# Experiences of patients who have undergone bronchoscopy with 'cautious' sedation and analgesia


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# Declaration

This thesis contains no material published elsewhere or extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma.

No parts of this thesis have been submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person's work has been used without due acknowledgement in the main text of the thesis.

All research procedures reported in the thesis received the approval of the relevant Ethics/Safety Committees (where required).

I regularly gained assistance from my supervisors, Professor Paul Fulbrook, Professor Kwun Fong and Associate Professor Chantal Ski. Initial proofing was conducted by Maria McDade and final proofing was conducted by Dr Gaye Wilson. All remaining errors are my own.

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# Outputs from this thesis

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# Abstract

## Background

Bronchoscopy is a procedure that is used to investigate and treat respiratory conditions and disease. Sedation and analgesia are administered during the procedure to reduce the side effects of discomfort and cough. The use of sedation and analgesia is cautioned in patients with chronic obstructive pulmonary disease (a high-risk respiratory disease), due to the perceived increased risk of complications. A review of the associated literature examining adult patients' experiences during flexible bronchoscopy found no qualitative articles on the subject. Due to the numerous quantitative survey-based studies, a significant gap in the literature was identified; that of the patient experience during bronchoscopy.

## Aim

The overarching aim of this research was to investigate the experiences of patients undergoing bronchoscopy with sedation and analgesia. This investigation was conducted in two parts: i) a systematic review of the associated literature and ii) a qualitative study involving patients with high-risk respiratory disease. The aim of the systematic review of patient experiences during bronchoscopy with sedation and analgesia was to provide a synthesis of current information on the subject, highlight best practices in the field, and identify gaps in the literature. A qualitative study was then conducted to investigate patients' experiences during bronchoscopy with 'cautious' sedation and analgesia. The aim of this study was to understand the lived experience of patients with high-risk respiratory disease who have undergone bronchoscopy.

## Methods

A systematic literature review, based on Cochrane methodology, was undertaken to identify randomised controlled trials involving adult patients who had undergone fibreoptic bronchoscopy with or without sedation. Eight databases were searched (CINAHL, MEDLINE Complete, Cochrane, PubMed, Web of Science, EMBASE, PsycINFO, and Scopus. Two reviewers independently screened titles and abstracts of the resultant database searches. Studies were excluded if they did not include outcome measures that assessed the patient experience of the procedure. After screening was completed, two independent reviewers then assessed the included studies for quality and extracted the relevant data. Any discrepancies between reviewers were then assessed by a third independent reviewer.

The qualitative interview study was performed using a phenomenological approach, based on the descriptive and interpretive writings of van Manen (1990, 1997). Participants (n = 13) were interviewed twice using unstructured interviews; the first, two hours post-procedure and the second, 1–7 days post-procedure. Interviews were transcribed and then analysed using hermeneutic phenomenological reflection (van Manen, 1990). The principal intention of hermeneutic phenomenological research is to uncover, examine and reflect upon the lived experience.

## Results

The systematic review identified 19 studies for inclusion. Cochrane's risk-of-bias tool was implemented to identify evidence-based methodological features that are known to increase the risk of bias in trials. In a number of studies, assessing for risk of bias was problematic due to the number of unclear descriptions of the study methodology, particularly in aspects of sequence generation, allocation concealment, and blinding. It

should be noted that blinding was not always an option, due to physical differences of interventions for treatment and control arms of the included studies. Further, selective outcome reporting bias was indeterminable as study protocols were rarely available. Self-reported patient outcomes included pain, comfort, cough, satisfaction, memory of the test, breathlessness, asphyxiation, fear, distress, global tolerance, nausea, dreaming, secretions, worst moment of the experience, and willingness to repeat the procedure. Data from five studies were published with limited findings represented in bar graphs, and only one study author responded to requests for further data. In all studies, data were collected via survey using closed-ended questions. Patients were mostly asked to rate outcomes of the procedure on various scales, otherwise they were asked dichotomous questions (yes/no responses) to determine the existence of any procedural outcomes. Results were published as means (with standard deviations) or median scores with or without score ranges.

In the interview study, themes were identified that included fears such as the participants may have lung cancer or the procedure would be distressing. Some participants were fully aware during the procedure, which included negative experiences of choking and coughing. For several, this was quite traumatic. Some participants were unaware during the procedure. Post-procedure participants commonly reported experiences of sore throat, cough and aggravation of asthma. However, most participants accepted the negative aspects of their experience, regarding them as a necessary evil in order to obtain a diagnosis for their respiratory condition. The care and expertise of the bronchoscopy staff, as perceived by the participants, helped to offset some of their fears.

# Conclusions

The eligible studies in the literature review showed that the risk of bias was more likely to be low in most areas except selective outcome reporting. The risk of bias was more likely to be unclear in relation to selective outcome reporting due to the general lack of published study protocols. Overall, when comparing the participants' experiences of pain, coughing and willingness to repeat the procedure, the studies identified that greater amounts of sedation and/or analgesia resulted in subjects reporting fewer negative outcomes. A meta-analysis was not conducted due to the heterogeneity between studies, namely the varied manner in which results were published and the lack of consistency of the outcome measures that were reported.

The qualitative interview study showed that many participants who underwent bronchoscopy with cautious sedation experienced awareness during the procedure. Whilst the degree of participants' awareness was variable, more often than not awareness resulted in a negative patient experience. This was, for the most part, due to the discomfort of the procedure and to the participants' contextual fears and concerns about their diagnosis. A number of recommendations have been made to help manage the patient experience. The use of effective communication strategies by healthcare workers throughout the peri-bronchoscopy procedure could elicit patient fears and aid in resolving these fears. Provision of educational material that informs the patient about what to expect from the procedure and how it might make them feel may reduce their fears of the procedure as hurtful. In addition, medical management of common patient experiences may reduce the extent of these experiences. In conclusion, although the use of deeper sedation might ameliorate

much of the negative patient experience, this must always be balanced against their risk of respiratory complications.

# Chapter One: Introduction

## 1.1 Overview

The purpose of Chapter One is to provide a rationale for this research that investigates the patient experience of bronchoscopy with sedation and analgesia. It begins with a brief overview of the bronchoscopy procedure and the administration of sedation before focusing on the burden of this condition from the patient perspective. The discussion focuses on an ethical opinion of authority. An overview of the literature examining patient experience is presented and significant gaps identified. The Chapter concludes with the research study aim, objectives, questions, and organisation of this thesis.

## 1.2 Delineation of bronchoscopy

Bronchoscopy is an established diagnostic and interventional procedure for investigation and treatment of respiratory conditions and disease. A bronchoscopy enables inspection of the lungs via a bronchoscope passed through the nose or mouth into the large airways. It also enables the passage of instruments for inspection, sampling and treatments of the small airways and surrounding tissue of the lungs.

## 1.3 Purpose of bronchoscopy

Generally, the purpose of bronchoscopy is to either diagnose (diagnostic bronchoscopy) or treat (therapeutic bronchoscopy) a respiratory condition. Common indications of respiratory conditions are abnormal respiratory symptoms and/or abnormal chest radiology. Abnormal respiratory symptoms include: haemoptysis, persistent cough, dyspnoea, stridor, chest pain, localized wheeze, persistent chest infection, persistent pneumothorax and hoarse voice (Kaparianos, Argyropoulou, Sampsonas, Zania, Efremidis & Spiropoulos, 2008; Saxon, 2012).

Abnormal chest radiography includes abnormal lung tissue, enlarged mediastinal nodes, collapsed airways and collapsed lungs. The aim of diagnostic bronchoscopy is to diagnose respiratory conditions and determine appropriate treatment. This is enabled by the visual inspection of the lungs and collection of abnormal tissue from large airways, mediastinum and lung peripheries. The aim of therapeutic bronchoscopy is to improve patient morbidity in relation to their respiratory condition. Therapeutic bronchoscopy can provide a pulmonary toilet (when the patient has a persistent infection), remove foreign bodies, debulk tumours, control bleeding, dilate strictures, facilitate insertion of stents for collapsed airways, provide a reduction of excessive lung volume in patients with emphysema and reduce increased airway muscularity in patients with uncontrolled asthma (Pagana et al., 2017; Saxon, 2012).

## 1.4 Contextualization of bronchoscopy patient populations

Populations of patients who have bronchoscopy differ between various countries and studies. Data collected regarding patient characteristics also varies between studies, however most studies collect data regarding patient age and gender. A Spanish study collected data from 152 patients of which the mean age was 51.9 years and the percentage of male participants was 30.9%. In a Swedish study by Grendelmeir et al. (2014) the mean age of their 702 patients was 61.5 years and the percentage of males was 57.5%. In a Portuguese study by Rolo et al. (2012) the mean age was 56 years and percentage of male patients was 66%. According to these studies the age of patients undergoing bronchoscopy is trending at over 50 years of age. There does not appear to be a gender trend of more or less male patients having the procedure compared to female patients.

Some studies have collected data regarding patient indications for the procedure. A longitudinal study conducted over 5 years in Greece examined patient indications for bronchoscopy in 4,098 cases (Kaparianos et al., 2008). They found that 92% were for diagnostic purposes and 8% were performed for therapeutic purposes. They identified four common indications for bronchoscopy: haemoptysis (21.1%), fever (19.1%), chronic cough (18.2%) and abnormal radiological findings (13.9%). Suspicion of lung cancer was not one of the indications listed for bronchoscopy. Signs of lung cancer include: haemoptysis, cough and abnormal radiological findings (Cancer Australia, 2012). On their cohort, Grendelmeir et al. (2014) found that the indications for bronchoscopy from their patients were suspicions of malignancy (25.1%), interstitial lung disease (10.7%), infection (33.8%), chronic cough (3.7%), haemoptysis (2.1%), bronchial toilet (10.0%), stenting (2.7%), laser therapy (1.1%) and miscellaneous (10.4%). Yoon et al. (2010) conducted a smaller study of 64 patients having bronchoscopy in Scandinavia. In their study, the indications for bronchoscopy were tumour diagnosis (60.0%), Infection (29.68%), haemoptysis (0.03%) and other (0.1%). It is difficult to compare the data collected from these different studies but there appears to be a trend towards the following indications: tumour diagnosis, infection, cough and haemoptysis.

Some studies have also collected data regarding patient co-morbidities. Grendelmeir et al. (2014) collected data relating to 14 patient comorbidities ranging from COPD to intravenous drug use. The five most common patient comorbidities were solid malignant tumour (41.5%), chronic obstructive pulmonary disease (33.6%), Immunosuppression (28.5%), coronary artery disease (13.8%) and haematological disease (13.8%). Schlatter et al. (2011) collected data from 300 patients regarding 7 possible comorbidities. The five most common comorbidities of patients were malignancy (29.7%), immunosuppression (16.7%), COPD

(16.3%), diabetes (6.3%) and alcoholism (3.7%). Common co-morbidities between the studies were malignancy, immunosuppression and COPD.

## 1.5 Procedural description

Bronchoscopy is often conducted in a specialised suite within a day surgery unit, within a theatre, in an endoscopy unit or an intensive care unit. The patient is usually given a topical anaesthetic spray to numb the upper airway and sedation to improve comfort. The thin tube of the bronchoscopy is then inserted into the airway via the nose or mouth. This often leads to the patient coughing, which is addressed by applying more anaesthetic to the patient's vocal cords and throughout the lungs as the bronchoscope passes further into the airways. Visual inspection of the airways ceases after inspection of the entrance to each lung lobe and the entrances to each lobe segment. If inspection of the mediastinum or peripheral areas of the lungs is required, then an ultrasound bronchoscope or ultrasound probe can assist in visualisation of the abnormal tissue. Various instruments, including the ultrasound probe, can be inserted through the bronchoscope to aid in the collection of specimens or treatment of the lungs. The procedure is usually performed within 30 to 45 minutes (Pagana et.al., 2017). The length of the procedure is often extended to 60 minutes in the research candidate's centre of practice if it requires the use of ultrasound during bronchoscopy. Patients are generally observed after bronchoscopy for at least one hour, after which time the patient will usually have recovered from the sedation and oral anaesthetic (AFT Pharmaceuticals, 2015; Apotex, 2014; Generic Health, 2014). Recovery from the sedation administered during bronchoscopy is dependent on type of sedation administered (Clark et al., 2009). Clark et al. (2009) found that propofol was superior to midazolam in shortening

recovery time. They found that within 10 minutes of the procedure 90% of the patients in the propofol group were alert compared to 50% of the patients from the midazolam group.

## 1.6 Bronchoscopy (with or without sedation)

Typically, during a bronchoscopy, a physician administers sedation and/or analgesia to relieve the common procedural side effects of discomfort and cough (Gasparini, 2011). Variations in patient tolerance of the procedure have been observed when different sedative agents are administered; specifically when stronger sedatives are used that require an anaesthetist for administration (Lo et al., 2011). Due to financial deficiencies and staff shortages, there may not be an anaesthetist present. This limits the use of stronger sedative agents (AFT Pharmaceuticals, 2015), which may improve patient tolerance of the procedure (Lo et al., 2011). Without the presence of an anaesthetist, the role of managing a patient's airway becomes the responsibility of a nurse. The nurse supports the patient airway, titrates oxygen administration, and works as the patient advocate. As the patient advocate, the nurse informs the physician of the patient's level of sedation and tolerance of the procedure. Patient advocacy is a nursing duty according to various nursing codes of ethics (International Council of Nurses, 2012; Nursing and Midwifery Board of Australia, 2008). As a patient advocate, the nurse is required to protect their patients' physical, psychological and emotional wellbeing (Nursing and Midwifery Board of Australia, 2008). A patient advocate is essential for the procedural patient, as the patients are sedated and their mouths are obstructed by equipment, which results in an inability to voice their needs.

## 1.7 Procedural risk of bronchoscopy

Physicians are trained to act in the patient's best interest, and weigh the risks of the procedure against the benefits (Medical Board of Australia, 2014; Fifty-seventh World

Medical Assembly, 2006). The benefits of performing a bronchoscopy for the patient include collecting information that can be used to provide a diagnosis of their respiratory condition or disease; this information can then be employed to plan the most fitting, individualised health care. The risks associated with the bronchoscopy include hypoxaemia, cardiac arrhythmia, pneumothorax, bleeding, fever and infection (Du Rand et al., 2013). The bronchoscopy procedure can lead to hypoxia due to the administration of procedural sedation and/or analgesia (Apotex, 2014; Generic Health, 2014). Many physicians perceive the risk of hypoxaemia as greater when the patient has co-morbidities, such as chronic obstructive pulmonary disease (COPD), respiratory failure and/or they are elderly (Du Rand et al., 2013). Chronic obstructive pulmonary disease is characterised by a progressive irreversible decrease in lung volume (Harris et al., 2010). All of these co-morbidities are commonly associated with hypoxia. As a consequence, the British Thoracic Society guidelines for bronchoscopy (Du Rand et al., 2013) recommend giving sedation and analgesia 'cautiously'. However, the British Thoracic Society and the pharmaceutical drug companies do not specifically define cautious sedation and analgesia (Du Rand et al., 2013; AFT Pharmaceuticals, 2015; Apotex, 2014; Generic Health, 2014). A common sedative administered during bronchoscopy is midazolam (Du Rand et al., 2013), which is given to promote patient comfort during the procedure and provide a level of amnesia (Du Rand et al., 2013; Apotex, 2014). Several studies have demonstrated that physicians underestimate patients' discomfort during bronchoscopy (Hadzri et al., 2010; Putinati, Ballerin, Corbetta, Trevisani & Potena, 1999). This may occur in light of the amnesic effect of midazolam whereby physicians assume that a patient will not remember the procedure.

Nursing staff from the research candidate's centre of practice who have acted as the patient advocate during bronchoscopies with 'cautious' sedation and analgesia have reported that

some patients' behaviour was symptomatic of suffering. Anecdotally, nurses perceived patients as suffering when they repeatedly coughed, gagged and/or attempted to remove the bronchoscope before the procedure was completed. When this occurred, nurses intervened by comforting the patient and talking them through the procedure.

There has been no study in the research candidate's centre of practice regarding the prevalence of this patient behaviour and/or the burden of this behaviour on the patient or health care centre. Within the current literature, it has been reported that physician- and patient-reported tolerance of the procedure increased with sedation (Cases Viedma et al., 2010; Contoli et al., 2013). It has also been found that physicians may underestimate patient discomfort during the procedure (Palayew et al., 2004). In regards to burden of this behaviour, Cases Viedma et al. (2010) found that the sedation shortens length of the procedure and Contoli et al. (2013) found that the absence of sedation did not increase the diagnostic yield from the procedure.

Berglund, Westin, Svanström & Sundler (2012) found that patients experienced suffering in health care when their feelings were ignored, resulting in feelings of vulnerability and powerlessness. At the research candidate's centre of practice, nurses' observations of patients during bronchoscopy with cautious sedation and analgesia has raised a number of questions. Key questions included: Do the patients feel that their feelings during the procedure are ignored by the staff; if patients were under sedation during a bronchoscopy, were their coughing, gagging and attempts to remove the bronchoscope conscious or unconscious behaviour; could the patients recall their behaviour following the procedure; and what impact did this behaviour have on the patients following the procedure?

## 1.8 Ethical opinion of authority

In a discussion paper concerning bronchoscopy and sedation (Gasparini, 2011), it was suggested that patients should undergo this procedure without discomfort. Gasparini (2011) summarised several studies that had trialled variations in drugs commonly administered during bronchoscopy. In the study by Clark et al. (2009) patients reported that propofol provided increased rates of patient tolerance, and reduced rates of pain, breathlessness and nausea during the procedure when the sedative was compared to midazolam. However, propofol manufacturers recommend that it should only be administered by an anaesthetist due to the associated risks of respiratory depression (AFT Pharmaceuticals, 2015), which may cause hypoxia. This can be problematic in many endoscopy settings where procedures are conducted without an anaesthetist present, such as the research candidate's centre of practice.

## 1.9 Evidence of patient experience in bronchoscopy

Wolf, Niederhauser, Marshburn & LaVela (2014) provided a 14-year synthesis of existing literature used to define patient experience. Their literature review found 18 sources with no common definition for patient experience in health care. The various definitions were based on similar elements: interaction, culture, perception and continuum of care. As the basis of their enquiry into a definition for patient experience, Wolf et al. (2014) acknowledged and used The Beryl Institute's website's (n.d.) current definition for patient experience:

> *The sum of all interactions, shaped by an organization's culture, that influence patient perceptions across the continuum of care.*

Based on this definition, a search of the literature found several studies that measured patient perceptions of their experience during bronchoscopy with sedation and/or analgesia (Contoli et al., 2013; Palayew et al., 2004; Rolo et al., 2011). Patient perceptions were measured by asking each patient to evaluate specific outcomes of their interaction with the medication, equipment, staff and procedure (Bernascoi et al., 2009). However, the study outcomes and scales used to measure these outcomes varied between the different studies.

Hong, Choi, Park & Park (2015) performed a systematic review of randomised controlled trials that assessed the efficiency and safety of moderate sedation during flexible bronchoscopic procedures. The main aim of the review was to examine the efficiency of bronchoscopy under moderate sedation. Efficiency was measured by comparing patient willingness to repeat the procedure, procedure time, and patient experiences of pain and cough. The willingness of the subjects to repeat the procedure was examined in six studies, the data were pooled and it was found that sedated patients were significantly more willing to repeat the procedure than those who were not sedated ($p = 0.02$). Hong et al. (2015) pooled data from 3 studies that measured the length of the procedure when the patient received midazolam compared to when they received a placebo; length of the procedure was shorter when the patient received midazolam as sedation ($p = 0.02$). In three studies, where patients were given sedation or a placebo, the subjects self-reported their experiences of pain and cough, in two of these studies the subjects' experiences of pain ($p < 0.01$, $p < 0.001$) and cough ($p < 0.05$, $p < 0.001$) were significantly reduced in the sedated group. The third study used a different scale to measure patient experience of pain and cough so the results were not pooled for a meta-analysis (Hong et al., 2015).

Other patient experiences measured during bronchoscopy not included in the systematic review by Hong et al. (2015) were amnesia, distress, anxiety, breathlessness and choking (Cases Viedma, Pérez Pallarés, García, Reyes, Moret & Aldás, 2010; Gonzalez, De-La-Rosa-Ramirez, Maldonado-Hernandez & Dominguez-Cherit, 2003; Rolo et al., 2012). Summarising other self-reported patient experiences during bronchoscopy in a literature review may provide health care workers with more insight regarding patient experience. In addition, Hong et al. (2015) compared patient experience in bronchoscopy with sedation versus placebo; a systematic review that compared different sedative drugs would provide more evidence for best practice.

To date, no qualitative studies have explored the patient experience in bronchoscopy with sedation and analgesia. Using qualitative methodology, the data are collected from the person who has first-hand experience of the phenomenon, in this case bronchoscopy (Chandler & Munday, 2011). Furthermore, the person's own reflections or perceptions of their experience of a phenomenon have been described as their 'lived experience' (Chandler & Munday, 2011). It was determined that a qualitative exploration of patients' 'lived experience' during bronchoscopy under sedation and analgesia may: i) identify how coughing, distress and choking can affect a patient during the procedure; and ii) uncover unexpected problems that could be ameliorated with appropriately planned health care.

## 1.10 Overall research question, aims and objectives

The research question to be addressed is:

What is the patient experience of bronchoscopy with sedation and analgesia, particularly those with high-risk respiratory problems that require 'cautious' sedation and analgesia?

The aim of this research was two-fold:

i) to identify the patient experience during bronchoscopy with sedation and analgesia and

ii) to provide recommendations to inform best practice.

The specific objectives are to:

- review current literature regarding patient experience in bronchoscopy to identify gaps and best practice;
- explore the lived experience of patients with high-risk respiratory disease that undergo bronchoscopy with 'cautious' administration of sedation and analgesia;
- recommend risk management procedures to manage the negative patient experience that may occur during bronchoscopy with cautious sedation and analgesia;
- provide recommendations for the development of pre-procedural educational material; and
- provide recommendations for the development of an assessment tool to measure patient tolerance/satisfaction during bronchoscopy.

## 1.11 Organisation of the thesis

This master's thesis explores the patient experience of bronchoscopy. Chapter Two reviews, collates and synthesises the associated literature on this subject. Chapter Three explores patients' perception of their experience in bronchoscopy within the context of a qualitative research study. In Chapter Four, the study discussion and conclusions are presented, providing insights into patient experience and recommendations for patient care and future

research. Appendix 1 contains a protocol for a systematic review on the subject of patient experience in bronchoscopy.

# Chapter Two: Literature Review

## 2.1 Overview

The purpose of Chapter Two is to explore the literature relating to patients' experience of bronchoscopy. Components of this chapter include a rationale of why this topic was chosen, the research question and objectives, the methods based on Cochrane systematic review methodology, findings of the review, a synthesis of the findings and the conclusion.

## 2.2 Introduction

On investigation of the literature relating to patient experience in bronchoscopy, no qualitative studies were found that explored the patient experience whilst undergoing bronchoscopy. The literature search was expanded to include quantitative studies on the subject. It was found that many countries reviewed quantitative studies on the subject and then formulated national guidelines for patient management in bronchoscopy (Du Rand, et al., 2013; Shulimzon, 2010; Wahidi et al., 2011; Wood-Baker, Burdon, McGregor, Robinson & Seal, 2001). Within these guidelines, a common theme relating to patient experience was found: bronchoscopy is an uncomfortable procedure without sedation and/or analgesia. The foundation of this theme was based on several randomised controlled trials, which concluded that patients' comfort was improved with sedation and/or analgesia (Gonzalez et al., 2003; Putinati et al., 1999; Stolz, et al., 2004). In these trials, patients were asked to measure various aspects of their experience, which included amnesia, tolerance, pain, cough, choking, and willingness to repeat the procedure. To ensure a rigorous search of the literature, Cochrane methodology (Higgins & Green, 2011) was followed, and a literature review question, aims and objectives were formulated.

## 2.3 Research question, aims and objectives

The aim of this literature review was to explore the experiences of adult patients undergoing bronchoscopy. The research question for this literature review was framed so that the data collected could be generalised to the research candidate's institution of practice (adult patients undergoing fibreoptic bronchoscopy with various types and levels of sedation) and therefore be used in ongoing development of evidence-based nursing care. The research question was formulated using an evidence-based medicine process: population, intervention, comparison, outcome, study design (PICOS). PICOS is a systematic method of framing a research question to most accurately define the clinical problem (Liberati et al., 2009). The components of the acronym PICOS and their application are illustrated in Table 1.

**Table 1: Components of PICOS**

| Components | Description | Application |
|---|---|---|
| Patients | Patients involved in the clinical problem | Adult patients undergoing flexible bronchoscopy |
| Interventions | Interventions that can be used to ameliorate this problem | Randomised procedural sedative administration |
| Comparison | Additional interventions that can be compared to reduce the problem | Sedative +/- pre-medication or placebo |
| Outcome | Scales or tools that provide evidence that the problem has been minimised | Patient experience/satisfaction |
| Study design | Study design chosen | Randomised controlled trials |

With this in mind the research question was defined as:

*What is the adult patient experience of flexible bronchoscopy with sedation and/or analgesia using evidence from randomised controlled trials?*

The endpoint of this review was to promote best practice, and/or identify gaps in the current literature. Therefore the objectives for this literature review were to:

- identify data relating to patient experience during bronchoscopy with sedation and analgesia
- provide a synthesis of the data collected, highlighting data relating to best practice and any gaps in the current evidence.

## 2.4 Methods

The methodology used to conduct the review was based on recommendations from Cochrane (Higgins & Green, 2011), which includes problem identification, literature search, data evaluation, data analysis, data reduction, comparison, conclusions and presentation.

On completion of the review of the associated literature, no studies were found that focused specifically on the patient's experience of bronchoscopy. There were, however, over 500 studies relating to the subject of bronchoscopy and patient satisfaction. In these studies, patients were asked to rate their perceptions of different aspects of their procedure. Often these studies asked patients whether they were bothered or not by various aspects of the procedure, including anaesthetic spray, scope insertion, shortness of breath, and physician manner and skill (Hirose et al., 2008; Lechtzin, Rubin, White, Jenckes & Diette, 2002). Thus, this information was extracted to identify the 'patient experience'. To promote rigour and a high level of evidence, the literature review used a systematic method (Higgins & Green, 2011) to review randomised controlled trials that measured outcomes relating to patient experience in bronchoscopy. The review was registered with the Prospero International prospective register of systematic reviews as 'a systematic review of adult patients' experiences during flexible bronchoscopy with placebos and/or various pharmaceutical agents' (publication: CRD42016037583; see Appendix 1).

### 2.4.1 Data sources

Studies were identified using the databases CINAHL, MEDLINE Complete, Cochrane, PubMed, Web of Science, EMBASE, PsycINFO and Scopus. The search terms included the population (adult patients undergoing flexible bronchoscopy by either oral or nasal route),

intervention (randomised procedural sedative administration) and possible comparators (usual care/placebo vs other sedatives and/or analgesics). See the search terms below:

> *Bronchoscopy AND (fentanyl OR dormicam OR hypnovel OR flunitrazepam OR benzodiazepine OR lignocaine OR dextromethorphan OR midazolam OR lidocaine OR prilocaine OR lorazepam OR "nitrous oxide" OR ketamine OR alfetanil OR fospropofol OR disodium OR alfentanil OR propofol OR dexmedetomidine OR remifentanil OR hypnotics OR sedatives OR sedation OR hypnotics OR conscious sedation)*

The search was restricted to English language publications, as there was no funding for translation of non-English language publications. The references were uploaded to the Covidence website (https://www.covidence.org/), which is the primary screening and data extraction tool for the Cochrane Community (2017). It enabled two authors to independently screen study titles and abstracts (Saxon and Fong) and another researcher to resolve discrepancies (Ski). The full texts of the remaining studies after the initial screen were then uploaded to the Covidence website so that two authors (Saxon and Fulbrook) could independently select studies that met the literature review criteria. The discrepancies from the full-text screening were then resolved through discussion between two researchers.

### 2.4.2 Study selection/screening

The study selection criteria were based on each study's method, population, comparators, setting, outcome measures and age. Only studies that presented as randomised controlled trials were selected. The populations of these studies included only adult patients

undergoing flexible bronchoscopy by either oral or nasal approach. Studies with the following patient populations were excluded: patients undergoing rigid bronchoscopy, children, non-humans, ventilated patients, non-invasive ventilation patients, spinal injury patients, and patients with cognitive impairment. The comparators included usual care/placebo versus other sedatives/sedative + other pharmaceutical agents +/- premedication. Possible sedatives and analgesia included fentanyl, dormicam, hypnovel, flunitrazepam, benzodiazepine, midazolam, lorazepam, nitrous oxide, ketamine, alfetanil, fospropofol disodium, alfentanil, propofol, dexmedetomidine, remifentanil. The selected settings were day surgery units, hospital procedure rooms or theatres. All studies conducted in intensive care units were excluded. Studies were required to include outcomes that involved patients' self-reports of their experience of bronchoscopy, for example comfort, cough, pain, anxiety, distress and/or fear. An acceptable reported secondary outcome was willingness to repeat the procedure. These outcomes were measured with visual analogue scales/ Likert scales or yes/no answers on surveys. The measures were assessed post-procedure, when the patient was fully awake.

The age of the study was restricted to those published after 2001. In 2001, the British Thoracic Society was the first to introduce guidelines related to the use of sedation during bronchoscopy (British Thoracic Society Bronchoscopy Guidelines Committee, 2001). These guidelines recommend that sedation should be offered to patients to improve their comfort and tolerance of the procedure, if there are no contraindications. The guidelines also recommend that sedation should be administered in incremental doses to prevent complications whilst promoting adequate sedation and amnesia. These guidelines are used in the research candidate's place of practice.

### 2.4.3 Data extraction

Within the Covidence online software, two authors independently extracted data from the included studies. The data extracted were study method quality, population, interventions and data from outcomes. Covidence uses the Cochrane risk-of-bias tool to establish the quality of study methods used to perform the randomised controlled trial. Each study method was judged as high/low or unclear in relation to randomisation, concealment, blinding, completeness of data collected, any incidence of selective outcome reporting, and other sources of bias.

### 2.4.4 Data analysis and synthesis

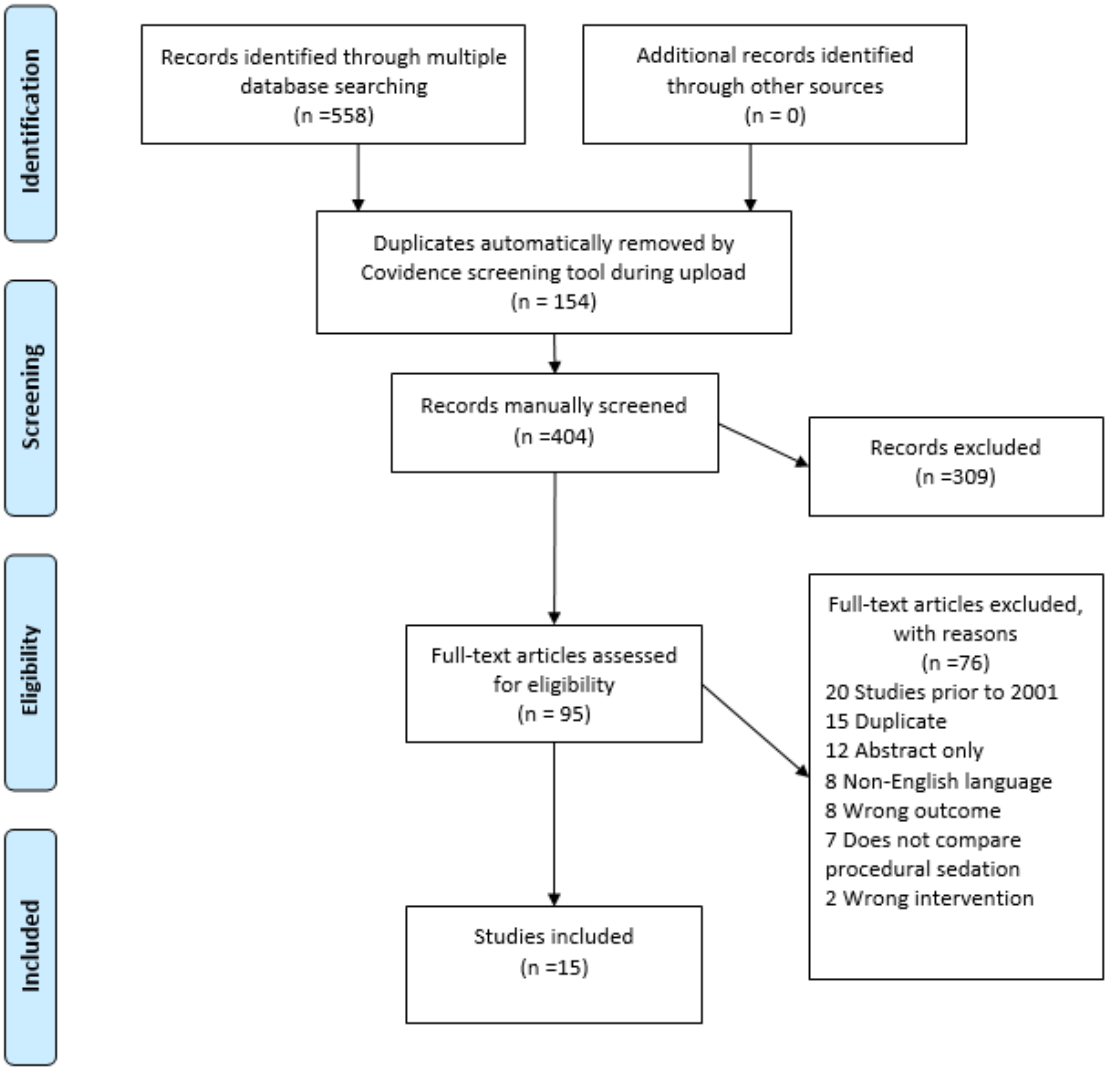
When meta-analysis of the patient-reported outcomes was considered, it was found that the retrieved studies were heterogenous in both the medications they compared and the outcomes that were measured. Due to the heterogenous nature of the selected studies, it was not appropriate to pool data for a meta-analysis. Thus, a narrative synthesis of the outcome data was conducted, to expose statistical differences between comparative populations in each study.

## 2.5 Results

The initial literature search identified 558 studies. No further studies were identified through other sources. After the initial literature search, the studies were uploaded using the Covidence™ online software. Fifty four duplicates were subsequently identified. The remaining titles and abstracts were then screened for relevance. Three hundred and nine studies were excluded because they did not meet the selection criteria. The full texts of 95 studies were then screened. A further 76 studies were excluded as they were published

prior to 2001, were a duplicate, were not a full study report, were not published in English, or used incompatible methods; in particular: outcomes did not include self-reported patient experience; comparators did not include a sedative; study was not randomised; or the sample was not adult or human.. The PRISMA diagram in Figure 1 shows the flow of studies through the study selection process.

**Figure 1: A review of adult patients' experiences during flexible bronchoscopy with placebos and/or various pharmaceutical agents PRISMA 2009 Flow Diagram**




*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

The studies included in the anaylsis (n = 15), were conducted in a variety of countries from Brazil to United Kingdom, and across a range of facilities including single or multiple centres, endoscopy units, hospitals, main operating theatres, and bronchoscopy suites. Sample sizes ranged from 18 to 702 participants. The mean age of patients ranged from 40 to 81 years. There were generally greater numbers of males than female subjects in all but two of the studies. Indications for the procedure were documented in nine studies; common indications were infection, suspected malignancy, staging of lung cancer, endobronchial obstruction, haemoptysis and chronic cough. Patient co-morbidities were identified in six studies, the data collected varied between studies and included the incidence of COPD, cardiovascular disease, diabetes, liver disease, tuberculosis, aquired immune deficiency syndrome, alcohol and/or drug abuse. All studies were randomised controlled trials with adult subjects. The pharmaceutical intervention was varied across the studies (see Table 2).

**Table 2: Systematic review study characteristics**

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range);Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Atassi et al. 2005 | France | Lung Disease Department of a tertiary care hospital | RCT (parallel group) | Patients who required FB for diagnostic purposes including BAL or bronchial biopsies | Intervention (n = 103): mean age 55.0 (13.4); sex M/F 80/23; weight (ns)Control (n =103): mean age 53.5 (14.2); sex M/F 72/31; weight (ns) | Nitrous oxide | Nitrogen and oxygen mixture | Pain, nasal pain, cough, willingness to undergo another procedure | When comparing participant rating levels of pain and cough, the Nitrous oxide was more favourable. There was no significant difference in willingness to repeat between the groups | |
| Cases Viedma 2010 | Spain | Endoscopy Unit of the Pneumology Department of La Fe University Hospital | RCT (parallel group) | Patients who underwent a fibrobronchos-copy at the Endoscopy Unit classified as having an American Society of Anaesthesiology risk I–III | Intervention (n = 79) Age 53.9 (15.5); sex M/F 25/54; weight (ns)Control (n =73): Age 59.6 (13.4); sex M/F 22/51; weight (ns) | Midazolam for sedation (0.07-1.0mg/kg) - n=79 | Placebo | Amnesia, distress, pain, cough, willingness to repeat procedure | When comparing amnesia, fear, pain, cough, breathlessness and willingness to repeat the procedure, the Midazolam group was more favourable | Patients in the placebo group were significantly older |
| Clark et al. 2009 | Switzer-land | Centre Valaisan de Pneumologie in Montana, Switzerland and at the University Hospitals of Geneva, Switzerland | RCT (parallel group) | Patients with an American Society of Anaesthesiology class of risk I–III | Intervention (n=43) Age 57.9 (11.4); sex M/F 27/ 27/16; weight 74.9 (15.6) Control (n=39) Age 55.2 (14.3); sex M/F 28/11 ; weight 71.6 (12.4 | propofol 135.1mg (n=43) | Midazolam 6.2mg (n=39) | Patient tolerance score, pain, nausea, breathlessness , cough | When comparing participant ratings of pain, breathless and nausea, the propofol group was significantly more favourable. There was no significant difference between the groups when evaluating global tolerance and cough | |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range);Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Contoli et al. 2013 | Italy | Bronchoscopy Unit, Respiratory Medicine, University Hospital | RCT (parallel group) | Patients who underwent diagnostic bronchoscopy for appropriate clinical indications | Intervention a. (n=33 )Age 58.6 (1.5); sex M/F 18/16; weight (ns) Intervention b. (n=33) Age 59.7 (1.7), sex M/F) 20/13; weight (ns) Control (n=34) Age 57.3 (1.8); sex M/F 19/14 ; weight (ns) | a. High dose Midazolam 0.07mg/kg b. Low dose Midazolam 0.35mg/Kg | Placebo | Patient tolerance score | When comparing patient tolerance ratings, for low dose Midazolam was comparable to the placebo, high dose Midazolam was comparable to low dose Midazolam but high dose Midazolam was significantly more favourable than those from the placebo | |
| de Padua 2004 | Brazil | Hospital / bronchoscopy suite | RCT (parallel group) | Patients undergoing routine diagnostic FOB | Intervention (n=20) Age 46.0 (18–71); sex M/F 15/5; weight (ns) Control (n=22) Age 50.5 (33–70); sex M/F 16/6; weight (ns) | Clonidine 3mcg/kg | Placebo | Comfort score | When comparing patient reporting of pain Clonidine was comparable to placebo | |
| Gonzalez et al. 2003 | Mexico | Department of Anaesthesia and Critical Care | RCT (parallel group) | Patients with clinical and roentgeno-graphic diagnosis of pneumonia, who underwent diagnostic FFB with broncho-alveolar lavage | Intervention (n=9) Age 40 (4); sex M/F 7/2; weight (ns) Control (n=9) Age 46 (5); sex M/F 6/3; weight (ns) | propofol 133mg | Placebo | Amnesia, pain, asphyxiation, cough, global tolerance of the procedure, willingness to repeat the procedure | When comparing participants ratings of amnesia, tolerance, pain, cough, choking and willingness to repeat procedure, the propofol group was significantly more favourable | More patients with AIDS in control group |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range);Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Grendelmeier et al. 2014 | Switzer-land | Bronchoscopy Suite | RCT (parallel group) | Consecutive patients who were to undergo bronchoscopy and met the selection criteria | Intervention (n=355)Age 61.2 (15); sex M/F 207/148 ; weight 71.5 (17.5) Control (n=347) Age 61.9 (14); sex M/F 197/150; weight 70.3 (17.7) | propofol bolus doses 226.6mg | propofol infusion 308.3mg | Cough, discomfort, anxiety, willingness to repeat the procedure | When comparing patient ratings of cough, discomfort, anxiety and willingness to repeat the procedure, there was no significant differences between the Proprofol bolus or infusion groups | There was a trend towards a higher number of patients with haematologic-al malignancy and hence immuno-suppression in the bolus group |
| Houghton et al. 2004 | UK | University Hospital | RCT (parallel group) | Patients requiring FB at a university hospital were recruited for the study | Intervention (n=29) Age (ns); sex (ns); weight (ns) Control (n=40) Age (ns); sex (ns); weight (ns) | Midazolam 4.2mg | Alfentanil 0.95mg | Discomfort, williness to repeat the procedure | When comparing participant ratings of cough, discomfort and willingness to repeat the procedure, there was no significant difference between Midazolam and Alfentanil groups | |
| Hwang et al. 2005 | South Korea | Hospital | RCT (parallel group) | Patients with an ASA of 1 or 2 who were undergoing elective fibreoptic bronchoscopy | Intervention (n=138) Age 58.3 (1.3); sex (ns); weight 60.6 (12.1) Control (n=138) Age 57.4 (12.7); sex (ns) weight 60.2 (11.1) | propofol 28.1mg/Keta-mine 14.0mg | propofol 28.2/Alfentanil 282mcg | Amnesia, dreaming, Satisfaction, Willingness to repeat the procedure | When comparing amnesia, dreaming and satisfaction, they were rated significantly greater in the propofol/keta-mine group but there was no significant difference in patient willingness to repeat the procedure | Two patients being over sedated in the PK group. However, both patients responded to commands within 2 min and no case had to be prematurely terminated because of over sedation |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range);Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Korteweg et al. 2004 | The Nether-lands | Endoscopy | RCT (parallel group) | Patients referred for diagnostic FFB | Intervention a (n=48) Age 65.7 (12.5); sex M/F 29/19 ; weight (ns) Intervention b (n=50) Age 67.1 (11.8); sex M/F 36/14; weight (ns) Intervention c (n=76) Age 62.2 (12.5); sex M/F 51/25 ; weight (ns) Control (n=84) Age 63.7 (13.7); sex M/F 58/26 ; weight (ns) | Intervention group a. Atropine 0.5mg /Codeine 20mg Intervention group b. Ipratropium bromide 0.5mg Intervention group c. Codeine 20mg | Placebo | Comfort | When comparing patients reporting of comfort and cough, there was no significance between the Codiene vs Ipratropium or Ipratropium bromide vs placebo or Codeine vs placebo. There were significantly ↓ratings for comfort and cough when Atropine / Codeine vs Codeine or Atropine / Codeine vs placebo | |
| Liao et al. 2012 | China | Intensive Care Unit of the Cancer Centre | RCT (parallel group) | Postoperative patients who had undergone thoracic surgery and had been referred for bronchoscopy | Intervention (n=98) Age 60.1 (8.4); sex M/F62/36; weight 58.2 (11.3) Control (n=99) Age 58.5 (9.1); sex M/F61/38 ; weight 57.0 (8.4) | Midazolam 5.8mg | Dexmedeto-midine 66.2mcg | Cough, discomfort, willingness to repeat procedure | When comparing patient reporting of pain and willingness to repeat the procedure, there was no difference between the Midazolam and Deme detomi-dine groups but midazolam led to a significantly better outcome for cough | |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range);Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Lo et al. 2011 | Taiwan | Tertiary medical centre | RCT (parallel group) | Patients undergoing elective FB and sedation | Intervention (n=223) Age 59.9 (13.1); sex M/F 145/78; weight 61.1 (11.3) Control (n=217) Age 61.9 (14.7); sex M/F 139/78; weight 59.9 (11.4) | propofol 198.6mg/Alfent-anil 325.4 mcg | Midazolam 6.8mg/Alfent-anil 350.3mcg | Anaesthetic inhalation, global tolerance, cough, dyspnea, pain, scope insertion | When comparing patient-reported global tolerance scope insertion discomfort, cough and breathlessness, Proprofol/Alfent-anil outperformed Midazolam/Al-fentanil, there was no significant difference when comparing ratings of pain or anaesthetic inhalation discomfort | |
| Rolo et al. 2012 | Portugal | Two Pulmonology Departments Centro Hospitalar S. João EPE and Hospital de Braga | RCT (parallel group) | Patients who underwent FOB | Intervention (n=50) Age 55.0 (14.4); sex M/F 32/18; weight (ns) Control (n=50) Age 57.1 (13.8); sex M/F 34/16; weight (ns) | Midazolam 2.56mg | Placebo | Worst moment of procedure (waiting period, procedure explanation, passage of bronchoscope through nose, passage of bronchoscope through vocal cords, endoscopic techniques, no unpleasant moments) Main complaint (nausea, cough, dyspnoea, pain), Willingness to repeat procedure | When comparing patients' worst moments - scope passage through vocal chords and main complaint cough, breathlessness and willingness to repeat the procedure, Midazolam out-performs the placebo. There were no significant differences in pain or nausea complaints | |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range); Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Ryu et al. 2012 | Korea | Operating theatre | RCT (parallel group) | Patients with ASA physical classification system status of I–III undergoing elective diagnostic flexible bronchoscopy | Intervention (n=35) Age 52.9 (23–69); sex M/F 18 /17; weight 60.6 (13.8) Control (n=35) Age 52.9 (27–67); sex M/F20/15 ; weight 62.1 (13.8) | propofol 2.8mcg/kg/min /Remifentanil 2.9mcg/kg/min (n=35) | propofol 2.37mcg/kg/min / dexmedetomidine 1.0mcg/kg/min (n=35) | Cough, satisfaction | When comparing patient-reported coughing and satisfaction scores, there was no significant difference between the groups | A larger no. in the Propofol Dexemedetomidine group had haemoptysis (10 vs 3) |
| Schlatter et al. 2011 | Switzerland | Clinic of Pulmonary Medicine and Respiratory Cell Research, University Hospital | RCT (parallel group) | Patients undergoing elective flexible bronchoscopy | Intervention (n=146) Age 64.4 (14.0); sex M/F 72/74; weight 69.4 (14) Intervention subgroup a. (n=56)(ns) Intervention subgroup b. (n=90)(ns) Control (n=154) Age 61.8 (16.3); sex M/F89/65; weight 71.8 (18) Control subgroup a. (n=44) (ns) Control subgroup b.(n=110) (ns) | propofol 200mg /hydrocodone 4mg a. inspection and washing group b. additional specimen group | propofol 260mg /placebo inspection/washings a. inspection and washing group b. additional specimen group | Discomfort, cough | When comparing particpant pain and cough scores, there was a significant difference when hydrocodone was added to propofol except for the short procedures; when measured as a subgroup there was no significant difference in scores | |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range); Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Schwarz et al. 2007 | Israel | Department of Pulmonology and Post-Anaesthesia Care Unit | RCT (parallel group) | Patients undergoing scheduled diagnostic or therapeutic FOB | Intervention (n=29) Age 61.8 (17); sex M/F 14/15; weight (ns) Control (n=30) Age 57.7 (16); sex M/F 11/19; weight (ns) | Midazolam 3.1mg / Dextrometh or-phan 90mg (n=29) | Midazolam 4.2mg /placebo (n=30) | Level of fear, pain, cough | When comparing participant reported pain and cough, there was no significant difference between the groups | Control group younger and more females |
| Silvestri et al. 2009 | USA | Twenty-four centres | RCT (parallel group) | Patients with an American Society of Anesthesiologists Physical Classification System status of P1 to P4 | Intervention (n=149) Age 60.8 (25–83); sex M/F 86/64 ; weight (ns) Control (n=103) Age 60.1 (22–84); sex M/F 55/48 (47.1); weight (ns) | Fospropofol 6.5mg/kg / Fentanyl (n=149) | Fospropofol 2mg/kg /Fentanyl (n=103) | Amnesia, comfort, satisfaction, willingness to repeat the procedure | When comparing participant amnesia and willingness to repeat the procedure, the higher-dose Fospropofol was significantly more acceptable; there was no significant difference in participants' ratings of cough or satisfaction between the groups | |
| Watts et al. 2005 | Ireland | Three centres | RCT (parallel group) | Patients who required bronchoscopy | Intervention (n=25) Age 81.6 (79.3–83.8); sex M/F 12/13; weight (ns) Control (n=25) Age 80.5 (78.2–82.7); sex M/F 12/13; weight (ns) | Temazepan 10mg nebulised lignocaine 4ml/2% | Alfentanyl BMI <23, 250mcg, BMI>23 500mcg | Discomfort, willingness to repeat the procedure | When comparing participants' rating of comfort and willingness to repeat the bronchoscopy, the Temazepan/ nebulised lignocaine group was significantly more positive than the Alfentanyl group | |

| Study identification | Country | Setting | Design | Population | Sample (mean, SD or range); Sex (n) M/F; weight kg (mean, SD) | Intervention group | Comparison/ control group | Outcome measures | Overall findings | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Yoon et al. 2011 | Korea | Seoul National University Bundang Hospital | RCT (parallel group) | Patients scheduled for elective bronchoscopy | Intervention (n=32) Age 58.8 (14.3); sex M/F 18/14; weight 62.0 (10.0) Control (n=32) Age 57.3 (11.6); sex M/F 17/15; weight 62.1 (12.5) | propofol 43.6mg /alfentanyl 435.7mcg (n=32) | propofol 46.2mg /placebo (n=32) | Cough, satisfaction | When comparing participants rating of cough and satisfaction, there were no significant differences between the groups | |

ASA = American Society of Anaesthsiologists, BAL = Bronchoscopic Alveolar Lavage, BMI = body mass index, FB = flexible bronchoscopy, kg = kilograms, M/F = male/female, mcg = microgram, mg = milligram, n = number, ns = no statistical difference in number between study groups, RCT = random controlled trial, SD = standard deviation

Quality assessment of the trials was conducted to evaluate if flaws in the study methods could have led to underestimation or overestimation of the effect of the study intervention (Higgins, et al., 2011). To ensure a systematic assessment of each study's methods, two authors independently assessed all 19 studies for risk of bias in their methodology (see Table 3). After quality assessment, it was found that no study had a clear record of avoiding the risk of bias across all potential sources of bias in their methodology. The area of least risk of bias within the group of studies was the completeness of outcome data presented. However, the area where methods bias was most unclear was the area of selective outcome reporting. The area with the greatest risk of bias was blinding of participants and personnel.

Outcome data collection was reported in a variety of ways, which made comparisons difficult. Five studies provided numbers (sum) or percentages in relation to patients' response to Likert scales, visual analogue scales and polar (dichotomous) questions (Atassi et al., 2005; Gonzalez et al., 2003; Houghton et al., 2004; Rolo et al., 2012; Silvestri et al., 2009). Five studies presented outcome data from Likert scales and visual analogue scales as means alone or with standard deviation or ranges (Cases Viedma et al., 2010; Clark et al., 2009; Hwang et al., 2005; Schwarz et al., 2007; Watts et al., 2005); two studies presented outcome data from visual analogue scales as medians with interquartile ranges (Grendelmeier et al., 2014; Schlatter et al., 2011); six studies presented outcome data from a Likert scale survey and visual analogue scales in graphs (Contoli et al., 2013; de Padua et al., 2004; Korteweg et al., 2004; Lo et al., 2011; Ryu et al., 2012; Yoon et al., 2011), and one study only reported on significant differences between intervention groups (Liao et al., 2012). Six authors were contacted with a request for further data. Two authors responded after the second email, one of whom responded by sending appropriate data (Contoli et al.,

2013). The only consistent outcome data, which were presented across all studies, were the results of significant difference testing between treatment groups (p values). Therefore, the outcome data tables (Tables 4–6) present p values to illustrate the significant differences between treatment groups.

The data tables (Tables 4–6) also include the various outcomes reported, however there was no consistency across the studies in either the outcomes assessed, the measures used to assess outcomes, or the manner in which the results were reported. For example, Likert scales were reported as mean and standard deviation (Cases Viedma et al., 2010), percentages (Silvestri et al., 2009), or graphically (Contoli et al., 2013). There were three studies that compared midazolam to a placebo, but the doses of midazolam were not consistent between the studies however all the studies reported that with larger doses of midazolam subjects evaluated the procedure more favourably. Two of these studies also reported on the patient experience of coughing however outcome data collection was variable. In one study participants were asked to identify their main complaint (of which cough was an option) and the other participants were asked to evaluate their experience of coughing during the procedure using a visual analogue scale.

**Table 3: Quality assessment of included studies**

| 1st Author | Sequence Generation | Allocation concealment | Blinding of participants and personnel | Blinding of outcome assessors | Incomplete outcome data | Selective outcome reporting | Other sources of bias |
|---|---|---|---|---|---|---|---|
| Atassi (2005) | Low | Low | Low | Unclear | Low | Unclear | Low |
| Cases Viedma (2010) | Low | Unclear | Low | Low | Low | Unclear | High |
| Clark (2009) | Unclear | Low | Low | Low | Low | Low | Low |
| Contoli (2013) | Low | Low | Low | Low | Low | Unclear | Unclear |
| dePadua (2004) | Unclear | Low | Low | Unclear | Unclear | Unclear | Low |
| Gonzalez (2003) | Unclear | Unclear | High | Low | Low | Low | Low |
| Grendelmeier (2014) | Low | Unclear | High | Low | Low | Low | Low |
| Houghton (2004) | Low | Low | Low | Low | Low | Unclear | Unclear |
| Hwang (2005) | Unclear | Low | Low | Low | Low | Unclear | Low |
| Korteweg (2004) | High | High | High | Unclear | Low | Unclear | High |
| Liao (2012) | Low | Unclear | High | Unclear | Low | Low | High |
| Lo (2011) | Low | High | High | Low | Low | Low | High |
| Rolo (2012) | Unclear | Unclear | Unclear | Unclear | Unclear | Unclear | Low |
| Ryu (2012) | Unclear | Low | Low | Low | Low | Low | Low |
| Schlatter (2011) | Low | Low | Low | Low | Low | High | Low |
| Schwarz (2007) | Unclear | Low | Low | Low | Unclear | Unclear | Low |
| Silvestri (2009) | Unclear | Unclear | Low | Unclear | Low | Low | Low |
| Watts (2005) | Unclear | Unclear | Low | Unclear | Low | Unclear | Low |
| Yoon (2011) | Low | Low | Low | Unclear | Low | Unclear | Low |

| Colour codes | |
|---|---|
| Low | Low risk of bias comparison between treatment groups |
| Unclear | Unclear risk of bias comparison between treatment groups |
| High | High risk of bias comparison between treatment groups |

## Table 4: Outcome data table—midazolam studies

| First Author (year) | Drugs used for sedation/analgesia | Population size | Psychological | | | | Physical | | | | | | | | | | Satisfaction | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Amnesia | Dreaming | Distress during test / Anxiety | Patient tolerance score | Pain / discomfort | Nasal pain / discomfort | Soreness in throat | Anaesthetic inhalation | Scope insertion | Comfort | Cough | Breathlessness | Nausea | Choking | Satisfaction | Repeat similar procedure |
| Cases Viedma (2010) | Midazolam (0.07-0.1mg/Kg) vs placebo | 152 | 0.0001 | | 0.001 | | 0.0001 | | | | | | 0.0001 | 0.0001 | | | | 0.002 |
| Contoli (2013) | Midazolam (0.035mg/kg) vs placebo | 67 | | | | NS | | | | | | | | | | | | |
| Contoli (2013) | Midazolam (0.07mg/Kg) vs Midazolam (0.035mg/kg) | 67 | | | | NS | | | | | | | | | | | | |
| Contoli (2013) | Midazolam (0.07mg/Kg) vs placebo | 66 | | | | <0.01 | | | | | | | | | | | | [illegible] |
| Houghton (2004) | Alfentanil (0.95mg) vs Midazolam (4.2mg) | 46 | | | | | 0.13 | 0.31 | 0.76 | | | | | | | | | vcccb |
| Liao (2012) | Midazolam (5.8mg)vs Dexmedetomidine (66.2mcg) | 197 | | | | | NS | | | | | | <0.001 | | | | | NS |
| Rolo (2012) | Midazolam (2.56mg) vs placebo | 100 | | | | | NS | | | | 0.017 | 0.002 | 0.03 | <0.001 | NS | | | 0.003 |
| Schwarz (2007) | Midazolam (3.1mg) /Dextromethorphan (90mg) vs Midazolam (4.2mg)/placebo | 59 | | | <0.005 | | 0.00005 | | | | | | <0.05 | | | | | |

Each of the studies compared patient experience outcome data between their treatment and control groups. Each study reported if there was a significant difference between the groups outcome values and presented this data as a p values. A p value was considered significant, when it was less than 0.05. Not all studies reported p values if they did not consider the value significant. All of the studies did not collect data for all of the outcomes listed on this table. If no data was collected for an outcome then the corresponding box is shaded yellow. If data collected for the outcome was not significant then the corresponding box is shaded red. If the data collected for the outcome was significantly different between the treatment group and the control group then the corresponding boxes are shaded green and the p value is displayed (the treatment group is always listed fired first in the "Drug used for sedation/analgesia" column). vs = versus, mg = milligram, BMI = body mass index, NS = not significant

## Table 5: Outcome data—Propofol studies

| First Author (year) | Drugs used for sedation/analgesia | Population size | Psychological | | | | Physical | | | | | | | | | | Satisfaction | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Amnesia | Dreaming | Distress during test / Anxiety | Patient tolerance score | Pain/ discomfort | Nasal discomfort | Lung pain/ discomfort | Anaesthetic inhalation | Scope insertion | Comfort | Cough | Breathlessness | Nausea | Choking | Satisfaction | Repeat similar procedure |
| Clark (2009) | Propofol (135.1mg) vs Midazolam (6.2mg) | 82 | | | | 0.051 | 0.026 | | | | | | 0.946 | 0.024 | 0.047 | | | |
| Lo (2011) | Propofol (198.6mg)/Alfentanil (325.4 mcg) vs Midazolam (6.8mg)/Alfentanil (350.3mcg) | 460 | | | | <0.001 | 0.138 | | | 0.084 | 0.012 | | 0.026 | 0.018 | | | | |
| Gonzalez (2003) | Propofol (133mg) vs placebo | 18 | <0.0001 | | | <0.01 | <0.01 | | | | | | <0.05 | | | <0.001 | | <0.01 |
| Grendelmeier (2014) | Propofol infusion (308.3mg) vs Propofol bolus doses (226.6mg) | 702 | | | 0.737 | | 0.942 | | | | | | 0.917 | | | | | 0.288 |
| Hwang (2005) | Propofol (28.1mg)/Ketamine (14.0mg) vs Propofol (28.2)/Alfentanil (282mcg) | 276 | <0.01 | <0.01 | | | | | | | | | | | | | <0.05 | NS |
| Ryu (2012) | Propofol (2.8mcg/kg/min) /Remifentanil (2.9mcg/kg/min) vs Propofol (2.37mcg/kg/min) /dexmedetomidine (1.0mcg/kg/min) | 70 | | | | | | | | | | | NS | | | | NS | |
| Schlatter (2011) | Propofol (200mg) /hydrocodone (4mg)vs Propofol (260mg) /placebo (inspection/washings) | 100 | | | | | 0.992 | | | | | | 0.899 | | | | | |
| Schlatter (2011) | Propofol (200mg) /hydrocodone (4mg)vs Propofol (260mg) /placebo (additional specimens) | 200 | | | | | 0.016 | | | | | | 0.036 | | | | | |
| Schlatter (2011) | Propofol (200mg) /hydrocodone (4mg)vs Propofol (260mg) /placebo | 300 | | | | | 0.037 | | | | | | 0.025 | | | | | |
| Silvestri (2009) | Fospropofol (6.5mg/kg)/Fentanyl vs Fospropofol (2mg/kg)/Fentanyl | 252 | <0.01 | | | | | | | | | NS | | | | | NS | <0.01 |
| Yoon (2011) | Propofol (43.6mg) /alfentanyl (435.7mcg) vs Propofol (46.2mg) /placebo | 64 | | | | | | | | | | | NS | | | | NS | |

Each of the studies compared patient experience outcome data between their treatment and control groups. Each study reported if there was a significant difference between the groups outcome values and presented this data as a p values. A p value was considered significant, when it was less than 0.05. Not all studies reported p values if they did not consider the value significant. All of the studies did not collect data for all of the outcomes listed on this table. If no data was collected for an outcome then the corresponding box is shaded yellow. If data collected for the outcome was not significant then the corresponding box is shaded red. If the data collected for the outcome was significantly different between the treatment group and the control group then the corresponding boxes are shaded green and the p value is displayed (the treatment group is always listed fired first in the "Drug used for sedation/analgesia" column). vs = versus, mcg = microgram, mg = milligram, BMI = body mass index, NS = not significant.

## Table 6: Outcome data—other drug studies

| First Author (year) | Drugs used for sedation/analgesia | Population size | Psychological | | | | Physical | | | | | | | | | | Satisfaction | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Amnesia | Dreaming | Distress during test/Anxiety | Patient tolerance score | Pain/ discomfort | Nasal pain/ discomfort | Lung pain/ discomfort | Anaesthetic inhalation | Scope insertion | Comfort | Cough | Breathlessness | Nausea | Choking | Satisfaction | Repeat similar procedure |
| Atassi (2005) | Nitrous oxide 9-12 L/min vs placebo | 205 | | | | | <0.05 | <0.01 | | | | | <0.05 | | | | | NS |
| De Padua (2004) | Clonidine (3mcg/kg) vs placebo | 42 | | | | | NS | | | | | | | | | | | |
| Korteweg (2004) | Atropine (0.5mg) /Codeine (20mg) vs Codeine (20mg) | 124 | | | | | | | | | | 0.035 | | | | | | |
| Korteweg (2004) | Atropine(0.5mg) /Codeine (20mg) vs placebo | 132 | | | | | | | | | | 0.0004 | 0.05 | | | | | |
| Korteweg (2004) | Codeine (20mg) vs Ipratropium bromide (0.5mg) | 126 | | | | | | | | | | 0.843 | | | | | | |
| Korteweg (2004) | Ipratropium bromide (0.5mg) vs placebo | 134 | | | | | | | | | | 0.352 | 0.585 | | | | | |
| Korteweg (2004) | Codeine (20mg) vs placebo | 160 | | | | | | | | | | 0.404 | 0.044 | | | | | |
| Watts (2005) | Temazepan (10mg) nebulised lignocaine (4ml/2%) vs Alfentanyl (BMI <23, 250mcg, BMI>23 500mcg) | 50 | | | | | 0.019 | | | | | | | | | | | 0.013 |

Each of the studies compared patient experience outcome data between their treatment and control groups. Each study reported if there was a significant difference between the groups outcome values and presented this data as a p values. A p value was considered significant, when it was less than 0.05. Not all studies reported p values if they did not consider the value significant. All of the studies did not collect data for all of the outcomes listed on this table. If no data was collected for an outcome then the corresponding box is shaded yellow. If data collected for the outcome was not significant then the corresponding box is shaded red. If the data collected for the outcome was significantly different between the treatment group and the control group then the corresponding boxes are shaded green and the p value is displayed (the treatment group is always listed fired first in the "Drug used for sedation/analgesia" column). vs = versus, L= litre, mcg = microgram, mg = milligram, BMI = body mass index, NS = not significant.

The psychological and physical outcomes were assessed using various response formats including visual analogue scales, Likert scales and dichotomous questions. Patient satisfaction outcome data were predominately measured with visual analogue scales and by measuring participants' willingness to repeat a similar procedure, with visual analogue scales or a dichotomous response. The most common outcomes that were measured were pain, cough and willingness to repeat the procedure. Dreaming, lung pain, anaesthetic inhalation discomfort and choking were each measured only once across the 19 studies. Outcome data were reported inconsistently.

Psychological outcomes that were assessed were amnesia, dreaming, tolerance, distress, and anxiety. The studies concluded that the degree to which participants rated these outcomes was related to the type and level of sedation or analgesia administered. Significant differences in amnesia ($p < 0.01$), anxiety ($p = 0.001$) and patient tolerance ($p = 0.026$) were found when sedation was compared to a placebo (Cases Viedma et al., 2010; Gonzalez et al., 2003; Schwarz et al., 2007). When the analgesic ketamine was added to propofol and compared to the analgesic alfentanyl and propofol, ketamine provided significantly higher ratings of amnesia ($p < 0.01$) and dreaming ($p < 0.01$) with minimal respiratory effects (Hwang et al., 2005). When high doses of fospropofol (6.5mg/kg) with fentanyl were compared to low dose fospropofol (2mg/kg) with fentanyl, there were significantly greater ratings of amnesia ($p < 0.01$) (Silvestri et al., 2009). When a propofol infusion was compared to propofol bolus delivery, there were no significant differences in participants' ratings of anxiety ($p = 0.737$) (Grendelmeier et al., 2003). When a low dose midazolam (0.035mg/kg) was compared to a placebo, no significant differences were reported in patient tolerance (Contoli et al., 2013). When lower doses of midazolam

(0.035mg/kg) were compared to higher doses of midazolam (0.075mg/kg), there was no difference in the patients' reported procedural tolerance. However, when the higher-dose midazolam (0.075mg/kg) was compared to a placebo, there was a significantly higher level of tolerance ($p < 0.01$) in the sedated group (Contoli et al., 2013). Propofol was more tolerable than a placebo (Gonzalez et al., 2003), and propofol alone was more tolerable ($p = 0.051$) than midazolam alone (Clark et al., 2009; Lo et al., 2011).

The studies examined patient reports of several physical outcomes: pain/discomfort, breathlessness, and choking. There were significantly higher ratings of the physical outcomes when non-sedated participants were compared to sedated participants (Atassi et al., 2005; Cases Viedma et al., 2010; Gonzalez et al., 2003; Schwarz et al., 2007; Watts et al., 2005). The sedative midazolam worked significantly better than a placebo at reducing participants' ratings of pain ($p < 0.001$; $< 0.001$), cough ($p < 0.001$; $< 0.05$) and breathlessness ($p < 0.001$) (Cases Viedma et al., 2010; Schwarz et al., 2007). Rolo et al. (2012) collected outcome data regarding patients' worst moments during the procedure and their main complaint regarding the procedure. They reported that there were significant differences between the sedated group and placebo group when patients were questioned if their worst moment was the passage of the bronchoscope through the vocal chords ($p = 0.017$) and if they had no worst moments ($p = 0.002$). It was theorised that this occurred due to amnesia of the procedure; unfortunately amnesia was not measured in this study. Rolo et al. (2012) also asked the patients which of the following potential side effects of the procedure was their main complaint: nausea, cough, dyspnoea and pain. There were significantly more complaints of cough ($p = 0.03$) and dyspnoea ($p < 0.001$) in the placebo group. This did not mean that patients did not complain of pain (8%) only that there was no

difference in this outcome between the patients in the sedated and placebo group. The sedative nitrous oxide also worked significantly better than a placebo in relieving pain ($p < 0.05$) and cough ($p < 0.01$) (Atassi et al., 2005). When the sedative temazepan was compared to alfentanil, the temazepan group rated their level of discomfort lower than that of the alfentanil group ($p = 0.019$) (Watts et al., 2005). There was no significant differences in relation to participants' pain ($p = 0.13$), nasal discomfort ($p = 0.31$) or throat soreness ($p = 0.76$) ratings when alfentanil was compared to midazolam (Houghton et al., 2004). When clonidine usage was compared to a placebo, there was no significant difference in participants' ratings of comfort (significance not reported) (de Padua et al., 2004). When participants sedated with propofol were compared to participants sedated with midazolam, propofol significantly reduced participants' ratings of pain ($p = 0.051$), breathlessness ($p = 0.024$) and nausea ($p = 0.047$) (Clark et al., 2009). When propofol with alfentanil was compared to midazolam with alfentanil, the propofol group rated better for scope insertion discomfort ($p = 0.012$), cough ($p = 0.026$) and breathlessness ($p = 0.018$) (Lo et al., 2011). When bolus dose propofol was compared to propofol infusion, there was no significant difference in participants' ratings of discomfort ($p = 0.942$) or cough ($p = 0.917$) (Grendelmeier et al., 2014).

Participants' willingness to repeat the procedure under the same circumstances was significantly higher in patients who were sedated with midazolam ($p = 0.002$; 0.003), propofol ($p < 0.01$) and temazepan ($p = 0.013$) than in patients who were given a placebo (Cases Viedma et al., 2010; Gonzalez et al., 2003; Rolo et al., 2012; Watts et al., 2005). There was no significant difference in participants' willingness to repeat the procedure when alfentanil was compared to midazolam ($p = 0.65$) or was compared to dexmedetomidine

(significance not documented), or when propofol infusion was compared to propofol boluses ($p = 0.288$), or when propofol with ketamine was compared with propofol and alfentanil (significance not documented), or nitrous oxide was compared to a placebo (significance not documented) (Atassi et al, 2005; Grendelmeier et al., 2014; Houghton et al., 2004; Hwang et al., 2005; Liao et al., 2012). When patient satisfaction was compared between Propofol/Ketamine and Propofol/Alfentanyl using a visual analogue score, Propofol/Ketamine was found to be more satisfactory ($p < 0.05$) (Hwang et al., 2005). Satisfaction scores were not significantly different when comparing Propofol/Remifentanil vs Propofol/Dexmedetomidine (significance not documented), Propofol/Alfentanil versus Propofol/placebo (significance not documented), or Fospropofol/ Fentanyl versus Fospropfol/Fentanyl (significance not documented) (Ryu et al., 2012; Silvestri et al., 2009; Yoon et al., 2011).

## 2.6 Discussion

The literature review found no qualitative studies that examined the patient experience during bronchoscopy with sedation and analgesia, therefore quantitative studies that measured aspects of the participant's experience were investigated. The outcomes used during the studies were heterogenous making a meta-analysis inappropriate therefore a descriptive discussion of these outcomes is presented. The quality of these studies was also evaluated.

In the included studies of the literature review, participants' perceptions of their experience were measured using a variety of outcomes: distress, anxiety, pain, discomfort, cough, breathlessness, nausea, and choking. These outcomes were measured in a variety of ways

using visual analogues scales (0–10 or 0–100), Likert scales and dichotomous questions. There was no consistency in the comparators used, outcomes measured or the scales and tools employed to measure these outcomes, making it too difficult to synthesise the results for a meta-analysis. Regardless of the different ways in which the procedure was performed, participants acknowledged experiencing some discomfort, such as procedure-related distress, anxiety, pain, discomfort, cough, breathlessness, nausea, and choking. The underlying source of these outcomes was not explored in the quantitative studies.

General patient satisfaction or willingness of the patient to return for a similar procedure was a common study outcome that was reported in the current literature. In two studies that measured both patient satisfaction and willingness to repeat the procedure, there was no consistency in the subjects' rating of both outcomes, indicating that they measured different aspects of the experience (Hwang et al., 2005; Silvestri et al., 2009). In the study by Hwang et al. (2005), study subjects who were given propofol and ketamine had more amnesia and higher satisfaction scores than those given propofol and alfentanil. However, there was no difference between the groups in terms of the subjects' willingness to repeat a procedure under the same conditions. In the study by Silvestri et al. (2009), the treatment group received high doses of fospropofol and the control group received lower doses of fospropofol. The treatment group had significantly higher ratings of amnesia and willingness to repeat the procedure, however there was no difference in comfort ratings or general satisfaction between these groups. In general, the literature review found that if, during bronchoscopy a treatment group was given sedation and a control group was given a placebo, then the satisfaction scores of the treatment group would be significantly higher

than those of the control group (Cases Viedma et al., 2010; Gonzalez et al., 2003; Rolo et al., 2012).

The included randomised controlled trials of adult patients undergoing flexible bronchoscopy since 2001 were identified as having some risk-of-bias problems. When they were appraised using the Cochrane risk-of-bias tool within the Covidence website (https://www.covidence.org/), the risk of bias was unclear in 30% of the judgements. Clark et al. (2009) had an almost perfect record of low bias but sequence generation was not described. Schlatter et al. (2011) published a study protocol and was judged as low bias in all other areas except selective outcome reporting, however it did not include data from some secondary outcome measures. This may be due to journal word limitations or non-significant findings. Risk of bias was also high at times in relation to blinding of participants or personnel when work protocols and/or obstacles were present (Grendelmeier et al., 2014; Liao et al., 2012; Lo et al., 2011).

## 2.7 Review limitations

A limitation of this systematic review was the quality of the randomised controlled trials that was identified as unclear in many studies. In general, the studies did not include clear descriptions of sequence generation, allocation concealment or blinding. Blinding was described as being too difficult in some studies due to study-site protocols and in many of the randomised controlled trials it was unclear if all outcomes were reported, as most studies did not provide a study protocol. The study by Schlatter (2011) did provide a study protocol, in which it was specified that data pertaining to patient side effects were to be collected 24 hours post-procedure, however in the study report there were no data

presented that related to patient side effects in that time frame. Another potential limitation identified as a source of bias in many of the studies was that patients were given more sedation when they were intolerant of the procedure. The inconsistency in outcomes should also be noted as factors that affected pooling of data from these randomised controlled trials. There was no consistency in outcomes selected to measure the patient experience, furthermore there was no consistency in the measures selected to assess outcomes or in the method of reporting the results.

## 2.8 Conclusions

In summary, the most frequent outcomes reported in the studies examining the patient experience in bronchoscopy were pain and cough. A commonly reported secondary outcome was patient willingness to repeat the procedure. Based on the current literature, it is concluded that providing sedation for patients during bronchoscopy results in reduced rates of distress, anxiety, pain, discomfort, cough, breathless, choking, and a greater willingness to repeat the procedure. Of note, the quality of the randomised controlled trials that are the basis of these conclusions is somewhat unclear, and a further source of bias was that in many of the studies patients were given more sedation when they were intolerant of the procedure. Given these findings, publishing study protocols may help to resolve many of the bias issues of the studies to date. Importantly, this review identified a significant gap in the literature; that outcomes were not selected based specifically upon the patient experience. No study could be located that qualitatively examined the patient experience of bronchoscopy, and there may be other unpleasant consequences of the procedure that to date have not been examined. A qualitative study that explores the patient experience in bronchoscopy may provide evidence for more consistency in outcome measures that could

be used to more effectively evaluate health care interventions, which may improve the patient experience of the bronchoscopy procedure.

## 2.9 Chapter 2 summary

This systematic review identified a gap in the literature concerning the patient experience of bronchoscopy with cautious sedation and analgesia: to date no qualitative study has been carried out on this topic. Thus, the second component of this thesis attempts to fill this gap by conducting an interview-based study to identify the experiences of patients with high-risk respiratory disease during bronchoscopy. Further, the findings of the systematic review presented in Chapter 2 provide a guide for which to develop the conceptual framework and the questions that were used in the qualitative study. Chapter 3 details the conceptual framework, methodology and results of the qualitative study investigating the experiences of patients who have undergone bronchoscopy with cautious sedation and analgesia.

# Chapter Three: Qualitative Study

## 3.1 Overview

Chapter Three presents the findings of a qualitative study that implemented an interview method to explore the experiences of patients with high-risk respiratory disease who have undergone bronchoscopy with cautious sedation and analgesia. To begin, the conceptual framework is described along with the study design and the methodology employed.

## 3.2 Conceptual framework

A conceptual framework can explain a researcher's worldview of their research, enabling an identification of their rationale, assumptions and preconceptions (Lacey, 2010). This conceptual framework was developed after the research candidate evaluated their world view in relation to the clinical problem, their appraisal of literature dedicated to the clinical problem, and their exploration regarding the clinical problems fit with regard to potential research methods (Ravitch & Riggan, 2017). Concepts within the conceptual framework that relate to the research candidate's world view include: patient suffering, patient advocacy, and patients' best interests. Concepts that relate to the research candidate's appraisal of the literature include: literature that collects data relating to patient experience in bronchoscopy, guidelines relating to patient management during the procedure, and hospital policy regarding the procedure. After exploring the clinical problem fit with qualitative and quantitative research methodologies the research candidate selected phenomenological methodology as the most appropriate approach for this research. Phenomenological research methods explained by Van den Berg (1972) cited in van Manen (2014) encouraged the research candidate, who had a wealth of experience in the clinical

problem, to identify their assumptions, preconceptions and theories, then consciously disregard them in preference for the true story from the participants' perspectives; their 'lived experience'. Thereby guarding against the effects of prejudice and assumptions born of theory, research and the candidate's experience (van Manen, 2014), these concepts in the candidate's conceptual framework overlap and interact with each other (see Figure 2).

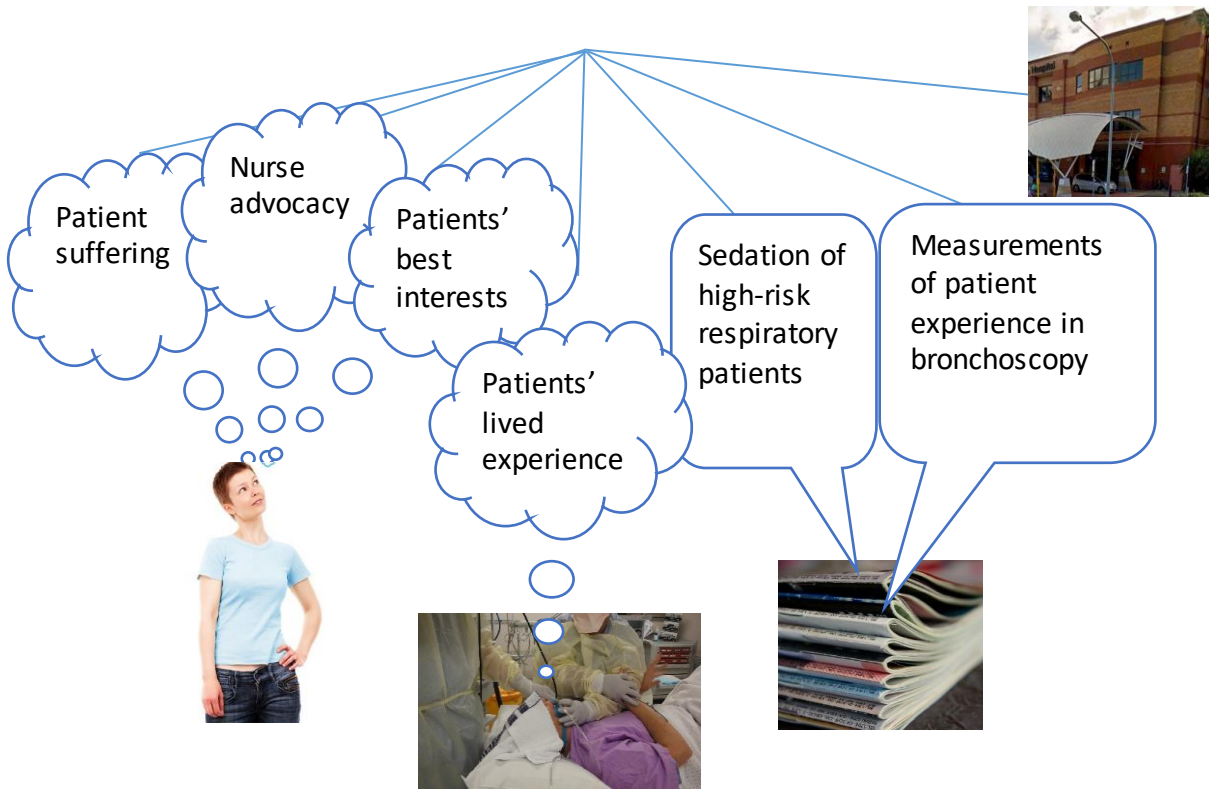



**Figure 2: Conceptual framework**

Suffering has been defined as the 'undergoing of pain, distress or tribulation' (Little et al., 1988). A clinical problem arises when staff suspect that a patient is suffering as a result of a medical procedure. This could be the case when patients undergo bronchoscopy with cautious sedation because they may cough, choke, or try to remove the bronchoscope before the procedure is completed. The staff placate the patient with words whilst physically preventing them from removing the instrument. If they are able, the physician administers more sedation. In the time it takes for the additional sedation to take effect or if the physician deems it too risky to give more sedation, the question arises whether staff are

ignoring the patient's needs, thereby potentially increasing their level of suffering (anecdotal evidence from the research candidate's centre of practice). Berglund et al. (2012) found that patients experienced suffering in health care when their feelings were ignored, resulting in feelings of vulnerability and powerlessness. It may be that the patient reactions are unconscious and they will have no recollection of the procedure when sedation is used cautiously, as research has reported that sedation can cause amnesia (Cases Viedma et al., 2010).

Patient advocacy in nursing can be seen as pleading for better patient care (Harris, Nagy & Vardaxiz, 2010). Patient advocacy has been a driving force to complete this study because the research candidate wishes to clarify whether or not the patient is suffering and, if they are, are there any interventions that could be implemented to positively affect their experience of the procedure (for which the nurse can advocate). Patient advocacy is a responsibility that has been bestowed upon the nursing populace due to the immediate, sustained and intimate nature of nursing, which provides insights into the patient's wellbeing (Gadow, as quoted in Gaylord & Grace, 1995). In the research candidate's centre of practice, the nurse who provides airway support during a bronchoscopy stands at the patient's head throughout the procedure, placing hands on their chin, holding their hand, talking to them and observing their behaviour, so that they may inform the physicians. Gaylord & Grace (1995) explain that, due to this special nurse-client relationship, failing to advocate for the patient can be synonymous with the nurse failing to conduct their duty. As such, it is a requirement of the Nursing and Midwifery Board of Australia (2008) that nurses protect their patients' physical, psychological and emotional wellbeing. When the patients are given heavier sedation by an anaesthetist, the nurses have not observed patients

attempting to remove the bronchoscope before the procedure was completed (observations and anecdotal evidence from the research candidate's centre of practice). Due to hospital and/or governmental financial constraints, anaesthetic support is not available for all bronchoscopy procedures and, in general, anaesthesia is used for interventional diagnostic or therapeutic procedures (these procedures are usually longer than general bronchoscopy procedures). Nursing advocacy is a driving force for the study but also contributed to the results. When the airway nurse talks to the patient, holds their hand and asks for more sedation during the procedure, they influence the patient experience. Exploring the patient experience through a qualitative study may ascertain ways to reduce possible suffering that quantitative studies are not able to achieve. Berglund et al. (2012) suggest that increasing knowledge regarding health care experiences would help to reduce unnecessary suffering.

It is necessary for physicians to consider the patient's best interests before embarking on any invasive procedures; the patient's best interests can be established by weighing the benefits of the procedure against the risks of the procedure (Medical Board of Australia, 2014). Studies have demonstrated that sedation during bronchoscopy can result in a more comfortable experience for the patient (Korteweg et al., 2004; Rolo et al., 2012). The literature associated with the sedatives administered during bronchoscopy (midazolam and propofol) has warned that these medications can decrease the patient's respiratory function (AFT Pharmaceuticals, 2015; Apotex, 2014). Guidelines for patient management in bronchoscopy suggest that sedative drugs should be given cautiously when the patient has pre-existing respiratory disease (Du Rand et al., 2013). Bronchoscopy in itself can decrease respiratory function (Peacock, Benson-Mitchell & Godfrey, 1990). A study by Peacock,

Johnson and Blanton (1994) concluded that there was an increased risk of complications from bronchoscopy when the patient had COPD. These complications included infection, pneumothorax, oxygen desaturation, respiratory failure, and death. However, the patients in this study who had COPD were significantly older than the control group, and they had more specimens procured during the bronchoscopy (biopsy, needle aspiration, and brushings). In addition, they were given a significantly lower level of sedation than the control group. The retrospective nature of this study did not allow for measurement of patient satisfaction between the groups. Hattotuwa, Gamble, O'Shaughnessy, Jeffery & Barnes (2002) studied 57 patients who had COPD and underwent bronchoscopy with sedation. They reported that this group had a 2% incidence of adverse events that required hospitalisation, and therefore concluded that bronchoscopy could be performed with a low incidence of adverse events.

When the physician contemplates the respiratory-compromised patient's best interests, they are required weigh the benefits of the procedure (provide a diagnosis to create a treatment plan) against the risks of the procedure (infection, pneumothorax, oxygen desaturation, respiratory failure, death). To judge that the benefit of performing the procedure outweighs the risk to the patient, the physician must consider the benefits of sedation (improved patient comfort, amnesia) against its risks (desaturation, respiratory failure, death). A compromise is often reached whereby a decision is made to give sedation cautiously. It has been recommended by the British Thoracic Society (Du Rand, et al., 2013) that sedation is administered cautiously to patients who have COPD (Du Rand et al., 2013). A physician may justify continuing a procedure even if the patient appears to be suffering (attempts to remove the bronchoscope, coughing and choking) because some studies have

concluded that the sedative has an amnesic effect (Cases Viedma et al., 2010, Korttila, Saarnivaara, Tarkkanen, Himberg & Hytonen, 1978). Evidence in the literature regarding patient experience during bronchoscopy is limited to quantitative studies. These quantitative studies report that certain sedatives decrease the patient's ratings of cough and pain during bronchoscopy (Atassi et al., 2005; Clark et al., 2009; Schlatter et al., 2011). Cases Videma et al. (2010) reported that the sedative midazolam is more effective in relieving discomfort and cough than a placebo. Clark et al. (2009) reported that propofol can improve patient tolerance and reduce cough when compared to midazolam during bronchoscopy. Using Propofol is expensive, as the drug guidelines recommend the presence of an anaesthetist due to its inherent short-acting respiratory risks (AFT Pharmaceuticals, 2015). A recent survey of bronchoscopies in Australia and New Zealand reflected that there was a high use of anaesthetic support for sedation in bronchoscopy when it was performed in the private sector (Barnett, Jones & Simpson, 2016).

Studies that have examined patient experience in bronchoscopy have influenced the patient experience positively due to the subsequent use of sedation in bronchoscopy (Salgado, Gomez, Navio & Anton-Pacheco, 2015; Barnett et al., 2016; Gaisl et al., 2016). However, there is also evidence to suggest that patients can remember discomfort, coughing and choking when undergoing bronchoscopy with sedation (Clark et al., 2009; Korteweg et al., 2004; Gonzalez et al., 2003). The outcomes measured in quantitative studies are most commonly physical symptoms of cough and pain. The cause and effect of these physical experiences is largely unexplored qualitatively.

Some studies have looked at alternative interventions to improve the patient experience in bronchoscopy. Colt, Powers and Shanks (1999) reported that music did not alter the patient's state of anxiety when undergoing bronchoscopy. Diette, Gregory, Lechtzin, Haponik, Devrotes & Rubin (2003) reported that distraction therapy with nature sights and sounds significantly reduces pain in patients undergoing bronchoscopy. A systematic review by Evans (2002) of 29 studies that investigated the effectiveness of music as a hospital intervention concluded that music did not reduce the anxiety of patients undergoing invasive procedures.

Other studies have examined hospital procedures and healthcare workers' techniques to identify factors that negatively affect the patient experience (Bernasconi, Chhajed, Müller & Borer, 2009; Contonli et al., 2013). The information collected is a rating of the patient experience in these areas. Obtaining information in this fashion does not necessarily facilitate the exploration of negative experiences. It is only by examining these negative experiences that the clinical problems associated with bronchoscopy may be ameliorated.

## 3.3 Methodological approach

To further understand the patient experience during bronchoscopy, a qualitative approach was used, employing phenomenology. Qualitative studies are focused on understanding the human experience as it is lived, through the collection and analysis of qualitative data that is subjective and descriptive (Polit & Beck, 2012). Conducting this type of research has given voice to the participants in this study. Phenomenology is a form of qualitative research where data are collected regarding a phenomenon, in this case, cautious use of sedation and analgesia during bronchoscopy.

Phenomenology attempts to describe the common meaning of a particular experience (phenomenon) for several individuals (Creswell, 2013). It examines the pure, basic and raw sensations, emotions and thoughts experienced by individuals who have experienced the phenomenon, the purpose of which is to present a piece of work that faithfully represents the participants' experiences and what it means to them (Denscombe, 2010). In health care, phenomenology can help the researcher to understand the thinking of patients during a healthcare intervention (Denscombe, 2010).

There are two main types of phenomenology: descriptive and interpretative. Phenemonology was founded in Europe by Edmund Husserl in 1908 when he pushed to transform philosophy into a rigorous science (Husserl, 2014). Husserl's approach was purely descriptive; he used phenomenology to philosophically describe the essence of a pure experience (van Manen, 2014). The essence of pure experience refers to the conscious experience of the participant during the phenomenon. In practice, this method includes the researcher bracketing their own preconceived beliefs and opinions about the phenomenon, to improve their vision of the 'essence of pure experience' (Husserl, 2014). Data are collected and analysed, and a description of the phenomenon's pure essence is presented (Grbich, 2013).

A student of Husserl, Heidegger, developed an interpretive approach called hermeneutics (Polit & Beck 2012), which not only described the patient experience of the phenomenon but interpretation and understanding of the human experience (Polit & Beck 2012). Van Manen's 1990–2014 writings further developed the hermeneutic method. His approach to phenomenology (1990; 1997; 2014) was selected for this research study. He describes

phenomenology as a 'meaning-giving' method of research (van Manen, 2014). The aim of this method of research is to enable an understanding of how the experience affects the participant. His methods have been chosen for this study as the generalised meaning of participants' experience may influence healthcare plans, education tools and workers' empathy, and uncover previously overlooked issues (King & Thomas, 2013; Schneider, Whitehead, Elliott, Lobiondo-Wood & Haber, 2007). An understanding of how bronchoscopy affects the patient will enable staff to alter interventions during the procedure to improve the patient experience, or it may reassure staff that patients are not adversely affected by the procedure.

Van Manen's analysis involves teasing out themes from the data collected. In order to understand the participants' experiences of their world during the phenomenon, van Manen (1990; 1997; 2014) suggests reflecting on how the study's themes relate to universal themes of life: space, body, time and relationality. In this study, these universal themes refer to the day surgery and procedural space, sensations that the participant feels, participants' concept of time, and their interactions with healthcare workers. Presentation of these themes provides a generalised meaning of the participants' experience.

There are some advantages of phenomenology that coincide with this study. It is suitable for small-scale research where the budget is low, as it mainly relies on in-depth interviews rather than requiring sophisticated equipment: the main resource is the researcher themself. Phenomenological descriptions of the experiences can create interesting stories that could attract a wide range of readers. The stories can offer authentic accounts of the

complex phenomenon. It is also considered a humanistic type of research, as the researcher is making an effort to base their enquiry on human experiences (Denscombe, 2010).

Researchers who do not practise phenomenology often criticise the method by suggesting that it lacks scientific rigour: it is mainly descriptive, leads to problems with generalisation, and researchers have difficulty suspending presumptions, therefore results can be coloured by the researcher's beliefs (Denscombe, 2010). Van Manen's approach systematically attempts to uncover and describe the meaning of a lived experience (van Manen, 1990). His formalised methods of data collection, analysis and writing give structure to a research design, promoting credibility and dependability. His approach is not just a description of the participants' experience of the phenomenon but an interpretation of how it affects them.

Van Manen has proposed a researcher mind-set to reduce presumptions and beliefs from colouring the data, analysis and writing (van Manen 1990; 1997; 2014). He claims that researchers often know too much about a phenomenon from exposure to literature and life experience (van Manen, 1984), and it is therefore too difficult to bracket their own ideas. He suggests that it is better to be explicit about preconceived ideas, biases and theories as they are shallow in comparison with the real data that are collected (van Manen, 1984). He also suggests that the researcher identifies and maintains an awareness of these preconceptions to limit their effect on the research reflections (van Manen, 1984; 1990). Dowling (2007) also suggests that bracketing is not appropriate in the interview phase as it restricts development of a rapport between the researcher and participant. The research candidate, for this study, made two main assumptions: an axiological assumption that the combative patient finds the procedure traumatic, and an ontological assumption that each

participant's experience is different depending on their personality, background and personal experience (Creswell, 2013).

## 3.4 Research design

### 3.4.1 Clinical problem

A clinical problem was identified during some bronchoscopies where the patients were given sedation and analgesia cautiously, and the nurse assisting with patient airway perceived that the patient was in distress. The common perceived symptom of distress was when the patient attempted to remove the bronchoscope before the procedure was completed.

### 3.4.2 Cautious sedation and analgesia

Even though generally used in practice, there is no medical definition of cautious sedation and analgesia, therefore routine practices of physicians were observed, clinical expertise was sought, and data were collected and used to develop the following definition, for the purposes of this study:

> *Administration of sedation and analgesia in small doses over an extended period, whereby the patient can be aroused by verbal command or touch, has spontaneous ventilation and cardiovascular function also remains stable.*

In practice,

> *The clinician administers midazolam in 1–2mg doses and fentanyl in 25mcg doses, waits one to two minutes after each individual dose, and observes*

*the patient's response (cautious sedation and analgesia). When adequate sedation is achieved, the procedure is commenced. If the patient wakes during the procedure then additional doses of midazolam or fentanyl may be administered up to a maximum of 5mg and 100mcg, respectively.*

(Definition was created by Catherine Saxon with the assistance of Paul Fulbrook, Steven Leong, Rayleen Bowman and Kwun Fong, 2013.)

### 3.4.3 Research question

To investigate the clinical problem identified, a greater understanding of the patient experience was required. The aim was to provide examples of patients' experiences to influence embedded views of treating physicians (such as, patients do not remember the procedure due to the amnesic effect of sedative drugs), which in turn may influence practices.

The following research question was developed:

*What are the experiences of patients undergoing flexible bronchoscopy with sedation and analgesia, particularly those with high-risk respiratory disease that require 'cautious' sedation and analgesia?*

### 3.4.4 Research aim

The aim of the project was to understand the lived experience of patients with high-risk respiratory disease who have undergone bronchoscopy with cautious administration of

sedation and analgesia. The findings of this study will be used to inform bronchoscopy practice.

### 3.4.5 Setting

To decrease the time burden on participants, recruitment and interviews were conducted at The Prince Charles Hospital in Chermside, Queensland, in the departments where the patients would ordinarily receive medical care or treatment (outpatients department and post anaesthetic care unit). To maintain patient privacy, a private room was allocated for communication between the research candidate and the participants. All areas were fitted with emergency equipment and offered nearby access to medical staff.

### 3.4.6 Data collection

Data collection was conducted by the research candidate (a senior nurse experienced in bronchoscopy). No participants in the study received direct nursing care from the research candidate. Data were collected with face-to-face interviews. Phenomenological research relies on in-depth interviews with relatively few participants, sometimes with multiple interviews for each participant (Polit & Beck, 2012). Along with interview transcripts and interview notes, the following participants' characteristics were collected: age, gender, ethnicity, weight, indications for bronchoscopy, procedure type, medication administered, length of procedure, and length of interviews.

### 3.4.7 Evaluation of methods

To establish and maintain the credibility and authenticity of the study, an audit trail was developed to enable review of interview transcripts, data analysis and data syntheses by

Professor Paul Fulbrook (Polit & Beck, 2012). The repetition of themes between patients and during subsequent unstructured interviews was used to confirm data accuracy (Polit & Beck, 2012).

### 3.4.8 Ethical issues

Before the study started, ethic approvals were obtained from the HREC authorisation from the Research Governance Office (HREC/14/QPCH/49), site specific ethics approval (SSA/14/QPCH/90), and Australian Catholic University (2014160Q). The ethical issues considered were consent, confidentiality, risks versus benefits (National Health and Medical Research Council, 2007).

When approaching potential participants, the research candidate was empathetic, polite and enthusiastic when giving verbal and written study information (Polit & Beck, 2012). They were told that they were invited to participate in the study because they were going to have a bronchoscopy and they had a history of respiratory disease. They were informed that the aim of the study was to understand the experience of patients with chronic respiratory disease who underwent bronchoscopy and that this information could help improve the care and treatment of future patients, and that the potential commitment of the participant would be participation in two, one-hour, digitally recorded interviews. The first interview would take place two hours after the procedure and the other at their follow-up appointment or over the phone if they would not be returning to the hospital. The interviews were described as a conversation with someone, where they are doing most of the talking, so that they can talk about their personal experience. An example of the

questions asked is 'today you had a bronchoscopy, how did that make you feel or what was it like for you?' All this information was given in layman's terms.

The study information provided included how participants were selected for the study, that participation was voluntary, that they could withdraw at any time, and that their treatment would not be compromised if they refused to participate or withdrew from the study. Also included in the study information were the goals of the study, the type of data collected, the time commitment, examples of unstructured interview questions, a pledge of confidentiality and anonymity, the main risks and benefits to the participants, and the research candidate's contact information. To prevent coercion, potential participants were not asked to consent when they were in theatre, nor were they offered inappropriate gifts or promises of better treatment if they participated (Rebar, Gersch, Macnee & McCabe, 2011).

Potential participants were told that all their information would be kept confidential and private, and that their name and contact details would be kept separate from their study data. To maintain confidentiality, interviews would be conducted in private rooms. Participants would be given a pseudonym before the digitally recorded interview to minimise the risk of identification.

All information obtained during the interview was treated according to ethical guidelines (National Health and Medical Research Council, 2007). Computer files were stored in password-protected files. Consent forms, digital interview recordings and transcripts were securely stored at all times to prevent loss, damage or misuse. When not in use, the data were stored in a locked filing cabinet in the Nursing Research and Practice Development Centre, on level 5 of the Clinical Sciences Building at The Prince Charles Hospital. All data will

be destroyed five years post study publication; electronic files will be deleted and paper will be shredded (Australian Catholic University, 2013; Greene, 2009; National Health and Medical Research Council, 2007).

### 3.4.9 Risks versus benefits

Benefits of the study to the participant included debriefing (emotional processing, education, reassurance and social support (North & Yutzy, 2010); stimulation by participation, and pride for contribution to health care (Polit & Beck, 2012). At the end of the two interviews, each participant was given a $25 gift certificate to compensate for costs associated with participation in the project such as loss of time, transport, and parking. Potential risks included psychological distress, fatigue, boredom and loss of time in the interview process (Polit & Beck, 2012). These risks were minimised by the professional psychological and medical support provided during the interview process and no such problems were identified during the interview process.

To reduce risks associated with psychological or physical distress in the patient with respiratory disease, the following plan for psychological and physical distress was developed. In order to provide minimal psychological distress, interviews were unstructured, allowing participants to talk as much or as little about the experience as they desired. If distress occurred, the interview was to be halted and the participant was to be given the option to continue when they were calm, or given the opportunity to reschedule the interview for another convenient time, or they could withdraw from the study. If required, the participants would have been given a referral to the onsite psychologist or accompanied to the mental health acute care department.

To reduce the risk of physical distress, candidates who had a history of shortness of breath or chest pain associated with emotional distress were to be withdrawn from the study. Safe management of physical distress involved access to emergency equipment in all interview rooms, including an emergency buzzer system to notify emergency medical staff. The interviewer also had documented competency in basic life support and clinical experience in observation and management of patients with physical distress. At all times, participants had access to medical staff to facilitate administration of oxygen if required and to provide other emergency health care. If required, the participant could also have obtained a referral to the mental health department to learn techniques to limit respiratory symptoms when distressed. This did not occur during any of the participants' interviews.

### 3.4.10 Recruitment methods

Purposive sampling was used to recruit up to 15 participants (allowing for participant withdrawal or exclusion due to participants' clinical condition). The inclusion criteria were:

- patients who were scheduled for a bronchoscopy with cautious sedation and analgesia
- patients who had COPD and/or respiratory failure.

Recruitment occurred after the patient's outpatient appointment when the physician had decided it was medically advisable to perform a bronchoscopy.

## 3.5 Data collection

Merriam (2009) determined that interviews are necessary when the participant's interpretation of a phenomenon is required. Some advantages of data collection via

interviews include depth of information provided, insights, minimal equipment requirements, participants' priorities can be identified, flexibility, high response rate, high validity, and may be therapeutic to participants (Denscombe, 2010). Interviews can produce depth and detail regarding a subject with appropriate probing and length, leading to new insights. Interviews also enable the consideration of participants' tone, body language, priorities, opinions and ideas. Interviews can be flexible, as questions can be changed to collect the appropriate data from different types of participants with different personalities and stories. Response rates are usually high, as interviews can be rearranged to suit the participant. The interview enabled direct contact with the participant, and data were checked for accuracy and relevance at the time of the interview, therefore promoting validity. Interviews may also have been therapeutic to the participant, as they were able to debrief about an experience to someone whose purpose was to listen, take note of their ideas and not be critical (Denscombe, 2010).

Some disadvantages of interviews include the amount of time taken, no standardisation of data collected, participants may not have told the truth, and digitally recording interviews may have inhibited some participants (Denscombe, 2010). The time burden on the participant was increased with data collection via an interview. Interviewing, transcribing interviews and analysing data were all time consuming, but that was a sacrifice that the research candidate was willing to take, in order to collect this type of data. The data that were collected were a reflection of the unique experience of the individual participant. Some researchers may argue that this adversely affects reliability and generalisability. Social desirability may also have influenced the responses of the participants, in that the participant may have told the researcher what they thought the researcher wanted to hear.

To help manage this, the research candidate wore clothes that were of equivalent status to the participant, rather than a uniform, to ensure that they did not look like a health professional. Van Manen (1990) also advises that the researcher be personable in order to win the trust of the interviewee. He further suggests that the researcher dress neatly in casual attire so they look approachable and that they should be friendly before requesting information on the phenomenon under examination (van Manen, 1990).

Participants were involved in two in-depth, unstructured, digitally recorded interviews. The first interview was conducted around one hour post-procedure, prior to discharge, and the second interview was held 1–10 days later, at the participant's convenience, in the outpatient department (while waiting for results) or by telephone if the participant was not required to return to the outpatient department. The second interview allowed for further fact checking, and was also unstructured. Each of the participants' two interviews was compared for consistency regarding their experience.

The telephone interview allowed collection of data from participants at distant geographical locations (Denscombe, 2010). The telephone interviews had some disadvantages compared to the face-to-face interviews in that there was a reduction in non-verbal cues. Non-verbal cues can assist with determining the meaning of the participants' experience and the truth of the participants' recollections. Other difficulties that were considered were the difficulty in determining if contact was with the correct person, that participants may be less open and/or uncooperative during a phone conversation, and that phone calls were unlikely to exceed 20–30 minutes. One participant was uncooperative regarding the scheduling of the second interview and another was very distressed and did not want to participate in a

second interview, having been given a diagnosis of lung cancer. In both cases, the first interview was used for study data and no second interview was conducted. Interview recordings were transcribed verbatim and combined with the research candidate's field notes (observations related to participants' verbal tone and body language during the interview).

Van Manen's (2014) objective in phenomenological interviewing is to obtain an account of a participant's lived experience in narrative form, not a discussion about the experience. He concedes that this is very difficult and provides several pointers regarding settings, researcher approach and time constraints. He suggests that formal settings are not conducive to thinking about life stories. In order to promote patient privacy, interviews were held in a private room. Due to patient safety requirements, the interviews were conducted in rooms of the hospital but the research candidate only included essential medical equipment in the room, which was discreetly positioned. The participants were offered a hot or cold drink and snack of their choice, not hospital issue or in hospital crockery. When the experience of the phenomenon was broached, the research candidate was enthusiastic and open about the subject. In order to promote a full account of the participant's experience, the interview was arranged for when it did not need to be rushed (van Manen, 2014), that is, one hour prior to discharge.

The research candidate turned on the recorder at the beginning of the interview and then had a friendly conversation before data collection was commenced to allow inhibitions to wear off. The research candidate was friendly and courteous at all times, and conducted the interview as a conversation so the participant did not have to give more information than

they wished. Instead of asking questions to start data collection, van Manen (1990) suggests asking the participant to think of the phenomenon then explore the experience to the fullest. Prompts to facilitate the interview included 'tell me what that was like for you', or 'how did that make you feel?'. Other suggestions included silence to allow the respondents to gather their thoughts, repeating the respondent's last sentence if they got lost or if the respondent started to generalise the experience. The research candidate asked questions such as 'What was it like for you?' (van Manen, 1990).

## 3.6 Data analysis

Van Manen (1990; 1997; 2014) suggests three methods to uncover thematic aspects of the experience:

- Wholistic approach: the researcher reviews the data collected for each interview, selects any significant phrases within the text that capture the whole text's central meaning, and formulates a phrase to express the central meaning.
- Selective reading: the researcher reads the text several times, and highlights statements or phrases that are important or revealing about the phenomenon.
- Line by line approach: the researcher reads every sentence or paragraph and interprets what each sentence reveals about the phenomenon.

When using these three approaches to study the text, several themes emerged (see example in Table 7). The themes were consolidated and refined as they arose in different participants' interviews. Van Manen (1990) suggests reflecting on the study themes in relation to the participants' world. For ease of analysis, he suggests breaking up the

participants' world into four existential themes. These four themes are considered interactive and can help express the participants' world (van Manen, 1990):

- Spaciality (Space): participants' perceptions of the space in which the phenomenon occurs.
- Corporeality (Body): how the participants' physical, emotional, psychological body and presence is affected by the phenomenon (bronchoscopy).
- Temporality (Time): the participants' subjective perception of time before, during and after the phenomenon.
- Relationality (Others): interactions between the participant and other people during the phenomenon.

The final analysis involved writing and re-writing about the themes (van Manen, 1990). Data were presented thematically; each theme was described and represents the participant's experiences of the phenomenon (van Manen, 1990).

**Note**: The study protocol and ethical paperwork were written and approved prior to the publication of van Manen's 2014 text in which he included an additional existential theme: *Materiality* (Lived things). Due to ethical restrictions, this existential theme was not considered in the current study.

**Table 7: Example of analysis process**

| Method | Description | Example |
|---|---|---|
| Wholistic approach | Written phrase that expresses the central meaning | John found the throat spray and introduction of the instrument into his throat made him choke and he tried to cough it out. John could hear them discussing the procedure and feel the instrument wriggle inside him. John was angry but accepting of his circumstances. |
| Selective approach | Selection of phrase that is revealing about the phenomenon | *Oh tried coughing it up all the way down, and every now and then they would move it or wriggle it and you can feel that, and it made you want to cough. Yeah. There was no real pain or anything. Just really made it cough. They yeah, said a bit more, and a bit more, and another one of these, and another one of them, and away they kept on going until I got done. 2a4.2 (2nd participant, 1st interview, page 4, line 2 of interview transcript)* |
| Line by line approach | Line by line Interpretation | *I don't want to choke 2a5.20 (2ND participant, 1st interview, page 5, line 20 of interview transcript)*<br><br>John was upset that the procedure made him choke. |
| Reflection of the theme in relationship to the world we live in | Space, body, time, relationality | Space: John was aware during the procedure.<br><br>Body: The procedure made John cough and choke, he did not feel any pain and he could feel the scope moving inside him. He was angry that the procedure made him choke.<br><br>Relationality: John could hear the doctors talking, he knew they were doing their job. He said all the staff were good down there. He was angry that he did not go to sleep. He did not blame the doctors for his choking and coughing. |

## 3.7 Findings

### 3.7.1 Participants

To provide rich examples of the phenomenon, 13 participants were interviewed. After the interviews were transcribed and analysed, it was judged that the data were sufficient and of adequate quality (Malterud, Siersma & Guassora, 2016). All participants were diagnosed with the high-risk respiratory disease, COPD. All bar one participant had been told that they may have lung cancer and that the procedure would help make a diagnosis. Due to the organisation's cohort, all participants were white Australians. They were aged between 30 and 70 years and were predominantly male (see Table 8). In Australia, the rate of COPD increases with age and is higher in males (Australian Institute of Health and Welfare, 2017). Three participants declined to participate in the study. Twelve participants were excluded from participating for the following reasons: their follow-up outpatient appointment was too late for conducting the second interview, they were given amounts of sedation greater than the study's definition of cautious sedation, they had a sore throat after the procedure, or their procedure was abandoned or cancelled (see Table 9).

**Table 8: Participant and procedure details**

| Participant pseudonym | Age (years) | Gender | Weight (kg) | Lignocaine (mg) | Midazolam (mg) | Fentanyl (mcg) | Indications for procedure | Procedure | Length of procedure (min) |
|---|---|---|---|---|---|---|---|---|---|
| **Bob** | 59 | M | 76 | 220 | 4 | 75 | Haemoptysis + RML mass | Diagnostic + BAL | 31 |
| **John** | 65 | M | 83 | 260 | 7 | 0 | Shortness of breath, changes on x-ray | Diagnostic +EBUS G/S | 55 |
| **June** | 79 | F | 60 | 200 | 4 | 75 | X-ray changes | Diagnostic +EBUS G/S | 46 |
| **George** | 80 | M | 82 | 200 | 5 | 0 | Haemoptysis + Right Pleural effusion | Diagnostic + Wash | 9 |
| **Ian** | 79 | M | 77 | 220 | 3.5 | 100 | Haemoptysis | Diagnostic + Wash | 23 |
| **Nathan** | 81 | M | 74 | 220 | 5 | 100 | RLL Mass | Diagnostic +EBUS G/S | 25 |
| **Kelly** | 78 | F | 72 | 260 | 4 | 75 | RML Mass | Bronch +TBLBx | 23 |
| **Penny** | 70 | F | 65 | 220 | 5 | 100 | Haemoptysis + history of lung cancer | Diagnostic + Wash | 19 |
| **Mark** | 55 | M | 35 | 220 | 5 | 100 | RL mass | Diagnostic +EBUS G/S | 28 |
| **Rachel** | 35 | F | 34 | 140 | 3 | 100 | Persistent cough bronchiectasis | Diagnostic + Wash | 9 |
| **Sam** | 69 | M | 124 | 220 | 2.5 | 50 | Haemoptysis + history of small cell lung cancer | Diagnostic + Wash | 15 |
| **Alec** | 48 | M | 98 | 260 | 8 | 100 | Lung mass | Diagnostic + Wash + Endo bronchial biopsy and brush | 32 |
| **Cameron** | 56 | M | 74 | 140 | 5 | 100 | Haemoptysis | Diagnostic + Wash | 22 |

**Table 9: Excluded participants**

| Reason | N (%) |
|---|---|
| Follow-up appointment too late for interview | 1 (6) |
| Cautious sedation not used | 8 (53) |
| Procedure failed | 1 (6) |
| Procedure cancelled | 1 (6) |
| Participant withdrew due to sore throat post-procedure | 1 (6) |
| **Total** | **12** |

### 3.7.2 Themes

Six themes emerged from the data analysis: '*Waiting there'*; '*The worst part'*; '*Being aware'*; '*Feelings of comfort and safety'*; '*After effects'*; and *'Feelings of acceptance or dissatisfaction'.*

'Waiting there' included the participants' experiences of frustration and where they dwelt on their fears. The 'worst part' for participants in this study was the choking and coughing they experienced. 'Being aware' during the procedure meant that they recalled episodes of choking and coughing and were hurt by physicians' conversations that they overheard during the procedure. Participants also reported on the 'Feelings of comfort and safety' during the procedure. As denoted by the theme 'After effects', there were notable physical and psychological effects of the procedure. 'Feelings of acceptance or dissatisfaction' reflects that participants often accepted their negative experiences due to their perception that the procedure was a necessary evil but some participants remained hurt and angry due to their experience; they felt that they should have been treated differently.

### *3.7.2.1 Waiting there*

This theme is a result of exploring participants' experiences before and after the procedure. Feelings of frustration were common during the waiting time before the bronchoscopy. Participants discussed waiting for long periods, going without food for too long, and having to complete a large amount of paperwork for admission. These circumstances, along with fear and anxiety regarding their procedure and potential diagnosis, were compounded while they were 'waiting there'. Ian and George were particularly frustrated by the waiting time and length of fasting pre-procedure:

> *I arrived there at ten past eight, and I never got into the theatre until quarter past one, and I'd been on a fasting from the afternoon before. I went—oh well you can say I went twenty hours without food … That is something that will have to be improved on. What happened to country people getting priority?* (Ian)

> *I was waiting there longer than what it took. I was supposed to have it—I was first off the rank they told me at eight am. The got me—the car that comes from Bribie—they go all over Bribie more or less, but they only picked up about two, four, six or seven passengers and I got in about seven forty. I thought, oh well I'll get in straight away. But there were other people here before me and they got in before me and they got it.* (George)

From these discussions, it was clear that some participants waited and fasted a long time before the procedure. Having hunger pains did not make the experience enjoyable for them. Participants did not discuss their occupation during the time they waited before the

procedure, other than their frustrations and fears. While waiting post-procedure, Kelly felt neglected. She did not know who her nurse was and when the doctor was coming to give her the results.

> *I have to say it degenerated ... I didn't get to leave until four o'clock ... I said to somebody passing by, 'Excuse me but how long do you think I'm going to have to be here now?' This lovely young woman said, 'Who's your nurse?' I said, 'I don't know.' … nobody seemed to give an axe whether I was there or I wasn't, or anything else …* (Kelly)

Kelly's feelings were compounded by the space in which she recovered. It was busy with numerous patients; she was told to go to sleep by staff despite these circumstances.

> *Why don't you have a snooze? Yeah, well how the hell can you have a snooze when there's about 20 people roaring around? … Now, I don't mind at all not sleeping, because I'm not a sleeper. But the idea of suggesting to someone that, oh why don't you have a snooze while you're waiting to get your tea and sandwich, I mean, hello. Have a snooze? Give me another shot and then maybe I'll have a snooze.* (Kelly)

Kelly's interactions with the staff during recovery led to feelings of frustration and hurt; she felt the staff did not care.

Some participants were not concerned about long waiting times. Alec was aware of his environment while he waited. He was aware that the staff were busy and had commitments

before his procedure. He accepted that, even though it was not optimal, as described below, he had to wait.

> *I was in the recovery room before the procedure on the long list, but I suppose you've got to wait in line for your turn, but other than that, I was really impressed.* (Alec)

John and Kelly were particularly frustrated by the paperwork required pre-procedure; they felt it was excessive:

> *The nurse took me in and done all the paperwork. Seemed liked 10 mile of it ... just too much paperwork. Even the nurse is struggling with it, I reckon.* (John)

> *… as an old public servant who used to be pretty good at paperwork, it seems to me that there's a huge amount of repetition and strange things, like sending you home with an envelope full of stuff for you to read and fill in prior to your procedure, which makes a great deal of sense. But then when you get here, they've got yet another form which asks for very similar information but in more detail and different things like specialist.* (Kelly)

Participants' perceptions of the hospital's admission procedure were not always positive. They often found the environment and interactions with the staff frustrating in relation to paperwork, waiting and fasting time. Further, their fears contributed to the negative experience of waiting there. A common fear among participants was that the procedure

would hurt. They were scared that the procedure would be uncomfortable and make them cough. This is illustrated in the following quotes:

> *Pretty nervous beforehand actually ... oh, just the fact they were going to stick cameras down my throat ... I was worried about—yeah, well, whether I was going to cough, you know was it going to be sore afterwards and things like that you know?* (Alec)

> *I thought it was going to be actually very cruel … I expected it to be hurtful … I was dreading it so much.* (June)

Two participants were not scared; the basis for this lack of fear focused on their experience of similar procedures and religious faith. See quotes from Kelly and Ian below:

> *I'm not a nervous … I'm a very stoic person … I've had a lot of endoscopies and it's very similar.* (Kelly)

> *I wasn't even—not nervy about it. I don't know, it's—I've just got faith in this. I believe there is arrangements.* (Ian)

Fear or anxiety related to the participant's potential diagnosis was a common experience. Most participants were aware that they may have lung cancer and the bronchoscopy was a tool to confirm or deny this diagnosis. Participants' experiences of fear and anxiety, relating to their procedural results, are illustrated in the following quotes:

*A bit nervous about seeing any of them … I just don't like the results sometimes.* (John)

*I'm just hoping it's not very big.* (June)

*I'm still 'trepidatious' because I don't know what the result is going to be … of course, today is the day I really find out.* (Kelly)

*When I'm coughing up blood like that, I thought I'd definitely have to—but they're saying the CAT scan and the X-rays have come up good. But I suppose there's no guarantee still. Now I'll just wait and see. I got here as early as I can. If you put things off—keep putting things off, you're going to die. Things only get worse. That's what happened to my father.* (Cameron)

The psychological strain was evident during participants' conversations. For example, Bob said:

*Woke up in the middle of the night and you know you just sort of hash a few things … a big infection or it could be a cancer ... it was just churning away inside … So some sort of pre-med I suppose, something to calm you down a bit.*

Participants were worried about how much time they would have to live, if they had lung cancer. As one participant stated,

*I won't find out about it until Thursday but it has been a long, I found out basically last Tuesday so it has been a long week. And to go from waking up in the morning to possibly having it.* (Mark)

*I'm hoping it could be a year, it could be 10 years or something, 20 years.* (Bob)

In summary, this theme describes the participant experience while 'waiting there', i.e. before their procedure. No participants described this as a pleasurable experience, and the waiting time was perceived as excessive. The physical and psychological effects of waiting included feelings of hunger, frustration, neglect and fear. Participants feared that the procedure would hurt and the results would determine how much longer they had to live. Interactions with staff on admission included excessive amounts of paperwork, for the participants and the nurses. Over an extended period of time, the staff in recovery were unable maintain positive interactions with a participant, leaving them feeling neglected, which was exacerbated by their perception that the recovery room was noisy and not conducive to sleep. Although the waiting period was largely considered to be a largely negative experience, participants did not perceive this as the worst part of their experience.

### *3.7.2.2 The worst part*

When participants were not aware during the procedure, they commonly described the throat spray as the worst part of their experience. It was considered distasteful, and resulted in feelings of choking and difficulty in swallowing. This is illustrated in the quotes below:

*I always comment about how horrible it tastes … I have to say that that was uncomfortable for a little bit, because you could feel that there was mucus there but you felt you couldn't swallow, although he assured me that you can swallow you just don't think you're swallowing.* (Kelly)

*The worst part was spraying the stuff in my mouth … just yucky, you know … Whether he didn't wait long enough or what, and I gagged and it was dreadful, absolutely dreadful. I was so glad when he finished. I thought that … I'm going to gag.* (June)

*The spray that they put down your throat … I don't know what it is supposed to do but yeah. It built up, built up and there was a bit of a gurgle up. Sort of you can't breathe because it's stuck in your throat.* (Ian)

Coughing and/or choking during the procedure were the worst part of the experience for some participants. They remembered the coughing and choking because they were aware during the procedure. This was upsetting for them, however they did not want to make the procedure more difficult for the physician because they felt that the physician was trying to help them. Participants were also worried that the physician's ability to obtain a diagnosis for their condition would be thwarted if they continued coughing, but they could not stop the coughing so they became upset.

*Had this thing stuck down me throat … tried coughing it up all the way down, and every now and then they would move it or wriggle it and you can feel that, and it made you want to cough ... There was no real pain or anything. Just really made it cough … Choking was the worst. I felt I didn't*

*want to choke, because it would probably make it harder for them, so I was struggling not to cough or anything. But yeah I suppose that was the worst part … maybe they've got enough I don't know.* (John)

*I coughed nearly all the time that he was doing it ... They kept spraying inside the mouth to ... well they were trying to stop the coughing because I couldn't help coughing … I knew I was coughing a lot … I couldn't help coughing because you've got this thing in your throat … When I didn't go to sleep, well I felt that I would have been better if I went to sleep … You see, last time I had the—whatever you call it, right down into my lung they put me out; right out and I had a good sleep. But this time they didn't …* (George)

The worst part for participants was the physical experience of coughing and choking. This resulted in feelings of distress. This, in part, was due to participants' desire to not make the procedure difficult for the staff. Participants expressed a high regard for the staff and a strong desire to obtain a diagnosis of their condition.

### *3.7.2.3 Being aware*

Participants' experiences of being aware during the procedure included coughing and choking, difficulty breathing, fear that they were disrupting the procedure, and hearing information at an inappropriate time. When participants were aware during the procedure, they were aware of what the staff were talking about. This was particularly concerning for Bob, because he thought he needed a biopsy to obtain a diagnosis regarding his possible lung cancer. When he overheard that the doctors could not take a biopsy he was angry. He

thought this would prolong the process for his diagnosis. He wanted to know how much longer he had to live.

> *I can remember like them saying … can't go there … no, can't see it there … I could almost tell where they were poking the 'scope from the way they were talking … but I couldn't feel anything … now I know they haven't done a biopsy ... I can't see how they're going to tell anything.* (Bob)

Being aware during the procedure caused physical difficulties in breathing and coughing. Participants found the mouth guard inserted prior to the procedure to be uncomfortable. They were often perturbed by having their eyes partially covered with a cloth. Some could remember seeing the thin black instrument (bronchoscope) when it was inserted into their mouth, and some participants felt that the physicians should have put them to sleep. In addition, when participants were awake during the procedure, they said that this caused further anxiety because they were given an additional opportunity to worry about their circumstances and success of the procedure.

> *They covered my eyes up and they put this thing in your mouth (mouth guard) and it's a bit hard to breathe …. I went through the whole thing. I couldn't feel him doing—not down but it didn't hurt. I cough nearly all the time that he was doing it … I would have been better if I went to sleep. Then you're not worried about it.* (George)

> *Every now and then they would move it or wriggle it and you can feel that, and it made you want to cough. Yeah. There was no real pain or anything. Just really made it cough. They yeah, said a bit more, and a bit more, and*

*another one of these, and another one of them, and away they kept on going until I got done.* (John)

Not all participants were disturbed about being aware during the procedure. June found that the drugs relaxed her and due to her curious personality she enjoyed the experience. She recalled:

*No, I was wide awake the whole time … I could see what was going on, like I could—I saw what I thought was a black thing in front of me, just a line. But didn't feel a thing. The only thing that was nasty was the ... down the throat (throat spray) … know I was too busy having a little sticky beak. I'm shocking … It was just like I was drunk … I felt like I was having a wonderful time.* (June)

Just under half the participants had no awareness during the procedure. They were, of course, not upset about this experience. Some quotes illustrating this positive experience include:

*Once he put the stuff in there, away I went … once they knocked me out that was it.* (Ian)

*I don't remember nothing.* (Nathan)

Being aware during the procedure led to negative physical (choking and coughing) and psychological (worry about hindering the procedure, information at inappropriate times) experiences. However, interactions between participants and staff in the procedure room provided participants with some positive experiences.

### *3.7.2.4 Feelings of comfort and safety*

Participants recalled feeling comforted and safe in the procedure room. They believed that the staff provided a relaxed atmosphere; they distracted the nervous participants with chatter and humour. The participants described feeling safe during the procedure as staff displayed their skills and experience. It was also discussed that the participants felt that there were enough staff in the procedure room to safely care for them if something went wrong. Participants described staff as being helpful, efficient, caring, pleasant and comforting. In this way, participants felt they were able to place their bodies into the care of the procedure room staff.

> *Bit of humour, lighten the mood, I wasn't so stressed when they started talking about different things. One of the nurses, she was talking about glasses and that, so just getting your mind off the actual procedure eases it as well.* (Rachel)

> *I was very impressed with … the way they've been on the ball.* (Alec)

> *But you know I didn't have any problems with—you know the people in theatre were very friendly and stuff like that. Everybody knows their job and does their job, and very efficient and stuff like that.* (Bob)

> *I wasn't worried at all … I know there was a shitload of people there with instruments and stuff; I didn't feel in danger of dying.* (Cameron)

> *The staff was good down there.* (John)

*They were wonderful, really wonderful.* (June)

*I put my life in his hands because he is a terrific man. Terrific doctor …* (George)

The number of staff that filled the procedure room was overwhelming at times for one participant:

*They're around you like a mob of flies. You know all over the place … is about seven or eight there … well, one was doing this and one was doing something else … I probably was a bit anxious I suppose.* (George)

Participants felt that the procedure room was not always pleasant, but was a safe environment. They were able to entrust their bodies into the care of the procedure room staff. This was due in part to the interactions between the participants and the procedure room staff. There were 'after effects' of the procedure that included some negative experiences.

### *3.7.2.5 After effects*

Participants experienced many physical 'after effects' of the procedure, including headaches, sore throat, coughing, and discomfort. These effects generally did not last more than 24 hours. Participants also described factors that may have contributed to these after affects: insertion of the instrument in their throat, and flushing of fluid into their lungs, as illustrated in the following quotes:

*I had a stinking headache. But I had a headache before I went in anyway, so that's probably the same.* (Bob)

*When I got … home my head was like a pumpkin … I finished up with a roaring headache.* (George)

*Still a bit sore in the throat. Was pretty sore.* (John)

*I've got a slight discomfort on the roof of my mouth, from the whatever.* (Kelly)

*Sore throat was for probably a couple of days.* (Rachel)

*I think they flushed my lungs a bit with the camera down there … might have shaken … the mucus … to try and get me to bring … (mucus) up and out of the lungs … My asthma … for the first 24 hours, it was like a dry hacking cough … bit of a sore throat … for probably a couple of days.* (Rachel)

*Only a bit of chest discomfort, like a bit of … you know sometimes when you move the wrong way or breathe.* (Bob)

*Probably tired more than anything.* (Penny)

*I've been drowsy and nodding on and off, but apart from that you know I didn't feel any, I wasn't feeling weird or anything.* (Mark)

However, not everyone experienced after effects. For example, June said:

*I felt marvellous. So they said 'how do you feel?' I said, 'Wonderful'. They said 'really'? I said, 'Yeah'. I said I felt like nothing's happened. But you know I might have been on a high too, who knows? I felt pretty good actually.*

Participants frequently discussed the corporeal after effects of the procedure. There were the physical effects of headaches, sore throat and aggravation of asthma and the psychological effects of anger, resentment and anxiety. There were residual effects of anger towards hearing that the physicians were unable to obtain a sample during the procedure and anger due to the circumstance where they did not sleep during the procedure. There was the ongoing anxiety relating to the procedural results and whether the physician was able to get the required specimens during the procedure. Participants also discussed aspects within this theme, in relation to their experience, of temporality. For example, participants were frustrated when the time for discharge was prolonged, and with the time it was taking to garner the procedural results. Participants were also dwelling on the meaning of these results in respect of how much time they had to live. These feelings of anxiety and frustrations influenced participants' feelings of acceptance of the phenomenon or resulted in dissatisfaction.

### *3.7.2.6 Feelings of acceptance or dissatisfaction*

Some participants accepted that the procedure was a necessary experience. Positive relationships with the staff, necessity of the procedure, and amnesia during the procedure facilitated this notion of acceptance. John was aware during his procedure but Kelly was not.

*But anyhow, you learn to put up with that (procedures) … they were all good down there, all the staff was good down there, they all joked and carried on. So … What more could you ask for?* (John)

*Well I mean if you've got to do it, you've got to do it. There's no point in … But the only trepidation of course now, is the results.* (Kelly)

When Bob reflected on his experience of the procedure he was not as positive as John or Kelly; he was not happy that he was aware during the procedure.

*I went in there under the thought that I was going to have a biopsy on this thing that's in my lung here or whatever, but they didn't do a biopsy. So now I know they haven't done a biopsy, whereas I suppose if I was asleep I wouldn't know, I would have been none the wiser until I went on Tuesday. So whether that's good or bad, I don't know.* (Bob)

George was also vocal about his dissatisfaction regarding the procedure and how it was carried out; the fact that he was aware during was also considered a negative experience.

*When I didn't go to sleep, well I felt that I would have been better if I went to sleep. Then you're not worried about it and you are not … I wanted a bit of sleep anyhow. I only had about two and a half hours the night before.* (George)

Perceptions of acceptability or dissatisfaction were affected by the participants' relations with healthcare workers during the procedure. Participants were comforted by staff in the procedure room. The procedure was a necessity, if the participants wanted a diagnosis and

prognosis for their condition. The procedural results were required so that the participants could plan for the time they had left to live. When participants were not aware during the procedure, their perception of the experience was not coloured by the negative consequences of awareness during the procedure.

## 3.8 Reflections following second interview

The data collected were from both the initial interview post procedure and the follow-up interview 1-10 days post procedure. Both interviews were unstructured thereby avoiding any prompts to confirm previously acquired data. None of the participants changed their stories. If a participant was disturbed by the procedure during the first interview then they again brought up their concerns in the second interview. Emotions were more muted in the second interview for Bob. Bob apologised for being so angry in the initial interview (he was angry about not getting a biopsy during his procedure). Consequences of the procedure were explored during the second interview. In the second interview Kelly debriefed about having to wait a long time before discharge and Rachel talked about having a sore throat and aggravation of her asthma for a couple of days. The second interviews allowed confirmation of data collected from the participants' first interviews and the collection of more data relating to the consequences of the procedure.

## 3.9 Summary

A qualitative study was conducted to investigate experiences of patients who undergo bronchoscopy with 'cautious' sedation and analgesia. The underlying conceptual framework for this study involved a number of interrelating concepts including patient advocacy, suffering, the patient's best interests and current literature, which led the researcher to a

design a study that investigated the patient experience of this phenomenon. The research design was based on the phenomenological writings of van Manen (1990; 1997; 2014). Data was collected from 13 participants. The themes discovered within the participants' interview transcripts were not independent of each other. Themes were teased from the data when more than one participant had a similar experience. Each theme gives examples of patients' experiences of this phenomenon. The themes will now be discussed in relation to current literature.

# Chapter Four: Discussion and Conclusions

## 4.1 Overview

The final chapter of this thesis, Chapter Four, presents the discussion of the qualitative interview study in relation to the concepts raised in the systematic review. Chapter Four also includes the qualitative study limitations and conclusions, and ends with implications for future research based on the systematic review and the qualitative study.

## 4.2 Discussion

The conceptual framework for this thesis is based on the interaction of a number of concepts that influence the patient experience. The concept of advocacy in connection with nursing frameworks is not new. Bramlett, Gueldner & Sowell (1990) discussed the roles of various theorists who linked advocacy to nursing frameworks. Advocacy is an ingrained part of nursing practice (Barmlett al., 1990) and the underlying motive for conducting this investigation. The research candidate has aimed to prevent advocacy and other framework concepts (suffering, patients' best interests, current literature, and hospital policy) from influencing the thesis findings. The rigour of the literature review was in part protected by the use of Covidence online software, which incorporates Cochrane guidelines for systematic reviews. The website ensures that more than one reviewer is involved in the selection of studies, evaluating study quality and extraction of data. Phenomenological methods and, more specifically, van Manen's (1984; 1990; 1997; 2014) writings have been used to safeguard the data collected in the qualitative study. Van Manen (2014) directed the research candidate to abandon her own prejudices that were rooted in her conceptual framework and concentrate on the data collected. The qualitative study findings will be

compared to current literature so that the themes can be interpreted in the context of prior knowledge.

Bronchoscopy is considered an unpleasant procedure without sedation (British Thoracic Society Bronchoscopy Guidelines Committee & Subcommittee of Standards of Care Committee of British Thoracic Society, 2001; Gonzalez et al., 2003). In 2001, the British Thoracic Society provided guidelines for sedation use in bronchoscopy. This was in response to conclusions from randomised controlled trials that measured the patient experience in bronchoscopy with sedation. The reports indicated that the negative symptoms associated with bronchoscopy decreased with sedation (Crawford, Pollock, Anderson, Glavin, Macintyre & Vernon, 1993; Maltais, Laberge & Laviolette, 1996; Rees, Hay & Webb, 1983). Other thoracic societies followed suit in Australia and New Zealand (Wood-Baker et al., 2001), Israel (Shulimzon, 2010) and America (Wahidi et al., 2011). Recent surveys in Australia and New Zealand, Switzerland, and Spain reported that sedation during bronchoscopy is routinely used in most of the hospitals (Gaisl et al., 2016; Salgado et al., 2015). Eighty-eight percent of patients having flexible bronchoscopies in Germany are sedated (Hautmann et al., 2016), however patients are still having bronchoscopy without sedation. The most recent survey from the United Kingdom was conducted by Smyth & Stead (2002). They found that 63% of physicians sedated patients and 14% administered analgesia. The most recent survey in Japan found that 36% of physicians provided sedation (Asano et al., 2012).

The study conducted for this thesis used a sample of patients who had COPD and underwent fibreoptic bronchoscopy. The participants were given cautious sedation and

analgesia. Data were collected via unstructured interviews to reduce bias in data collection and were analysed with phenomenological methods based on the writings of van Manen (1990; 2014). The study participants recalled many experiences of the phenomenon. Psychological experiences included distress, anxiety and frustration. Physical experiences included coughing, breathlessness, choking, sore throat and headache. Often, participants were satisfied with their experience but, due to awareness during the procedure and feelings of neglect post-procedure, some participants were dissatisfied. Some aspects of these experiences have been measured in bronchoscopy studies previously. Studies have asked patients to measure aspects of their psychological and physical experience plus their overall satisfaction in regard to the experience.

The patient self-reported outcomes that have been used previously to measure the psychological impact of bronchoscopy include amnesia, distress and intolerance. In the current literature concerning patient experience in bronchoscopy, these psychological outcomes were often more adverse when lower levels of sedation were administered during the procedure (Cases Viedma et al., 2010; Gonzalez et al., 2003; Lo et al., 2011; Hwang et al., 2005; Schwarz et al., 2007; Silvestri et al., 2009). Cases Viedma et al. (2010) and Gonzalez et al. (2003) found that sedation versus a placebo resulted in greater amnesia and less negative physical experiences. Unfavourable psychological outcomes were reduced when midazolam or nitrous oxide were given to patients during bronchoscopy compared to administration of a placebo (Atassi et al., 2005; Cases Viedma et al. 2010). Patients reported these negative experiences less when they underwent the procedure with propofol rather than midazolam (Clark et al., 2009), or when propofol and ketamine were administered

versus propofol and alfentanil (Hwang et al., 2005). Not all studies concerning patient experience in bronchoscopy asked patients to report on psychological outcome measures.

Cases Viedema et al. (2010) found that patients who had sedation in bronchoscopy were more likely to have amnesia. Just under half of the qualitative study participants had amnesia. The lack of amnesia often resulted in negative experiences. One participant was upset when he heard information from the doctors at an inappropriate time. If the patient had amnesia, then this distress could have been avoided. Other experiences that caused distress were largely related to physical experiences including throat spray, coughing and choking, headaches, sore throat and aggravation of asthma.

The anxiety of the participants in this study was triggered by fear that the procedure would be uncomfortable and, in some cases, the fear that if they coughed the doctor would not obtain the required specimens for their diagnosis and prognosis. Poi, Chuah, Sirinivas & Liam (1998) performed a mixed methods study to elicit patients' fears before bronchoscopy. They found that the most common fear was that the procedure would be painful. This fear may be unfounded in respect to the qualitative study conducted in this thesis as none of the participants said that the procedure was hurtful; they often said it did not hurt. Poi et al. (1998) reported other common fears including breathing difficulties, irritation in the throat, bronchoscopy findings, sedation, and local spray. They found that the doctors tended to tell patients why they were performing the procedure but not how, recommending that written information for patients should be provided, listing the sensations that they are likely to experience. In this research, the study participants recalled not knowing enough about how the procedure would affect them. The literature that participants received prior to the

procedure described how the procedure would be performed, but not how it would make them feel. The education that the physician gave the participants before the procedure was not explored as a component of this thesis.

Most of the participants in this study had been informed that they may have lung cancer prior to being given information and instructions about the bronchoscopy. Results of cognitive-psychological experiments have reported that a patient's recall of medical information after being given bad news is reduced (Kessels, 2003). Kessels (2003) and van Osch, Sep, van Vliet, van Dulmen and Bensing (2014) make suggestions to improve patient recall after the delivery of bad news. They suggest that the person delivering the patient education needs to consider first the patient's emotional needs, then provide simple and specific instructions with supportive written and visual documentation. Although the participants of this study were scared before the procedure, this was often reduced once they arrived in the procedure room. The study participants found that the presence of a large—perceived as competent—health care team that was humorous and relaxed reduced their anxiety. Humour is known to reduce stress and increase a person's ability to cope (Tremayne, 2014).

Another common cause of anxiety for the qualitative study participants was the fear that they had lung cancer and may receive a poor prognosis. This was found to be a fear in a previous study that explored patient fears prior to bronchoscopy (Poi et al., 1998). The review of the associated literature identified a communication technique, referred to as affective communication, to manage this fear (van Osch et al., 2014). This technique includes asking the patient what they fear, listening to their fears, exploring the validity of

these fears and then explaining how they will be supported. The findings of the qualitative study have increased awareness regarding bronchoscopy patient fears. Recommendations to reduce these fears include strategising patient education pre-bronchoscopy, including asking patients about their fears, discussing their fears, informing them of when they would receive the results from their procedure, and describing how they will be supported during and post-procedure.

Frustration was not an outcome measured in any of the quantitative studies in bronchoscopy. However, it was identified on the current qualitative study where participants' feelings of frustration were found to be related to hospital policies and procedures, namely large amounts of documentation, long fasting and waiting times. Paperwork is a requirement for patient safety and quality care, but the administrative burden can shift the focus from the patient care to paperwork (American Hospital Association, 2006). Fasting times were not measured in this study, but it is apparent that some participants fasted in excess of the current recommendations. Fasting is required prior to a bronchoscopy to prevent aspiration of food or fluids into the lungs (Ignatavicius, Workman & Winkelmann, 2014). Recommendations for fasting before bronchoscopy are four hours for food and two hours for clear fluids (Shulimzon, 2010; Du Rand et al. 2013). Research has reported that fasting procedures lower blood sugar levels, which can be associated with higher levels of aggression in frustrating situations (DeWall, Deckman, Gailliot & Bushman, 2011). Waiting time is not a new cause of frustration in the hospital system; a systematic review of patient satisfaction in emergency departments found that waiting time was one of the predictors of in-patient dissatisfaction (Boudreaux & O'Hea, 2004). Van Manen (1990) suggests that experiences of time seem to speed up when people

enjoy the experience and slow down when they do not (van Manen, 1990). He also suggests that experiences of waiting can feel extended due to inactivity during this time (van Manen, 2014). Those who participated in the qualitative study did not describe the environment for which they waited prior to their procedure, other than they thought that it was a busy space. However, they did discuss how they dwelt on their fears during this waiting time. Given that they had time to dwell on their fears, it is possible that they were physically inactive during this time, potentially increasing their perception of longevity during the waiting period.

The literature review found that when patient experiences in bronchoscopy were measured, the main physical outcomes measured were pain and cough. The participants' ratings of pain and cough were reduced with greater amounts of sedation and the addition of analgesia (Atassi et al., 2005; Cases Viedma et al., 2010; Gonzalez et al., 2003; Schlatter et al., 2011; Silverstri et al., 2009). Unfortunately, other physical impacts of the procedure were not consistently or were rarely measured, such as breathlessness and choking, but when used, participants generally rated them lower when they were given more sedation (Cases Viedma et al., 2010; Clark et al., 2009; Gonzalez et al., 2003; Rolo et al., 2012; Lo et al., 2011). Bronchoscopy patient perceptions of comfort during the procedure have been identified as independent of their perceptions of cough and breathlessness during a study conducted by Lo et al. (2011). This study compared two drug regimens: i) the treatment group received propofol and alfentanil; and ii) the control group received midazolam and alfentanil. The researchers asked their subjects to rate their tolerance of the procedure, experience of cough, breathlessness, and comfort. They found that the treatment group rated their tolerance significantly higher than the control group, and rated their experiences

of cough and breathlessness significantly lower than the control group, but there was no significant difference between the group's ratings of comfort. This may be explained by the fact that both groups received a pharmaceutical drug relief (alfentanil) as part of the drug regime.

In the current qualitative study, participants experienced coughing and choking because of the throat spray, automatic reflexes, and awareness of the passage of the bronchoscope in their lungs during the procedure. Participants' descriptions of the throat spray included distaste, throat swelling, choking, and difficulty swallowing. Discomfort related to the throat spray in bronchoscopy was measured by Lo et al. (2011) and Contoli et al. (2013). Lo et al. (2011) found that there was no significant difference in discomfort from throat spray when patients who had propofol were compared to patients who had midazolam. It is unclear from the Lo et al. (2011) study whether the patient's throat was sprayed with local anaesthetic before or after sedation was administered. Contoli et al. (2013) also measured patient experience of the throat spray but the results were not reported, as the experience was measured as part of an overall tool to measure patient tolerance of the procedure. Some qualitative study participants described throat swelling after their throat was sprayed pre-procedure. This is not a new finding. One study found that a significant number of patients with asthma have airway constriction after throat spray (McAlpine & Thomson 1989).

The patient experience of coughing and choking has been measured in quantitative bronchoscopy studies: patient ratings of coughing and choking decrease with increased sedation. To the research candidate's knowledge, the effects of coughing and choking on

the patient have not been explored until this thesis. Coughing and choking caused the qualitative study participants distress and fear. The participants feared that they were making the procedure difficult for the staff and as a consequence they may not obtain the specimens for the procedural diagnosis. The qualitative study participants recalled breathlessness as a post-procedure experience, but no participants mentioned that they were short of breath during the procedure. Lo et al. (2011) asked their subjects to rate their breathlessness during bronchoscopy. Their study compared patients' experience of bronchoscopy with propofol or midazolam. They found that the midazolam group had significantly higher ratings of breathlessness. Amnesia was not measured in this study.

No qualitative study participants described experiences of nausea. The only study on the subject of bronchoscopy that measured patient experience of nausea in bronchoscopy was by Rolo et al. (2012). They compared the use of midazolam as a sedative with a placebo. They found no significant difference in patient ratings of nausea between these groups.

None of the qualitative study participants recalled the procedure as being painful. Participants did describe some experiences that they thought were uncomfortable; these included coughing and choking. They described headaches and sore throat as post-procedure discomfort.

Qualitative study interviews were unstructured, thereby not allowing direct questioning regarding pain. The review of current literature found that pain was the most common outcome measured to reflect patient experience in bronchoscopy. In these studies, subjects rated their levels of pain lower when they were given sedation (Cases Viedma et al., 2010;

Gonalez et al., 2003; Schlatter et al., 2011; Schwarz et al., 2007). More research is required to determine why participants would find the procedure painful.

Some participants of the qualitative study accepted that the bronchoscopy experience was necessary. They described an overwhelming desire to find a diagnosis and prognosis for their condition. The positive relations with the staff in the procedure room may have influenced their ability to accept the procedure and the negative experiences. Unclear satisfaction and dissatisfaction were related to participants' awareness during the procedure. There have been some studies that have measured patients' degree of awareness during bronchoscopy (Silvestri et al., 2009; Cases Viedma et al., 2010), but its impact on the patient's experience has not been explored previously. While awareness and potential distress may be alleviated with greater levels of sedation, this may increase the risk of complications. Risks may be reduced with the choice of sedation. Propofol provides a higher quality of sedation than midazolam (Clark et al., 2009) and due to its short half-life and rapid action it is often the drug of choice for older patients with COPD (Gruber & Tschernko, 2003). In a recent study by Stolz et al. (2004). It was reported that the use of propofol was relatively safe in high-risk respiratory patients with only minor adverse events (hypotension and oxygen desaturation). Propofol may have some benefits but its use is limited to the presence of an anaesthetist, which increases the overall cost of the procedure.

## 4.3 Limitations

In this qualitative study, limitations included not observing the participants' bronchoscopies. Observation notes from an independent researcher of the participant procedures could

have validated participants' stories and determined if amnesic participants exhibited signs of suffering or distress during the procedure. Also, interviewing participants pre-procedure may have increased the richness of the data. When participants were interviewed post-procedure, their recollections may have been colored by their immediate concerns of the impending diagnostic results. The study provides examples of patient experiences in this procedure and can only be used for theoretical generalisation. It is also important to acknowledge that the research candidate's past observations of patient distress while undergoing bronchoscopy may have colored the research. To limit this, the research candidate conducted unstructured interviews (reducing the risk of leading questions) and rejected her own prejudices and theories to concentrate on the real data, as this was more significant (van Manen, 1984; 2014).

## 4.4 Conclusions

Patient experience during bronchoscopy is relatively unexplored. The literature review in this thesis found no qualitative studies exploring the subject. The current literature is quantitative and is focused on measurement of aspects of the patient experience: most commonly, patients were asked to express their perceived experience of pain, cough and willingness to repeat the procedure on various scales or with dichotomous questions. These scales or questions have been used to compare the patients' negative experiences when undergoing the procedure with different treatment regimens. It has been identified that when the patient is sedated there are significantly less negative experiences for the patients. The qualitative study presented in this thesis confirmed that some patients who undergo bronchoscopy encounter negative experiences. Patients experienced common fears, for example, the throat spray was unpleasant, consequences of awareness were

significant, common consequences of the procedure were identified, and some participants accepted the negative experiences in order to obtain a diagnosis.

The qualitative study demonstrated that some patients are aware during bronchoscopy when cautious sedation and analgesia were used, and may have full recollection of the procedure with its attendant discomforts. Participants remembered coughing and choking and the ensuing feelings of distress. The qualitative study also found that awareness during the procedure could lead to the disclosure of information to the patient at an inappropriate time, such as difficulties associated with the procedure, obtaining a biopsy, or diagnostic outcomes. Specific to the setting, this study uncovered issues regarding repetitive and lengthy documentation procedures, and unnecessarily long fasting and waiting times. These are amenable to improvement. As explored in previous studies, it was confirmed that patient fear was a problem before bronchoscopy and it was discovered that little attention was accorded to participants' potential experience of the bronchoscopy and how it might feel. However, despite their negative experiences, participants were accepting of their experience, considering it a 'necessary evil' in order to obtain a diagnosis.

## 4.5 Implications for practice

The implications of this qualitative study include providing new findings and recommendations for practice. This thesis has provided a definition of 'cautious' sedation and analgesia that may be used in relation to bronchoscopy procedures and further research in this area. The qualitative data and analysis explored the patient's experiences during bronchoscopy. The resulting findings could increase health care workers' empathy. The discussion of these findings in comparison to current literature may influence practice.

As revealed in this study, patients sometimes have fears prior to their procedure, which may be caused by inadequate patient education. The patients often fear that they have a life-threatening diagnosis. Patients may be aware during the procedure and may be able to recall what is discussed. They may recall the presence of the bronchoscope in their throat and their bodies' unconscious responses of coughing and/or choking. They may also remember worrying that their coughing and choking could make it more difficult for the physician and as a consequence the physician may not be unable to obtain the specimens required for their diagnosis. Common consequences of the procedure are sore throat, coughing and headaches. Patients may also feel neglected, if they wait too long for service.

The associated literature provides suggestions to ameliorate some of the problems that are faced when a patient undergoes bronchoscopy with cautious sedation and analgesia. Poi et al. (1998) discuss educating patients on how the procedure will make them feel, not only how it will be performed. Van Osch et al. (2014) discuss using affective communication techniques to manage patients' fears when they have been given bad news. Stolz et al. (2004) suggest the use of propofol as a sedative in cases where the patient has COPD, as the drug has a short half-life and can reduce patient awareness. Unfortunately, the use of propofol is limited due to greater financial and employment burdens.

The findings of this study could also be used as the basis for a tool to measure patient experience in bronchoscopy in future research.

## 4.6 Future research

This thesis has explored patients' experiences of bronchoscopy. A literature review was performed and studies were retrieved and evaluated that measured various aspects of

patient experience during bronchoscopy. The qualitative study explored in-depth the experiences of COPD patients who had the procedure. However, the scope of this research can be expanded, and this section presents some future research directions.

The literature review could be upgraded to a systematic review with meta-analysis. There are two systematic reviews that include the subject of patient experience in bronchoscopy. These reviews restrict their review of patient experience to pain, coughing and patient willingness to repeat the procedure. A meta-analysis of awareness, choking and breathlessness would be difficult due to the limited number of studies that have measured these physical aspects of patient experience during bronchoscopy but a description of these findings may alert procedural staff to these unexplored areas of patient experience. The development and psychometric evaluation of a tool to measure the patient experience in bronchoscopy based on the findings from this review and qualitative study may be beneficial for future research. Currently, outcomes and scales used to measure patient experience in bronchoscopy are numerous and varied, and not based on published qualitative studies. The outcomes and scales used are not consistent across studies and do not always measure awareness during the procedure, which, as the qualitative study has described, has both physical and psychological implications post-procedure. To ensure a robust psychometric validation of this tool, a multicentre mixed-method study could be performed.

A prospective multi-centre mixed methods study of patient experience in bronchoscopy that does not limit the participants to those with high-risk respiratory disease could lead to a broader understanding of the patient experience in bronchoscopy. An exploration of the

patient experience of the phenomenon in relation to the incidence of longer and more difficult procedures may provide data that could positively influence management of patient sedation. Action-research studies may be appropriate to assist in ameliorating specific study-site problems as the conclusions drawn in these studies are data-based that usually draw the data from multiple sources. Site problems include unclear explanation of procedure to patients, excessive paper work, and waiting and fasting times. With action research, the conclusions emerge slowly over the course of the study as researchers challenge emerging conclusions by pursuing disconfirming evidence.

Another suggestion for further research is an exploration of the problems related to the dissemination of qualitative study findings. It has been observed that clinicians tend to have a greater confidence in quantitative rather than qualitative research. Exploration of local physicians' responses to the qualitative findings may facilitate the process of disseminating the study's findings outside the local facility and thereby influence embedded views of internal and external treating physicians. Another study may be required that combines collection of qualitative and quantitative data to satisfy the physicians' desire for quantifiable clinical evidence.

An underlying reason for conducting this study was to verify the nurse's perceptions that many patients were consciously not tolerating the procedure. The nurses wanted to advocate for their patients; nurses at the site of the study alerted the research candidate that patients may be aware and negatively affected by the procedure. It was unclear if the patients' reactions were conscious or unconscious. Within the literature on the subject of bronchoscopy, there have been studies where midazolam has been given for sedation

during bronchoscopy (Cases Viedma et al., 2010). These studies have concluded that patients have been willing to repeat this procedure when given midazolam for sedation. From the data collected in this qualitative study, some participants were consciously not tolerating the procedure. It is unclear if the participants who had no recollection of the procedure displayed behaviours of procedure intolerance. Exploring the match between nurses' experience and patients' experience may increase understanding of the nursing and patient relationship during this phenomenon.

In summary, the aim of future research in this area needs to be focused on broadening the exploration of the patient experience in bronchoscopy. This would involve the development and psychometric evaluation of a tool to measure patient experience in bronchoscopy that would enable systematic comparison and assessment of various interventions that have the potential to improve the patient experience during bronchoscopy. In addition, novel strategies should be explored in regard to dissemination and translation of this new information to reach both practice and policy.

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# Appendix 1

This appendix includes a published study protocol for a systematic review on the subject of patient experience in bronchoscopy with or without various pharmaceutical agents.

PROSPERO International prospective register of systematic reviews

# A systematic review and meta-analysis of adult patients' experiences during flexible bronchoscopy with placebos and/or various pharmaceutical agents

*Catherine Saxon, Paul Fulbrook, Chantal F Ski, Kwun Fong*

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## Review question(s)
Research question: What is the adult patient experience of flexible bronchoscopy with sedation and/or analgesia?

Objective 1: To identify evidence of patient experience during bronchoscopy with sedation and analgesia.

Objective 2: To provide a synthesis of data collected, best practice and highlight any gaps in the current evidence.

## Searches
Databases searched included:

CINAHL, MEDLINE Complete, Cochrane, PubMed, Web of Science, EMBASE, PsycINFO, and Scopus.

The search terms included the population (adult patients undergoing flexible bronchoscopy by either oral or nasal route), intervention (randomized procedural sedative administration) and possible compartors (usual care/placebo vs other sedatives and/or analgesics).

The search was restricted to English language publications after 2001.

The search will be re-run prior to publication.

Additional search strategy details can be found in the attached PDF document (link provided below).

## Types of study to be included
Randomized controlled trials only.

## Condition or domain being studied
Bronchoscopy is a diagnostic and therapeutic procedure used to diagnose and manage respiratory problems.

## Participants/ population
Populations of the studies that were included in this review include adult patients undergoing flexible bronchoscopy by either oral or nasal approach.

Studies with the following patient populations were excluded: patients undergoing rigid bronchoscopy, children, non-humans, ventilated patients, non-invasive ventilation patients, spinal injury patients, mentally incapacitated patients.

## Intervention(s), exposure(s)
Bronchoscopy is often performed with sedation and analgesia to reduce negative experiences such as; anxiety, dyspnoea, cough and pain. Studies which used randomized procedural sedative and analgesia administration during bronchoscopy were included. Studies which do not investigate patient experience with procedural sedation and/or analgesia were excluded.

## Comparator(s)/ control
Comparators include; usual care/placebo vs. other sedatives/sedative + other pharmaceutical agents +/- pre-medication.

Possible sedatives and analgesia included; fentanyl, dormicam, hypnovel, flunitrazepam, benzodiazepine, midazolam, lorazepam, nitrous oxide, ketamine, alfetanil, fospropofol disodium, alfentanil OR propofol OR dexmedetomidine OR remifentanil.

## Context
Studies in day surgery units and hospitals procedure rooms or theaters will be included but studies conducted in intensive care units will be excluded.

## Outcome(s)
### Primary outcomes
Self-reported patient experience/satisfaction e.g. comfort, cough, pain, anxiety, distress, fear, alertness/wakefulness, event memory.

These outcomes could have been measured with Visual Analogue scales/Likert scales or yes/no answers on surveys. They would have been measured post-procedure when the patient was awake.

### Secondary outcomes
The secondary outcome was willingness to repeat procedure.

This outcome could have been measured with Visual Analogue scales/Likert scales or yes/no answers on surveys. The data would have been collected post-procedure when the patient was awake.

## Data extraction, (selection and coding)
The title and abstracts screening was conducted by two researchers. Another researcher resolved discrepancies. The full text screening will also be conducted with two researchers and the discrepancies will be resolved through discussion between these two researchers or a third researcher if necessary.

Extraction of data is to be conducted by two researchers. Data to be extracted will include; quality of the study , study details, methods, population, interventions, comparators, patient experience outcomes (comfort, cough, pain anxiety, distress, fear, alterness/wakefulness, event memory and willingness to repeat procedure).

The entire process will be managed by Covidence online software for data synthesis of systematic reviews.

## Risk of bias (quality) assessment
The risk and bias will be assessed by two researchers. The following study methods will be judged as high/low or unclear; randomization, concealment, blinding, completeness of data collected, incidence of selective outcome reporting, other sources of bias.

## Strategy for data synthesis
A quantitative synthesis of data will be used where possible to allow for a meta-analysis. When limited quantitative data is available then a narrative synthesis will be used.

## Analysis of subgroups or subsets
"None planned"

## Dissemination plans
Publication in a medical or nursing journal and presentation at a conference.

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| Risk of bias (quality) assessment | Yes | No |
| Data analysis | No | No |