al 1996, Pugin et al 1991, Minotuli et al 1990, Mann et al 1987, Caughey et al 1985). NB-BAL is able to sample fluid specifically from the lower respiratory tract. Diagnostic yields from 42% to 85% have been reported (Koumbourlis and Kurland 1993, Alpert et al 1992, Minotuli et al 1990, Piperno et al, 1988), with a 69% yield in the study presented in Chapter Two.

7.2.2 NB-BAL Complications

There are reports of nursing staff acquiring TB from children requiring ET suctioning (Curtis et al 1999, Rabalais et al 1991), implying a potential risk of infection to the therapist performing NB-BAL. Appropriate infection control precautions should therefore always be taken, particularly in the South African context where infectious diseases such as TB are common.

The paediatric NB-BAL studies described in Chapters Two and Three of this thesis have excluded patients with raised intracranial pressure, haemodynamic instability and coagulation disorders due to the potential complications identified from data relating to ET suctioning (Darlow et al 1997, Alpert et al 1992, Singh et al 1991, Perlman and Volpe 1983, Anderson and Chandra 1976). Therefore, the effects of NB-BAL in these patients

cannot be described.

Early studies of paediatric NB-BAL reported no clinically significant patient complications (Schindler and Cox 1994, Koumbourlis and Kurland 1993, Alpert et al 1992, Minotuli et al 1990, Piperno et al 1988). The majority of these initial studies did not report oxygenation or ventilation requirements or document arterial blood gases. One could not, therefore, conclude from them that NB-BAL was safe in critically ill, unstable children and infants. The investigations presented in Chapter Two and Three of this thesis highlighted potentially serious adverse effects of paediatric NB-BAL, which at the time of investigation had not been reported elsewhere. These were the first prospective studies documenting the side-effects of NB-BAL, which have subsequently also been reported in a retrospective study by Burmester and Mok (2001).

The investigations described in Chapters Two and Three demonstrated that hypoxia was a frequent complication of NB-BAL. In most cases it was mild and self-limiting, as was also reported by Burmester and Mok (2001), Dargaville et al (1999), and Baughman and Conrado (1998), but in some cases prolonged, severe episodes of hypoxia were observed, requiring increased FiO_2 levels and ventilatory support.

NB-BAL-induced hypoxia may be caused by a combination of: O_2 deprivation (if the O_2 flow is disconnected); interruption of ventilation with an associated decrease in airway pressure; airway occlusion by the suction catheter; aspiration of intrapulmonic gas during prolonged suctioning; the effect of the lavage itself; and coughing.

During NB-BAL, the catheter remains in the tracheobronchial tree and thus partially obstructs the airway (effectively markedly increasing airway resistance) for longer periods than during normal ET suctioning; repeated suctioning manoeuvres are performed without allowing recovery time; and a large amount of saline is instilled into the lungs.

The repeated application of negative pressure may lead to loss of lung volume with resulting hypoxia, an hypothesis supported by the ET suctioning studies presented in Chapters Three to Six of this thesis, as well as by other authors (Simbruner et al 1981, Rosen and Hillard 1962).

Unfortunately, with the currently available equipment, it was not possible to determine if the hypoxia associated with NB-BAL was directly related to a loss of lung volume with a decrease in Cdyn. This is partly because of measurement difficulties as the CO₂SMO Plus! would have to be disconnected for the duration of the NB-BAL procedure. More importantly, though, if readings were taken before and after NB-BAL, results would be invalidated by the fact that the patients who experience prolonged hypoxia during or immediately after NB-BAL require manual ventilation in order to improve their SaO₂. This manual ventilation is likely to hyperinflate the lungs, acting as a recruitment manoeuvre, with a subsequent effect on Cdyn. A non-invasive tool able to measure real-time changes in lung volumes and regional ventilation during NB-BAL would facilitate such a study, as suggested later in this chapter. The fact that SaO₂ did respond to manual ventilation in most cases suggests that the manual ventilation may be effective as a RM following NB-BAL. Unfortunately this was not delivered in a standardised manner and conclusions cannot be made in this regard. Further investigations into the benefits of a RM performed after NB-BAL are recommended.

It is likely that the added airway obstruction caused by the suction catheter could also cause CO₂ retention. In this regard, monitoring patients' capnography using the CO₂SMO Plus! prior to and after NB-BAL may be interesting, but blood gas analysis would be more accurate (Main and Stocks, 2004).

The volume of saline introduced into the lungs during NB-BAL may decrease the available surface area for gaseous exchange and unretrieved saline could interfere with alveolocapillary O₂ exchange (Ridling et al 2003). It is interesting to note that in many experimental models of ALI, the injury is induced by means of saline lavage (Allen et al 2002, Rimensberger et al 1999, Neumann et al 1998). This implies that repeated NB-

BAL could result in lung injury, although the volume of saline instilled in clinical practice is likely to be much less than the amount used to induce lung injury in animal models. A method of monitoring changes in regional lung ventilation during and following NB-BAL would provide insight into these effects.

Burmester and Mok (2001) were unable to identify predictive factors for NB-BAL complications and Dargaville et al (1999) were unable to demonstrate a propensity for desaturation based on severity of lung disease. In contrast to these studies, the investigations of Chapters Two and Three demonstrated for the first time that there was a significantly greater risk of more marked and more prolonged desaturation in patients with high OI and low PaO₂/FiO₂ ratios, as seen in patients with ARDS and ALI.

Cardiac arrhythmia with significant desaturation followed by death has been reported in a child undergoing bronchoscopic BAL with pulmonary hypertension and congestive heart failure secondary to upper airway obstruction (Wagener et al 1987). It was postulated that hypoxia-induced increased pulmonary vascular resistance could precipitate worsening heart failure. In addition, when there is pulmonary hypertension in the presence of high pulmonary vascular pressure, markedly negative intrapleural pressures during partially obstructed aspiration may result in fluid transudation from the pulmonary vessels thereby precipitating acute pulmonary oedema (Wagener et al 1987) which may be exacerbated by fluid overload as a result of poor recovery of BAL fluid (Bye et al, 1987). As a result of these concerns, patients with pulmonary hypertension and cardiac failure were excluded from the investigations described in Chapters Two and Three.

Prolonged, clinically significant changes in blood pressure requiring escalation of inotropic support have been reported following NB-BAL (Burmester and Mok 2001). This was not a complication observed in the research presented in this thesis. Invasive monitoring would be required to evaluate acute changes in blood pressure occurring during the procedure.

Bronchial haemorrhage was observed in one patient during NB-BAL, as reported in Chapter Two. This had also been observed following nonbronchoscopic protected brush specimens and NB-BAL by Labenne et al (1999).

Pneumothorax is a particular risk of NB-BAL as the suction catheter is passed far beyond the ETT into the bronchi themselves (Anderson and Chandra 1976), and this has been reported as a complication of NB-BAL in neonates (Labenne et al 1999). No incidences of pneumothorax were caused in the 70 patients studied in the investigations of Chapters Two and Three.

Diagnostic BAL in patients with pneumonia may cause intravascular translocation of toxins or mediators, producing pyrogenic and hypotensive effects (Pugin and Suter 1992, Labenne et al 1999). Patient temperature was not recorded during NB-BAL in these studies, but this should be included in future investigations.

On application of negative suction pressure, most of the instilled saline is removed along with some of the surfactant-containing alveolar lining fluid (Burmester and Mok 2001). This may result in atelectasis with subsequent hypoxia. As a result of the concern about washing out of surfactant it has been suggested that NB-BAL may exacerbate existing respiratory disease, particularly in infants with neonatal Respiratory Distress Syndrome. However, in a controlled trial, repeated NB-BAL in newborn infants did not appear to be associated with radiological changes suggesting that surfactant was not consistently removed (Kotecha 1999). Considering there was only one controlled trial investigating this NB-BAL effect, with good theoretical grounds for surfactant removal, it was decided not to include premature neonates in these studies.

7.2.3 NB-BAL indications and contraindications

NB-BAL is effective in identifying pulmonary pathogenic processes, as was shown by the high diagnostic yield in Chapter Two and by previous authors (Kotecha 1999, Panero et al 1995, Koumbourlis and Kurland 1993, Minotuli et al 1990, Piperno et al 1988), and is a valuable diagnostic procedure for use in intubated, mechanically ventilated patients.

It is suggested that specific indications for NB-BAL should include radiological or clinical evidence of lung disease, raised infectious markers and a deteriorating clinical picture despite optimal management. It was found in Chapters Five and Six of this series of investigations that a single-catheter insertion suctioning procedure, as performed when obtaining a TA for bacterial culture, resulted in far fewer episodes of hypoxia or arrhythmias than those which occurred as a result of NB-BAL ($p < 0,0001$). This was true even when comparing ET suctioning to NB-BAL performed with ventilation maintained (Chapter Three). As a result of these findings, it is recommended that NB-BAL should not be used repeatedly on patients as part of the routine monitoring of emerging pathogens. NB-BAL should ideally be performed on stable patients as soon after intubation as possible, before bacterial ETT colonisation has occurred and/or in the event of a changing clinical picture with signs of infection and unknown pathogen. Frequent TAs may be sufficient in detecting potential respiratory tract pathogens in order to start appropriate antibiotic therapy in the event of raised septic markers.

In summary of the above findings, the following should serve as precautions or contraindications to paediatric NB-BAL:

- haemodynamic instability (change of $\geq 20\%$ in HR, MABP or SaO₂ over at least the preceding six hours);
- pulmonary haemorrhage;
- pulmonary oedema;
- cor pulmonale with pulmonary hypertension;
- clinical or measured raised intracranial pressure (as seen by raised fontanel or measured intracranial pressure > 15 mmHg);
- congestive cardiac failure;
- coagulopathy, with platelet count $< 50 \times 10^9/l$. NB-BAL may be considered after transfusion of blood products if the coagulopathy has resolved;
- neonatal respiratory distress syndrome;

- premature, small-for-gestational-age infants due to the risk of intraventricular haemorrhage; and
- NB-BAL is not appropriate after a decision has been made to withdraw ventilatory support, offer palliative care or limit invasive and unpleasant procedures.

Considering the high diagnostic yield of NB-BAL reported in Chapter Two, it might be worth the risk of performing the procedure in certain high-risk patients despite the presence of contraindications, where there have been no other positive cultures. These patients, however, should be selected carefully. Consideration should be given to the risk: benefit ratio for the child, the financial cost of the investigations, and how NB-BAL findings would influence patient management. The risk of performing NB-BAL in certain patients may be outweighed by the potential benefits of a correct diagnosis.

The results of Chapter Three confirm that desaturation is more severe in patients with markers of severe respiratory disease, as seen by high OI and VI and low PaO₂/FiO₂. Therefore, it is recommended that special precautions be taken with regard to sedation, level of preoxygenation and technique during NB-BAL in patients with high oxygenation and ventilation requirements, particularly in patients with OI > 10, VI > 20 and with PaO₂/ FiO₂ < 150. Again, however, it must be noted that in patients with poor OI or PaO₂/ FiO₂ it may be even more important than usual to identify disease aetiology by means of NB-BAL.

It is suggested that bronchoscopic BAL (which allows direct visualisation of the airways) is indicated where there is localised lung disease and ETT >4,5mm ID. This is preferable as specific sampling from the area of pathology can be obtained. In infants with small ETT ID, and unilateral lung disease, directed blind NB-BAL can be performed by positioning the patients with their head away from abnormal lung (Kotecha 1999).

The potential complications of NB-BAL should not be minimised. All patients should be carefully monitored throughout the procedure (Pattishall et al 1988) and resuscitation

equipment should be available at all times.

7.2.4 Paediatric NB-BAL technique

Numerous NB-BAL techniques have been reported (Burmester and Mok 2001, Dargaville et al 1999, Koumbourlis and Kurland 1993, Alpert et al 1992). Based on these studies as well as the reports on the benefits of closed-system ET suctioning (Choong et al, 2003), Chapter Three of this thesis proposed a simple, effective, novel NB-BAL technique. This new method allows ventilation to continue throughout the procedure, and was shown to effectively reduce the severity of desaturation events that occurred as a result of NB-BAL. This method was found to be effective, inexpensive, and easy to perform and is therefore the recommended NB-BAL technique for use in the South African context. A detailed description of the technique, for use as a clinical guideline, is presented below:

7.2.4.1 Preparation

1. Prior to BAL, patients should receive sedation – usually morphine or midazolam as a 0,1mg/kg intravenous bolus.
2. ECG and pulse oximetry monitoring must be used throughout.
3. A manual resuscitation bag, with O₂ flow turned on, should be ready at the patient's side.
4. Preoxygenate with 100% inspired O₂ for approximately one minute prior to NB-BAL and maintain this FiO₂ throughout until the patient's SaO₂ returns to prelavage levels.
5. Place two layers of *Tegaderm* transparent dressing (3M Health Care, USA) over the ETT port to seal the ventilator system. Pierce the *Tegaderm* with a needle.

7.2.4.2 NB-BAL Procedure

1. Insert an end-hole suction catheter of appropriate size (Chapter Four) through the *Tegaderm*, into the ETT; wedge the catheter as far distally as possible and then withdraw very slightly (< 0,5cm).
2. Introduce the first lavage volume of 1ml per kg body weight of 0,9% saline at

room temperature, through the catheter.

3. Attach the suction catheter to a mucus extractor with wall unit suction applied.
4. Continue suctioning until no more saline is withdrawn. Movement of the catheter of about 5mm is permissible to maximise fluid return.
5. Two further lavages of 1ml/kg body weight of saline solution are performed through the same catheter in the same position. The catheter is not withdrawn in between suction events.
6. The first aliquot is discarded, and the subsequent two are collected in the same mucus extractor and sent for analysis.
7. If a patient's SaO₂ drops to ≤ 80 % at any stage during the procedure the catheter must be withdrawn immediately while attempting to suction as much fluid back as possible in the process. If immediate improvement does not occur, the patient should be manually ventilated with 100% oxygen until SaO₂ returns to pre-lavage levels. The procedure should not be repeated until the patient has been haemodynamically stable for at least twelve hours following the NB-BAL attempt.

7.2.4.3 NB-BAL Processing

1. The second and third aliquot are combined and sent to the laboratory.
2. According to clinical indications, the specimen may be sent for microscopy, culture and sensitivity; viral culture; TB studies; extended fungal culture; *Pneumocystis jiroveci* immunofluorescence; and histology for any or all of cytology, fat laden macrophages, haemosiderin laden macrophages and viral inclusion bodies.

7.2.5 NB-BAL: Conclusion

Based on the results of the investigations described in this thesis, as well as a synthesis of the available literature, this section presents an overview of the reasons for performing diagnostic NB-BAL; the complications associated with the procedure and recommends an evidence-based NB-BAL guideline for use in the PICU.

NB-BAL is an effective procedure for the diagnosis of pulmonary disease processes in ventilated infants and children. This procedure is, however, not without risks to both staff and patients. Numerous complications of NB-BAL exist, with hypoxia being the most common. As a result, care should be taken in performing NB-BAL on haemodynamically unstable patients and patients with coagulation defects, cardiac or brain abnormalities.

By following a defined protocol, one can ensure that the most effective specimen is obtained from the lower respiratory tract, whilst minimising the risk to young and vulnerable patients.

7.3 ET suctioning

ET suctioning is a procedure performed on all patients with an artificial airway in order to remove secretions and prevent airway obstruction (Guglielminotti et al, 1998; Young, 1995).

In addition to the regular tracheal toilette performed by nursing staff, ET suctioning is an integral component of CPT, in order to remove secretions mobilised during chest manipulations and positioning. Physiotherapists also obtain TAs by ET suctioning for microbacterial analysis.

Based on available published literature as well as the results of Chapters Four to Six of this thesis, this synthesis aims to summarise the complications associated with ET suctioning; and it recommends a suctioning guideline, based on the best available current evidence, including indications, contraindications and technique for use in the PICU.

7.3.1 Effects of ET suctioning

ET suctioning carries a risk of infection to the therapist performing the procedure (Curtis et al 1999, Rabalais et al 1991). Therefore, it is essential to adhere to the institutional infection control procedures, particularly in the South African context where numerous children present with infectious diseases such as TB.

Chapter Five presents the first study of its kind prospectively investigating the effects of a standardised single-insertion suctioning procedure in a heterogeneous group of critically ill paediatric patients.

Suctioning causes a range of complications, including hypoxia (Hohlhauser et al, 2000; Skov et al, 1992; Singh et al, 1991; Graff et al, 1987; Simbruner et al, 1981; Fox et al, 1978; Rosen and Hillard, 1962), bradycardia (Kohlhauser et al, 2000; Segar et al, 1993; McCauley and Boller, 1988; Simbruner et al, 1981; Ehrhart et al, 1981; Cabal et al, 1979) and other arrhythmia's (Simbruner et al, 1981; Ehrhart et al, 1981), raised intracranial pressure (Kerr et al, 1999; Durand at al, 1989; Fanconi and Duc, 1987), bacteraemia (Bailey et al, 1988), pneumothorax (Loubser et al, 1989; Anderson and Chandra, 1976), mucosal trauma (Loubser et al, 1989; Bailey et al, 1988; Nagaraj et al, 1980; Kuzenski, 1978) and loss of ciliary function (Bailey et al, 1988).

Owing to the above concerns, patients were excluded from participating in the studies described in Chapters Five and Six if there was a possibility of their intracranial pressure increasing to unacceptable levels or if they were haemodynamically unstable.

Few of the above complications occurred during the investigations presented in Chapters Five and Six. The only adverse events noted were two episodes of transient desaturation and a single episode of relative bradycardia. The episodes of hypoxia occurred despite adequate pre-oxygenation in two patients with ARDS (Bernard et al, 1994). The bradycardia was most likely due to vagal nerve stimulation by the suction catheter (McCauley and Boller, 1988). Hypoxia may have been limited by hyperoxygenating the

patients before and immediately after suctioning, and by the fact that only a single-catheter insertion procedure was performed.

Atelectasis has been observed following ET suctioning (Boothroyd et al, 1996; Ehrhart et al, 1981; Hippenbecker and Guthrie, 1981; Polacek and Guthrie, 1981; Nagaraj et al, 1980; Brandstater and Muallem, 1969; Rosen and Hillard, 1962), which has been attributed to the aspiration of intrapulmonic gas (Ehrhart et al, 1981), mucosal oedema (Boothroyd et al, 1996), or bronchial obstruction as a result of mucosal trauma (Nagaraj et al, 1980).

Chapters Five and Six confirm that ET suctioning causes a significant, reproducible decrease in C_{dyn} following ET suctioning ($p < 0,000001$). The most likely cause of this decrease in C_{dyn} was loss of lung volume. When combining patient data from Chapters Five and Six, a significant decrease in V_{te}^{mech} was observed following ET suctioning ($p = 0,03$), confirming that the decrease in C_{dyn} was likely to reflect a loss of lung volume.

The *in vitro* study described in Chapter Four suggested that lung volume loss would be related to the CA:AD ratio, as it was found that the amount of negative pressure produced in the lung model was significantly affected by CA:AD. The combined data analysis described in Chapter Six confirms the results of Chapter Five, namely that the change in C_{dyn} occurring following ET suctioning is directly related to the CA:AD ratio ($p = 0,005$). This finding had not previously been published. This relationship implies that the most severe lung volume changes are likely to occur during ET suctioning of neonates and young infants intubated with small ID ETT; and supports the hypothesis proposed in Chapter Four.

ET suctioning has been shown to cause pain and discomfort (Simons et al, 2003; Van de Leur et al, 2003; Payen et al, 2001; Evans et al, 1997; Bergbom-Engberg and Haljamae, 1989). This may be reflected in Chapters Five and Six, where combined data on patients' RR was shown to increase significantly following ET suctioning ($p < 0,01$). This increase in RR may, however, reflect compensation to the loss of ventilation occurring during the suctioning procedure. Patients were all receiving morphine infusions for general

procedural analgesia. Specific pain behavioural scores were not recorded before and after suctioning; therefore it is not possible to relate a median increase of three bpm following suctioning to clinically relevant pain or discomfort. Future research studies should include a pain behavioural score to assess the affect of suctioning and CPT on patients' pain and discomfort levels.

It has been suggested that ET suctioning causes a decrease in airway resistance, by the removal of pulmonary secretions (Fox et al, 1978). In contrast to this suggestion, the combined data of Chapters Five and Six confirm that ET suctioning does not have an effect on dynamic airway resistance ($p > 0,05$). These data are likely to be valid as the median percentage ETT leak was low (Main et al, 2001). Guglielminotti et al (1998) also found that resistance did not decrease below presuction levels after an initial increase related to transient bronchoconstriction. It is likely that resistance would only decrease significantly if large amounts of mucus were removed from the airways during suctioning. Suctioning, for this study, was performed on patients who were undergoing ET suctioning at a specific time and who did not necessarily have secretions in the airways at the time of the study intervention. It is also possible, as mentioned in Chapter Five, that suctioning-induced lung volume loss may have increased airway resistance (Young, 1984), thus negating the effect of clearing the large airways. Main et al (2004) also found that ET suctioning did not affect respiratory resistance, whilst CPT and suctioning resulted in a decrease in resistance. This may suggest that CPT combined with ET suctioning improves secretion clearance more effectively than ET suctioning alone. Future research is recommended to compare a standardised ET suctioning procedure with standardised CPT on lung dynamics, in order to improve the reproducibility and generalisability of the study of Main et al (2004).

7.3.2 Indications for ET suctioning

From the investigations described in this thesis, as well as those reported in the literature, it is apparent that there is still no clear evidence that ET suctioning improves respiratory mechanics. Conversely, most evidence points to the detrimental effects of ET suctioning on lung mechanics. Despite this, the procedure is clearly an essential component of

physiotherapeutic intervention and nursing care in order to clear secretions from artificial airways. However, the method and frequency in which the procedure is performed is still open to debate.

Loubser et al (1989) suggested that there was no clear benefit for a routine regimen of ET suctioning in ventilated babies, in which case infants will often be suctioned in the absence of secretions. It has been shown in this thesis that ET suctioning reproducibly results in a decrease in Cdyn, attributable to a loss of lung volume. As discussed in Chapters Five and Six, this recurrent derecruitment and subsequent rerecruitment on reconnection to the ventilator (Chapter Six), may exacerbate lung injury (Maggiore et al, 2003; Suh et al, 2002; Taskar et al, 1997). Therefore, preventive measures are important. It is possible that the most important measure is to avoid ET suctioning as far as possible (Dhyr et al, 2003).

It is recommended that infants and children should not be placed on a strict suctioning schedule, as was the practice in RCWMCH PICU for many years and is still the current practice in many PICUs worldwide. Rather, ET suctioning should be performed only when clinically indicated in order to maximise secretion removal; and minimise the complications, pain and discomfort to the patient. Exceptions to this may include patients receiving muscle relaxants who will not be able to cough.

It is suggested that patients should be suctioned only when there are audible secretions in the ETT; if an intubated child is coughing; if there is clinically apparent increased work of breathing (Branson et al, 1993); if a child desaturates or becomes bradycardic as a result of secretions; if a child requires a TA for culture and following CPT in order to clear mobilised secretions. If patients are ventilated using machines with displayed flow-volume loops, a saw-toothed pattern may indicate the presence of secretions in the ETT.

7.3.3 Precautions and Contraindications to ET suctioning

Considering that all intubated and ventilated patients require ET suctioning, there can be no absolute contraindications to the procedure.

It is recommended that special care be taken with patients who have raised intracranial pressure, as this can be exacerbated by ET suctioning and coughing (Kerr et al, 1999; Durand et al, 1989; Fanconi and Duc, 1987) as can pulmonary hypertension (personal observation). Patients with pulmonary oedema and pulmonary haemorrhage should only be suctioned when absolutely necessary as suctioning may exacerbate these conditions (Demers, 1982).

7.3.4 An evidence-based clinical paediatric ET suctioning guideline

7.3.4.1 Monitoring

The patient's HR, blood pressure and SaO₂ should be carefully monitored at all times, by means of pulse oximetry and ECG monitors as well as clinical observation. Clinical observations should include patient colour (to detect early cyanosis); signs of respiratory distress (such as sweating, tachypnoea, marked costal recessions); and signs of pain or anxiety.

7.3.4.2 Suction catheter size

The appropriately sized catheter should be used, considering the ETT size and the secretion viscosity (Table 7.1). This guideline was developed from the findings of the *in vitro* study presented in Chapter Four. It is based on the best evidence currently available, but has not been subjected to rigorous testing by means of a prospective controlled clinical trial. It is recommended that this guideline be used until stronger evidence for suction catheter size selection is available. The catheter should be large enough to effectively suction thick secretions but not so large that it traumatises or occludes the airway, which would lead to greater negative pressure accumulation (Chapter Four) and lung volume loss (Chapters Five and Six). Doubling the ETT ID gives an indication of which FG catheter size to use for efficacy and safety (for example, with a 3,5mm ID ETT, a size 6 or 7 FG catheter could be used).

Table 7.1 A proposed guideline for suction catheter selection

Age	Weight (kg)	ETT (mmID)	Catheter (FG)		
			Liquid	Medium	Thick
Newborn	<1	2,0	5	5	5
Newborn	1	2,5	5	5	6
Newborn	2	3,0	5	6	6
Newborn	3,5	3,5	5	6	7
3 months	6	3,5	5	6	7
1 year	10	4,0	6	7	7
2 years	12	4,5	6	7	8
3 years	14	4,5	6	7	8
4 years	16	5,0	7	8	8
6 years	20	5,5	7	8	8
8 years	24	6,0	8	10	10
10 years	30	6,5	8	10	12
12 years		7,0	8	10	12

7.3.4.3 Vacuum pressure

The suction pressure should be high enough to be effective but not so high that it damages the mucosa. There is still no high-level evidence supporting a maximum safe, and effective suction level but the results of Chapter Four suggested that suction pressures up to 360 mmHg measured at the vacuum source were more effective in removing secretions than using vacuum pressures of ± 200 mmHg. The clinical implications of using these two pressure levels were not assessed clinically, in order to ensure standardisation of the suctioning technique in the clinical studies presented in Chapters Five and Six. Further research in this regard is necessary. Until clear evidence is available, it is suggested that therapists and nurses use the lowest pressure that effectively removes the secretions, with the least adverse clinical reaction. Suction pressures should be < 400 mmHg.

7.3.4.4 Patient position

For the investigations described in Chapters Five and Six, patients were positioned in supine or prone for standardisation. Where possible, patients should be positioned in side lying turned away from the therapist in order to avoid patients aspirating if they vomit and to protect the person from direct contact with infectious secretions. Where side lying is not possible or impractical, the patient's head should be turned away from the therapist.

7.3.4.5 Sterility

It does not appear to be necessary to use a sterile suctioning technique. In a randomised controlled trial of 486 intubated children and infants, it was found that reusing a disposable suction catheter in the same patient over a 24-hour period did not affect the incidence of pneumonia (Scoble et al, 2001). Strict infection control procedures should be employed to prevent the spread of pathogenic organisms between patients and from the patient to the therapist. For example, clean gloves should be worn at every suction event. More research into the influence of different suctioning techniques on the occurrence of nosocomial pneumonia is recommended.

7.3.4.6 Preoxygenation

Branson et al (1993), in their ET suctioning guideline, stated that patients should receive hyperoxygenation by the delivery of 100% O₂ for >30 seconds prior to the suctioning event. In order to standardise the suctioning procedure in this series of investigations, the above guideline was used. Hodge (1991) suggested increasing the FiO₂ by 10-20% higher than the baseline FiO₂. Neither of these recommendations is supported by high-level evidence.

In a systematic *Cochrane* review, Pritchard et al (2003) showed that preoxygenation decreased hypoxaemia at the time of suctioning, but other clinically important outcomes, including the adverse effects of hyperoxia, were not known. Only one study was able to be included in the review, and this was considered to be of poor quality due to small sample size; unknown randomisation blinding; limited generalisability; limited short-term

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MABP	mean arterial blood pressure
MAP	mean airway pressure
MV	minute volume
NB-BAL	nonbronchoscopic bronchoalveolar lavage
O₂	oxygen
OI	oxygenation index
ΔP	peak change in pressure
PaCO₂	arterial partial pressure of carbon dioxide
PaO₂	arterial partial pressure of oxygen
PEEP	positive end-expiratory pressure
PICU	paediatric intensive care unit
PIP	peak inspiratory pressure
PRISM	paediatric risk of mortality
R_e	dynamic expiratory airway resistance
R_i	dynamic inspiratory airway resistance
RM	recruitment manoeuvre
RR	respiratory rate
RCWMCH	Red Cross War Memorial Children's Hospital
SaO₂	oxyhaemoglobin saturation measured by pulse oximetry
SI	study intervention (Chapter Six)
TA	tracheal aspirate
TB	tuberculosis
TV	tidal volume
VI	ventilation index
V_{te}^{mech}	expiratory mechanical tidal volume
V_{ti}^{mech}	inspiratory mechanical tidal volume
V_{te}	expired tidal volume
V_{te}^{spont}	expiratory spontaneous tidal volume
V_{ti}^{spont}	inspiratory spontaneous tidal volume
v:v	volume:volume

APPENDIX B

GLOSSARY

Acute lung injury (ALI): Respiratory illness of acute onset, involving bilateral infiltrates on chest radiographs, absence of clinical evidence of left atrial hypertension, $\text{PaO}_2/\text{FiO}_2 \leq 300$ (Matthews and Noviski, 2001).

Acute respiratory distress syndrome (ARDS): Respiratory illness of acute onset, involving bilateral infiltrates on chest radiographs, absence of clinical evidence of left atrial hypertension, $\text{PaO}_2/\text{FiO}_2 < 200$ (Matthew and Noviski, 2001).

Allocation Concealment: Randomization is concealed if the person who is making the decision about enrolling a patient is unaware of whether the next patient enrolled will be entered in the treatment or control group (Guyatt et al, 2002).

Airway pressure: Airway pressure is the pressure measured at the patient's airway during mechanical ventilation, and is determined by the sum of the alveolar pressure and the pressure required to deliver flow across the airways (determined by the airway resistance). Alveolar pressure is the pressure in the distensible parts of the respiratory tract and is determined by the tidal volume and the lung/chest compliance. Airway pressure is equal to alveolar pressure when there is no flow occurring (Elton, 1990).

Airway resistance: Resistance is the amount of pressure required to deliver a given flow of gas and is expressed in terms of a change in pressure divided by flow (Elton, 1990).

Area Difference (AD): difference between the internal cross-sectional area of the endotracheal tube and the external cross-sectional catheter area.

Atelectasis: collapse of alveoli, lung, or lung segments.

Before-After Trial: Investigation of an intervention in which the investigators compare the status of patients before and after the intervention (Guyatt et al, 2002).

Blind (or Blinded): The participant of interest is unaware of whether patients have been assigned to the experimental or control group (Guyatt et al, 2002).

Boyle's Law: The volume of gas is inversely proportional to the pressure applied to it.
 $P.V = K$

Catheter area: area difference (CA:AD): the ratio of external cross-sectional catheter area to area difference.

Chi-square Test: A statistical test that examines the distribution of categorical outcomes in two groups, the null hypothesis of which is that the underlying distributions are identical (Guyatt et al, 2002).

Closing capacity: that volume of gas present in the lungs when the small conducting airways begin to collapse.

Comorbidity: Disease(s) that coexist(s) in a study participant in addition to the index condition that is the subject of the study (Guyatt et al, 2002).

Compliance: see **Dynamic Respiratory System Compliance**

Complication / adverse event: A deleterious change in physiological or clinical status as a result of an intervention.

Confidence Interval: Range of values within which it is probable that the true value lies for the whole population of patients from whom the study patients were selected.

Control Group: A group that does not receive the experimental intervention.

Convenience Sample: Individuals or groups selected at the convenience of the investigator or primarily because they were available at a convenient time or place (Guyatt et al, 2002).

Correlation: The magnitude of the relationship between different variables or phenomena.

Desaturation: A decrease in oxyhaemoglobin saturation.

Dynamic compliance (C_{dyn}): The result of dividing the delivered tidal volume by the peak airway pressure. Peak airway pressure is determined by lung compliance, airway resistance, inspiratory flow rate and tidal volume (Elton, 1990).

Exclusion Criteria: Criteria that render potential subjects ineligible to participate in a particular study (Guyatt et al, 2002).

Flow limitation through a collapsible tube: The velocity of gas molecules (cm/s) and the cross-sectional area (cm²) determine the volume of flow passing through a tube per unit of time (mL/s): flow = velocity x area

Functional residual capacity (FRC): the volume of gas that remains in the lungs at resting expiratory level (Tooley, 1982).

Generalisability: The ability to generalize the findings of a study to a larger group of similar people.

Haemoptysis: Coughing up blood.

Health professionals/health care professionals: All persons with a health-based certification, for example physicians, nurses, medical doctors, physiotherapists, pharmacists, occupational therapists, respiratory technicians, and counselors.

Heterogeneity: Differences between patients, or differences within patients.

Hypoxia: Reduced oxygen, either concentration or pressure.

Inclusion Criteria: Investigators specify the inclusion criteria to define the population who will be eligible for a study (Guyatt et al, 2002).

Informed Consent: A potential participant's expression of willingness, after full disclosure of the implications, to participate in a study.

Intention-to-Treat Analysis: Analyzing patient outcomes regardless of whether they actually received the planned intervention.

Laplace's Law: For a given surface tension, the pressure required to hold a given sphere open is inversely proportional to the radius of the sphere. $P = 2T/r$

Minute volume (MV): The volume of air breathed per minute. $MV = \text{tidal volume} \times \text{respiratory rate}$.

Outcomes: Changes in health status that may occur in following subjects or that may stem from exposure to a causal factor or to a therapeutic intervention (Guyatt et al, 2002).

Overview: A type of review in which primary research relevant to a question is examined and summarized, and an effort is made to identify all available literature (published or unpublished) that pertains to that question (Guyatt et al, 2002).

Oxygenation index (OI) = $(MAP(FiO_2(100)/PaO_2))$ (Peters, 1998).

Poiseuille's Law: In the presence of laminar flow, the resistance provided by a tube is proportional to its length and 4th power of its radius. $R = 8.L.\eta/(\pi.r^4)$ (R – resistance; L – length of tube, η - viscosity of the gas)

Primary investigator: for the purposes of this thesis, the primary investigator refers to the author, Brenda Morrow.

Random: Governed by a formal chance process in which the occurrence of previous events is of no value in predicting future events (Guyatt et al, 2002).

Random Allocation: Allocation of individuals to groups by chance.

Randomised controlled trial: Experiment in which individuals are randomly allocated to receive or not receive an experimental procedure and then followed to determine the effect of the intervention (Guyatt et al, 2002).

Reliability: Refers to the consistency or reproducibility of data (Guyatt and Rennie, 2002).

Reproducibility: The ability of a measure to yield the same result when reapplied to patients (Guyatt and Rennie, 2002).

Respiratory System Compliance: Compliance is a measure of the distensibility of the chest. It is expressed as volume change per unit change in pressure (expressed as ml/cmH₂O/kg body weight). Compliance is defined by the relationship between volume and pressure in the lungs. It depends on many factors including tissue elasticity, lung water content, surfactant action, pulmonary blood flow and volume, and the visco-elastic properties of the entire respiratory system (including the chest wall) (Elton, 1990).

Sensitivity: The proportion of people who truly have a designated disorder who are so identified by the test. The test may consist of, or include, clinical observations.

Standard Error: The standard deviation of an estimate of a population parameter (thus, the standard error of the mean is the standard deviation of the estimate of the population mean value) (Guyatt et al, 2002).

Statistical Significance: A result is statistically significant if the null hypothesis is rejected. That is, the probability of the observed results, given the null hypothesis, falls below an arbitrary threshold (Guyatt et al, 2002) (for the purposes of this research, $p = 0,05$).

Suctioning event/procedure/manoeuvre: The insertion of a suction catheter through the ETT and the application of negative pressure as the catheter is being withdrawn.

Tertiary Care Center/Hospital: A medical facility that receives referrals from both primary and secondary care levels and usually offers tests, treatments, and procedures that are not available elsewhere. Most tertiary care centers offer a mixture of primary, secondary, and tertiary care services so that it is the specific level of service rendered rather than the facility that determines the designation of care in a given study. (Guyatt et al, 2002).

Time constant: The Time Constant of the lung describes the phenomenon whereby a given percentage of a passively exhaled breath of air will require a constant amount of time to be exhaled regardless of the starting volume, given constant lung mechanics. Mathematically, the time constant is defined as total compliance multiplied by the airway resistance and the resulting value is expressed as seconds (Elton, 1990).

Tidal volume (TV): the volume of gas inspired or expired during each normal (unforced) ventilation cycle.

Transpulmonary pressure: The pressure difference between the airways and the pleural space.

Type I error: The null hypothesis is rejected when it is really true.

Type II error: The null hypothesis is accepted when it is actually false.

Validity: In relation to studies of diagnosis or therapy, a study is valid insofar as the results represent an unbiased estimate of the underlying truth (Guyatt et al, 2002).

Ventilation index (VI) = $(RR(PaCO_2(PIP/1000)))$ (Peters, 1998).

University of Cape Town

APPENDIX C

CONSENT FORMS FOR CHAPTER FIVE

CONSENT FORM FOR PARTICIPATION IN A CLINICAL RESEARCH PROJECT	
Title of Project: An investigation into the effects of endotracheal suction on lung dynamics in intubated, ventilated patients.	
Principal Investigator: B. Morrow Other Investigators: A. Argent, M. Futter	
Outline Explanation: Your child is presently being mechanically ventilated to support his/her breathing whilst he/she is unable to do so. He/she has also been given medication to make him / her more comfortable. Whilst the tube is in the airway, your child will need to be suctioned regularly to remove any secretions that may be in the tube, in order for the airway to be kept clear to breathe. We would like your permission to measure the pressure inside your child's chest while he/she is being suctioned in order to determine possible side – effects of suction and ways to prevent these potential problems. This would be done by attaching the tube to a monitor which will read pressure changes in the lungs. Your child would then be suctioned in the same way as is done routinely by nursing staff. If you decide not to allow your child to be part of the study, it would not affect their care in the intensive care unit. Your contribution, however, would help to improve routine patient care in the future. Thank You	
I (Name) _____	parent/guardian of (child's name) _____
of (address) _____	_____
_____	_____
_____	_____
hereby consent to my child / ward taking part in the above investigation, the nature and purpose of which have been explained to me.	
Signature _____	
Investigator _____	
Witness _____	

**PROJEK: KLINIESE NAVORSING
TOESTEMMING TOT DEELNAME AAN PROJEK**

Titel van Projek: 'n Ondersoek in die effekte van endotracheiese suiging in die longdinamika van pasiënte wat aan 'n lugpyp gekoppel is.

Hoofnavorser: B. Morrow
Mede-navorsers: A. Argent, M. Futter

Omskrywing van die proses:

Vanwêre die feit dat u kind huidiglik nie by die vermoë is om onafhanklik asem te haal nie, is hy / sy aan 'n meganiese asemhalingstoestel gekoppel om sy / haar asemhaling te ondersteun / vergemaklik. Hy / sy het ook medikasie ontvang om meer gemak tydens die proses te verseker.

Terwyl die pyp in die lugweë is, sal u kind gereelde suiging van die lugkanale benodig. Hierdie proses verhoed die opbou van enige sekresies wat dalk in die pyp aanwesig mag wees. Dit is belangrik dat die lugweë ter alle tye oop is om asemhaling te vergemaklik. Ons wil graag hiermee u toestemming vra om die druk binne u kind se bors te meet terwyl sy / haar lugweë skoongesuij word. Sodoende kan ons enige nuwe - effekte van die suigingsproses, en die voorkoming daarvan, bepaal. Hierdie proses word soos volg uitgevoer: die lugpyp word eenvoudig aan 'n drukmonitor gekoppel. U kind sal dus roetine suigingsproses, soos uitgevoer deur die verpleegpersoneel, ondergaan.

Ons kan u verseker dat 'n besluit teen deelname aan die projek nie die kwaliteit van behandeling vir u kind in die intensiewe eenheid sal beïnvloed nie. U bydrae kan egter help om die daaglikse versorging van pasiënte te verbeter.

Baie dankie

Ek, _____ (volnaam), die ouer / voog van _____ (kind se naam), _____ woonagtig by _____ (huisadres)-

Verleen hiermee toestemming dat my kind aan bogenoemde projek kan deelneem. Ek verklaar dat ek die proses en die doel daarvan ten volle verstaan.

Handtekening: _____

Navorsers: _____

Getuie: _____

Datum: _____

**IFORM YESIVUMELWANO UKUTHATHA INXAXHEBA KUPHANDO | LOLINGO
LWEKUNIKI**

Umxholo Wolingo: Uphando malunga nesiqhamo sokutsala umoya kumbizo kwimiphunga ngemibhobho, kwizigulana ezikhubazekileyo.

Inqununu Ephandayo: B. Morrow
Abanye Abaphandi: A. Argent, M. Futter

Ugqabazo Lwenkcazelo:

Umntwana wakho uyewafumana uncedo lokuba angeniselwe umoya ukuxhasa indlela aphefumla ngayo njengokuba engasakwazi oko. Uye wanikwa namayeza ukwenzela azokufumana ukukhululeka, ayekelele umzimba.

Ngelixa umbhobho ukwinkampani yendlela zomoya umntwana wakho kuzakufuneka afumane ufunxo rhoqo ukukhupha uxakaxa olungabalusembhobheni, ukuze umbhobho okwinkampani zomoya uhlale ucocekile okwenzela ukuphefumla. Singathanda imvumelwano yakho ukuthatha umlinganiselo wobunzima ngaphakathi esifubeni somntwana ngalomzuzu efumana ufunxo ukwenzela ukuba imonakalo zolufunxo esizakuzikhusela ngayo ezingxaki. Lendlela iyakwenziwa ngokuthi kutsalwe kumbhobho osesuswini kancinci endleleni siyincamathisele kwipressure monitor. Umntwana wakho uyakuphefumla ngolufilobo olunye naxa ezabe esenziwa ngabongikazi rhoqo.

Ukuba ugqiba kwelokuba awuvumi umntwana wakho athathe inxaxhebe kolulingo lwesisifundo lonto ayukumchaphazela nganto indlela azakujongwa ngayo kwigumbi labucala. Inxaxhebe yakho izakunceda ukuphakamisa umgangatho wendlela izigulana ezinakekelwa ngayo kwixesha elizayo.

Enkosi!

Mna (igama) _____ umzali / ummeli ka (igama
omntwana) _____
Ohlala (idilesi) _____

Ndiyavuma ukuba umntwana wam athathe inxaxheba koluphando
lungentla imbangi yoko ibiseyichaziwe kum.

Tyikitya _____

Umphandi _____

Ingqina _____

APPENDIX D

CONSENT FORMS FOR CHAPTER SIX

Consent Form for Participating in a Clinical Research Project

Title of Project: An investigation into the effects on lung dynamics of a lung recruitment manoeuvre following endotracheal suctioning, in mechanically ventilated paediatric patients.

Principal Researcher: B. Morrow (Tel: (021) 658 5111 bleep 4100 with any queries)

Co - Researchers: A. Argent, M. Futter

Outline Explanation:

Your child is presently being mechanically ventilated through a tube in the airway to help him/her breathe whilst he/she is unable to do so. Whilst the tube is in place, your child will need to be suctioned regularly to remove any secretions, so that the airway is clear to breathe.

We are conducting research to try and limit the complications of suctioning. Therefore we would like your permission to measure your child's lung function before and after suctioning. This would be done by attaching the airway tube to a monitor, which will read pressure changes in the lungs. The monitor in no way affects the baby's comfort or ventilation. Your child would then be suctioned in the same way as is done routinely by nursing staff. One group of babies will also undergo a "recruitment manoeuvre": after suctioning, the principal investigator would attach an anaesthetic bag to the airway tube and deliver a certain sustained pressure for 30 seconds to fully expand the lungs. Monitoring would continue for half an hour thereafter.

If you decide not to allow your child to be part of the study, it would not affect his/her care in the intensive care unit. Although participating in this research may have no direct benefits for your baby, your contribution would help to improve routine patient care in the future. Your baby's name will not be used in any publication resulting from this research.

Thank You

I (Name) _____ parent/guardian of (child's name) _____

of (address) _____

_____ hereby consent to my child / ward taking part in the above investigation, the nature and purpose of which have been explained to me.

Signature _____

Investigator (name and signature): _____

Witness (name and signature): _____ Date: _____

PROJEK: KLINIESE NAVORSING

TOESTEMMING TOT DEELNAME AAN PROJEK

Titel van Projek: 'n Onderzoek in die effekte van 'n long- opblaasprosedure na endotrachiese suiging in die longdinamika van pasiënte wat aan 'n lugpyp gekoppel is.

Hoofnavorser: B. Morrow (tel: (021) 658 5111 Bleep 4100 vir enige navrae)

Mede-navorsers: A. Argent, M. Futter

Omskrywing van die proses:

Vanwêre die feit dat u kind huidiglik nie by die vermoë is om onafhanklik asem te haal nie, is hy / sy aan 'n meganiese asemhalingstoestel gekoppel om sy / haar asemhaling te ondersteun / vergemaklik.

Terwyl die pyp in die lugweë is, sal u kind gereelde suiging van die lugkanale benodig. Hierdie proses verhoed die opbou van enige sekresies wat dalk in die pyp aanwesig mag wees. Dit is belangrik dat die lugweë ter alle tye oop is om asemhaling te vergemaklik. Ons het opgelet dat daar sekere nuwe – effekte van die suigings – proses mag wees, en deur die projek wil ons probeer om die nuwe – effekte te voorkom. Ons wil graag hiermee u toestemming vra om die druk binne u kind se bors te meet voor en na sy / haar lugweë skoongesuig word. Hierdie proses word soos volg uitgevoer: die lugpyp word eenvoudig aan 'n drukmonitor gekoppel. Dit is heeltemal gemaklik vir die kind en sal glad nie die asemhaling beïnvloed nie. U kind sal roetine suigingsproses, soos uitgevoer deur die verpleegpersoneel, ondergaan. Sommige kinders sal ook 'n prosedure ondergaan wat die longe deur middel van 'n ballon – toestel 'n sekere druk vir 30 sekondes sal aangee, om die longe weer vol te maak.

Ons kan u verseker dat 'n besluit teen deelname aan die projek nie die kwaliteit van behandeling vir u kind in die intensiewe eenheid sal beïnvloed nie. Daar sal nie miskien enige voordeel vir u kind wees om in die projek deel te neem nie, maar u bydrae kan egter help om die daaglikse versorging van pasiënte in die toekoms te verbeter. U baba se naam sal glad nie in enige publikasies, wat as gevolg van die projek geskryf is, verskyn nie.

Baie dankie

Ek, _____ (volnaam), die ouer / voog van _____ (kind se naam), woonagtig by (huisadres) _____

Verleen hiermee toestemming dat my kind aan bogenoemde projek kan deelneem. Ek verklaar dat ek die proses en die doel daarvan ten volle verstaan.

Handtekening: _____

Navorsers (naam en handtekening): _____

Getuie(naam en handtekening): _____

Datum: _____

IMVUME YOTHATHO NXAXHEBA KUPHANDO OLUZAKUQHUTYWA

ISIHLOKO SENQUBO:uphando ngokuchaphazeleka kwemiphunga emva kokusetyenziswa kwezifunxi ezithi zisetyenziswe kumbiza kubantwana abancediswa ukuphemfumla ngezixhobo zokubaphefumlisa

INTLOKO YOPHANDO:Ngu B.MORROW: (021) 658 5111 bleep 4100)
UMNCEDISI: Ngu DR A .Argent noDR Futter

INKCAZO NGENQUBO YOPHANDO.

Umntwana wakho ngoku uncediswa ngesixhobo esizakuthi simncedise ekuphefumleni de abe uyakwazi ukuziphefumlela .Ngefilixa lombojana uhla ngoqhoqhoqho ukuya emiphungeni ,umntwana wakho ufuna ukufunxwa rhoqo kulo mbobo ukuze ungaminxani luxakaxa, nokwenzela lombobo uhlale uvulekile.

Siqhuba uphando ukuzama ukunciphisa ingxaki ezithi zize nokukufunxwa .Ngoko sicela imvume yakho yokuba sivavanye ukusebenza kwemiphunga yomntwana wakho phambi na nasemva kokufunxwa kwakhe.Lento iyakuthi yenziwe ngokuthi kudityaniswe lombojana ukuqhoqhoqho wakhe nesixhobo esakuthi simncedise ngokubonisa utshintsho kuxinzelelo lomoya kwemiphunga yakhe.Esishxhobo asizukuphazamisana nokuphemfumla kwakhe.Umntwana wakho uzakufunxa njengesiqhelo ngumongikazi .

Iqela labantwana eliyakuthi likhethwe kolu phando emva kokuba lugqityiwe ukufunxwa luyakwenziwa oku kulandelayo:

Intloko yophando iyakudibanisa isingxotyana esinomoya esiyakuthi sikhuphele isixa somoya othile kwi- miphunga yomntwana. Esi sixhobo sona sibonisa ukusebenza kwemiphunga yomntwana siyakuqhuba kangangesiqingatha seyure (30minutes) ukuvula imiphunga yomntwana.

Ukuba uzive ungenakunizela ngomntwana wakho kolu phando lonto ayizukuchaphazela unyango kwanokukhathaleleka kwakhe ewodini .Igalelo lakho liyakunceda ekuphuculeni nasekukhuphuleni izinga lonyango.

Nakwixa elizayo.

ENKOSI.

Mna(Igama).....umzali/umgcini ka
(igama lomntwana).....

Idilesi.....
.....
.....
.....

Ndinika ivume ngomntwana wam ukuba athathe inxaxheba yewadi koluphando lukhankanywe ngentla olu njongo zalo nobume balo lucaciswe ngokupheleleyo kum.

Sayina.....

Umphandi.....

Inqina.....

APPENDIX E

EQUIPMENT

1. Electrocardiological and pulse oximetry monitor (Marquettehellige Eagle 3000 patient monitor, MILW, WI, U.S.A.; Ohmeda Biox Pulse Oximeter, Crest Healthcare, R.S.A).
2. "Trachi" suction catheters (EMS-Ven Medical Products, R.S.A)
3. Mucus extractor (EMS – Ven Medical products, R.S.A)
4. Newport Ventilators model E100m, Newport Medical Instruments, Inc. USA
5. BIRD[®] Mark 5 ventilator (Bird Products, Palm Springs, California)
6. Newport Ventilators models E100i and E100m (Newport Medical Instruments, Inc. USA)
7. HFOV (SensorMedics Model 3100A Oscillatory Ventilator, © 1996, California, USA).
8. ETT (Portex, R.S.A)
9. Tracheostomy (Shiley, U.S.A).
10. *Tegaderm* transparent dressing (3M Health Care, USA)
11. *Prestik* (an oil – based polybutene sealant, Genkem (Pty) Ltd under license from Bostik Ltd, England).
12. Wall mounted suction apparatus (Gabler Instruments, R.S.A),
13. Ohaus[®] Analytical Standard AS 200 Electronic Scale
14. CO₂SMO Plus! Model 8000 Respiratory Profile Monitor (Novamatrix Medical Systems Inc. USA)
15. CO₂ / flow sensor (Novamatrix Medical Systems Inc. USA),
16. *Analysis Plus* for Windows Version 5.0 (Novamatrix Medical Systems Inc, USA).
17. *Statistica* for Windows release 5.1 Statsoft Inc
18. *Statistica* for Windows, Kernel Release 5.5, StatSoft Inc, USA
19. *Statistica* (Kernel Release 6.1, StatSoft Inc 1984 – 2003)
20. Word processing by *MS @ Word* 2000, Microsoft Corporation

