Nurse-Administered Procedural Sedation and Analgesia in the Cardiac Catheterisation Laboratory: A Mixed Methods Study

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Abstract

The cardiac catheterisation laboratory (CCL) is a specialised medical radiology facility where both chronic-stable and life-threatening cardiovascular illness is evaluated and treated. Although there are many potential sources of discomfort and distress associated with procedures performed in the CCL, a general anaesthetic is not usually required. For this reason, an anaesthetist is not routinely assigned to the CCL. Instead, to manage pain, discomfort and anxiety during the procedure, nurses administer a combination of sedative and analgesic medications according to direction from the cardiologist performing the procedure. This practice is referred to as nurse-administered procedural sedation and analgesia (PSA). While anecdotal evidence suggested that nurse-administered PSA was commonly used in the CCL, it was clear from the limited information available that current nurse-led PSA administration and monitoring practices varied and that there was contention around some aspects of practice including the type of medications that were suitable to be used and the depth of sedation that could be safely induced without an anaesthetist present.

The overall aim of the program of research presented in this thesis was to establish an evidence base for nurse-led sedation practices in the CCL context. A sequential mixed methods design was used over three phases.

The objective of the first phase was to appraise the existing evidence for nurse-administered PSA in the CCL. Two studies were conducted. The first study was an integrative review of empirical research studies and clinical practice guidelines focused on nurse-administered PSA in the CCL as well as in other similar procedural

settings. This was the first review to systematically appraise the available evidence supporting the use of nurse-administered PSA in the CCL. A major finding was that, overall, nurse-administered PSA in the CCL was generally deemed to be safe. However, it was concluded from the analysis of the studies and the guidelines that were included in the review, that the management of sedation in the CCL was impacted by a variety of contextual factors including local hospital policy, workforce constraints and cardiologists' preferences for the type of sedation used.

The second study in the first phase was conducted to identify a sedation scale that could be used to monitor level of sedation during nurse-administered PSA in the CCL. It involved a structured literature review and psychometric analysis of scale properties. However, only one scale was found that was developed specifically for the CCL, which had not undergone psychometric testing. Several weaknesses were identified in its item structure. Other sedation scales that were identified were developed for the ICU. Although these scales have demonstrated validity and reliability in the ICU, weaknesses in their item structure precluded their use in the CCL. As findings indicated that no existing sedation scale should be applied to practice in the CCL, recommendations for the development and psychometric testing of a new sedation scale were developed.

The objective of the second phase of the program of research was to explore current practice. Three studies were conducted in this phase using both quantitative and qualitative research methods. The first was a qualitative explorative study of nurses' perceptions of the issues and challenges associated with nurse-administered PSA in the CCL. Major themes emerged from analysis of the qualitative data regarding the

lack of access to anaesthetists, the limitations of sedative medications, the barriers to effective patient monitoring and the impact that the increasing complexity of procedures has on patients' sedation requirements.

The second study in Phase Two was a cross-sectional survey of nurse-administered PSA practice in Australian and New Zealand CCLs. This was the first study to quantify the frequency that nurse-administered PSA was used in the CCL setting and to characterise associated nursing practices. It was found that nearly all CCLs utilise nurse-administered PSA (94%). Of note, by characterising nurse-administered PSA in Australian and New Zealand CCLs, several strategies to improve practice, such as setting up protocols for patient monitoring and establishing comprehensive PSA education for CCL nurses, were identified.

The third study in Phase Two was a matched case-control study of risk factors for impaired respiratory function during nurse-administered PSA in the CCL setting. Patients with acute illness were found to be nearly twice as likely to experience impaired respiratory function during nurse-administered PSA (OR=1.78; 95%CI=1.19-2.67; p=0.005). These significant findings can now be used to inform prospective studies investigating the effectiveness of interventions for impaired respiratory function during nurse-administered PSA in the CCL.

The objective of the third and final phase of the program of research was to develop recommendations for practice. To achieve this objective, a synthesis of findings from the previous phases of the program of research informed a modified Delphi study, which was conducted to develop a set of clinical practice guidelines for nurse-administered PSA in the CCL. The clinical practice guidelines that were developed set

current best practice standards for pre-procedural patient assessment and risk screening practices as well as the intra and post-procedural patient monitoring practices that nurses who administer PSA in the CCL should undertake in order to deliver safe, evidence-based and consistent care to the many patients who undergo procedures in this setting.

In summary, the mixed methods approach that was used clearly enabled the research objectives to be comprehensively addressed in an informed sequential manner, and, as a consequence, this thesis has generated a substantial amount of new knowledge to inform and support nurse-led sedation practice in the CCL context. However, a limitation of the research to note is that the comprehensive appraisal of the evidence conducted, combined with the guideline development process, highlighted that there were numerous deficiencies in the evidence base. As such, rather than being based on high-level evidence, many of the recommendations for practice were produced by consensus. For this reason, further research is required in order to ascertain which specific practices result in the most optimal patient and health service outcomes. Therefore, along with necessary guideline implementation and evaluation projects, post-doctoral research is planned to follow up on the research gaps identified, which are planned to form part of a continuing program of research in this field.

Candidate's statement of sources

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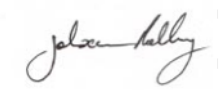
Statements of Contributions to Jointly Published Work

Statement of contributions for Chapter 2

Nurse-administered procedural sedation and analgesia in the cardiac catheter laboratory: An integrative review. *International Journal of Nursing Studies (2011), 48*(8), 1012-1023.

Aaron Conway	**Overall contribution 60%** Performed search of the literature and data extraction and data extraction Analysis and interpretation of data Drafted the article and revised it critically for important intellectual content	
Karen Page	**Overall contribution 20%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
John X Rolley	**Overall contribution 15%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
Linda Worrall-Carter	**Overall contribution 5%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	

Statement of contributions for Chapter 3

A review of sedation scales for the cardiac catheterisation laboratory. *Journal of PeriAnesthesia Nursing.* (Accepted 6th May 2013)

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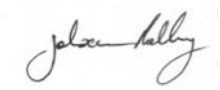
John X Rolley	**Overall contribution 10%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
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Linda Worrall-Carter	**Overall contribution 5%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	

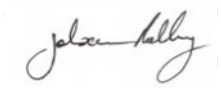
Statement of contributions for Chapter 4

Issues and challenges associated with nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A qualitative study. *Journal of Clinical Nursing* (In press). DOI: 10.1111/jocn.12147

Aaron Conway	**Overall contribution 65%** Conception and design of study Data collection Transcribed interview data Analysis and interpretation of data Drafted the article and revised it critically for important intellectual content	
John X Rolley	**Overall contribution 20%** Conception and design of study Data collection Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
Paul Fulbrook	**Overall contribution 10%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
Karen Page	**Overall contribution 5%** Conception and design of study Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	

Statement of contributions for Chapter 5

Trends in nurse-administered procedural sedation and analgesia across Australian and New Zealand cardiac catheterisation laboratories: Results of an online survey. *Australian Critical Care* (Accepted 27th May 2013)

Aaron Conway	**Overall contribution 70%** Conception and design of study Data collection Analysis and interpretation of data Drafted the article and revised it critically for important intellectual content	
John X Rolley	**Overall contribution 15%** Conception and design of study Data collection Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
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Risk factors for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A matched case-control study. *European Journal of Cardiovascular Nursing* (In press) DOI: 10.1177/1474515112470351

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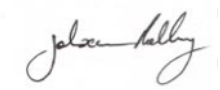
John Rolley	**Overall contribution 5%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	
Paul Fulbrook	**Overall contribution 5%** Analysis and interpretation of data Made critical revisions to draft versions for important intellectual content	

Statement of contributions for Chapter 7

Clinical practice guidelines for nurse-administered procedural sedation and analgesia in Australian and New Zealand cardiac catheterisation laboratories: A modified Delphi study. (Drafting)

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	Conception and design of study	
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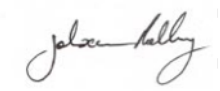
	Drafted the article and revised it critically for important intellectual content	
John X Rolley	**Overall contribution 20%**	
	Conception and design of study	
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Table of Contents

Full Peer-Reviewed Publications Presented in this Thesis

Chapter	Status/ Permissions	Year	Journal	Authors	Title
2	Published/ License No. 298635-0292174	2011	International Journal of Nursing Studies	**Conway, A** Page, K Rolley, JX Worrall-Carter, L	Nurse-administered procedural sedation and analgesia in the cardiac catheter laboratory: An integrative review
3	Accepted 6th May 2013	-	Journal of PeriAnesthesia Nursing	**Conway, A** Page, K Rolley, JX Worrall-Carter, L	A review of sedation scales for the cardiac catheterization laboratory.
4	In press DOI: 10.1111/jocn.12147 Permission requested	-	Journal of Clinical Nursing	**Conway, A** Rolley, JX Fulbrook, P Page, K	Issues and challenges associated with nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A qualitative study.
5	Accepted 27th May 2013	-	Australian Critical Care	**Conway, A** Rolley, JX Page, K Fulbrook, P	Trends in nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: Results of an online survey.
6	In press DOI:10.1177/1474515112470351 Permission requested	-	European Journal of Cardiovascular Nursing	**Conway, A** Page, K Rolley, JX Fulbrook, P	Risk factors for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A matched case-control study.
7	Drafting	-		**Conway, A** Rolley, JX Page, K Fulbrook, P	Clinical practice guidelines for nurse-administered procedural sedation and analgesia in Australian and New Zealand cardiac catheterisation laboratories: A modified Delphi study.

Peer-Reviewed Published Abstracts Arising from this Thesis

Journal	Year	Authors	Title	Citation details
Circulation	2012	**Conway, A** Page, K Rolley, JX Fulbrook, P	Acute illness is a risk factor for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterization laboratory.	Volume 126; A9423
Heart, Lung & Circulation	2012	**Conway, A** Rolley, JX Fulbrook, P Page, K	Australia and New Zealand nurses' perceptions of nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A qualitative study	Volume 21; Supplement 1; S6
Heart, Lung & Circulation	2012	**Conway, A** Page, K Rolley, JX Fulbrook, P	Respiratory monitoring practices during nurse-administered procedural sedation and analgesia could be improved by using capnography to monitor ventilation.	Volume 21; Supplement 1; S287-288

Associated Publications during PhD Candidature

Year	Journal	Authors	Title
2013	Research in Nursing & Health, 36(3), 320-324.	**Conway A,** Rolley JX, Page K, Fulbrook P, Thompson, DR	Improving statistical analysis of matched case-control studies.

Conference Presentations Arising from this Thesis

Chapter	Type	Year	Conference	Authors	Title
7	Oral	2013	Australasian Cardiovascular Nursing College's Annual Scientific Meeting	**Conway, A** Rolley, JX Page, K Fulbrook, P	Trends in nurse-administered procedural sedation and analgesia in Australian and New Zealand cardiac catheterisation laboratories: An online survey.
6	Poster	2012	American Heart Association's Scientific Sessions	**Conway, A** Page, K Rolley, JX Fulbrook, P	Acute illness is a risk factor for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterization laboratory.
6	Invited oral	2012	Australia and New Zealand Endovascular Therapies	**Conway, A** Page, K Rolley, JX Fulbrook, P	Acute illness is a risk factor for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterization laboratory.
6	***Oral**	**2012**	**The Prince Charles Hospital Research Forum**	***Conway, A*** **Page, K Rolley, JX Fulbrook, P**	**Acute illness is a risk factor for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterization laboratory.**
4	****Oral**	**2012**	**Cardiac Society of Australia and New Zealand's Annual Scientific Meeting**	***Conway, A*** **Rolley, JX Fulbrook, P Page, K**	**Australia and New Zealand nurses' perceptions of nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A qualitative study**
2 & 6	Poster	2012	Cardiac Society of Australia and New Zealand's Annual Scientific Meeting	**Conway, A** Page, K Rolley, JX Fulbrook, P	Respiratory monitoring practices during nurse-administered procedural sedation and analgesia could be improved by using capnography to monitor ventilation.

2 & 6	*****Poster & mini-oral**	**2012**	**Australasian Cardiovascular Nursing College's Annual Scientific Meeting**	***Conway, A*** **Page, K Rolley, JX Fulbrook, P**	**Respiratory monitoring practices during nurse-administered procedural sedation and analgesia could be improved by using capnography to monitor ventilation.**
2 & 6	Oral	2012	Sigma Theta Tau International's International Nursing Research Congress	**Conway, A** Page, K Rolley, JX Fulbrook, P	Respiratory monitoring practices during nurse-administered procedural sedation and analgesia could be improved by using capnography to monitor ventilation.
2	Oral	2011	Australasian Cardiovascular Nursing College's Annual Scientific Meeting	**Conway, A** Page, K Rolley, JX Worrall-Carter, L	Intra-procedural nurse-administered sedation in the cardiac catheterisation laboratory.
3	*****Poster & mini-oral**	**2011**	**Australasian Cardiovascular Nursing College's Annual Scientific Meeting**	***Conway, A*** **Page, K Rolley, JX Worrall-Carter, L**	**A review of sedation scales for the cardiac catheterisation laboratory.**
3	Oral	2011	St Vincent's Hospital, Melbourne Research Week	**Conway, A** Page, K Rolley, JX Worrall-Carter, L	A review of sedation scales for the cardiac catheterisation laboratory.

***Presentation was a runner-up for the Novice Researcher Prize**

****Presentation was a runner-up for the CSANZ 2012 Nursing Prize**

*****Presentation won the prize for its category**

Definition of terms and abbreviations

Following are definitions for key terms referred to within this thesis.

Cardiac Catheterisation is a collective term for all procedures in which a catheter is inserted percutaneously (via needle puncture through the skin) into either the arterial or venous peripheral vessels and then manipulated for the purpose of diagnosing or treating cardiovascular disease.

Cardiac Catheterisation Laboratory (CCL) is a complex, highly sophisticated medical and radiological facility where patients with both chronic-stable and life-threatening cardiovascular illness are evaluated and treated. In addition to the cardiologist performing the procedure, a diverse interdisciplinary team including nurses, radiographers and cardiac technologists staffs the CCL.

Cardioversion involves the passage of direct current electricity across the heart, synchronized to the heart rhythm, to terminate supraventricular tachycardias or ventricular tachycardias (Sargent, 2009).

Conscious sedation equates to the level of moderate sedation, as defined by the American Society of Anesthesiology's delineation of the continuum of anaesthesia (Gross et al., 2002).

Coronary angiography is a percutaneous, intra-arterial procedure used to diagnose coronary artery disease.

Coronary angioplasty is a percutaneous, intra-arterial procedure used to treat obstructive coronary artery disease. A small deflated balloon is introduced into the coronary artery and inflated to open up the stenotic region of the vessel (Muggenthaler, Singh, & Wilkinson, 2008).

Coronary stenting is a percutaneous, intra-arterial procedure used to treat obstructive coronary artery disease. A small tubular, mesh structure is left in place after angioplasty balloon inflation to help keep the artery open (Muggenthaler et al., 2008).

Capnography is the non-invasive measurement of the partial pressure of carbon dioxide in exhaled breath. A waveform tracking the level of carbon dioxide is displayed to show changes in carbon dioxide concentration during the respiratory cycle (Krauss, Hess, Krauss, & Hess, 2007). Capnography is a diagnostic modality because changes in the shape of the waveform are diagnostic of disease conditions (Smalhout & Kalenda, 1975).

Deep sedation is a drug-induced depression of consciousness during which patients do not respond to verbal command but do respond to repeated physical or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained (Gross et al., 2002).

Electrophysiology study (EPS) involves the invasive introduction of intravenous and/or intra-arterial catheters with multi-polar electrodes positioned at various

intra-cardiac sites for the purpose of recording electrical activity from specific locations. The electrodes may also be used to stimulate electrical activity in the atria or ventricles by delivering pulses of current. Protocols are used to stimulate and record the electrical activity to diagnose arrhythmias (Lane, 1997).

End-tidal carbon dioxide ($ETCO^2$) is the concentration of carbon-dioxide at the end of exhalation (Sandlin, 2002). Normal range is between 35 and 45mmHg (Sullivan, Kissoon, & Goodwin, 2005).

General anaesthesia is a drug-induced loss of consciousness during which patients require assistance in maintaining a patent airway and positive-pressure ventilation may be required due to impaired ventilatory function (Gross et al., 2002).

Implantable cardioverter defibrillator (ICD) is an implantable device, which continuously monitors the heart rhythm and, on recognition of a sustained potentially fatal arrhythmia, is capable of defibrillation or other appropriate electrical therapy to terminate the arrhythmia (Timperley, Leeson, Mitchell, & Betts, 2008).

Minimal sedation is as a drug-induced state during which patients respond purposefully to verbal commands. Ventilatory and cardiovascular functions are unaffected (Gross et al., 2002).

Moderate sedation is a depression of consciousness during which patients respond purposefully to verbal commands. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained (Gross et al., 2002).

Percutaneous coronary intervention (PCI) is a collective term for coronary angioplasty and coronary stenting.

Permanent pacemaker (PPM) is a device consisting of a pulse generator and one or more electrodes, known as leads. The pulse generator is implanted beneath the skin on either side of the chest. The leads are inserted into the chambers of the heart, via the subclavian vein, where they rest against the endocardium. The pulse generator stimulates the heart muscle to contract by generating an electrical impulse, which is transmitted along the lead to the endocardium (Davies, 2009).

Procedural sedation and analgesia (PSA) implies that the patient is in a state of drug-induced tolerance of uncomfortable or painful diagnostic or interventional, dental or surgical procedures. Lack of memory for distressing events and/or analgesia are desirable outcomes, but lack of response to painful stimulation is not assured (ANZCA, 2010).

Radiofrequency ablation (RFA) radiofrequency waves are applied directly to the myocardium to treat arrhythmias using a catheter which is inserted using the femoral venous approach (Tabbernor, 2006).

INTRODUCTION

Overview

The focus of this chapter is to situate the program of research within the context of the broader literature. As such, the chapter commences with a brief overview of the burden of cardiovascular disease before progressing more specifically into CCL processes for diagnosis and treatment of cardiovascular disease, including the roles of the various CCL staff. The discussion then focuses on why nurse-administered PSA has become an important part of practice in the CCL setting and identifies the research problem associated with nurse-administered PSA that is addressed by the program of research presented within this thesis. To conclude the chapter, the research aim, objectives and design as well as the outline of thesis is provided.

Cardiovascular disease

Cardiovascular disease (CVD) stems from dysfunction of the vascular system, manifesting as a result of chronic underlying pathologies, such as hypertension, atherosclerosis and thrombosis (Lippy, Bonow, Mann, & Zipes, 2008). An example of how chronic underlying pathologies develop into CVD is the progression of atherosclerosis in arteries (Badellino, 2008). Figure 1.1 illustrates this process.

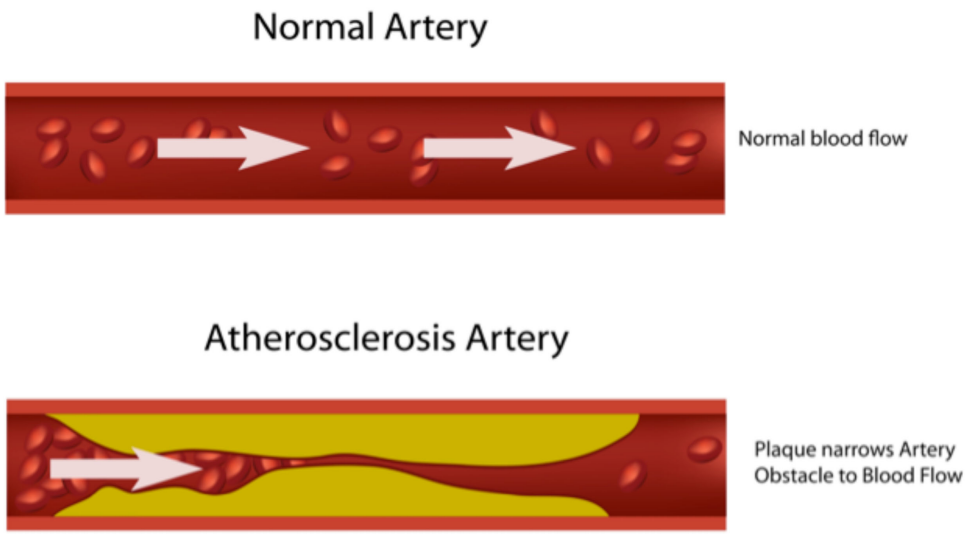


Figure 1.1 – Atherosclerosis *(Used with permission)*

A build up of atherosclerosis in the coronary arteries causes the syndrome known as coronary heart disease (CHD), which is the most common form of CVD (AIHW, 2011). However, CHD is but one manifestation of an entire spectrum of syndromes. Other forms of CVD include cerebrovascular disease, peripheral vascular disease, hypertensive heart disease, valvular dysfunction and dilated cardiomyopathy. These disease states can ultimately lead to compromised

function of multiple organs in the body, and in turn, cause mortality (AIHW, 2011). As such, not only does CVD affect a considerable proportion of the global population, but it is also the leading cause of death (WHO, 2008).

In Australia specifically, CVD is the number one cause of mortality among men and women (AIHW, 2011). Therefore, it remains a public health issue of considerable importance. However, it is important to note that significant improvements in CVD associated mortality have been achieved since the 1960s, when CVD accounted for 60 000 deaths annually (AIHW, 2004, 2011). In 2007, there were approximately 14 000 fewer CVD deaths (AIHW, 2011). The decline in CVD death rates has been driven largely by the considerable improvements in the prevention, detection and management of CVD that have characterised the discipline of cardiology over the past 50 years (AIHW, 2009). These improvements stem from an increased awareness of the impact that lifestyle factors, such as physical inactivity, smoking, obesity, hypertension and high cholesterol, have on the development of CVD leading to advances in chronic disease management programs and pharmacological treatment (Clark, Hartling, Vandermeer, & McAlister, 2005; Yusuf et al., 2004). Another integral component of the advances in the detection and treatment of CVD are the diagnostic and interventional procedures performed in the CCL.

Role of CCL procedures in diagnosing and treating CVD

Numerous procedures are performed to diagnose and treat CVD in the CCL of which the most common is the coronary angiogram (Patel et al., 2012). This

procedure was first performed in 1958, yet remains to this day the 'gold-standard' for the diagnosis of CHD (Patel et al., 2012). The second most common procedure is percutaneous coronary intervention (PCI) (Silber et al., 2005). The first form of PCI, percutaneous transluminal coronary angioplasty (PTCA), was first performed in 1977. While initially developed to treat obstructive coronary atherosclerosis, as shown in Figure 1.2, application of this technique to the setting of acute myocardial infarction (which is characterised by acute total occlusion of a coronary artery due to rupture of atherosclerotic plaque and subsequent thrombus formation) has led to significant improvements in survival compared to medical treatment (Badellino, 2008). Primary PCI reduces risk of mortality by 32% compared with thrombolysis and is gold-standard treatment for patients diagnosed with acute ST-elevation myocardial infarction (Aroney, Aylward, Kelly, Chew, & Clune, 2006; Cucherat, Bonnefoy, & Tremeau, 2004).

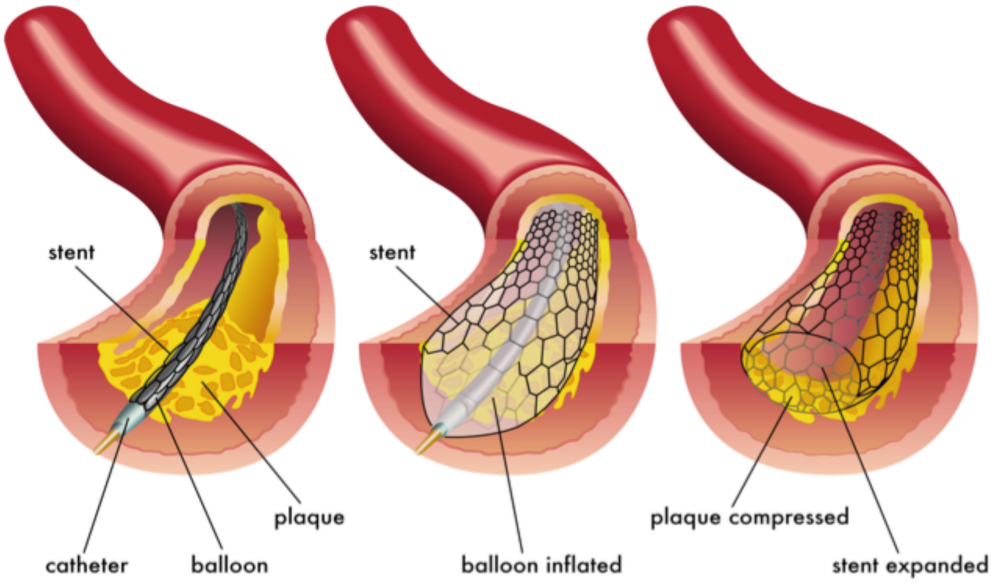
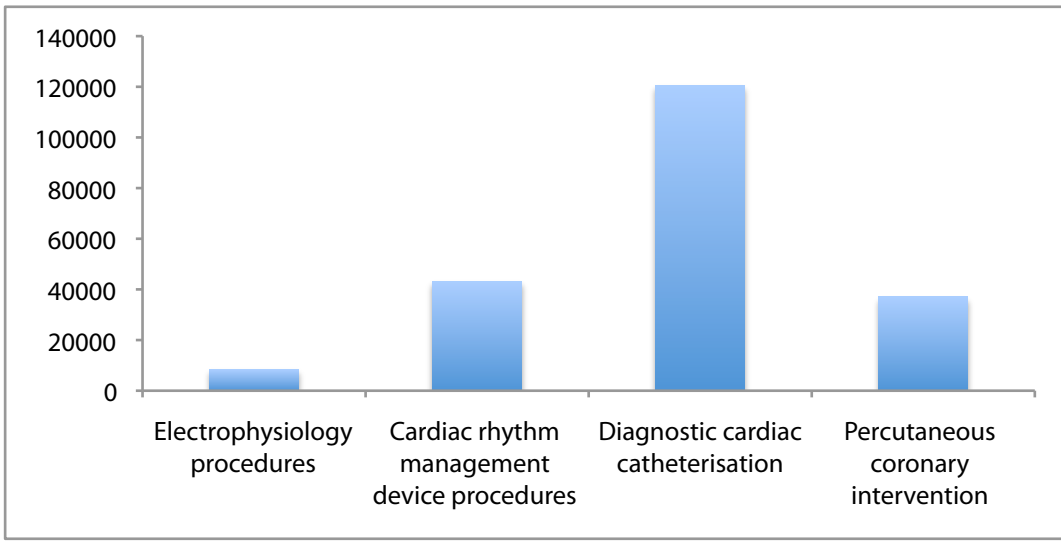


Figure 1.2. Coronary angioplasty *(Used with permission)*

Another intervention performed in the CCL that has been shown to improve survival is the insertion of an implantable cardioverter-defibrillator (ICD) (Ezekowitz et al., 2007). These cardiac rhythm management devices are used for primary prevention (implant with no previous event) or secondary prevention (implant after a previous event) of life-threatening cardiac arrhythmias, including ventricular tachycardia and ventricular fibrillation (Timperley et al., 2008).

In Australia, a large number of procedures are performed in the CCL setting. Figure 1.3 displays the most recent publicly available data on several of the common procedures performed in CCLs (AIHW, 2009-2010). As can be seen, there is high demand for CCL procedures, with over 200,000 performed in Australia each year. As such, the CCL can be described as a complex, highly sophisticated medical and radiological facility where patients with both chronic-stable and life-threatening cardiovascular illness can be evaluated and treated.



Legend: **Electrophysiology procedures** include diagnostic studies and ablation of cardiac arrhythmias; **Cardiac rhythm management device procedures** include permanent pacemakers, temporary pacing lead insertions, implantable cardioverter defibrillator implants, cardiac resynchronisation therapy implants and loop recorder implants; **Diagnostic cardiac catheterisation** includes right heart catheterisation, coronary angiography and left heart catheterisation; **Percutaneous coronary intervention** includes elective, primary and rescue percutaneous coronary intervention.

Figure 1.3 Procedures performed in Australia in 2009-2010 *(Source: AIHW)*

The role of nursing in the CCL

In addition to the doctor, a diverse interdisciplinary team of nurses, radiographers and cardiac physiologists work together to perform procedures in the CCL. Recently, some work has been undertaken, which is related directly to this thesis, to define the nursing discipline within CCLs in Australia and New Zealand. The following definition for nursing within the CCL was produced:

> *"Interventional cardiovascular nursing is an advanced practice role within the nursing discipline, which is specific to the care of people undergoing procedures within a cardiovascular catheterisation laboratory. Interventional Cardiovascular Nurses perform integral roles throughout the peri-procedural period as part of a diverse interdisciplinary team. Interventional Cardiovascular Nurses posses a highly advanced and continuously adapting knowledge and skill base, spanning the management of stable, elective patients through to the critically unstable, that is unique to the rapidly evolving evidence-based therapies used during procedures performed within this setting."* (J.X. Rolley, Conway, & Page, Under Review)

Typically, CCL nurses can perform one of three roles at any one time. One role is that of a scrub nurse. This role is similar to a scrub nurse in the operating theatre, yet it differs in that, generally, there is no medical practitioner acting as

the first assistant to the physician/surgeon performing the procedure, as is common practice in the operating room. In the CCL, the scrub nurse instead fulfils the role of first assistant. Therefore, in addition to traditional scrub nurse responsibilities such as preparing and draping the procedure site and preparing other sterile equipment, their role may vary, depending on local preferences. Examples include injection of contrast medium into coronary arteries and inflation of angioplasty devices as well as other advanced duties that require specialised training to perform.

Another role is the scout nurse. Again, this role is similar to the scout role in the operating theatre. Yet, it differs because, generally, there is not an anaesthetist present during procedures performed in the CCL. Therefore, the scout nurse assumes responsibility for duties that would normally be performed by an anaesthetist in the operating room. Some of these duties may include administration of medication and initiation of basic or advanced life support in circumstances of clinical deterioration. These practices are performed by the scout nurse in addition to other duties including, but not limited to:

- Preparing the equipment required to perform procedures;
- Ensuring equipment required to monitor the patient's cardiovascular and respiratory function during the procedure is attached to the patient appropriately**;**
- Ensuring equipment is functioning correctly and troubleshooting any malfunctions that may occur;
- Identifying equipment alternatives that are appropriate to use; and

- Undertaking a surgical count.

The third possible role performed by nurses in the CCL is the monitor role, in which the nurse is responsible for continuously monitoring the patient's electrocardiogram for rhythm changes and changes indicative of ischaemia. They are also responsible for continuously monitoring, as well as periodically measuring and recording, haemodynamic function.

While the discussion above provides a broad overview of roles that can be undertaken by nurses in the CCL, it is important to note that the roles performed by nurses vary substantially not only between institutions, but also internationally. In the United States, for example, cross-training of nurses, radiographers and cardiac technicians who work within the CCL setting is encouraged (SCIP, 2002). In this regard, all of the disciplines at one time or another may perform the scrub, monitor and radiography technician role. Within the Australian and New Zealand region, there is crossover of roles between cardiac technicians and nurses assuming the monitor role, and crossover between the radiographers, cardiac technicians and nurses assuming the scrub role.

It is important to note that the scout role, though, is largely reserved for the nursing discipline. While many factors drive this role, such as legal requirements related to the administration of medication and the common requirement for initiation of advanced life support during a procedure, one other main driver is the very frequent requirement for administration of sedative and analgesic

medications. This is because the management of PSA is complex, and requires advanced knowledge of the effects that sedative and analgesic medications have on physiology, the ability to promptly identify signs of clinical deterioration, and the skilful application of therapies to restore or support declining cardiac and respiratory function (Odom-Forren & Watson, 2005).

The rationale for PSA during CCL procedures

PSA is used during procedures performed in the CCL for numerous reasons. For example, during PCI, the total occlusion of coronary arteries during balloon angioplasty results in a transient period of myocardial ischaemia, producing angina-like symptoms (Baum, 2005; Eastwood, 2008). Also, radiofrequency ablation of cardiac arrhythmias is particularly painful when performed close to autonomic nerves and/or the oesophagus (Calkins et al., 2007). In addition, all procedures require a degree of immobilisation, which can become uncomfortable during particularly long procedures, especially for patients with pre-existing musculoskeletal injuries (Beddoes, Botti, & Duke, 2008). Commonly, PSA is required for this reason. Also, patients undergoing medical procedures without a full general anaesthetic can become anxious due to concerns about seeing or feeling the body cut open (Mitchell, 2009). PSA is used to relieve such feelings of distress.

Several studies have demonstrated that the administration of PSA during procedures performed in the CCL is effective and as a consequence, general anaesthetic is not commonly required. For example, in a consecutive series of

500 patients undergoing ICD implant with PSA, only 3.8% experienced discomfort to the degree that they would prefer a general anaesthetic (as opposed to PSA) if they were to undergo procedures of a similar nature in the future (Fox et al., 2007). Similar findings have been reported in studies on electrophysiology studies and pacemaker implants (Pachulski, Adkins, & Mirza, 2001).

Because a general anaesthetic is not usually required, an anaesthetist is not routinely assigned to the CCL (Gaitan, Trentman, Fassett, Mueller, & Altemose, 2011). Instead, to manage pain, discomfort and anxiety during the procedure, nurses administer a combination of sedative and analgesic medications according to direction from the cardiologist performing the procedure. This practice is referred to as nurse-administered PSA.

Despite the common use of nurse-administered PSA in the CCL, it is important to appreciate that this practice is controversial because of the adverse effects that sedative and analgesic medications may have on cardiac and respiratory function and the implications for patient safety. A detailed explanation of this problem is expanded upon below.

Research problem

Historically, regardless of the clinical practice setting, PSA was the sole domain of anaesthetists or medical practitioners because they were considered to possess the necessary knowledge and training to manage the potential life-threatening complications associated with the administration of sedative and analgesic medications. For example, during PSA protective reflexes can become

compromised and respiration can become depressed. This impact on the patient's physiology presents considerable risks to their safety for several reasons. First, without fully functioning protective reflexes, the ability to clear secretions is impaired, leading to potential aspiration of oral or gastric contents, which can cause severe complications such as aspiration pneumonia. In-hospital mortality for this complication has been cited as high as 70% (DeLegge, 2002). Second, during sedation, inadequate pulmonary oxygenation and ventilation in the context of sedation is caused by a depressed respiratory drive or relaxed pharyngeal musculature (Aitkenhead, Smith, & Rowbotham, 2007). Respiratory drive depression can result in hypopnoeic hypoventilation (diminished tidal volume respiration), bradypnoea (reduced respiratory rate) or even periods of apnoea (absence of respiration). Relaxation and consequent displacement of the pharyngeal musculature can cause partial obstruction of the sedated patient's airway and lead to inadequate oxygenation. In a study of malpractice claims arising from PSA during procedures performed outside the operating theatre inadequate oxygenation or ventilation was the most common mechanism of injury (Robbertze, Posner, & Domino, 2006).

In the 1980s, however, because of the extra costs associated with utilising an anaesthetist for the administration of PSA, the practice of nurse-administered PSA was first described (Odom-Forren & Watson, 2005). At this time, the main controversy surrounding nurse-administered PSA centred on whether or not the administration of any form of PSA, regardless of the depth of sedation induced, was within the scope of practice of a registered nurse (Odom-Forren, 2005). This

debate was resolved following publication of a position statement by the American Nurses' Association (ANA, 1991), which endorsed registered nurses to administer conscious sedation, and outlined patient monitoring standards and nurse education objectives. More contemporary guidelines, developed most notably by the American Society of Anesthesiology (ASA) and the Joint Commission of Accreditation of Healthcare Organizations (JCAHO), provided further reinforcement that PSA could be administered without an anaesthetist present (Gross et al., 2002; JCAHO, 2005).

As a consequence of the publication of the various position statements and guidelines cited above, and also due to a global endeavour to limit the costs of healthcare, the practice of nurse-administered PSA gained traction over the years. Now, countless patients around the world receive nurse-administered PSA during medical procedures. Furthermore, with advances in medical technology continuing to expand the indications for minimally invasive surgical techniques, the use of nurse-administered PSA during medical procedures is likely to expand further.

Yet, despite the modern day common use of nurse-administered PSA in contemporary medical practice, there are several controversies surrounding the topic that pervade the academic literature. One such controversy is the administration of 'deep sedation' without an anaesthetist present. Deep sedation is characterised by depression of consciousness such that the patient will only respond once repeated physical or painful stimulation is applied (Odom-Forren & Watson, 2005). It is also generally accepted that there is a more

pronounced effect on the patient's physiology once the level of deep sedation is reached (Malamed, 2003). For this reason, guidelines developed by the American Society of Anesthesiology in 2002, followed by other anaesthesia organisations, such as the Australia and New Zealand College of Anaesthetists (ANZCA), recommended that deep sedation should not be induced without an anaesthetist present (ANZCA, 2010; Gross et al., 2002). There has been considerable resistance to the uptake of the recommendations concerning deep sedation in these guidelines from numerous medical specialties including emergency, gastroenterology, radiology and cardiology (Hummel & Awad, 2011; Kottkamp et al., 2011; Motas, McDermott, Vansickle, & Friesen, 2004; Samuelson, Lundberg, & Fridlund, 2008; Wutzler et al., 2012). This is because the recommendations are contradictory to evidence which indicates that deep sedation is safe without an anaesthetist present provided it is administered by trained practitioners following strict patient monitoring protocols (Green & Krauss, 2011; Hummel & Awad, 2011).

Another controversial issue focuses on the pharmacological agents that are appropriate to be administered by nurses for PSA without an anaesthetist present. The most widely publicised debate focused on the use of propofol. Similar to the administration of deep sedation, the guidelines developed by anaesthetists recommend that propofol should not be administered without an anaesthetist present (Gross et al., 2002). Gastroenterologists have been the most prolific in establishing the evidence for propofol as a safe medication alternative for nurse-administered PSA during medical procedures (Liu et al.,

2009; Poon et al., 2007; Vargo et al., 2000). Despite this research, there is continued debate over the appropriateness of propofol for nurse-administered PSA, as evidenced by the recent reviews and editorials published on this topic in various medical journals (Blayney, 2012; de Bono, 2012).

One further contemporary issue related to nurse-administered PSA is that health care providers are increasingly being held accountable for avoidable serious hospital-acquired complications. One strategy that is currently being used to drive down the rate of avoidable adverse events in health care is for financial reimbursement to be directly linked with quality outcomes. This is of relevance to nurse-administered PSA because the Department of Health in the United Kingdom has now defined failure to monitor and respond to oxygen desaturation during PSA and over-sedation with midazolam as 'never events' (NHS, 2011). As such, the healthcare organisation will not be reimbursed for services if an adverse event occurs that is associated with an overdose of midazolam, if oxygen saturation was not monitored while midazolam was administered or if actions were not implemented to correct oxygen desaturation during PSA with midazolam. This policy highlights the general consensus that PSA-related complications are preventable.

Unfortunately though, the frequency that these adverse events occur cannot be appreciated from the present literature. Widespread reporting of adverse events related to PSA has not occurred as it has for adverse events related to general anaesthesia during surgery and in critical care settings (Gibbs, 2009; Whittaker, 2011). As a consequence, there are no data available to accurately determine the

number of PSA-related adverse events that have occurred in recent years. However, establishment of the NHS policy cited above is implicitly indicative that PSA-related complications do occur.

While it is clear that nurse-administered PSA is very commonly used in many procedural clinical settings, such as the emergency department, radiology and endoscopy units and in particular the CCL, it is also evident that there is a considerable degree of variability in practice and patient safety continues to be a concern. While further research is therefore clearly warranted in all clinical areas that utilise PSA, the research presented in this thesis is focused on the specific setting of the CCL.

The research program aim, objectives and design are outlined below.

Aim and objectives of the program of research

The overall aim of the program of research was to establish an evidence base for nurse-led sedation practices in the CCL context.

The following research objectives guided the program of research:

1. Appraise the existent evidence;
2. Explore current practice; and
3. Develop recommendations for practice.

Research design

A sequential mixed-methods design was used to address the research objectives over three phases. Figure 1.1 graphically demonstrates how each of the studies undertaken as part of the doctoral program of research link together and highlights each study's objectives and methods. As can be seen, the three phases correspond directly to the overall objectives set for the program of research.

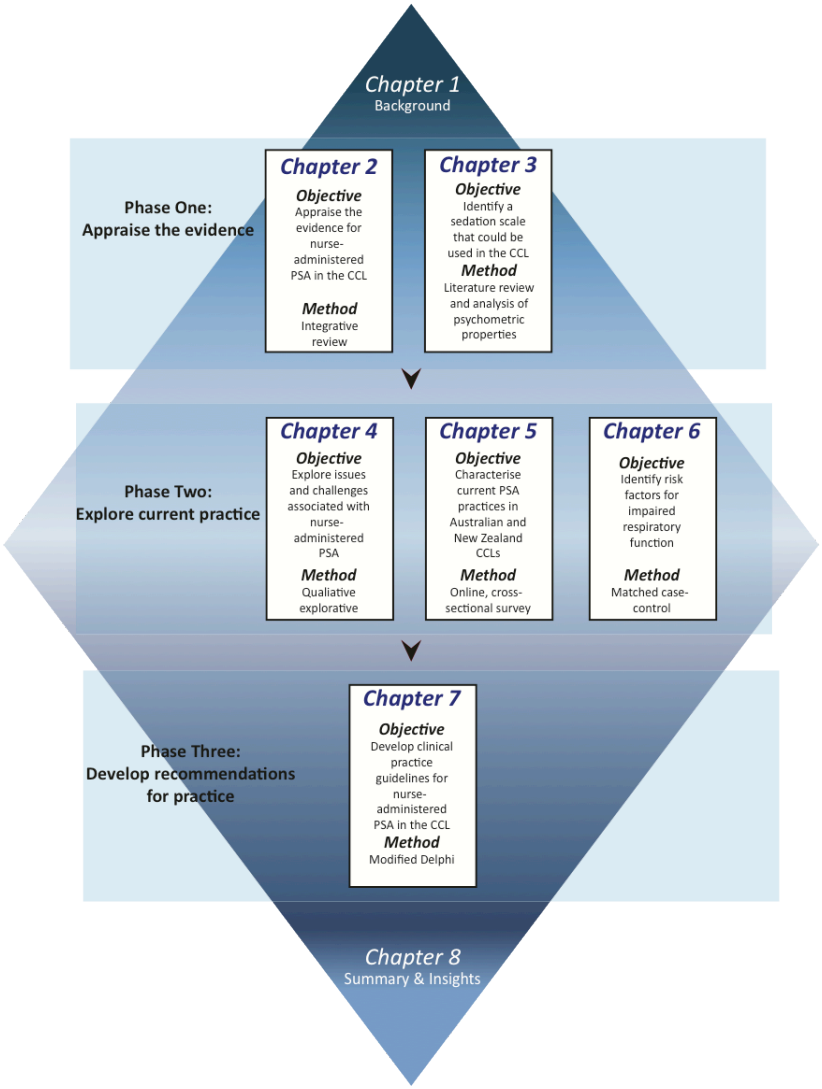


Figure 1.1 Thesis Structure

Mixed Methods: Rationale

The use of single quantitative or qualitative methodology may not always be sufficient to fully understand the phenomenon of interest (Doyle, Brady, & Byrne, 2009). The mixed methods research design addresses this problem, wherein researchers using this design, often apply both quantitative and qualitative methods in a single study (Doyle et al., 2009; Tashakkori & Creswell, 2007).

The primary reason that a mixed methods design was employed for this program of research was that it enabled a comprehensive and complementary investigation of the research topic that would not have been possible using a single methodology. In this program of research, the use of mixed methods not only permitted the systematic examination of measurable variables (using quantitative methods), but also made in-depth exploration of issues possible (using qualitative methods) (Creswell & Plano Clark, 2007). This facilitated a very comprehensive examination of important issues that may not have been possible should only quantitative or qualitative methods have been utilised (Creswell, 2009).

In addition to facilitating a comprehensive examination of issues, mixed methods designs may also permit findings from an initial phase to inform subsequent phases of a program of research. This particular type of design is known as a sequential mixed method design (Andrew & Halcomb, 2009). As there was limited previous research focused on the topic of nurse-administered PSA, this

program of research was undertaken in a sequential manner in order to build research on findings from the previous phases.

Thesis Outline

This section provides a brief outline of the thesis by introducing the content of each chapter.

Chapter One has provided the background to the research problem addressed by the program of research presented within this thesis, set the aims and objectives and stated the research design. As stated above, the program of research consisted of three phases using a sequential mixed methods design.

Phase one of the program of research is presented in Chapter Two and Chapter Three. The objective of this phase was to appraise the existing evidence for nurse-administered PSA in the CCL.

Chapter Two presents a study that used an integrative review method. The aims were to identify and appraise studies about PSA and to identify contemporary practices from other procedural areas using PSA relevant to practice in the CCL to be considered in future research and practice initiatives.

Chapter Three presents a structured review of the literature and analysis of psychometric properties, which was conducted to identify a sedation scale that could be used to monitor level of sedation in the CCL.

Phase Two of the program of research is presented in Chapter Four, Chapter Five and Chapter Six. The objective of this phase was to explore current nurse-administered PSA practices in the CCL context.

Chapter Four presents a qualitative explorative study, which was conducted to explore nurses' perceptions of the issues and challenges associated with nurse-administered PSA in the CCL.

Chapter Five presents a cross-sectional survey, which was conducted to characterise nurse-administered sedation practice in Australian and New Zealand CCLs.

Chapter Six presents a matched case-control study, which was conducted to identify risk factors for impaired respiratory function during nurse-administered PSA in the CCL setting.

Phase Three of the program of research is presented in Chapter Seven. The objective of this phase was to develop recommendations for practice.

Chapter Seven presents a modified Delphi study, which was conducted to develop a set of clinical practice guidelines for nurse-administered PSA in the CCL.

It is also important to note that Chapters 2 through 7 are presented as complete manuscripts. The manuscripts have either been published, accepted for publication or are currently undergoing, or being prepared for, peer review in academic journals. As such, the new knowledge contributed by the research

program will be accessed by a wide and international audience as a result of the dissemination process associated with publication in an academic journal.

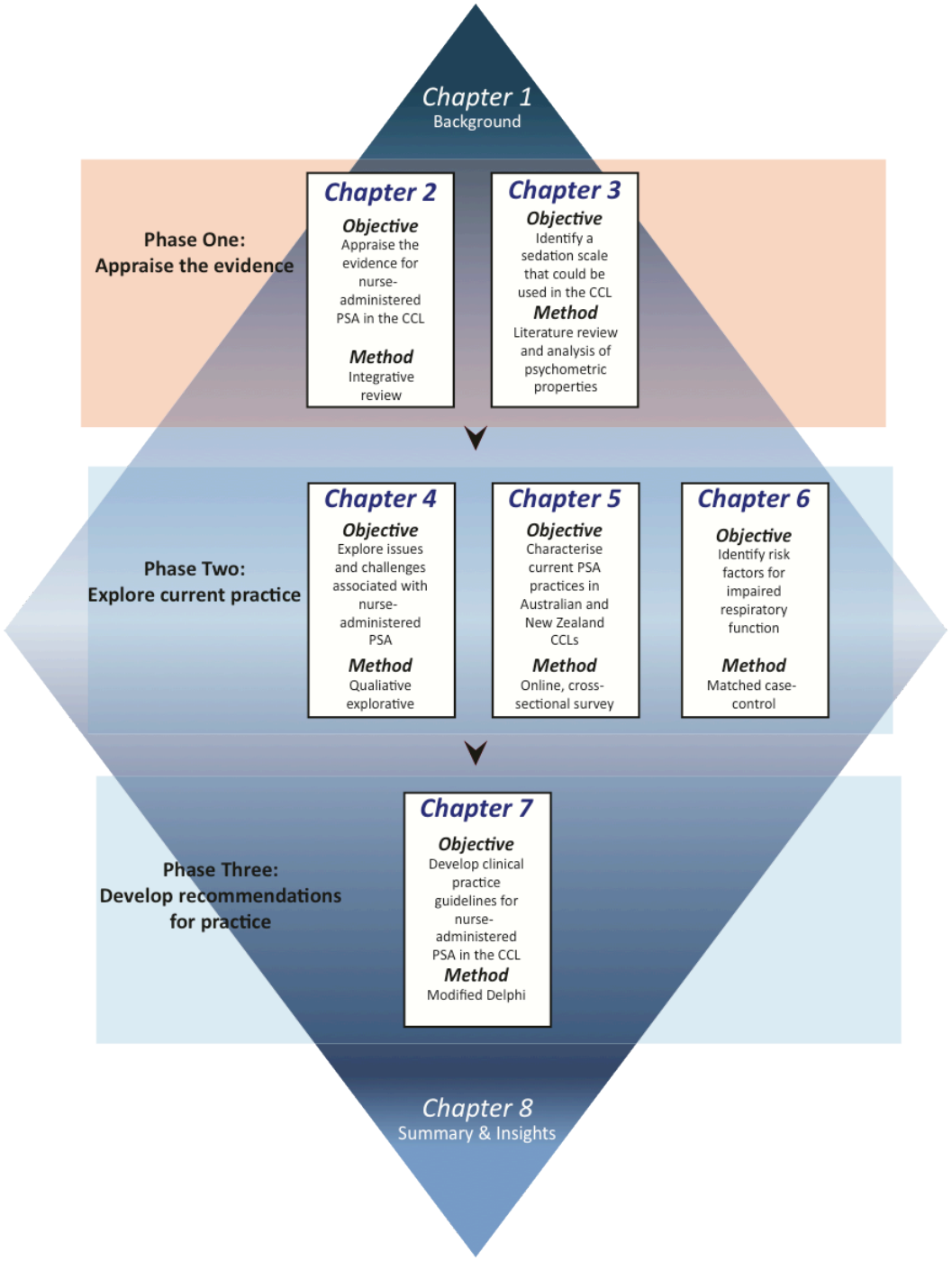
As each individual study has its own unique rationale and addresses particular research objectives in relation to specific gaps in the evidence, the background information as well as the aims/objectives, methods, results, discussion, limitations and conclusions are all included as part of each manuscript. In addition, at the start of Chapters 3 through 7, a short introduction will state how the ensuing chapter is linked to or builds upon previous research undertaken within the research program. Also, it should be noted that each manuscript is formatted according to the specific journal's style, except for the use of APA referencing, which is used throughout the thesis for consistency.

Chapter Eight brings the thesis to a close by presenting a summary of the new knowledge produced from the program of research as well as the planned direction for further research.

Summary

This introduction first identified the research problem before stating the research aim, objectives and design of the program of research. Then, the outline of the thesis was provided. The following chapter presents the first of the series of linked studies that were conducted as part of the doctoral program of research, which was an in-depth integrative review of the evidence for nurse-administered PSA in the CCL.

PHASE ONE


Chapter 1
Background
Phase One:
Appraise the evidence
Chapter 2
Objective
Appraise the evidence for nurse-administered PSA in the CCL
Method
Integrative review
Chapter 3
Objective
Identify a sedation scale that could be used in the CCL
Method
Literature review and analysis of psychometric properties
Phase Two:
Explore current practice
Chapter 4
Objective
Explore issues and challenges associated with nurse-administered PSA
Method
Qualiative explorative
Chapter 5
Objective
Characterise current PSA practices in Australian and New Zealand CCLs
Method
Online, cross-sectional survey
Chapter 6
Objective
Identify risk factors for impaired respiratory function
Method
Matched case-control
Phase Three:
Develop recommendations for practice
Chapter 7
Objective
Develop clinical practice guidelines for nurse-administered PSA in the CCL
Method
Modified Delphi
Chapter 8
Summary & Insights

CHAPTER TWO

Nurse-administered procedural sedation and analgesia in the cardiac catheter laboratory: An integrative review

Aaron Conway, Karen Page, John X Rolley & Linda Worrall-Carter

International Journal Nursing Studies (2011), 48(8), 1012-1023.

Abstract

Objectives

To identify and appraise the literature concerning nurse-administered procedural sedation and analgesia in the cardiac catheter laboratory.

Design and Data sources

An integrative review method was chosen for this study. MEDLINE and CINAHL databases as well as The Cochrane Database of Systematic Reviews and the Joanna Briggs Institute were searched. Nineteen research articles and three clinical guidelines were identified.

Results

The authors of each study reported nurse-administered sedation in the CCL is safe due to the low incidence of complications. However, a higher percentage of deeply sedated patients were reported to experience complications than moderately sedated patients. To confound this issue, one clinical guideline permits deep sedation without an anaesthetist present, while others recommend against it. All clinical guidelines recommend nurses are educated about sedation concepts. Other findings focus on pain and discomfort and the cost-savings of nurse-administered sedation, which are associated with forgoing anaesthetic services.

Conclusions

Practice is varied due to limitations in the evidence and inconsistent clinical practice guidelines. Therefore, recommendations for research and practice have been made. Research topics include determining how and in which

circumstances capnography can be used in the CCL, discerning the economic impact of sedation-related complications and developing a set of objectives for nursing education about sedation. For practice, if deep sedation is administered without an anaesthetist present, it is essential nurses are adequately trained and have access to vital equipment such as capnography to monitor ventilation because deeply sedated patients are more likely to experience complications related to sedation. These initiatives will go some way to ensuring patients receiving nurse-administered procedural sedation and analgesia for a procedure in the cardiac catheter laboratory are cared for using consistent, safe and evidence-based practices.

Background

Numerous factors have driven the practice of nurse-administered procedural sedation and analgesia (PSA) in the cardiac catheter laboratory (CCL). These factors are diverse and complex including cost (Kezerashvili et al., 2008), workforce constraints (Geiger et al., 1997) and increasing demand for cardiology procedures (Fox et al., 2007). Although improvements in technology have reduced the invasiveness of CCL procedures, in some instances the frequency and duration of the procedure and also the pain and discomfort caused by necessary procedural techniques, requires administration of sedatives and/or analgesia. In the CCL this is generally done without an anaesthetist present (Pachulski et al., 2001). The American Society of Anesthesiology (ASA) and the Australia and New Zealand College of Anaesthetists (ANZCA) have formulated generic clinical guidelines for PSA administered in any clinical area without an anaesthetist present (ANZCA, 2010; Gross et al., 2002), and the North American Society for Pacing and Electrophysiology (now known as the Heart Rhythm Society) had developed a set of guidelines for PSA for electrophysiology procedures (Bubien et al., 1998). As yet though, there has not been a comprehensive review to determine the current state of evidence regarding PSA in the CCL. Therefore, this integrative review was conducted to identify and appraise studies about PSA. A further aim was to identify contemporary practices from other procedural areas using PSA relevant to practice in the CCL to be considered in future research and practice initiatives.

Procedural Sedation and Analgesia

PSA is where medication is administered for the purpose of sedation and analgesia during a medical procedure. This article will use PSA to refer to administration of sedative medications by the nurse, prescribed by the cardiologist without an anaesthetist present. Interchangeable terms for PSA include conscious sedation and intravenous sedation. PSA is representative of Guedel's first stage of anaesthesia (Malamed, 2003). In this stage, medications such as opioids and benzodiazapines are used to suppress sensory and motor function while the patient remains in a conscious state (Malamed, 2003).

Method

Review Questions

The following research questions were used to identify literature specific to the aims of the review:

- What evidence is available to inform the practice of PSA in the CCL?
- Is there evidence in other procedural areas using PSA to inform practice in the CCL?

Design

Initial searching of the literature identified evidence informing PSA in the CCL from a range of experimental and non-experimental designs as well as

prospective and retrospective, descriptive and observational studies. An integrative review method permits analyses of diverse methodologies, and as such, was selected as an appropriate structure for the review (Whittemore & Knafl, 2005).

While Medline and CINAHL databases should contain journal articles reflecting contemporary PSA practices in western-based health care, the database search was widened to include The Cochrane database of systematic reviews and the Joanna Briggs Institute. High-level evidence derived from systematic reviews of quantitative and qualitative research studies are contained here. The corresponding author conducted all searches of the literature and JXR later replicated the Medline and CINAHL database search and checked the number of articles to validate the terms used. Reference lists and Google Scholar were also used to search for literature not found when searching the databases.

Articles were included in the review provided they met the following criteria:

- Empirically-derived original research reports; or
- Systematic reviews of primary research/meta-analyses; or
- Professionally endorsed clinical practice guidelines relevant to international CCL standards; and
- Published in peer-reviewed journals;
- English language only;
- Published after 1995;
- Research involving adults over the age of 18 years;

- Sedation in the CCL, or other procedural areas, administered by non-anaesthetic trained personnel.

A flow chart of studies from search to inclusion is provided in Figure 2.1. Articles that met the inclusion criteria were critically analysed using the Health Care Practice Research Development Unit's (2003) evaluation tool for quantitative studies and the level of evidence of each study was determined using the "Designation of Level of Evidence" (p.56) framework (NHMRC, 1998). Data extracted from each study were developed into a summary table by AC. The process for categorising data for the summary table was reviewed by JXR, KP & LW-C.

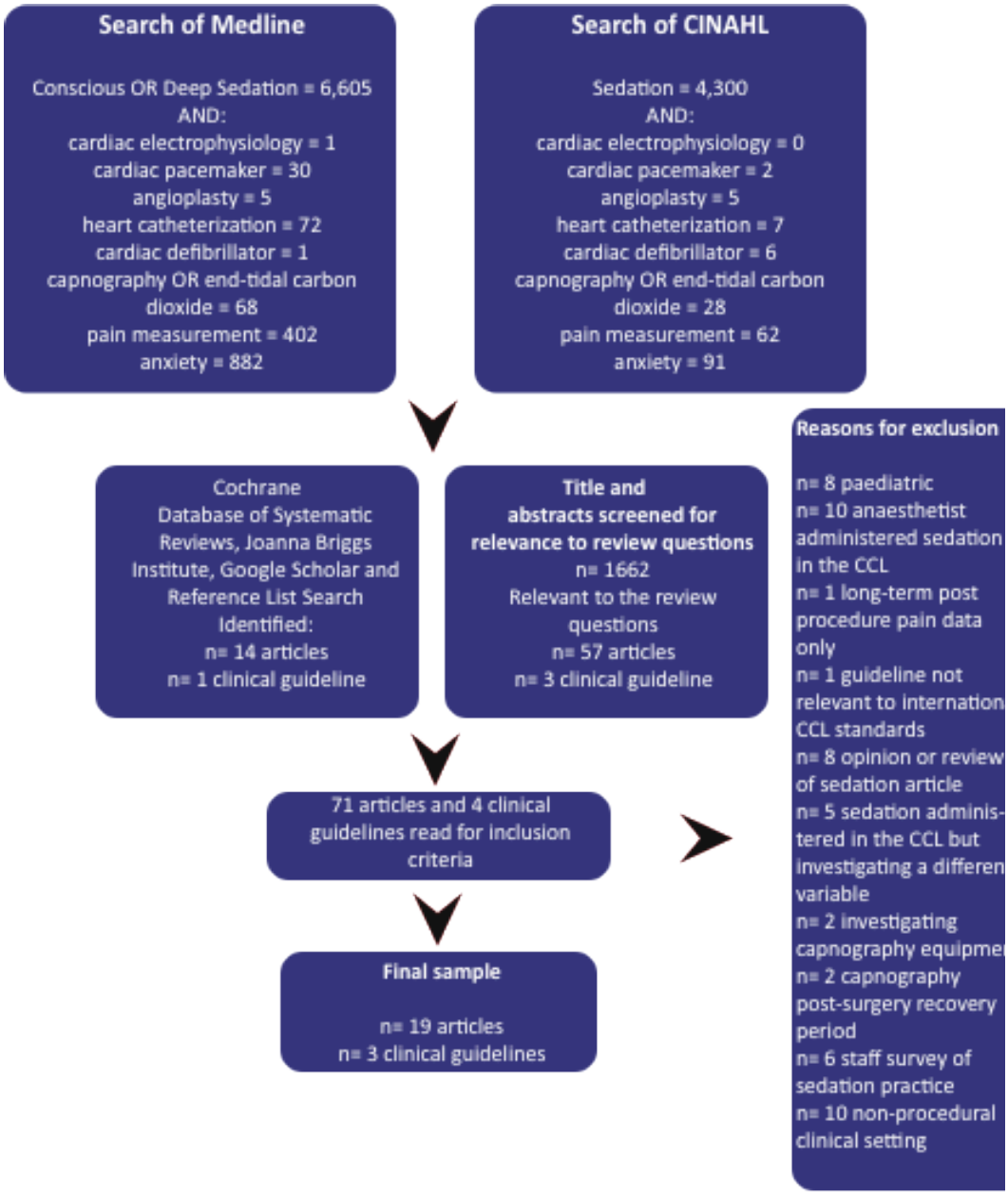


Figure 2.1 Search Strategy

Results

Nineteen articles and three clinical guidelines met the inclusion criteria. Table 2.1 displays a summary of the evidence. The results will be discussed in detail under the following categories: “Safety”; “Monitoring ventilation during sedation”; “Pain and discomfort”; “Economic impact”; and “Education”.

Table 2.1 Summary of reviewed studies

AUTHOR, YEAR	DESIGN	SAMPLE	RELEVANT FINDINGS	LEVEL OF EVIDENCE
Deitch et al, 2010	Randomised controlled trial of capnography for patients undergoing procedures in the emergency department	*n*=132 Capnography=68 Blinded=64	• All patients that developed hypoxia exhibited respiratory depression first • Capnography decreased rate of hypoxia (effect size 17%; p=0.035; 95% CI 1.3%-33%)	II
Qadeer et al, 2009	Randomised controlled trial of capnography for endoscopy with sedation using capnography	*n*=247 Open (OG)=124 Blinded (BG)=123	• Significant difference in hypoxia between two groups, BG *n*=85 (69%), OG *n*=57 (46%) (Effect size not reported; p=<.001) • 35% of hypoxic events occurred with normal ventilation	II
Yarchi et al, 2009	Prospective observational study of endoscopic procedure with sedation using capnography	*n*=57 Sedation=19 GA=38	• Included both patients with sedation and patients with general anaesthesia limiting generalisability of this study with the others included in the review • Capnography contributed significantly to detection of respiratory events	IV

Beddoes et al, 2008	Prospective observational study of patients undergoing cardiac catheterisation	*n*=119	• 9% patients reported discomfort related to pre-existing conditions • Significant correlation between procedure length and patient reports of discomfort	IV
Deitch et al, 2008	Randomised controlled trial of supplemental oxygen for patients undergoing procedures in the emergency department	*n*=110 Supplemental Oxygen=56 Control Group=54	• Supplemental oxygen trended towards reducing hypoxia in sedated patients. • Effect size of 10% (p=.3; CI -24%-7%) was below the set 20% threshold considered to be clinically significant	II
Kezerashvili et al, 2008	Consecutive series of cardiac catheter laboratory procedures with sedation	*n*=9558 C/C=3819 TOE=260 EPS=5479	• No assessment of patient acceptability or comfort **Complications related to sedation** *n*=9 0.1% complication rate *n*=3 0.03% anaesthetic staff required to intervene	IV
Rozario et al, 2008	Randomised controlled trial of sedated patients undergoing endoscopic procedures	*n*=389 Oxygen=194 No oxygen=195	• Patients receiving oxygen were 98% less likely to experience desaturation than controls (Effect size not reported; OR=0.02; 95%CI: 0.004-0.06; p=.0001)	II

Deitch et al, 2007	Randomised controlled trial of supplemental oxygen for patients undergoing procedures in the emergency department	*n*=80 Supplemental Oxygen=44 Control Group=36	• Supplemental oxygen did not reduce hypoxia (Effect size 0%; p=.97; CI -15%-15%) • Rate of hypoxia was lower than anticipated • Study was underpowered • Blinded capnography identified respiratory depression undetected by clinicians	II
Fox et al, 2007	Retrospective review of patients undergoing ICD implant with deep sedation	*n*=500 patients	**Complications related to sedation** • No deaths or tracheal intubations • *n*=373 (75%) described procedure as acceptable • *n*=41 (11%) experienced discomfort	IV
Marquie et al, 2007	Prospective two-group trial of patients undergoing ICD implant with deep sedation or general anaesthesia	*n*=118 GA=45 DS=73	• Pain rated >4/10 in 18% of GA group and 27% of sedation group (p=ns) • Understanding of the procedure was significantly correlated with low pain scores	II

Burton et al, 2006	Prospective observational study with clinicians blinded to capnography in emergency	*n*=60	• 20 respiratory events were identified • Capnography detected events prior to other monitoring techniques in 70% of cases	IV
Fu et al, 2004	Study in operating theatre and recovery area to determine effect of supplemental oxygen on detection of hypoventilation	Theatre: *n*=45 Recovery: Oxygen=133 Room air=155	• Decrease in Sp02 only detected in patients who breathed room air when minute ventilation reduced by half to mimic hypoventilation Arterial desaturation 400% higher in patients not receiving oxygen (9% vs 2.3%; p=0.02)	III-1 & II
Koniaris et al, 2003	Retrospective review of endoscopic procedures to determine benefits of capnography	*n*=4,846 procedures *n*=600 monitored with capnography	• *n*=14 (0.29%) cases of oversedation – artificial ventilation or sedation reversal required. • *n*=0 cases of oversedation when capnography was used • Complication rates not significantly different (p=0.30)	IV

Miner et al, 2002	Prospective observational study in emergency department with sedation using capnography	*n*=74	• Respiratory depression seen in 33 patients (44.6%) • All patients with respiratory depression exhibited characteristics consistent with respiratory depression on capnography	IV
Vargo et al, 2002	Prospective observational study of endoscopic procedure with sedation using capnography	*n*=49	• 54 episodes of respiratory depression • Only 50% of episodes detected by oximetry	IV
Pachulski et al, 2001	Consecutive series of cardiac catheter laboratory procedures with sedation	*n*=700 RFA=175, EPS=163, PPM=261, ICD=101	**Complications related to sedation** • Hypotension in 14 patients (2%) • 5 patients (0.7%) recollected the procedure • 2 patients (0.3%) reported pain	IV

Lipscomb et al, 1998	Non-randomised trial comparing ICD implant under general anaesthetic or sedation	*n*=12 GA *n*=33 Sedation	**No complication data reported** • 32 sedated patients did not recall the procedure. • One patient was aware of "pushing" as the device was placed • *n*=4 were mildly uncomfortable and N=3 were aware while defibrillation threshold testing was performed	III-3
Geiger et al, 1997	Consecutive series of electrophysiology procedures with sedation	*n*=536 EPS	• No assessment of patient acceptability or comfort **Complications related to sedation** • No deaths or tracheal intubations • Oxygen desaturation (4.6%) • Hypotension (2.6%)	IV

Natale et al, 1996	Prospective observational study of patients undergoing ICD implant with deep sedation	*n*=53	• Investigators assessed for recollection of pain as indicator of patient acceptability and comfort of the procedure **Complications related to sedation** • No deaths or tracheal intubations • Hospital stay not prolonged	IV

Legend: EPS= Electrophysiology procedure; PPM= Cardiac Pacemaker; ICD= Implantable cardioverter defibrillator; TOE= Transoesophageal echocardiogram; C/C= Cardiac catheterisation; GA= General anaesthesia; DS=Deep sedation. Level of Evidence: NHMRC (1998) "Designation of Level of Evidence" (p.56) adapted from the US Preventative Services Taskforce (1989).

Safety

A major consideration of the studies about PSA conducted in the CCL concerned safety. Included in the review are three studies of PSA for a range of CCL procedures and also two studies of PSA specifically for implantable cardioverter-defibrillator (ICD) implantation. Safety outcomes, which included the incidence of mortality, respiratory and haemodynamic complications, were measured. There was a low incidence of complications related to PSA and thus each author advocated its safety (Geiger et al., 1997; Kezerashvili et al., 2008; Pachulski et al., 2001). The details of the studies will now be discussed. Also, important differences between PSA for implantable cardioverter defibrillator (ICD) implant and PSA for other procedures performed in the CCL are outlined in order to explain their disparate complication rates.

Three studies, which used consecutive series designs, investigated sedation-related complications in a diverse range of procedures such as cardiac catheterisation, pacemaker implant and electrophysiology procedures (Geiger et al., 1997; Kezerashvili et al., 2008; Pachulski et al., 2001). In the study by Geiger et al., (1997), 536 patients underwent a range of electrophysiology studies with PSA consisting of midazolam, meperidine (pethidine) and phenergan or a combination of midazolam and fentanyl. The authors concluded these PSA practices were safe and acceptable. However, there were instances of oxygen desaturation (n=25, 4.6%) and hypotension (n=14, 2.6%) observed in this study. Both nursing and medical intervention was required to support or restore haemodynamic and respiratory function to protect the safety of patients who

received sedation. Oxygen desaturation was reversed with opioid antagonists and airway support manoeuvres, while hypotension was treated successfully with intravenous fluid replacement. There were no instances of death, and no need for tracheal intubation or a prolonged hospital stay for patients included in this study (Geiger et al., 1997).

Interventions were also required in the Kezerashvili et al. (2008) and Pachulski et al. (2001) studies due to sedation-related complications. Discussed first is a study of 700 consecutive patients who received midazolam and fentanyl during an electrophysiology procedure in the CCL (Pachulski et al., 2001). The procedures included diagnostic electrophysiology, radiofrequency ablation of arrhythmias or implantation of pacemakers and ICD's. Reversible oxygen desaturation (n=17, 2.4%) and hypotension (n=14, 2%) were the reported sedation-related complications. Again, there were no instances of death or tracheal intubation. In contrast, Kezerashvili et al. (2008), the study with the largest sample size of all studies in this review, reported a complication rate of 0.1% (death, clinical instability, hives). Procedures included 3, 819 catheterisations, 260 transoesophageal echocardiograms and 5, 479 electrophysiology procedures. There were 5 deaths among the cohort of patients in this study, and the authors stated a possible role of sedation could not be excluded. A thorough description of respiratory complications such as the incidence of hypoxia was not reported in this study.

Establishing the safety of PSA in ICD implantation was approached in the ICD studies by reporting complications such as oxygen desaturation and hypotension,

similar to the studies of Geiger et al. (1997) and Pachulski et al. (2001). However, there are procedural differences between ICD studies and those reporting sedation for other procedures in the CCL. Deep sedation was induced for defibrillation threshold testing (Fox et al., 2007; Natale et al., 1996). Deep sedation is further along the continuum of anaesthesia than the level of sedation provided for other cardiac procedures (Kezerashvili et al., 2008). In both of the ICD studies, respiratory complications were reported at a higher rate than those reported in studies not requiring a deep level of sedation for a procedure (Kezerashvili et al., 2008, Pachulski et al., 2001). Nevertheless, ICD implant with PSA, even when deep sedation is used for defibrillation threshold testing, was reported as safe practice by Fox et al. (2007) and Natale et al. (1996).

Considerable importance was placed on reporting respiratory complications in PSA studies. Intuitively, this is understandable given sedative medications can induce respiratory depression (Gross et al., 2002). The authors reported that no patients required tracheal intubation and rates of hypoxia ranged between 2.4 and 9.4%. Table 2.2 presents the respiratory complications for each of the CCL studies.

Table 2.2 Respiratory Complications for PSA in the Cardiac Catheter Laboratory

Author	Complications	Incidence
Fox et al. (2007)	Airway problems requiring sedation reversal	n=36 (7.5%)
	Artificial ventilation	*n*=1 (0.2%)
	Emergency anaesthetic support intubation	*n*=0 (0%)
Pachulski et al. (2001)	Endotracheal intubation	*n*=0 (0%)
	Hypoxia (Sp02> 80% <90%)	*n*=17 (2.4%)
Geiger et al. (1997)	5% reduction from baseline Sp02 requiring sedation reversal	*n*=14 (2.6%)
	5% reduction from baseline Sp02 caused by airway obstruction requiring airway alignment	*n*=11 (2%)
	Endotracheal intubation	*n*=0 (0%)
Natale et al. (1996)	Endotracheal intubation	*n*=0 (0%)
	Reduction of Sp02 requiring:	*n*=5 (9.4%)
	Sedation reversal	*n*=3 (5.6%)
	Airway adjuncts	*n*=2 (3.7%)

Other procedural areas, which used PSA, classified respiratory complications differently. Table 2.3 presents studies that investigated PSA in emergency departments (ED) and endoscopy suites.

Table 2.3 Respiratory complications for PSA in Emergency and Endoscopy

Author, Year	Specialty	Complications	Incidence
Deitch et al, 2010	Emergency	Respiratory depression defined by presence of at least one of the criteria below:	Capnography group *n*= 39(57%); Blinded group *n*= 37(58%)
		Sp02 <93%	Capnography group *n*= 17(25%); Blinded group *n*= 27(42%)
		ETCO2 >50mmHg	Capnography group *n*= 9(23%); Blinded group *n*= 8(22%)
		Change in ETCO2 value of 10mmHg from baseline	Capnography group *n*= 27(69%); Blinded group *n*= 23(62%)
		Loss of capnography waveform	Capnography group *n*= 2(5%); Blinded group *n*= 5(13%)
Qadeer et al, 2009	Endoscopy	Hypoxia (Sp02<90% for >15seconds	Blind arm *n*=85 (69%) Open arm *n*=57 (46%) p=<0.001
		Require supplemental oxygen	Blind arm *n*=82 (66.7%) Open arm *n*=65 (52.4%) p=0.02
		Apnoea (loss of capnography waveform for >15 seconds)	Blind arm *n*=77 (62.6%) Open arm *n*=51 (41.1%) p=<0.001
		Abnormal ventilation (loss capnography waveform >5 sec<15 sec, >75% decrease in waveform amplitude for > 5 sec.	Blind arm *n*=101 (82.1%) Open arm *n*=95 (76.6%) p=0.29
Yarchi et al, 2009	Endoscopy	Cardiorespiratory event classified as change in ETCO2 by 20% and one of the following:	*n*=32 (56%) one event and *n*=5 two events (8.7%)

		Cardiorespiratory event classified as change in ETCO2 by 20% and one of the following:	*n*=32 (56%) one event and *n*=5 two events (8.7%)
		Sp02<90%	Not reported
		20% change in respiratory rate	Not reported
		20% change in pulse rate	Not reported
Deitch et al, 2008	Emergency	Respiratory depression defined by presence of at least one of the criteria below:	Oxygen group *n*=30 (53%); Room air group *n*=22 (40%)
		Sp02 <90%	Oxygen group *n*=10 (18%); Room air group *n*=15 (28%)
		ETCO2 >50mmHg	Oxygen group *n*=1 (0.02%); Room air group *n*=2 (0.04%)
		Change in ETCO2 value of 10mmHg from baseline	Oxygen group *n*=23(41%); Room air group *n*= 13(24%)
		Loss of capnography waveform	Oxygen group *n*= 1(0.02%); Room air group *n*= 1(0.02%)
Rozario et al, 2008	Endoscopy	Hypoxia (Sp02 <95%)	Supplemental oxygen *n*=24 (12.4%) Room air *n*=138 (70.8%)
Deitch et al, 2007	Emergency	Respiratory depression defined by presence of at least one of the criteria below:	Oxygen group *n*=20(45%); Room air group *n*=19 (52%)
		Sp02 <90%	Oxygen group *n*=5 (11%); Room air group *n*=2 (6%)

		Respiratory depression defined by presence of at least one of the criteria below:	Oxygen group *n*=20(45%); Room air group *n*=19 (52%)
		Sp02 <90%	Oxygen group *n*=5 (11%); Room air group *n*=2 (6%)
		ETCO2 >50mmHg	Oxygen group *n*=12; Room air group *n*=8 (22%)
		Change in ETCO2 value of 10mmHg from baseline	Oxygen group *n*=12 (27%); Room air group *n*=9 (25%)
		Loss of capnography waveform	Oxygen group *n*=7 (19%); Room air group *n*=7 (19%)
Burton et al, 2006	Emergency	Acute respiratory event defined by criteria below:	*n*=20 (33%)
		Sp02<92%	*n*=19 (31.6%)
		Increase in supplemental oxygen in response to apnoea, hypoventilation, or desaturation	*n*=14(23.3%)
		Use of bag-valve mask or oral/nasal airway for ventilator assistance or apnoea	*n*=4 (6.6%)
		Airway alignment maneuvers	*n*=9 (15%)
		Verbal or physical stimulation	*n*=20 (33%)
		Sedation reversal	Not reported
		Investigational Acute Respiratory Events defined by criteria below:	*n*=36 (60%)

		Acute respiratory event defined by criteria below:	*n*=20 (33%)
		Sp02<92%	*n*=19 (31.6%)
		Increase in supplemental oxygen in response to apnoea, hypoventilation, or desaturation	*n*=14(23.3%)
		Use of bag-valve mask or oral/nasal airway for ventilator assistance or apnoea	*n*=4 (6.6%)
		Airway alignment maneuvers	*n*=9 (15%)
		Verbal or physical stimulation	*n*=20 (33%)
		Sedation reversal	Not reported
		Investigational Acute Respiratory Events defined by criteria below:	*n*=36 (60%)
		Change in ETCO2 level >10mmHg from baseline	Not specified
		ETCO2 <30mmHg or >50mmHg	Not specified
Miner et al, 2002	Emergency	Respiratory Depression noted by findings below:	*n*=33 (44%)
		ETCO2 > 50mmHg	*n*=24 (32%)
		ETCO2 <50mmHg but Sp02<90%	*n*=5 (14.8%)
		ETCO2 <50mmHg but loss of capnography waveform	*n*=4 (5%)
		Respiratory Complication noted by requiring assisted ventilation	*n*=11 (14.8%)
Vargo et al, 2002	Endoscopy	Respiratory depression defined by presence of at least one of the criteria below:	54 episodes in 28 patients
		Apnoea	Not reported

	Respiratory depression defined by presence of at least one of the criteria below:	54 episodes in 28 patients
	Apnoea	Not reported
	Disordered Respiration	Not reported
	Acute respiratory event defined by presence of at least one of the criteria below:	30 episodes detected
	Hypoxia (sp02 < 90%)	Identified 27 episodes (50%) of respiratory depression
	Alveolar hypoventilation (ETCO2 25% > baseline)	Identified 3 episodes (5.5%) of respiratory depression

Legend: ETCO2=End-tidal Carbon Dioxide; SpO2=Peripheral oxygen saturation

Respiratory complications were expanded in the ED and endoscopy studies to include measurements derived from capnography and end-tidal carbon dioxide (ETCO2) monitoring that indicate respiratory depression.

Monitoring ventilation during sedation

Currently, capnography has not been identified as a requirement for monitoring ventilation in clinical guidelines for all sedation administered without an anaesthetist (ANZCA, 2010, Gross et al., 2002). The consensus statement from the ASA recommends capnography for deep sedation but not for moderate sedation (Gross et al., 2002). However, all but one study (Koniaris, Wilson, Drugas, & Simmons, 2003), which used capnography to monitor the ventilation

of patients who received PSA in procedural areas, demonstrated that this technology detected respiratory depression earlier than observation of respiratory function and oximetry (Burton, Harrah, Germann, & Dillon, 2006; Deitch, Miner, Chudnofsky, Dominici, & Latta, 2010; Miner, Heegaard, & Plummer, 2002). Table 1 presents the specific details of how much capnography improved safety outcomes, or, how much more effective it is in detecting respiratory depression than oximetry and observation of respiration alone.

The majority of studies in which ventilatory monitoring has been reported have taken place in endoscopy suites and ED. In the ED, patients' acute respiratory events were detected by capnography prior to oxygen desaturation or observed hypoventilation (Burton et al., 2006, Miner et al., 2002). In another study that blinded capnography values from one group, using capnography decreased the rate of hypoxia by 17% (42% vs. 25%; p=.035; 95% CI: 1.3%-33%) (Deitch et al., 2010). Similar positive findings were evident in the endoscopy setting. Yarchi et al. (2009) found capnography significantly contributed to prediction of respiratory events, Qadeer et al. (2009) concluded from the results of their study that capnography improves safety outcomes for patients receiving PSA by reducing the frequency of hypoxia and Vargo et al., (2002) found only 50% of episodes of respiratory depression were detected by oxygen saturation or visual assessment of respiration. Consequently, the authors contend that peripheral oxygen saturation monitoring and observation of respiration does not give an accurate indication of existing hypoventilation or of its duration.

There is further evidence to substantiate the claim made by the authors above that oxygen saturation monitoring is inadequate to detect abnormalities in respiration, especially when supplemental oxygen is administered. Burton et al. (2006) and Deitch et al. (2010) reported that capnography detected respiratory depression earlier than oxygen saturation monitoring in sedated patients who received oxygen supplementation.

However, the literature concerning routine administration of supplemental oxygen for all patients who receive PSA is contradictory. For example, two randomized controlled studies (Deitch, Chudnofsky, & Dominici, 2007, 2008) that compared supplemental oxygen and room air administration during PSA in the ED failed to achieve the primary outcome of reducing the rate of hypoxia by 20%. Failing to recruit the required number of participants calculated in the power analysis was cited as the reason why supplemental oxygen did not reduce hypoxia in the Deitch et al. (2007) study. However, the later study in 2008 by the same authors was appropriately powered, yet again supplemental oxygen did not reduce hypoxia by 20% (Effect size 10%; p=.3; CI -24%-7%). The authors stated there was a lower incidence of hypoxia in both groups than anticipated from the literature and speculated if a positive finding would have resulted had they recruited more participants to power the study to detect a smaller difference between the groups. In contrast to these findings, it was identified in a prospective randomised, non-blinded, controlled trial that patients receiving supplemental oxygen during endoscopy were 98% (OR=0.02; 95%CI: 0.004-0.06; p=.0001) less likely to experience desaturation than the control group (Rozario,

Sloper, & Sheridan, 2008). Also, arterial desaturation was 400% higher in post-operative patients not receiving oxygen (Effect size not reported; 9% vs 2.3%; p=0.02) (Fu, Downs, Schweiger, Miguel, & Smith, 2004).

Pain and discomfort

Pain and related discomfort are common reasons why PSA is administered for procedures in the CCL (Bubien et al., 1998). An investigation of pain and discomfort using standardised rating scales was conducted in two studies, while a further two studies used less rigorous methods to collect data to discern comfort and pain during the procedure.

Discomfort and pain level were investigated in patients undergoing cardiac catheterization who received minimal conscious sedation (Beddoes et al., 2008). A 6-point Likert scale ranging from 'very uncomfortable' to 'very comfortable' and a visual analogue scale (0=no pain, 10=worst pain possible) were used to measure discomfort and pain respectively. Patients' mean pain rating was 4.03 (SD 3.06) and 35.3% reported discomfort. Pre-existing conditions were identified as causing significant discomfort to 9% of patients (Beddoes et al., 2008). A smaller proportion of patients, 11% (Fox et al., 2007) and 12%, (Lipscomb, Linker, & Fitzpatrick, 1998) experienced discomfort in studies that investigated ICD implant with PSA. However, unlike the Beddoes study, scales were not used in these ICD studies to measure pain and discomfort.

Pain rating scales were used in a prospective two-group study by Marquie et al. (2007), who assessed for pain in patients undergoing ICD implant using PSA or

ICD implant using a short general anaesthesia. Pain ratings using visual analogue scores (0=no pain, 10=unbearable pain) after defibrillation for the PSA group or after the procedure for the general anaesthesia group were collected and compared across the two groups. Even though pain scores were higher in the PSA group, the authors concluded that sedation was an acceptable method to facilitate implantation of an ICD because the difference in pain scores between the two groups was non-significant (Marquie et al., 2007).

Economic impact

The savings associated with using PSA in the CCL were reported in a study of a consecutive series of 9, 558 patients (Kezerashvili et al., 2008). $5,365,691 USD was saved over a decade, which was attributed to forgoing anaesthetic services. No other study reported cost considerations of PSA in the CCL.

Education

The ASA (Gross et al., 2002) and ANZCA (2010) clinical guidelines stipulate an individual other than the person performing the medical procedure should be present to monitor the patient's condition and they should be trained in basic life support and satisfactory sedation practices (basic knowledge of pharmacology and identification of complications). This recommendation was formed by consensus of expert opinion rather than empirical evidence, as the clinical guidelines stated the literature is silent on the effect of training of personnel on patient outcomes (Gross et al., 2002).

The literature was examined to determine the extent of education and training about sedation provided to nurses who administer PSA in the CCL. In most of the studies, the nurses who administered sedation to patients received education about PSA from local departments of anaesthesiology (Geiger et al., 1997, Kezerashvili et al., 2008, Pachulski et al., 2001). Nurses were examined on key concepts of safe PSA administration and management prior to being permitted to administer PSA in the CCL. No authors reported that the training and education provided was a contributing factor to the low incidence of sedation-related complications.

Limitations of studies

There was a lack of homogeneity in sample characteristics and differences between normal and abnormal reference ranges of physiological variables such as oxygen saturation and blood pressure between studies. As the variability in sample characteristics and the different reference ranges for physiologic variables could account for the variability in the complication rate, a meta-analysis was not attempted.

Clinical guidelines for PSA in the CCL are inconsistent. Deep sedation for defibrillation threshold testing is contradictory to current clinical guidelines for sedation without an anaesthetist present (ANZCA, 2010, Gross et al., 2002). However, earlier guidelines developed by NASPE (Bubien et al., 1998), do support the use of deep sedation for defibrillation threshold testing without an anaesthetist present.

Only quantitative designs have been used to research pain and discomfort experienced by patients who received PSA (Fox et al., 2007, Marquie et al., 2007, Natale et al., 1996). Also, not all of the studies used standardised rating scales to measure pain and discomfort.

Discussion

Administration of sedative medications without an anaesthetist present was considered safe by the authors of each study (Geiger et al., 1997, Kezerashvili et al., 2008, Pachulski et al., 2001). Even in studies contradictory to current ASA guidelines for PSA without an anaesthetist present (Gross et al., 2002), in which deep sedation was induced for ICD implantation, the authors all reported this was safe (Fox et al., 2007, Natale et al., 1996). Arguably though, more sensitive and accurate measures of respiratory status have been recorded in studies located in the ED and endoscopy suite compared with studies conducted in the CCL. In these settings, in addition to peripheral oxygen saturation monitoring and observation of respiration, capnography has been used to detect respiratory depression (Burton et al., 2006, Yarchi et al., 2009, Qadeer et al., 2009). As such, the safety of PSA in the CCL has not been as comprehensively assessed as it has in the other procedural areas.

Although it can be argued current clinical guidelines do not recommend capnography for sedation considered to be less than deep (Gross et al., 2002), research shows deep sedation is being administered in the CCL without an anaesthetist present (Fox et al., 2007; Natale et al., 1996). Furthermore, there is

evidence derived from studies in the ED and endoscopy suites (Deitch et al., 2010, Qadeer et al., 2009, Yarchi et al., 2009) showing capnography has the potential to aid the ability of nursing and medical staff to promptly identify respiratory depression and consequently improve safety for patients who receive sedation in the CCL.

While the acute onset of illness that precipitates admission to the ED may seem appropriate justification for the use of capnography to detect respiratory depression in this patient population, a higher number of studies were found in the endoscopy suite setting. In this context, patients undergo elective, urgent or emergency procedures, in a manner similar to which procedures occur in the CCL. It is acknowledged that differences exist in the level of sedation required and the medications used for PSA in the endoscopy setting compared with the CCL, however, the evidence gained from testing the use of capnography during endoscopic procedures also supports monitoring carbon dioxide for PSA in the CCL. For these reasons, capnography requires further investigation in the CCL setting.

Another important finding in this review centres on education of nurses who administer PSA without an anaesthetist present. Low complication rates were reported when nurses administered sedation in the CCL. In the majority of these studies, the nurses who administered the sedation undertook education about PSA concepts and were assessed for competence. Potentially then, educating staff to an advanced practice level is one of the factors contributing to the low incidence of complications. Unfortunately, the research designs employed by the

studies in this review (Geiger et al., 1997, Kezerashvili et al., 2008, Pachulski et al., 2001) will not permit inference about the positive effect of education on patient outcomes.

Finally, it is known workforce constraints can delay a patient's procedure until an anaesthetist can be arranged for a procedure, and, delaying a procedure increases the cost to the health service by increasing the length of the patients' hospital stay (Fox et al., 2007). Accordingly, this review also considered the economic impact of using PSA in the CCL. Cost-savings of forgoing anaesthetic services have exerted major influence over CCL practice as anecdotal evidence suggests PSA is now integrated into CCL nurses' scope of practice and is common (Geiger et al., 1997, Kezerashvili et al., 2008, Pachulski et al., 2001). This is despite the facts that there is still a lack of clear, nursing-specific clinical guidelines and educational objectives, a lack of concordance between medical practice in the CCL and the existent guidelines which stipulate the safe level of sedation to be administered without an anaesthetist present (Gross et al., 2002) and also a lack of rigorous empirical research into patient outcomes. Furthermore, although cost is a major factor driving PSA in the CCL, actual cost-effectiveness data cannot be considered in great detail. Only one study reported cost-savings associated with using PSA in the CCL. These savings were attributed to forgoing anaesthetic services (Kezerashvili, et al., 2008). The lack of research that evaluates the economic impact of PSA may be related to the fact that forgoing anaesthetic services has an immediate cost-benefit associated with not having to pay an anaesthetist. However, other economic considerations

associated with PSA administration by nurses are worthy of investigation. These include the cost implications of interruptions to the procedure, recovery time and staffing ratios.

Limitations of the review

The integrative review permits inclusion of studies from a range of disciplines using various methodologies (Whittemore and Knafl, 2005). However, generalizations without careful consideration from studies conducted in other clinical areas to the CCL are not appropriate due to differences in medications used (Deitch et al., 2010), sedation levels (Natale et al., 1996) and classifications of respiratory complications (Burton et al., 2006, Deitch et al., 2010, Geiger, et al., 1997). For these reasons, significant research findings derived from these clinical areas should be examined further within the CCL.

Implications for Practice

In practice, vigilant attention and a specialised skill set is required of nursing staff who administer sedation without an anaesthetist present so they are able to intervene with appropriate actions to protect the safety of patients (Geiger et al., 1997, Kezerashvili, et al., 2008, Pachulski, et al., 2001). Nurses, who administered sedation to patients in the studies that investigated the safety of nurse-administered PSA in the CCL, were provided with specialised training in sedation concepts as it is recommended by the ASA guidelines (Gross et al., 2002). However, there is no evidence available to determine the extent to which this guideline is adhered to in the real-world setting. In addition, even with such

scrutiny by a highly educated staff member, treatment for respiratory compromise in the CCL is potentially delayed without using capnography. Evidence shows respiratory depression can remain undetected without capnography (Vargo et al., 2002).

Another consideration to take into the practice environment is the inconsistency between clinical guidelines (ANZCA, 2010, Bubien, et al., 1998, Gross, et al., 2002). The ASA guidelines (Gross et al., 2002) do not permit deep sedation but the NASPE clinical guidelines (Bubien et al., 1998) do advise deep sedation can be induced for patients undergoing ICD implants without an anaesthetist. Although in the literature, the level of sedation administered by nurses without an anaesthetist present appears to vary, it cannot be definitively determined whether cardiologists are adhering to the more current ASA guidelines and using anaesthetists when deep sedation is required for a procedure in the CCL. However, as a higher percentage of deeply sedated patients were reported to experience complications than the moderately sedated patients (Fox et al., 2007, Geiger et al., 1997, Natale et al., 1996, Pachulski et al., 2008), it is essential that nurses are educated and provided with vital equipment such as capnography to monitor ventilation should administration of deep sedation become accepted within the CCL nursing scope of practice.

Implications for research

Research efforts should entail a more comprehensive analysis of patient and health service outcomes for CCL PSA. Using classifications of respiratory

complications in line with contemporary PSA practice (Burton et al., 2006, Qadeer, et al., 2009), using standardised rating scales to measure pain and discomfort and investigating the economic impact of sedation-related complications are steps to achieve this. Also, it has been established there is evidence from the ED and the endoscopy suite, which calls for an investigation into the use of capnography in the CCL setting. Finally, local departments of anaesthesiology have set the education requirements of nurses who administer sedation in the CCL (Geiger et al., 1997, Kezerashvili et al., 2008, Pachulski et al., 2001). Instead of relying on individualised effort at different institutions, a standardized set of educational objectives is required. This will be a necessary step before further research can be conducted to determine the effect of this education on patient outcomes.

Conclusion

The evidence supports the use of nurse-administered PSA in the CCL. There were low rates of sedation-related complications among patients who received PSA from a nurse in the CCL, and, there were cost-savings associated with forgoing anaesthetic services. However, practice is varied due to inconsistent clinical guidelines regarding the level of sedation that can be administered safely without an anaesthetist present. Given these findings, this review considered both evidence about nurse-administered PSA in the CCL and evidence derived from other clinical settings, which use PSA, to identify salient clinical practice

issues and make recommendations for research so that patients can receive safe, consistent and evidence-based care.

A review of sedation scales for the cardiac catheterisation laboratory

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Preamble

In addition to comprehensively reviewing the literature on sedation, which was specific to the CCL setting, studies on sedation that had been conducted in other clinical settings were also extensively reviewed in order to identify evidence-based practices that could also be applied to the CCL setting. It was identified through this review of the literature that standardised assessment of level of sedation has been shown to improve clinical outcomes in the intensive care unit (ICU) (Muller et al., 2008; Quenot et al., 2007). As sedation is also commonly used in the CCL setting, standardised assessment of level of sedation also has the potential to facilitate effective procedural sedation and analgesia in this setting. However, for this potential to become realised, a validated scale to measure level of sedation either needed to be identified or developed. The manuscript presented in this chapter is a review of the literature that was undertaken to address these identified gaps in the literature.

Abstract

Sedation scales have the potential to facilitate effective procedural sedation and analgesia in the cardiac catheterization laboratory (CCL). For this potential to become realised, a scale that is suitable for use in the CCL either needs to be identified or developed. To identify sedation scales, a review of Medline and CINHAL was conducted. One sedation scale for the CCL, the NASPE SED, and 15 Intensive Care Unit (ICU) scales met the inclusion and exclusion criteria. Analysis of the scale's item structures and psychometric properties was then performed. None of these scales were deemed suitable for use in the CCL. As such, further research is required to develop a new scale. The new scale should consist of more than one item because it will be the most effective for tracking the patient's response to medications. Specific tests required to conduct a rigorous evaluation of the new scale's psychometric properties are outlined in this paper.

Introduction

Procedural sedation and analgesia (PSA) is a technique used during procedures in the cardiac catheterisation laboratory (CCL) in which a state of drug-induced depression of consciousness is induced to suppress patients' awareness of pain and discomfort, reduce feelings of anxiety and induce amnesia.(Malamed, 2003) In the CCL, generally the 'scout' nurse will administer sedative and analgesic medications intravenously, usually by means of incremental bolus doses of a benzodiazepine and an opioid. The prescription for the medication is usually given verbally, directly from the cardiologist who is performing the procedure, and typically, no other medical practitioners are present.

The aim of PSA is to effectively relieve the noxious sensory experiences such as pain, discomfort, anxiety and agitation that patients encounter during the procedure while inducing only the minimum necessary depression of consciousness. However, there are individual variations for each patient in terms of the analgesic and anxiolytic effect of PSA as well as the degree to which the medications depress consciousness (Sessler, Grap, & Brophy, 2001). As such, it is essential for the nurse to monitor for symptoms of the noxious sensory experiences, observe consciousness and communicate assessment findings to the cardiologist, in order to maintain effective PSA medication titration throughout the procedure.

Although they were not developed specifically for PSA, sedation scales are currently the only standardised assessment tools available, which have been validated to measure noxious sensory experiences during medical procedures and level of consciousness concurrently. Sedation scales were first developed in the Intensive Care Unit (ICU). Numerical ranks are assigned to observable clinical behaviours that are known to be associated with changes in the level of consciousness and the degree of pain, anxiety, agitation or discomfort. One or more items with graded responses are used to measure the noxious sensory experience and consciousness domains. The sum of all item scores provides an overall score that indicates level of sedation (Sessler et al., 2001).

It is important to note, though, that there are differences between patients who receive sedation in the ICU and the CCL. For example, a likely cause of anxiety and agitation in the ICU is delirium (Ely et al., 2004). Whereas in the CCL setting, anxiety and agitation is more likely related to patient concerns about the outcome of the procedure, or from the paradoxical excitation effect of sedative medications (Beddoes et al., 2008; Denman, 2010). Also, the type and amount of sedation used in the ICU is different to that used in the CCL. Nevertheless, sedation scales have been applied to other clinical settings more similar to the CCL, such as emergency and radiology departments and the endoscopy unit, for the management of PSA during medical procedures (Dere et al., 2010; Gill, Green, & Krauss, 2003). In this regard, they show great potential for their use in the CCL setting.

Furthermore, the probable clinical usefulness of standardised sedation assessment in the CCL has been postulated previously. In 1998 an expert panel convened by the North American Society for Pacing and Electrophysiology, now known as the Heart Rhythm Society, suggested nurse-administered PSA in the CCL be maintained according to a sedation scale (Bubien et al., 1998). The panel developed a sedation scale for use in the CCL by adapting the Aldrete Post Anesthetic Recovery Score (Aldrete & Kroulik, 1970). The scale was named the NASPE SED. Despite this recommendation from the expert panel, no research suggests that the NASPE SED, or any other sedation scale, is currently used by CCL nurses in clinical practice. Potentially, the NASPE SED is not used because the scale has limitations that render it not suitable for clinical practice. However, a review of this scale's item structure or psychometric properties has not previously been undertaken to ascertain its limitations or to determine its suitability for use in clinical practice.

Another reason to commence an examination of the clinical usefulness of sedation scales in the CCL setting is that a vast amount of research conducted in the ICU suggests using a sedation scale reduces the amount of time that patients are not optimally sedated, which in turn has translated into improved clinical outcomes. There have been reports of reduced incidence of ventilator-associated pneumonia, which is mediated by shorter duration of mechanical ventilation, and less risk of unplanned extubation associated with the use of a sedation scale (Muller et al., 2008; Quenot et al., 2007). Unfortunately, no research has previously been conducted to demonstrate the extent to which

sedation is maintained at an optimal level in the CCL setting. In the absence of this evidence, it can only be tentatively hypothesised that using a sedation scale to perform standardised assessment of level of sedation, similar to that which occurs in the ICU, may also result in optimisation of nurse-administered PSA in the CCL and in turn lead to improved clinical outcomes for patients.

While the potential benefits of sedation scales can only be tentatively hypothesised, which is due to the general dearth of research evidence about PSA in the CCL setting specifically, it does make sense clinically that using sedation scales would aid nurses to identify the many noxious sensory experiences associated with procedures in the CCL. For example, there are many aspects of the procedures that are painful, such as intra-coronary artery balloon inflations and radiofrequency ablation. Patients must also remain immobilised during the whole procedure. Prolonged immobilisation during a long procedure has been known to cause a considerable amount of discomfort, especially for patients with pre-existing musculoskeletal injuries (Beddoes et al., 2008). Also, simply being awake during a medical procedure and feeling or seeing the body cut open can be anxiety producing for some people (Mitchell, 2009). Furthermore, patients who undergo procedures in the CCL are anxious about the outcome of their procedure (Gallagher, Trotter, & Donoghue, 2010). Increased vigilance in assessing for these noxious sensory experiences with the aid of a standardised assessment tool could prompt earlier titration of sedative and analgesic medications. Early intervention may lead to improved patient-reported

satisfaction with the procedure, as there would be less time that the patient experiences pain and discomfort before initiation or titration of sedation.

It is also likely that using a sedation scale in the CCL may also help to maintain patients' consciousness at the desired level, which could potentially reduce the incidence of PSA-related respiratory complications, because respiratory depression is more likely to occur if the patient is deeply sedated. Deep sedation is a state of depressed consciousness where the patient is not responsive to verbal commands (Odom-Forren & Watson, 2005). Deep sedation is only required to facilitate particularly painful aspects of certain procedures performed in the CCL. For instance, defibrillation threshold testing may be required during implantable cardioverter defibrillator implants and cardioversion may be required during radiofrequency ablation. For the other procedures, only moderate sedation, where the patient is able to respond to verbal commands, is indicated. However, there are individual variations for each patient in terms of the degree to which the medications depress consciousness. Accurately determining the patient's present level of consciousness before initiating further doses of sedative and analgesic medication, so as not to induce deep sedation when it is not intended or required, is therefore desirable.

While the evidence from the ICU setting and the knowledge of current PSA practice in the CCL indicates that using sedation scales in the CCL could potentially improve patient outcomes if they are used in this setting, much further research is required in order to substantiate this claim. Before any research focused on using a sedation scale to improve outcomes for PSA in the

CCL can be initiated, a sedation scale that is suitable for use in the CCL needs to be identified. Therefore, the first objective of this study was to identify sedation scales from all clinical settings. The second objective of this study was to appraise the psychometric properties of sedation scales identified in the review to determine their ability to be used in the CCL setting. In the case that a suitable scale could not be identified, the third objective of the study was to identify elements of what would constitute a suitable sedation scale for the CCL and to also identify the specific tests required to conduct a rigorous evaluation of a new scale's psychometric properties.

Method

This study involved identification of literature describing sedation scales and their psychometric properties. The identified scales are summarised and critiqued for their potential suitability for use in the CCL. Although several associated principles were applied to enhance methodological rigour of this review, such as using a protocol to guide the review and clearly defining and presenting the inclusion criteria, search strategy and search outcomes, this was not a systematic review (*Centre for Reviews and Dissemination*, 2001). Furthermore, as the aim was to review sedation scales to determine their potential suitability for use in the CCL setting and not to determine the effectiveness of using a sedation scale in the CCL setting in terms of their effect on clinical outcomes, a critical appraisal of the sedation scales is presented

instead of a critical appraisal of the quality of each article; as is usual practice for a systematic review.

Search methods

A search of the two major health databases for the medicine, nursing and allied health specialties, Medline and CINAHL, was conducted to identify sedation scales. In addition, manual searching of the reference lists of identified articles was conducted. Search terms, including results of the search strategy at each stage of the process are presented in Figure 3.1.

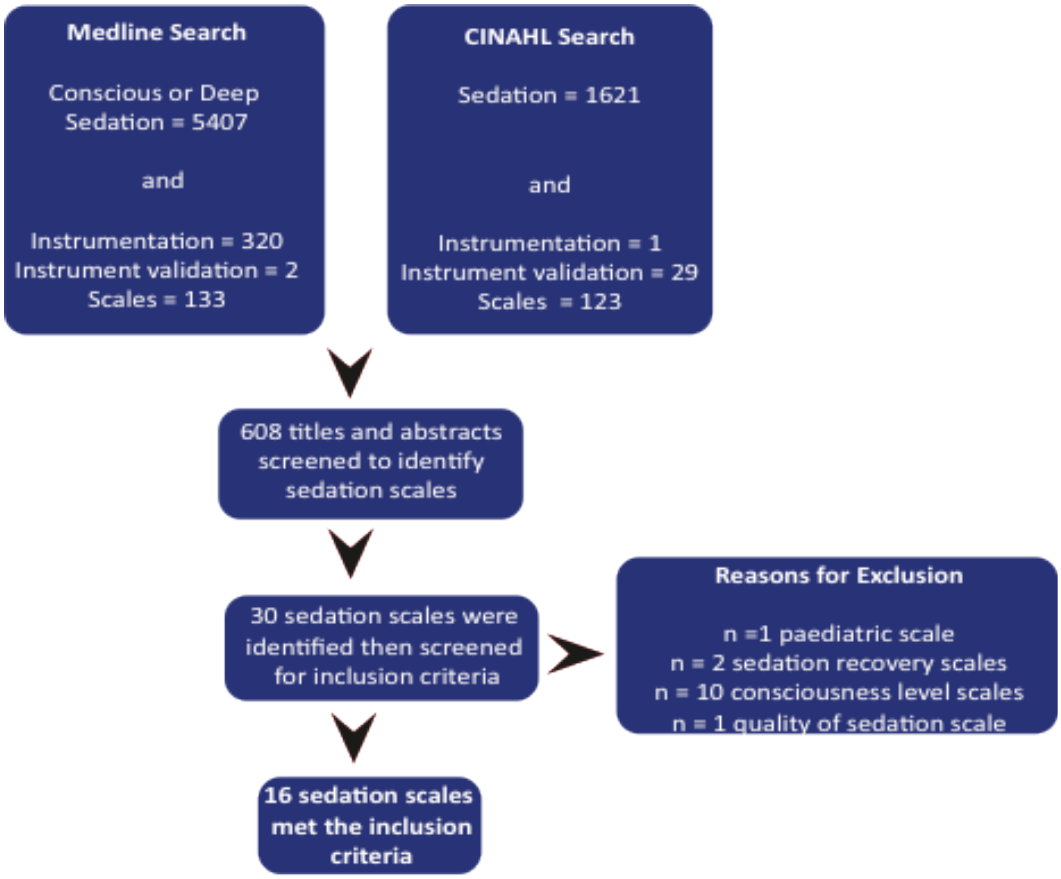


Figure 3.1 Search results

Inclusion and exclusion criteria

Identified sedation scales were included in this review if they were:

- Developed for the CCL; or
- Developed for another clinical setting, but have previously undergone psychometric testing.

Identified sedation scales were excluded from this review if they were:

- Developed and only used in the paediatric setting;
- Focused on sedation recovery;
- Focused solely on measuring consciousness; or
- Focused solely on measuring the quality of sedation for research rather than clinical practice purposes.

Data abstraction

A standardised process was used to abstract data for each of the scales that fit the inclusion and exclusion criteria. Data that was abstracted included the scales' development process, their item structures and details about published clinical or psychometric testing. A summary of the abstracted data for each scale is presented in Table 3.1.

Table 3.1 Description of reviewed sedation scales

Scale (Year)	Scale Development Process	Scale used in other settings or research	Scale Structure			Clinical Testing
			Domains	Items	Range	
Adaptation to Intensive Care Environment (ATICE) **(2003)**	Literature review to identify domains followed by 7 focus groups of nurses, residents and intensivists in France & Canada	For sedation protocol and compared with BIS in ICU (De Jonghe et al., 2005; Trouiller et al., 2009)	**Consciousness** – **awakeness** (graded from spontaneous eye movement to no response to verbal or physical stimuli) and **comprehension** (graded by ability to open eyes, open mouth, eye contact, nodding head & closing eyes while opening mouth) **Tolerance** - **calmness** (graded from calm, agitated but respond to verbal order, not respond to verbal order, life-threatening agitation) **ventilator synchrony** (graded by use of accessory muscles, cough, respiratory rate, blockade of inspiratory respiration) and **face relaxation** (graded from face relaxation to moderate-severe-permanent provoked grimacing)	5	0-9 0-10 Deeper level of sedation/ agitation with lower score.	Tested in 152 observations of 80 patients. Strong inter-observer reliability (Intra-class co-efficient 0.99, 0.92), acceptable internal consistency (Cronbach α0.82, 0.67) and high degree of responsiveness after increasing or weaning sedation (De Jonghe et al., 2003).
American Association of Critical Care Nurses Sedation Scale **(2005)**	Expert Consensus	No	**Consciousness -** Awake and aware of environment **Agitation** - Body movement, patient noises, patient statements **Anxiety** - Faces anxiety scale **Sleep** - Observed sleep, patient's perceived quality of sleep **Ventilator Synchrony** - Breathing pattern	8	8-40	Not reported

Bloomsbury Sedation Score **(2004)**	Not reported	2 studies used this scale to assess sedation in ICU (Botha & Mudholkar, 2004; Moons, Sels, De Becker, De Geest, & Ferdinande, 2004)	**Consciousness** –graded from response to voice, to movement, to painful stimuli and natural sleep **Agitation** – no guidance to grade agitation	1	-3 to 3 or sleep	Not reported
Brussels Sedation Scale **(1999)**	Not reported	No	**Consciousness** – responds to verbal or painful stimuli **Agitation** – no guidance to grade agitation	1	1-5	Not reported
Cambridge Sedation Scale **(1990)**	Not reported	Used in sedation protocol to reduce ventilator associated pneumonia & compared with auditory evoked potential to measure depth of sedation in ICU (Rassin et al., 2007; Schulte-Tamburen, Scheier, Briegel, Schwender, & Peter, 1999).	**Consciousness** – response to voice or tracheal suctioning, unrousable, paralysed or asleep **Agitation** – no guidance to grade agitation	1	1-7	Not reported

COMFORT Scale (1992)	Literature review and survey of nurses	Adapted for adult ICU population for pre-term infants and has been used in various studies of sedation protocols in ICU (Ashkenazy & DeKeyser-Ganz, 2010; Ista, de Hoog, Tibboel, & van Dijk, 2009; Johansson & Kokinsky, 2009; Wielenga, De Vos, de Leeuw, & De Haan, 2004).	**Alertness** – deeply asleep to highly alert **Calmness/Agitation** – calm to panicky **Respiratory Response** – no coughing or spontaneous respiration to fights ventilator coughing or choking **Physical Movement** – no movement to vigorous including torso & head **Mean Arterial Pressure** - any observation low to 6/6 observations high **Heart Rate** – as above **Muscle Tone** – relaxed, no tone to extreme rigidity and flexion of fingers/toes **Facial Tension** – face relaxed to grimacing	8	8-40 Ranges from deep sedation to highly agitated	Strong inter-observer reliability (κ=0.71), significant correlation with VAS for sedation and pain (Johansson & Kokinsky, 2009). A further study also observed strong inter-observer reliability (0.78, $p<0.05$). However, the arterial pressure and heart rate items were found not to be sensitive to detecting the state of "discomfort" in the adult population (Bear & Ward-Smith, 2006).
Harris Scale (1991)	Not reported	Used in validity study for SAS. Harris, SAS and RS used with 45 ICU patients (R. R. Riker, Fraser, Simmons, & Wilkins, 2001).	**General Condition** – range from confused & uncontrollable to conscious & calm to unrousable. **Compliance with ventilation** – unable to control ventilation, fighting ventilator, coughing but tolerating, tolerating.	3	3-14	Not reported

Luer Sedation Scale (1995)	Not reported	Compared with MAAS for medical ICU patients. Luer was more variable (Hogg et al., 2001).	**Consciousness** – ranges from no response to painful stimuli to awake, calm & co-operative. **Agitation** – ranges from restless to combative. Also includes parameters like breathing over ventilator, increased airway pressure, decreased oxygen saturation, increased heart rate and blood pressure to indicate increased agitation. Original scale also integrated lorazepam dosage requirements for sedation.	1	1-8	Not reported
Minnesota Sedation Assessment Tool (MSAT) (2004)	4 phases. First, 5 focus groups of nurses. Second, draft & pre-test in hypothetical scenario of a 2-domain instrument with single item for each domain. Third, modified to motor activity scale & arousal scale and tested inter-observer reliability. Fourth, scale validation (C. Weinert & McFarland, 2004).	Can only be used for ventilated patients. Two studies conducted by scale developer to determine effect of sedation on post-ICU recovery (Craig Weinert & Sprenkle, 2008; C. R. Weinert & Calvin, 2007).	**Motor Activity** – highest level of motor activity over 10 minutes from no movement to movement of central muscle group. **Arousal** - ranges from eyes stay closed and no patient movement in response to stimulation to eyes open spontaneously with tracking. Also requires observer to judge sedation “adequate”, “undersedated” or oversedated” using any clinical information available and the scale.	2	1-5 for each item	Inter-observer reliability correlation κ=0.85. Moderate correlation between MSAT and VICS (C. Weinert & McFarland, 2004). Disparate constructs between the scales may explain lack of correlation.

Motor Activity Assessment Scale (MAAS) **(1997)**	Modified from SAS	Used to validate MSAT, compared with objective sedation measurements and in several studies to maintain a steady state of sedation among participants (Burkard, 2003; K. Samuelson, Lundberg, & Fridlund, 2006; K. A. M. Samuelson et al., 2008; C. Weinert & McFarland, 2004). Not used in setting outside ICU.	**Consciousness** – unresponsive to calm & co-operative **Agitation** – restless & co-operative to dangerously agitated. Motor responses include opening eyes, raise eyebrows, turn head, moves limbs, adjust sheets/clothes, picks/uncovers sheet from self, attempting to sit up, pulling at tubes/catheters.	1	1-6	More reliable (κ=0.83) than subjective assessment by VAS (intraclass coefficient = 0.32). Inter-observer reliability correlation κ =0.72. MAAS had less variation than Luer and stronger intraclass coefficient. Validity established by close approximation between MAAS scores and VAS assessment as well as changes in patient variables commonly associated with agitation (hypertension, tachycardia, agitation-related events) (Devlin, Boleski, & Mlinarek, 1997).
New Sheffield Sedation Scale **(1992)**	Adapted from Ramsay Scale to have more description about condition for each level of sedation than previous scales (Olleveant, Humphris, & Roe, 1998).	Sedation protocol to reduce ventilation time and decrease sedative, analgesic and inotrope use (Botha & Mudholkar, 2004).	**Consciousness** –range from awake to sluggish response stimulation to no response. **Agitation** – patient can be restless, or have compromised ventilation, oxygenation and general condition, may show signs of distress during cares. **Optimum level of sedation** – patient just asleep but responds to stimulation with eye opening or hand squeeze and can tolerate cares.	1	1-6	Reliability established (κ=0.73) (Laing, 1992).

Nursing Instrument for Communication of Sedation (NICS) **(2010)**	Aimed to develop simpler scale that is easier to recall and use for nurses to communicate patient sedation status. Method used to develop the scale is not reported (Mirski et al., 2010)	No other studies have been conducted.	**Consciousness** – range from awake and calm, lethargic but responsive, following commands only briefly to unresponsive to deep stimulation. **Agitation**– physical risk to self and others, pulling at tubes etc, frequent or constant motor activity, fidgety.	1	-3 to 3	Construct validity established by strong correlation with the RASS in both intubated and non-intubated patients (r=.98, p=0.001). Face validity established by survey of 53 nurses. NICS rated as easy to score, intuitive, clinically relevant, preferred over RASS, SAS, RS & MAAS. Criterion validity established by comparing scores with level of arousal (r=0.96, p<0.05. Inter-observer reliability was very good (r>0.9).

Ramsay Scale (RS) **(1974)**	The scale was developed to monitor sedation level of patients receiving alphaxalone-alphadalone in ICU. No specific methods for development of the scale are reported (Ramsay, Savege, Simpson, & Goodwin, 1974).	One of the most researched sedation scales. It is also extensively utilised in clinical practice with 66.4% of 192 ICU's surveyed in the UK using this scale(Reschreiter, Maiden, & Kapila, 2008). Used in interventional radiology, endoscopy and in one study in the cath lab (Manjrekar, Kane, Dewoolkar, & Shroff, 2008; Nascimento, Modolo, Silva, Santos, & Carvalho, 2007).	**Consciousness** – ranges from co-operative, calm & tranquil, responding to commands, brisk response to stimulus, sluggish response & no response. **Agitation** – anxious restless or both. Only one level for agitation.	1	1-6	Poor inter-observer reliability among a sample of ICU nurses watching simulations of sedated patients (Olson, Lynn, Thoyre, & Graffagnino, 2007). More recently it was found adding instruction improved reliability (van Dishoeck, van der Hooft, Simoons, van der Ent, & Scholte op Reimer, 2009). Studies to validate the scale against objective measurements suggest there may a ceiling effect to the Ramsay Scale as there was a diminished capacity to distinguish between varying levels of deep sedation (Consales, Chelazzi, Rinaldi, & De Gaudio, 2006; Hernandez-Gancedo et al., 2006).

Richmond Agitation & Sedation Scale (RASS) **(2000)**	Detail of scale development is not reported.	Compared with objective sedation measurements, in studies to decrease ventilation time in weaning protocols, studies about sedation and delirium and in studies about various pharmacologic agents (Ely et al., 2003; Grap et al., 2003; Karamchandani, Rewari, Trikha, & Batra, 2010; Masica et al., 2007; Turkmen, Altan, Turgut, Vatansever, & Gokkaya, 2006; Williams et al., 2008).	**Consciousness** – range: alert & calm, drowsy, light sedation, moderate sedation, deep sedation, unrousable. **Agitation** – range: restless, agitated, very agitated, combative. Corresponding description of patient state is provided with each sedation level and is administered in 3 defined steps.	1	-5 to 4	Excellent inter-observer reliability, construct, criterion and face validity (Sessler et al., 2002). First scale to detect changes in sedation status over time and correlated with administered doses of sedative medications (Ely et al., 2003).
Sedation Agitation Scale (SAS) **(1999)**	Nursing descriptions of sedation/agitation were numerically graded (R. Riker, Picard, & Fraser, 1999).	Compared with objective measurements in ICU and for sedation protocols (Arbour, Waterhouse, Seckel, & Bucher, 2010; Frenzel, Greim, Sommer, Bauerle, & Roewer, 2002). Also, studies investigating SAS in sedation protocols failed to achieve the targeted sedation level and reduce ventilation time (Bennett, 2008; de Wit & Epstein, 2003).	**Consciousness** – range: calm & cooperative, oversedated, very oversedated, unrousable. **Agitation** – range: agitated, dangerously agitated, immediate threat to safety. Corresponding description of patient state is provided with each sedation level.	1	1-7	High inter-observer reliability in numerous studies, high correlation with Ramsay Scale (Brandl et al., 2001; Ruseckaite & Bucknall, 2008; Ryder-Lewis & Nelson, 2008).

Critical appraisal

Elliott's (2007) criteria for assessing the performance of a measuring instrument was used to analyse the scales in order to determine their suitability for use in the CCL. Elliott's criteria were chosen because they provide a comprehensive appraisal of each of the psychometric properties of a measuring instrument and also because they have previously been used to evaluate the psychometric properties of scales used in nursing practice (Cameron, Worrall-Carter, Driscoll, & Stewart, 2009).

Results

Results of the search strategy are presented in Figure 3.1. Thirty sedation scales were identified in the literature search of the two major health databases. No further sedation scales were identified by manually searching the reference lists of identified articles. Of the thirty sedation scales identified, 16 met the inclusion and exclusion criteria (Table 3.1). Of these 16 scales only one scale, the NASPE SED (Bubien et al., 1998), was developed for the CCL setting and all others were developed for the ICU. However, it was identified that many of the ICU scales had similar item structures. Examining each scale from the ICU that had similar item structures would have been redundant with regard to the primary purpose of this review, which was to identify a sedation scale that could be used in the CCL. Therefore, only one scale of those that had similar item structures was selected for in-depth examination of its properties to determine suitability for

use in the CCL setting. The scale that has been used and tested the most in the clinical setting was selected.

The ATICE (De Jonghe et al., 2003), AACN (DeJong et al., 2005), COMFORT (Ambuel, Hamlett, Marx, & Blumer, 1992) and the MSAT (C. Weinert & McFarland, 2004) scales all measure consciousness and various other aspects such as agitation, pain and ventilator synchrony using more than one item. Of these, the ATICE and the COMFORT have been used and tested the most in the clinical setting. However, the only investigation of the COMFORT scale in an adult population found that the measurement of blood pressure and heart rate were not sensitive enough to detect a state of "discomfort", suggesting it would not be a suitable scale for use in adult patients undergoing procedures in the CCL (Ashkenazy & DeKeyser-Ganz, 2010). For this reason, the ATICE was selected for in-depth review instead of the COMFORT scale.

The RASS (Sessler, Gosnell, & Grap, 2000), Bloomsbury (Akrofi et al., 2005; Moons et al., 2004), Harris (Harris, O'Donnell, MacMillan, & Mostafa, 1991), Luer (Luer, 1995), MAAS (Devlin et al., 1997), New Sheffield (Laing, 1992), NICS (Mirski et al., 2010) and SAS (R. Riker et al., 1999) all measure consciousness and agitation in one item with the deepest depression of consciousness rated at one end of the scale and the most severe ranking for agitation at the other. Of these, the RASS has been used and tested the most in the clinical setting. As such, it was selected for in-depth review.

While the Ramsay (Ramsay et al., 1974), Brussels (Detriche, BerrÃ©, Massaut, & Vincent, 1999) and Cambridge (O'Sullivan & Park, 1990) also measure consciousness and agitation using one item, there is only one grading for agitation. Of these, the Ramsay scale was selected for in-depth review because it has been used and tested the most in the clinical setting.

The four scales selected for in-depth review of their psychometric properties were the Ramsay Scale (Ramsay et al., 1974); the Richmond Agitation Sedation Scale (RASS) (Sessler et al., 2000); the Adaptation to the Intensive Care Environment (ATICE) scale (De Jonghe et al., 2003); and the only scale developed for the CCL, the North American Society for Pacing and Electrophysiology Sedation Scale (NASPE SED) (Bubien et al., 1998). The psychometric properties of the scales were examined using Elliott's performance criteria for a measuring instrument (Table 2) (Elliott, 2007). Psychometric properties of the NASPE SED have not been evaluated and different methods of psychometric testing have been conducted for the RASS, Ramsay and ATICE. For this reason, only the relevant aspects of Elliott's[6] performance criteria were used to examine the scales according to the psychometric data that was available. A definition for each of Elliott's criteria is provided in Table 3.2. Reliability is presented first, followed by validity, responsiveness, reassessment of validity and reliability and identifying and addressing strengths and weaknesses of the instrument.

Table 3.2 Analysis of sedation scales

Elliott's performance criteria		Definition	NASPE SED	Ramsay	RASS	ATICE
Reliability	Inter-observer	Correlation test for different observers' estimates of the same phenomenon.		Weak correlation (κ=0.28) (Olson et al., 2007). After instructions were added, κ=0.9 (van Dishoeck et al., 2009).	Strong correlations found: r=0.956; κ= 0.91; r=0.86 (Ely et al., 2003; Rassin et al., 2007; Sessler et al., 2002).	Strong intra-class coefficient 0.92-0.99 (De Jonghe et al., 2003).
	Internal consistency	Statistical test to determine the extent to which each item measures the same construct (Not applicable for single-item scales).		Not Applicable	Not Applicable	Cronbach's alpha 0.87 for consciousness and 0.67 for tolerance (De Jonghe et al., 2003).
Validity	Content Validity	Extent to which items within the instrument reflect the intended domain that is being measured.			92% and 81% of 26 ICU nurses agreed or strongly agreed with the scoring scheme and that RASS provides consensus for goal-directed sedation (Ely et al., 2003). Four nurses and ICU director identified RASS for its clarity, variety of sedation/agitation states, user friendliness and speed (Sessler et al., 2002).	80 ICU nurses and 10 ICU doctors completed a survey. Mean score over 4.0 out of 5 for 80% of clinical sensibility items was achieved (De Jonghe et al., 2003).

	Factor Analysis	Statistical test to determine the underlying constructs measured within the scale (Not applicable for single-item scales).	Not Applicable	Not Applicable	Each item loaded highly on related domain and low on unrelated domain (De Jonghe et al., 2003).
	Concurrent Validity	Correlation between 2 measures of the same concept (sedation scales are compared with other sedation scales because there is no agreed true criterion).		Spearman's test between RASS & Ramsay r=-0.78 (Sessler et al., 2002).	Spearman's test between Ramsay and ATICE tolerance r= 0.43 and consciousness r=0.86 (De Jonghe et al., 2003).
	Convergent Validity	Correlation between 2 scores that theoretically measure the same construct.	Ramsay score and Bispectral index, auditory evoked potential, Heart-rate variability (Haberthur, Lehmann, & Ritz, 1996; Schulte-Tamburen et al., 1999).	RASS correlated significantly with Bispectral index, GCS scores, neuropsychiatric expert ratings and the onset of inattention in a attention-screening examination (Ely et al., 2003).	
	Predictive Validity	Statistical tests conducted to determine if the scale can predict future behaviour.		Patients with deeper levels of sedation trended towards being less likely to have a successful extubation (p=0.07) (Ely et al., 2003).	

	Contrasted groups	Correlation test for differences between 2 groups where scores are expected to contrast.	Wilcoxon rank sum tests found statistically significant differences ($p<0.05$) in RASS scores indicating a deeper level of sedation, as it was hypothesised, for ventilated vs non-ventilated patients, patients with vs without severe co-morbidities and patients above vs below 40 years of age (Sessler et al., 2002).	
	Hypothesis Testing	Underlying theory of the scale is tested with hypotheses regarding varying scores.		Amount of sedative medications administered over a 1-hour and a 24-hour period were collected and correlated with ATICE scores. Strong ($r>0.5$) and statistically significant ($p<0.001$) correlation indicated that components of the ATICE were influenced by sedative medications (De Jonghe et al., 2003).

Responsiveness	A clinically relevant change in score.			Standardised response means were calculated for ATICE scores from before and after an intervention to increase or decrease sedation. Changes in scores ranged from 0.6 to 1.8 (De Jonghe et al., 2003).
Reassessment of validity/reliability	Reliability and validity need to be retested to ensure the scale remains adequate because of alteration over time and with different samples.		Has been subject to validity and reliability testing in three separate studies with over 600 ventilated and non-ventilated ICU patients in total (Ely et al., 2003; Rassin et al., 2007; Sessler et al., 2002).	
Strengths and weaknesses appropriately addressed	Extent to which the authors of each measuring instrument have acknowledged the strengths and weaknesses of their instruments.	**Acknowledged weakness:** Lack of clarity in how to score a patient who exhibits clinical behaviours indicative of pain/agitiation as well as depressed level of consciousness (Hansen-Flaschen, Cowen, & Polomano, 1994).	**Acknowledged weakness:** Not effective in patients with either neurological or severe auditory impairment (Sessler et al., 2002).	**Acknowledged weakness:** Internal consistency testing indicated heterogeneity in its tolerance domain (De Jonghe et al., 2003).

Reliability

Inter-observer reliability was considerably weak (κ=.28) between 241 critical care nurses who used the Ramsay Scale to rate the sedation status of a simulated sedation encounter recorded on videotape (Olson et al., 2007). However, after adding instructions to explain how to conduct the assessment, weighted kappa scores of 0.9 indicated near perfect agreement between observers using the Ramsay scale in a study of 45 patients in a cardiac and thoracic ICU (van Dishoeck et al., 2009).

Excellent inter-observer reliability was demonstrated for the RASS with intra-class coefficient 0.956 for an entire ICU population (Sessler et al., 2002). In a further two studies the RASS exhibited excellent inter-observer reliability with correlations above 0.8 (Ely et al., 2003; Rassin et al., 2007).

For the ATICE, only ventilated patients were included in the sample, but again inter-observer reliability was strong with intra-class coefficients ranging from 0.92-0.99 (De Jonghe et al., 2003). Also, the ATICE was internally consistent, with Cronbach's alpha scores calculated for the consciousness and tolerance domains at 0.87 and 0.67 respectively (De Jonghe et al., 2003).

Validity

Content validity

Content validity of the RASS has been examined in two separate studies. In a study by Ely et al. (2003), a survey was distributed to 26 nurses, and 92% agreed or strongly agreed with the RASS scoring scheme and 81% agreed or strongly

agreed that the scale provided a consensus for goal-directed delivery of medications. In another study, four specialist ICU nurses and an ICU director identified the RASS for its level of clarity, variety of sedation and agitation states represented, user friendliness and speed (Rassin et al., 2007).

For the ATICE, content validity was established successfully during scale development. A survey that required a mean score over 4.0 out of 5 for 80% of responses to a clinical sensibility questionnaire was distributed to ten ICU physicians and 80 ICU nurses (De Jonghe et al., 2003).

Factor analysis

Using factor analysis, a two-factor solution confirmed the structure of the ATICE because each item loaded highly on its related domain (consciousness 0.93 & 0.94; tolerance 0.86, 0.79, 0.65) but low on its non-related domain (consciousness -0.16, 0.03; tolerance 0.04, 0.01, -0.32) (De Jonghe et al., 2003).

Concurrent validity

Sedation scales were compared with others that exhibited similar item structures to provide a measure of concurrent validity, because no “gold-standard” or agreed criterion exists. The Ramsay scale was used as the criterion for validity testing of the RASS and the ATICE (De Jonghe et al., 2003; Sessler et al., 2002). There was a strong correlation (r=0.78) between the RASS and the Ramsay scale in a study of 101 ventilated and non-ventilated patient observations (Sessler et al., 2002). However, this study also revealed that there was broader discrimination between levels of sedation for the RASS compared with the

Ramsay scale. Of the 39 patients who had a Ramsay score of 3, their RASS score ranged from +1 to -4. The authors reported that having more ranks to indicate the varying levels of a "sedated" or "agitated" state within a scale made them more beneficial for clinical practice because patient's responses to medication titration can be tracked more effectively (Sessler et al., 2002).

For the ATICE, only the consciousness domain and the calmness item within the tolerance domain were correlated with the Ramsay scale because the facial relaxation and ventilator tolerance items are clinically irrelevant to the Ramsay scale (De Jonghe et al., 2003). Only a moderate correlation was found between the tolerance domain and the Ramsay scale (0.43), but the consciousness domain of the ATICE was strongly correlated with the Ramsay scale (0.86) (De Jonghe et al., 2003).

Convergent validity

Three separate studies found strong correlations between Ramsay scores and Bispectral index, auditory evoked potential and heart rate variability respectively. In one large study of 275 ICU patients, RASS scores were compared with: Bispectral index (an objective electroencephalography measurement of consciousness) and Glasgow Coma Scale (a standardised instrument for neurologic monitoring used worldwide) to determine level of consciousness; an attention-screening examination to identify the onset of delirium; and also a neuropsychiatric expert's rating of level of consciousness (Ely et al., 2003). Results supported the validity of the RASS because there were significant

correlations (p<.001) between: RASS and GCS scores; RASS and Bispectral index; RASS and the neuropsychiatric expert's rating of the patient's level of consciousness; and RASS and the onset of inattention from the attention-screening examination (Ely et al., 2003).

Predictive validity

Data to support the predictive validity of the scales included in this review was not identified.

Contrasted groups

In the study by Sessler et al. (2002), statistically significant (p<0.05) differences were detected in RASS scores between: ventilated versus non-ventilated patients; patients with versus without severe co-morbid conditions as defined by the Acute Physiology and Chronic Health Evaluation II scores; and patients above versus below 40 years of age (Sessler et al., 2002).

Hypothesis testing

The ATICE developers hypothesised that sedative medications greatly influenced consciousness and tolerance of procedures (De Jonghe et al., 2003). To test this hypothesis, data about the amount of sedative medications administered in the last hour and the last 24 hours was collected for correlation with ATICE scores. The authors reported statistically significant results (r=>0.5; p=<0.001) indicating that components of the ATICE were effectively influenced by the amount of sedation administered (De Jonghe et al., 2003).

Responsiveness

Clinically relevant changes in ATICE scores were detected by calculating standardised response means before and after an intervention to increase or decrease level of sedation. Standardised response means ranged from 0.6 to 1.8, reflecting the ATICE's ability to detect a clinically relevant change in score (De Jonghe et al., 2003).

Reassessment of validity and reliability

Since the first study to test the psychometric properties of the RASS (Sessler et al., 2000), three studies with more than 600 ventilated and non-ventilated patients over a five-year period reassessed the reliability and validity of this scale (Ely et al., 2003; Rassin et al., 2007; Sessler et al., 2002). Strong inter-observer reliability for the RASS was observed in each of these studies ($r>0.8$).

Strengths and weaknesses appropriately addressed

A weakness of the Ramsay Scale was noted by Hansen-Flaschen et al. (1994) The authors raised concern about the lack of clarity regarding how to score patients who exhibit clinical behaviours indicative of pain or agitation as well as depressed consciousness by pointing out that a patient who is asleep but responds to verbal stimulation with agitation can be scored under two categories at different extremes of this type of sedation scale. A more recent study that added instruction to the Ramsay scale was conducted to address this limitation

and results suggested that with instruction inter-observer reliability was high (van Dishoeck et al., 2009).

Developers of the RASS noted that the baseline characteristics of patients with neurological impairments will not be consistent with other patients and those with auditory impairment will not be able to respond to verbal stimulation. As the RASS relies on distinguishing a difference in level of consciousness in response to the administration of sedation from a baseline normal level by eliciting responses to verbal stimulation, it is not effective in patients with neurological or auditory impairments (Sessler et al., 2002).

Developers of the ATICE acknowledged that internal consistency testing indicated heterogeneity in its tolerance domain. However, rather than deleting items to make the scale more homogenous, De Jonghe et al. decided to place more emphasis on content validity rather than internal consistency and chose not to modify the scale from its current form (De Jonghe et al., 2003).

Discussion

The first objective of this study was to identify sedation scales. In a search of the two major health databases, one sedation scale that was developed for the CCL, the NASPE SED, was identified. A further 15 ICU sedation scales that met the inclusion and exclusion criteria were identified.

The second objective of this study was to analyse the psychometric properties of the identified sedation scales in order to determine their ability to be used in the

CCL setting. Elliott's performance criteria for a measuring instrument were used (Elliott, 2007). There are three possible results of such interrogation: a finding that the scale is suitable for use in the target population, a finding that the scale requires some degree of psychometric testing in the target population, or a finding that a new or modified scale needs to be developed, followed by either part or the full complement of psychometric testing (Snyder, Watson, Jackson, Cella, & Halyard, 2007).

The NASPE SED did not satisfy any of Elliott's performance criteria for a valid measuring instrument (Elliott, 2007). Additionally, three points of weakness have not been identified or addressed by its developers. As its first weakness, the NASPE SED does not measure any noxious sensory experiences such as pain, anxiety, agitation or discomfort (Bubien et al., 1998).

The second weakness concerns the method it uses to measure consciousness. It was noted by Plum and Posner (1980) in "The Diagnosis of Coma and Stupor" that arousal and content of thought make up consciousness. In the NASPE SED, any response to verbal or physical stimulation is used to grade consciousness (Bubien et al., 1998). Therefore, only the arousal component of consciousness is assessed in the NASPE SED. In contrast, the RASS also assesses response to increasing level of stimulation but combines this assessment with determining patients' content of thought by measuring the amount of time the patient can hold eye contact (Sessler et al., 2001).

The third weakness of the NASPE SED relates to the respiration domain. Respiration is measured subjectively rather than with objective clinical observations such as oxygen saturation monitoring (Moller & Wittrop, 1990). The limitations of the NASPE SED identified in this review suggest that it is not suitable for use in the target population.

Similarly, using the Ramsay Scale, the RASS or the ATICE in the CCL is not suitable. Ramsay and the RASS are not suitable for the CCL because there is no option within these one-item scales for clinicians to rate patients who exhibit signs of pain, anxiety, agitation or discomfort as well as depressed consciousness. ATICE is not suitable because it contains clinical indicators for measuring sedation in mechanically ventilated patients, which is clinically irrelevant in the CCL setting.

Therefore, based on the results of this review, a reasonable option is to develop a new scale for the CCL and then conduct the full complement of psychometric testing. In the case that all the previous sedation scales were deemed unsuitable for use in the CCL setting, the third objective of this study was to identify elements of a suitable sedation scale for the CCL and to also identify the specific tests required to conduct a rigorous evaluation of a new scale's psychometric properties. Insights into the attributes that have made previously developed sedation scales valid and reliable were gained from the analysis of the psychometric properties of the ICU scales. From these insights, recommendations for the development and psychometric testing of a new sedation scale for the CCL are now presented.

Recommendations for future research

The new scale should consist of more than one item to measure each domain for two reasons. First, both the Ramsay scale and the RASS were criticised in the literature because there was no allowance within these one-item sedation scales for patients that exhibited clinical behaviours indicative of both depressed consciousness and signs of agitation (Hansen-Flaschen et al., 1994; Sessler et al., 2002). Second, the Ramsay Scale has been criticised because it only has one graded response to indicate that the patient is not tolerating the painful or uncomfortable aspects of a medical procedure; limiting its ability to track patients responses to medication titration (Sessler et al., 2002). Integrating more than one item within each domain would overcome these limitations.

Practical methods of measuring consciousness that could be integrated into the new scale were identified from the review. These include judging patients response to increasing levels stimulation and their ability to hold eye contact. Using this method to measure consciousness is effective because it includes both the arousal and content of thought components of consciousness (Ely et al., 2003; Plum & Posner, 1980).

No previous research has reported the measurement of the noxious sensory experiences that are associated with procedures within the CCL setting. It may be that validated items within ICU sedation scales could be applied to the CCL population. For instance, agitation has been measured in the ICU as the presence of uncontrolled aggressive movements or reaching for catheters and oxygen

masks. Also, pain and discomfort has been measured by assessing for facial tension, moaning and purposeful movements to change body position (De Jonghe et al., 2003; Ely et al., 2003). However, more research is required to validate these clinical indicators in the CCL setting. In this regard, the following are specific recommendations for psychometric testing of a new CCL scale.

First, content validity testing would need to be conducted to determine if the graded responses within each item are accurate according to a sample of clinicians who will use the scale in their practice. Second, because a multi-item sedation scale is recommended, factor analysis must be conducted to determine the underlying constructs measured within the scale (Norman & Streiner, 1994). For the same reason, Cronbach's alpha statistic must be calculated to determine internal consistency of items within each domain. Third, scale responsiveness can be determined by measuring level of sedation before and after an intervention to increase or decrease sedation and calculating standardised response means (De Jonghe et al., 2003). Fourth, level of sedation is deeper for patient's undergoing the more invasive procedures in the CCL (Fox et al., 2007; Natale et al., 1996). For instance, implantation of an implantable cardioverter defibrillator (ICD) in most cases requires defibrillation threshold testing under deep sedation (Timperley et al., 2008). Using an independent sample *t*-test to determine if there is a statistically significant difference in level of sedation in patients undergoing ICD implant with defibrillation threshold testing compared with patient's undergoing a permanent pacemaker implant would be an effective method to determine contrasted groups validity.

Limitations

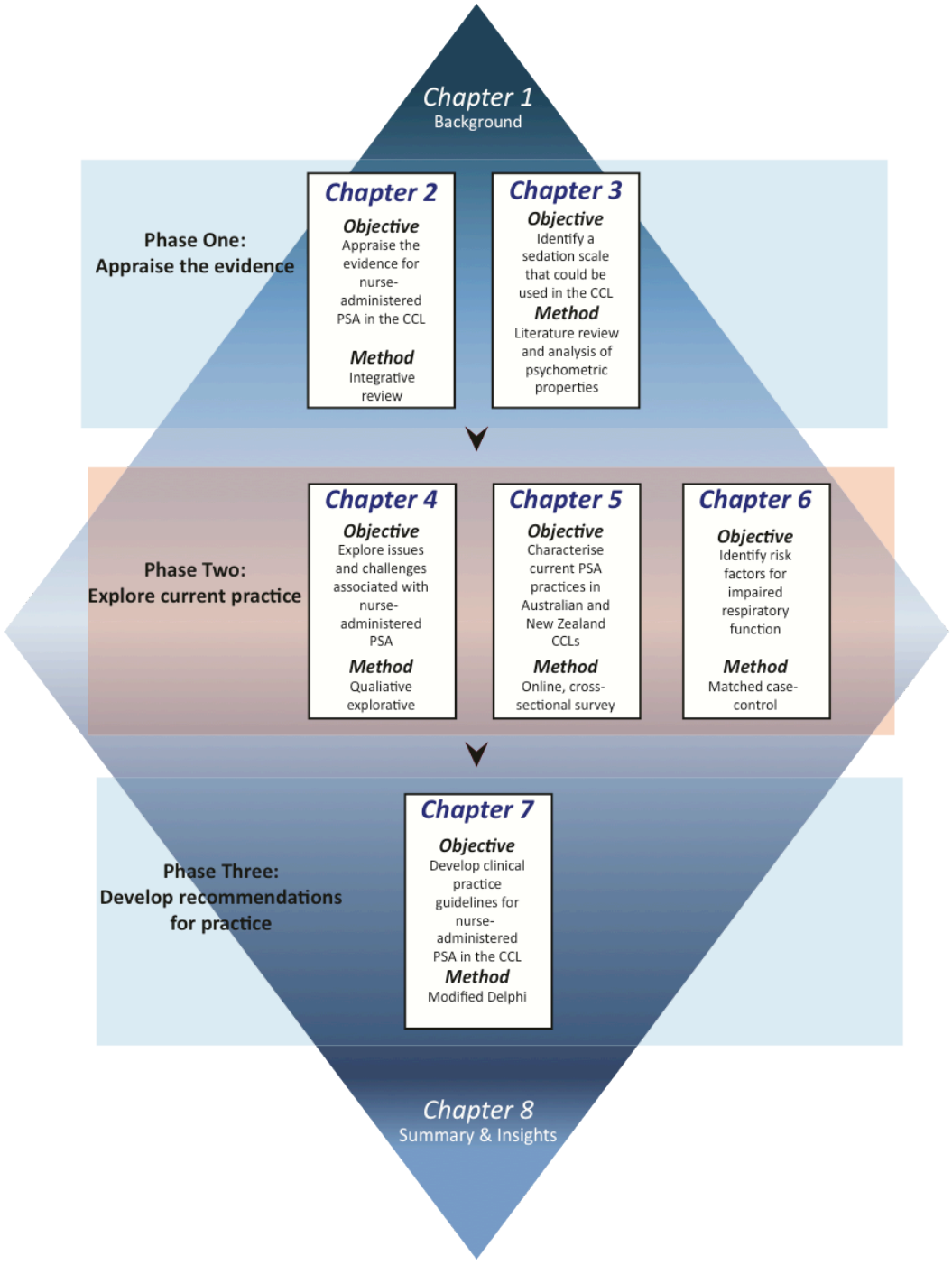
Including only two databases and not searching for unpublished literature could potentially have introduced a degree of selection bias and limited generalisability of this review. However, Medline and CINAHL are the two major health databases for the medicine, nursing and allied health specialties. As such, they most likely contain journal articles reflecting the most contemporary practice. Also, reference lists of included articles were searched in order to identify further sedation scales or further data on the psychometric properties of included sedation scales not already identified in the primary search.

Conclusion

This review aimed to identify sedation scales and analyse their psychometric properties to determine their suitability to be used during PSA in the CCL. One sedation scale that was developed for the CCL setting, the NASPE SED, and 15 others that were developed for the ICU were identified. The psychometric properties of the NASPE SED have not been evaluated. In addition, there is evidence to suggest it is not suitable because consciousness is not measured comprehensively, respiration is not measured objectively and it does not measure noxious sensory experiences, such as pain, anxiety, agitation or discomfort. Weaknesses identified in the item structure of the Ramsay, RASS and ATICE also render these scales unsuitable for use in the CCL. As such, it is reasonable to develop a new scale specifically for the CCL setting.

The new scale should consist of more than one item because it will be the most effective for tracking the patient's response to medications. However, more research needs to be conducted to validate that the scale can measure the unique clinical behaviours that CCL patient's exhibit, which indicate changes in their level of sedation. The specific tests required to conduct a rigorous evaluation of the new CCL sedation scale's psychometric properties have been identified in this review. Overall, this review has contributed vital groundwork to progressing a more standardised and accurate nursing assessment during PSA in the CCL setting and set priorities for future research undertakings in this field.

PHASE TWO


Chapter 1
Background
Phase One:
Appraise the evidence
Chapter 2
Objective
Appraise the evidence for nurse-administered PSA in the CCL
Method
Integrative review
Chapter 3
Objective
Identify a sedation scale that could be used in the CCL
Method
Literature review and analysis of psychometric properties
Phase Two:
Explore current practice
Chapter 4
Objective
Explore issues and challenges associated with nurse-administered PSA
Method
Qualiative explorative
Chapter 5
Objective
Characterise current PSA practices in Australian and New Zealand CCLs
Method
Online, cross-sectional survey
Chapter 6
Objective
Identify risk factors for impaired respiratory function
Method
Matched case-control
Phase Three:
Develop recommendations for practice
Chapter 7
Objective
Develop clinical practice guidelines for nurse-administered PSA in the CCL
Method
Modified Delphi
Chapter 8
Summary & Insights

CHAPTER FOUR

Issues and challenges associated with nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory:

A qualitative study

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Preamble

In Chapter 2, it was identified that the majority of research undertaken on the topic of nurse-administered PSA in the CCL focused on ascertaining the safety of this practice. While this research provides the discipline with reassurance that serious adverse events related to sedation are unlikely to occur, it provides little insight into the specific issues and challenges that nurses face in order to consistently deliver these optimal outcomes for patients. This chapter presents a qualitative study of Australia and New Zealand nurses' perceptions of nurse-administered PSA in the CCL, in which a number of important issues and challenges were identified and explored.

Abstract

Aim

To explore issues and challenges associated with nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory from the perspectives of senior nurses.

Background

Nurses play an important part in managing sedation because the prescription is usually given verbally directly from the cardiologist who is performing the procedure and typically, an anaesthetist is not present.

Design

A qualitative exploratory design was employed.

Methods

Semi-structured interviews with 23 nurses from 16 cardiac catheterisation laboratories across four states in Australia and also New Zealand were conducted. Data analysis followed the guide developed by Braun and Clark in order to identify the main themes.

Findings

Major themes emerged from analysis regarding the lack of access to anaesthetists, the limitations of sedative medications, the barriers to effective

patient monitoring and the impact that the increasing complexity of procedures has on patients' sedation requirements.

Conclusions

The most critical issue identified in this study is that current guidelines, which are meant to apply regardless of the clinical setting, are not practical for the cardiac catheterisation laboratory due to a lack of access to anaesthetists. Furthermore, this study has demonstrated that nurses hold concerns about the legitimacy of their practice in situations when they are required to perform tasks outside of clinical practice guidelines. In order to address nurses' concerns, it is proposed that new guidelines could be developed, which address the unique circumstances in which sedation is used in the cardiac catheterisation laboratory.

Relevance to clinical practice

- Nurses need to possess advanced knowledge and skills in monitoring for the adverse effects of sedation.
- Several challenges impact on nurses' ability to monitor patients during procedural sedation and analgesia.
- Pre-procedural patient education about what to expect from sedation is essential.

Introduction

As a general anaesthetic is mostly not required, it is not routine for an anaesthetist to be assigned to the cardiac catheterisation laboratory (CCL). Instead, the nurse performing the 'scout' role administers intravenous sedative and analgesic medications. Administration of sedative and analgesic medications for a medical procedure is commonly known as procedural sedation and analgesia (PSA) (Odom-Forren & Watson, 2005). Generally, PSA in the CCL is administered in the form of oral premedication with a small dose of a benzodiazepine followed by intravenous bolus doses of opioids and benzodiazepines. Midazolam and fentanyl is the most common medication combination (Gaitan et al., 2011). Doses are titrated on an individualised basis according to the degree of pain, discomfort and anxiety experienced. The prescription is usually given verbally, directly by the cardiologist performing the procedure, and typically, no other medical practitioners are present.

We previously published an integrative review focused on this topic. In this review, we identified that, overall, the evidence suggests nurse-administered PSA in the CCL is safe (Conway, Page, Rolley, & Worrall-Carter, 2011). However, cardiopulmonary complications, such as hypoxia and hypotension, did occur in a small percentage (2.4-9.4%) of patients in all studies reviewed (Fox et al., 2007; Geiger et al., 1997; Natale et al., 1996; Pachulski et al., 2001). Furthermore, a considerable number of patients in the studies reviewed reported experiencing pain and discomfort despite PSA (Beddoes et al., 2008; Fox et al., 2007; Lipscomb

et al., 1998). These results highlight the importance of identifying strategies to facilitate more effective PSA medication titration in order to improve safety, as well as the overall procedural experience, for the large number of people who undergo procedures in the CCL.

Complicating the matter is the fact that management of PSA is complex. It is characterised by a fine balancing act between providing adequate sedation and analgesia to patients so that they can tolerate the painful and uncomfortable aspects of medical procedures while avoiding the unwanted side effects of sedative and analgesic medications that may lead to adverse events. Moreover, no research has focused on identifying factors that impact nurses' ability to facilitate optimal PSA titration. Such research is needed because it could lead to development of strategies to improve the care of patients who receive nurse-administered PSA in the CCL. Therefore, the research presented in this article was conducted to contribute to the currently limited literature available on this topic to inform nursing practice. The aim was to explore issues and challenges associated with nurse-administered PSA in the CCL setting from the perspectives of senior CCL nurses.

Method

A qualitative exploratory design was employed. The study was undertaken as a linked project with a program of research aimed at achieving a greater understanding of how senior nurses perceive practice in the CCL setting. As diverse perspectives of nurses who had considerable experience in the CCL

setting were required to achieve this objective and similar participants were also required to explore issues and challenges associated with nurse-administered PSA in the CCL, it was decided to conduct the two studies concurrently. In this regard, participants were recruited and interviews were conducted for both studies at the same time. It was decided this approach was the most optimal because it would facilitate an efficient use of resources and would considerably reduce participant burden. Specific details and findings of the concurrent study will be reported elsewhere (Under review). Ethical approval for these studies was received from the university human research ethics committee, signifying that appropriate measures were in place to protect the safety, rights and freedoms of the participants (HREC Register Number V2011 46).

Participants

Participants were sought from CCLs in public and private hospitals from both urban and regional areas in Australia and New Zealand. As such, participants were recruited via a professional organisation representing CCL nurses in Australia and New Zealand by email invitation. The following inclusion criteria were applied:

- Currently employed within the CCL setting as either:
    - Nurse Unit Manager/Clinical Nurse Manager;
    - Clinical nursing educator (or similar role); or
    - Senior nurse in terms of clinical practice experience (more than 3 years).

Data collection

Data were collected using semi-structured, in-depth interviews. The interviews enabled rich descriptions of participants' viewpoints and experiences to be gathered (Turner, 2007). Two researchers conducted interviews during August 2011 to February 2012. While the same group of nurses participated in both studies and interviews were conducted concurrently, other aspects of the method were distinct for each study. A separate set of questions was developed specifically for this study to be included in an interview schedule (Box 4.1). Although an interview schedule was used, there was flexibility for the researcher to explore participants' answers in further detail (Patton, 2002). Each interview was recorded digitally and transcribed verbatim within two days. All identifying information, such as names and institutions, was removed from the transcripts. Transcripts were then returned to participants to ensure their responses were represented faithfully. This also provided a further opportunity for participants to offer additional information. Transcripts were analysed separately for each study.

Box 4.1 Interview schedule

- What are the expectations of patients regarding sedation in CCL?
- What aspects of the CCL environment influence sedation practice during a procedure?
- What are your concerns, if any, around nurses administering sedation without an anaesthetist being present?
- In your opinion, what is the most effective method for measuring the effects of sedation and analgesia in the cardiac cath lab patient?
  a. And why?
- Do you have any other comments related to anything you have discussed?

Data analysis

Data were analysed using thematic analysis. Thematic analysis is commonly employed in qualitative nursing research as a means to identify, organise and describe, in rich detail, common patterns and themes that capture important elements in the data (Polit & Beck, 2004; Tajkovski, Schmied, Vickers, & Jackson, 2012). The process used to derive patterns and themes from the data was informed by the guide to performing thematic analysis developed by Braun and Clark (2006). In what would be described as a 'realist' approach to conducting thematic analysis by Braun and Clark, themes were derived from the data using an inductive process, without influence from underlying theoretical assumptions

or from the researchers' previous experiences. The focus was on exploring the reality of participants' experiences (Braun & Clark, 2006).

Transcription and subsequent re-readings of the transcripts enabled immersion in the data. Transcripts from each participant were analysed individually then pooled into a master document and analysed as a collective to identify categories and themes. The process from transcription to attaching excerpts to themes was documented by annotating the transcripts, thereby linking the data to the categories and themes that were produced (Lincoln & Guba, 1985). Figure 4.1 presents the category and thematic structure that emerged from the analysis, which was discussed and validated by all four members of the research team. In order to ensure trustworthiness, a summary of the themes was returned to participants for validation (Silverman, 2006). Participants confirmed the researchers' interpretations.

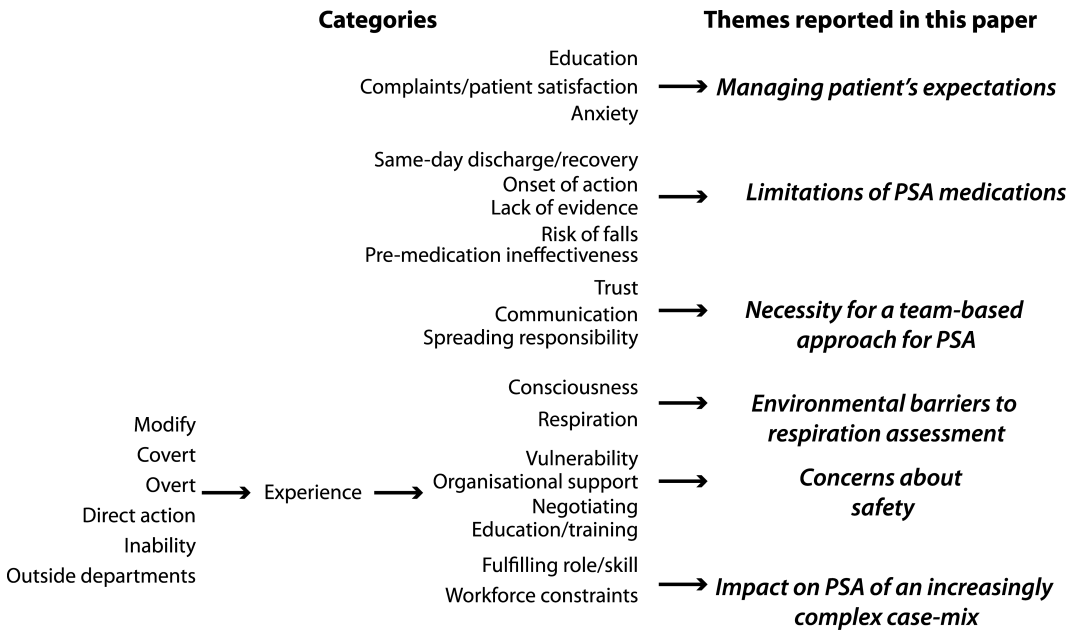

Figure 4.1 Thematic structure

Findings

The 23 participants were based in CCLs in 16 institutions within New Zealand and four Australian states (New South Wales, Queensland, South Australia, and Victoria). The majority of participants (n = 21) worked in urban centres. Fifteen participants worked in publicly funded hospitals. Participants generally held leadership positions, with the majority represented by clinical nurse managers (n = 14) and clinical nurse educators (n = 5). The mean time spent working in the CCL setting was 11 years (range 4 to 26 years). Most participants were female (n = 18).

Six themes emerged from the analysis: *Managing patients' expectations*; *Limitations of PSA medications*; *Necessity for a team-based approach*; *Environmental barriers to respiration assessment*; *The impact of an increasingly complex case-mix; and Concerns about safety*. These themes are described below, using quotes from the participants to evidence key aspects of the themes.

Managing patients' expectations

A recurring theme emerging from the data was the problems associated with inaccurate expectations of PSA. Participants noted that patients' expectations of PSA were often at odds with the degree of sedation that would actually be utilised during the procedure. For example, one nurse educator stated:

> *"A lot do come around with the perception that they will get like a general anaesthetic even though possibly, and I would say highly likely, that they would have been told it's just a local anaesthetic. But coming in to what we call a 'theatre,' they've just got the idea of being out to it."*

Participants felt that explaining the reasons why a general anaesthetic was not required could ameliorate patient concerns. However, as one clinical nurse manager explained in the following excerpt, challenges arose when patients became dissatisfied with their care because their expectation that the procedure would be pain-free was not met:

> *"And the other thing is doctors will misinform patients, 'You'll be asleep and unaware'; the amount of complaints that we get because the patient felt everything or heard everything that's going around, um we have to re-explain to the patients that you're not asleep, you're still conscious..."*

Limitations of PSA medications

Participants agreed that PSA medications currently used for CCL procedures had several limitations. For example, short-acting intravenous medications administered intra-procedurally were viewed as being more effective than oral premedication. Also, the perceived increased risk of falls associated with the administration of premedication was of concern to the participants. One clinical nurse manager noted:

"We get patients up and walking around from the theatres and I think that's a safety issue, they don't need to be pre-med'ed because there is a risk of falls."

Participants also frequently cited instances where the medications utilised during long electrophysiology procedures were unable to produce the desired effect, describing peaks and troughs in the level of sedation. As noted by a clinical nurse manager with six years' CCL experience, "...that's when they go deeper straight after the ablation's finished because you…bolus, bolus, bolus and then you have your periods of apnoea… ." Also, participants frequently articulated that undesirable side effects of PSA medications could be difficult to manage and disrupted procedures. As a nurse educator with over ten years' CCL experience described:

"Well, more commonly we see patients that get fidgety, they get agitated, move their hands up, contaminate the field, try to get off the bed."

Furthermore, participants reported that medications used during complex procedures sometimes resulted in prolonged post-procedure recovery, which consequently placed a considerable burden on staffing ratios. The following view, expressed by one of the clinical nurse managers, illustrates this concern:

"…obviously the more…sedation they have, the longer the recovery is here and…if we've got a long procedure (that) doesn't finish until 5.30 in the evening, nurses can be down here

until 8 o'clock at night waiting for them to be awake enough for them to go anywhere…"

Necessity for a team-based approach

Participants predominantly reported that a team-based approach was utilised with PSA prescribed by the cardiologist and administered by nurses. They also elaborated upon how this relationship works in practice, describing how, over time, as the nurse's experience in PSA builds, a level of trust is developed between both parties. As described by a clinical nurse manager with five years' experience, this facilitates optimal sedation titration:

"The operators determine the amount of sedation although in saying that the nurses will be monitoring that patient and say (to the doctor) "(the patient) is uncomfortable, can we give them another miligram of midazolam?" And they will just say, 'yeah yeah,' if they trust you."

However, regardless of the level of trust, participants felt it was essential that nursing assessment was communicated to the cardiologist as this information can be used to inform sedation titration. For example, participants indicated that nurses are able to assess the source of the patient's pain and discomfort. As explained by a highly experienced nurse educator, it is important for this information about the source of the patient's pain to be communicated to the cardiologist, as it may aid sedation titration:

> *"And usually a balance, if the movement is mainly just to rest the muscles, just tell the operator, they move mainly because the pain on the back, not from the procedure, it's just they need to move. And usually they will listen."*

The findings also suggest team-based management of nurse-administered PSA in the CCL extends beyond nurse and cardiologist interactions. In addition to the scout nurse, another team member, which may be a nurse or cardiac technician/physiologist, will be allocated to the procedure. Their primary responsibility is to continuously monitor, and periodically record, various electrocardiographic and haemodynamic measurements throughout the procedure. Participants explained that, at times, the scout nurse is also responsible for duties that necessitate they are absent from the procedure room. During these times the additional team member takes over responsibility for monitoring the patient's sedation status. This situation is illustrated by one of the clinical nurse managers:

> *"…we monitor their oxygen saturation levels and their respiratory rate on the haemo' system, so the cardiac tech's keep an eye on those numbers as well if we are doing other things."*

Environmental barriers to patient assessment

Another recurring theme, which emerged from the data, was there were barriers to effective patient assessment unique to the CCL setting. All participants viewed

respiration assessment as the most important element of patient monitoring during PSA. However, many expressed concern that ultimately they must rely on oxygen saturation monitoring alone as their main indicator of the patient's respiratory function. The major reason nurses had to rely on oxygen saturation monitoring to assess respiration was that surgical draping and medical imaging equipment obscured their view of the patient. Although respiratory inductive plethysmography is routinely integrated into the computerised monitoring system of CCLs, this technology was viewed as an unreliable alternative. As one nurse educator with 15 years' experience explained:

> *"...although their resp' rate is labelled there, we all know the monitoring system doesn't pick it up very well… it's more their [oxygen] saturations."*

However, in contrast to views expressed by the majority of participants, one clinical nurse manager with 6 years' experience, who was based in a CCL with a caseload favouring electrophysiology, noted that because of the limitations of oxygen saturation monitoring, capnography was considered to be a vital monitoring tool in her setting. She explained:

> *"We use capnography here as well because… obviously it's a lot quicker than oximetry, detecting any respiratory depression."*

Impact of an increasingly complex case-mix

A major theme, which emerged from the data, was that PSA in the CCL was becoming more and more complicated. Participants felt that procedures undertaken in the CCL were becoming increasingly complex and explained that, in addition, the patient population was burdened with significant comorbidities. A solution that one highly experienced nurse educator noted as being optimal, was to draw more upon anaesthetic services to help service the CCL. She suggested:

> *"I'm thinking once we're going down the track of… more complex procedures… that's where their role comes in that… basically the scout is looking after the scrub nurse… the anaesthetist is specifically looking after the airway and patients' pain management. I actually think it's an ideal scenario..."*

However, other participants expressed concerns about the impact workforce constraints had on the feasibility of this collaboration. One clinical nurse manager expressed this challenge very clearly by saying, "…now it's getting harder and harder to get anaesthetists…" Participants described, though, when anaesthetists were not available, the responsibility for administering PSA fell to the nurse, regardless of patient or procedure complexity.

Concerns about safety

Participants' concerns about safety centred specifically on the administration of PSA during electrophysiology procedures, such as implantable cardioverter-defibrillator (ICD) implants and ablation of cardiac arrhythmias. During these procedures, deep sedation may be induced for either defibrillation threshold testing or cardioversion and there is also the possibility that large doses of sedative medications may be required because of the long duration of some of the procedures, such as atrial fibrillation ablation. Participants described concerns about administering sedation in these situations because the administration of deep sedation without an anesthetist present is not supported by clinical guidelines developed by the Australia and New Zealand College of Anaesthetists (ANZCA). One nurse unit manager articulated quite clearly the seriousness nurses perceive this issue to be. She explained:

> *"…a few months ago I put my foot down with one particular EP doctor and said, 'Look you can't yell at the nurses and say give me this, give me that, when they're meant to be monitoring this patient who has got huge amounts of sedation on board.' You know it's like we're not trained in this area, we're not, we don't, we're entering a really scary zone and something's going to happen and then this nurse is going to be held to account."*

Participants described how experienced nurses tried to avoid situations where they did not feel confident administering prescribed medication. They achieved

this by conveying their assessment of the patient's sedation needs to the cardiologist; as illustrated by a highly experienced nurse educator:

> *"…I have certainly seen a number of nurses have said to the doctor concerned, 'She's really drowsy, do you think we should start off with one?'"*

However, 'speaking-up' was viewed as challenging for inexperienced nurses who they felt may lack confidence in PSA management skills. Notably though, it was viewed by the more senior nurses who were interviewed in this study, that if the nurse's position on what constitutes safe PSA management was not at least raised with the cardiologist, it could lead to adverse patient outcomes.

It should also be noted though, that participants who worked in CCLs with strong organisational support for nurse-administered PSA were less concerned about safety. In their institutions, anaesthetic departments had taken a lead role in developing hospital-wide PSA policies to enforce guidelines developed by the ANZCA, which are intended to apply to all clinical settings in which PSA is administered without an anaesthetist present. In their institutions, it was hospital policy that an anaesthetist must be present to administer PSA if 'deep' sedation was required for defibrillation threshold testing or cardioversion. However, participants noted these policies were only effective when they were supported with sufficient and timely access to an anaesthetist. A clinical nurse consultant at one of these institutions noted that procedures can become

delayed in circumstances where there is lack of access to an anaesthetist, which impacts negatively on the productivity of the unit. He stated:

> *"But that can affect our flow… because if we don't have the anaesthetic support that can be an ongoing reason why we're not getting activities done..."*

Discussion

This study was undertaken to explore the issues and challenges associated with nurse-administered PSA in the CCL setting from the perspectives of senior nurses. The most critical issue identified in this study was that participants were concerned about the legitimacy of their practice when required to administer sedation to patients who are not recommended to receive PSA without an anaesthetist present in clinical guidelines developed by the ANZCA. A lack of access to anaesthetists, was the main reason noted for nurses being required to administer PSA in situations that are currently not endorsed by the guidelines (ANZCA 2010). One previous study conducted in the United States confirms this finding. The authors noted that nurse-administered PSA is often used in place of monitored anaesthesia care because delaying the procedure due to lack of access to anaesthetic services causes disruption to the flow of work within the unit (Gaitan et al., 2011).

It's important to note though, that the abundance of evidence from research undertaken in the CCL setting indicates that nurse-administered PSA is safe, even in these complex situations, where, for example, deep sedation is induced for

defibrillation threshold testing. All the authors who have published studies on nurse-administered deep sedation in the CCL argued this practice was safe because all instances of impaired cardiopulmonary function were reversible with simple interventions (Fox et al., 2007, Kezerashvili et al., 2008, Sayfo et al., 2012). A likely underlying reason for participants' concern is that the code of professional conduct calls for nurses to practice in accordance with the standards of the profession and the broader health system (ANMC, 2006). So although participants explained the reasons why the guidelines developed by anaesthetists were not practical for the CCL setting, they felt that if a serious adverse event were to occur, they could be held to account given the fact they were required to administer sedation outside of an accepted standard of practice. Therefore, in order for CCL nurses to feel reassured that their actions regarding the administration and monitoring of PSA are indeed in line with best practice, it is proposed that new guidelines could be developed specifically for the CCL setting.

Another challenge identified concerned communication between the cardiologist and the nurse during a PSA encounter. Although participants viewed communication to the cardiologist regarding patient assessment about nurse-administered PSA as essential, they also noted it to be particularly challenging. While the importance of communication has not specifically been associated with effective PSA management in the CCL before, more broadly, lack of effective communication is known to be a cause of inadvertent patient harm in the hospital setting (Leonard, Graham, & Bonacum, 2004). Participants noted one

central aspect of the communication between nurses and cardiologists during PSA is 'speaking up'. This strategy of 'speaking-up' when nurses' identify less than optimal care is well-recognised in the health care literature as an effective method for averting errors (Sayre, McNeese-Smith, Leach, & Phillips, 2012). Furthermore, not 'speaking-up' has been shown to contribute to adverse events (Bromiley & Mitchell, 2009). However, participants noted that inexperienced nurses found it difficult to 'speak up'. It is important to note though, novice nurses were not represented in the sample, so future research will need to be conducted to confirm this finding. Nevertheless, experience has been linked to nurses' confidence in their ability to manage sedation in the ICU setting. Walker and Gillen (2006) found ICU nurses with more experience were more confident in their ability to manage sedation. For this reason, until junior CCL nurses demonstrate confidence in their ability to manage PSA via assertive communication with medical colleagues, it may be reasonable to provide opportunities for them to gain supported experiences in managing sedation through mentoring by senior staff.

A challenge identified in this study is the impact of utilising a team-based approach to monitor sedated patients. Clinical guidelines for PSA without an anaesthetist present recommend that one suitably qualified and competent person's primary duty is to monitor sedation during the procedure (ANZCA, 2010; Gross et al., 2002; JCAHO, 2005). In this study though, nurses articulated that a team-based approach was more practical. Commonly, in CCLs, either another nurse, or a cardiac technician/physiologist will monitor vital signs while

the scout nurse is acquiring equipment for the procedure. While participants generally deemed the team-based approach to patient monitoring during PSA was suitable for diagnostic and interventional coronary procedures, they noted that excluding a sedated patient from their direct vision in order to gather equipment was not optimal during electrophysiology-based procedures. The reason noted was that usually higher doses of PSA medications were used. Based on the findings of this study, consideration should be given to allocating two 'scout' nurses to all electrophysiology-based procedures so that one nurse can be responsible for patient monitoring, while the other nurse remains available for other duties. However, use of this approach has not been investigated in terms of its impact on patient or health service outcomes. Therefore, further research is recommended in this area. This should include cost-benefit evaluation regarding the increased requirement for nursing personnel.

There were issues identified in this study specifically related to medications used for PSA. In line with previous research, this study calls into question the routine use of oral premedication. In the largest and most recent randomised controlled study, 760 patients were randomised to receive either premedication with oral diazepam or no premedication before cardiac catheterisation or percutaneous coronary intervention. Patients who received the premedication were not, as anticipated, less anxious than controls (Woodhead et al., 2007). It's also important to note that there have been no studies investigating the benefit of using premedication for the other procedures performed in the CCL, such as the ablation of cardiac arrhythmias. In light of the lack of evidence to support

premedication, and also because participants agreed that intra-procedural PSA was more effective than oral premedication, further research would be valuable to evaluate the most effective pharmacological methods for PSA in the CCL. A further, related finding in this study was that participants perceived there was an increased risk of falls in the peri-procedural period associated with sedative premedication; this has not been observed previously in research. Nevertheless, it was a recurring theme in this study and therefore merits investigation in future clinical trials of premedication.

Limitations of the medications currently utilised for nurse-administered PSA during long electrophysiology procedures were also identified. Participants noted it is difficult to produce a steady state of pain and anxiety relief without inducing periods of respiratory depression and that it takes a long time for the sedative effects of the medications to subside resulting in a considerable burden on staffing requirements. Some in-roads have been made by electrophysiologists investigating the utility of new medications to produce more effective PSA. For instance, proceduralist-directed nurse-administered propofol sedation was effective intra-procedurally, in terms of facilitating successful completion of the procedure and an acceptable incidence of PSA-related complications, as well as post-procedurally, in terms of the length of time it takes the patient to recovery (Sayfo et al., 2012, Wutzler et al., 2012). Also, dexmedetomidine has been suggested as a potentially valuable adjunct to improve the effectiveness of the usual sedative and analgesic regimen, which consists of midazolam and fentanyl.

However, further study needs to be conducted to evaluate the safety of this particular medication in the cardiac population (Hayman et al., 2012).

One further challenge noted by participants regarding PSA medication in the CCL was that the combination of intravenous sedative and analgesic medications often induces paradoxical excitation. Paradoxical excitation due to sedation is reported to manifest as agitation, involuntary movements or hostility; particularly in the elderly or with high doses (Denman, 2010). Smaller doses of medications combined with complementary therapies, such as calming music, may be a more effective technique to reduce pain and anxiety during cardiac procedures than using large doses of sedation for patients at high risk of paradoxical excitation (Nilsson et al., 2009).

In terms of respiration assessment, even though maintaining normal respiration was the key goal for monitoring expressed by participants, the resources available to assess respiration were limited to oxygen saturation monitoring because surgical draping and medical imaging equipment obscured the view of the patient. Capnography is an alternative that has been suggested in circumstances where auscultation of breath sounds or direct observation of respiration cannot be performed (Koniaris et al., 2003). Thus, the use of capnography should be considered within the CCL context. Further research in this area would also be beneficial.

Another aspect requiring further research identified in this study relates to patients' expectations of PSA. Participants considered patients required greater

understanding of PSA in order to reduce dissatisfaction with the procedure. While studies around patient education about anaesthesia have shown positive outcomes on patient satisfaction in the operating theatre, research investigating the impact of patient education on satisfaction with procedures in the CCL is lacking (Krenzischiek, Wilson, & Poole, 2001). Integrating patient education about PSA into that which is already routinely provided to patients as part of the informed consent procedure would be the most practical method (Astley, Chew, Aylward, Molloy, & DePasquale, 2008).

Limitations

To maximise transferability of the study findings, a concerted effort was made to recruit a sample representative of the diversity of CCLs across Australia and New Zealand. Currently though, there is no publicly accessible CCL directory. For this reason, a broad cross-sectional sample was drawn geographically to represent the states of Australia and New Zealand. However, only small samples from each geographical area participated in the study, and there were regions in Australia and New Zealand, which were not represented. As such, it is possible that institutions not included in this study employed different methods to facilitate PSA from those described in this study. For this reason, the themes that emerged from this study are context-dependent and may not be transferable to all CCLs (Polit & Beck, 2010).

Relevance to international practice

As this study was conducted in Australia and New Zealand, the findings may describe practices and issues different to those found in other countries. Such differences may be due to variations in the roles of nurses, nursing-medical hierarchies, staffing ratios, differing caseloads and regulatory frameworks. However, it is important to discuss the findings in an international context, as there is little literature in this area.

One of the main findings of this study was that nurses perceived existent guidelines developed by anaesthetists for PSA without an anaesthetist present, which are intended to apply regardless of the clinical setting, are impractical for the CCL. As this study was conducted in Australia and New Zealand, the nurses interviewed in this study were referring specifically to the guidelines for the administration of PSA without an anaesthetist present in Australia and New Zealand (ANZCA 2010). However, these guidelines, produced and published by the ANZCA, provide similar recommendations for practice as those developed previously by the American Society of Anesthesiology in the United States of America (Gross et al., 2002). In contrast to Australia, New Zealand and America, no guidelines for PSA were identified in a comprehensive review of the literature that either broadly or specifically related to CCL practice in the UK or other European countries. In the absence of clinical practice guidelines, it is likely that local hospital policy is used to inform practice in these regions.

In addition to guidelines, some state boards of nursing in America regulate the administration of PSA when anaesthetic services are not utilised (Odom-Forren, 2005). No such nursing regulations exist to govern the administration of PSA in Australia and New Zealand. As the present study identified that in some circumstances workforce constraints and increasingly complex PSA requirements have rendered existent guidelines impractical for CCL nurses, it is possible this same problem exists in other countries. While further study would be required to confirm that guidelines for PSA are impractical for CCL practice requirements internationally, the possibility nevertheless highlights the importance for CCL nurses who administer PSA in the United States of America to be aware of regulations with regard to patient care.

With regard to the other key findings from this study, such as the limitations of PSA medications, patients' inaccurate expectations of PSA, and the barriers to patient monitoring, because the same CCL procedures are being conducted in other countries, it is likely these study findings are applicable internationally.

Relevance to clinical practice

Several issues of relevance to clinical practice were identified. First, findings emphasise that CCL nurses need to possess advanced knowledge and skills in monitoring for the adverse effects of sedation. Second, it was identified that it is often difficult for CCL nurses to observe respiration due to environmental barriers. Therefore we suggest consideration should be given to the use of capnography in such situations. Third, our findings indicate that a team-based

approach is predominantly used to monitor patients. Although participants agreed this was suitable for coronary procedures, concerns were expressed about the adequacy of this model for electrophysiology-based procedures. Thus, in the latter procedure, we suggest consideration should be given to the allocation of two 'scout' nurses. Finally, our findings highlight the importance of ensuring patients are aware that although sedative and analgesic medications will be administered, it is likely they will remain awake during the procedure. And, while all efforts will be made to ensure pain relief is provided, some aspects may be uncomfortable. It is important to note though, that findings represent the perspective of senior nurses, which have not been substantiated with patient outcome data. As such, a summary of the recommendations for future research derived from this study is presented in Box 4.2.

Box 4.2 Recommendations for research

- Clinical trial comparing oral benzodiazepine pre-medication with intra-procedural intravenous sedation and analgesia.
- Clinical trials of more novel PSA medication regimens during electrophysiology-based procedures in order to improve patient satisfaction and reduce recovery time.
- Evaluation of the benefits and costs of allocating two 'scout' nurses during nurse-administered PSA for electrophysiology-based procedures.
- Clinical trial of the added benefit of using capnography in addition to oxygen saturation and observation of respiration during PSA in the CCL setting.
- Clinical trial of the effectiveness of patient education on patient's perceived satisfaction with PSA.

Conclusion

This study was undertaken to explore the issues and challenges associated with nurse-administered PSA in the CCL setting from the perspectives of senior CCL nurses. While many issues and challenges exist, the most critical finding of this study was that participants explained that guidelines, which are intended to apply regardless of the clinical setting, were often not followed due to limited access to anaesthetic services in the setting of complex procedures. The participants perceived this to be a serious issue, because they feel that if a serious adverse event is to occur when nurse-administered PSA is used in complex procedural situations, the nurse could be held to account given the fact they were required to administer sedation outside of an accepted standard of practice. In order to address participants' concerns, it is proposed that a new set of guidelines could be developed. Developing guidelines, which address the unique circumstances in which sedation is used in the cardiac catheterisation laboratory, would be beneficial because they could potentially limit the variability in practice that exists between institutions and also aid nurses to develop the skills and knowledge base required for the provision of safe, consistent and evidence-based care of patients during sedation.

CHAPTER FIVE

Trends in nurse-administered procedural sedation and analgesia across Australian and New Zealand cardiac catheterisation laboratories: Results of an online survey

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Preamble

The previous study presented used a qualitative research design. While using a qualitative research design permitted an in-depth exploration of the issues and challenges associated with nurse-administered PSA in the CCL, no other research had previously been undertaken to characterise current nursing practices related to the administration and monitoring of PSA in the CCL setting. For this reason, a quantitative study was also undertaken which ran concurrently with the qualitative study (Creswell & Plano Clark, 2007). A descriptive cross-sectional survey design was used to establish the current trends in nurse-administered PSA in CCLs across Australia and New Zealand. This was the first study to quantify the frequency with which it is actually used, and characterise associated nursing practices.

Abstract

Background

Knowledge of current trends in nurse-administered procedural sedation and analgesia (PSA) in the cardiac catheterisation laboratory (CCL) may provide important insights into how to improve safety and effectiveness of this practice.

Objective

To characterise current practice as well as education and competency standards regarding nurse-administered PSA in Australian and New Zealand CCLs.

Design

A quantitative, cross-sectional, descriptive survey design was used.

Methods

Data were collected using a web-based questionnaire on practice, educational standards and protocols related to nurse-administered PSA. Descriptive statistics were used to analyse data.

Results

A sample of 62 nurses, each from a different CCL, completed the questionnaire that focused on PSA practice (represents 54% of estimated total number of CCLs in Australia and New Zealand). Nurse-administered PSA was used in 94% (*n*=58)

of respondents CCLs. All respondents indicated that benzodiazepines, opioids or a combination of both is used for PSA (*n*=58). One respondent indicated that propofol was also used. 20% (*n*=12) indicated that deep sedation is purposefully induced for defibrillation threshold testing and cardioversion without a second medical practitioner present. Sedation monitoring practices vary considerably between institutions as only 31% (*n*=18) of respondents indicated that comprehensive education about PSA is provided and a minority (45%; *n*=26) indicated that nurses who administer PSA must undergo competency assessment.

Conclusion

By characterising nurse-administered PSA in Australian and New Zealand CCLs, a baseline for future studies has been established. Areas of particular importance to improve include protocols for patient monitoring and comprehensive PSA education for CCL nurses in Australia and New Zealand.

Introduction

Procedures performed in the cardiac catheterisation laboratory (CCL) do elicit a certain amount of pain and discomfort even though they are minimally invasive and usually short in duration. As such, administration of procedural sedation and analgesia (PSA) is often required. PSA is a technique used during medical procedures in which a combination of sedative and analgesic medication are administered to suppress patients' awareness of pain and discomfort, reduce feelings of anxiety and induce amnesia (Malamed, 2003).

The research conducted on nurse-administered PSA in the CCL has mainly consisted of single-centre, consecutive cohort studies, which have evaluated this practice by ascertaining the incidence of sedation-related cardiopulmonary complications requiring intervention (Geiger et al., 1997; Kezerashvili et al., 2008; Pachulski et al., 2001). In each of these observational studies, the authors stated that strict hospital policies or protocols for the administration and monitoring of PSA were followed. Also, the nurses who administered PSA were not only trained in PSA techniques but also underwent a credentialing process organised by the anaesthetic department. Adverse events such as hypotension and decreased oxygen saturation occurred in 2.4-9.4% of patients, with 0.1% of a cohort (n=9558) experiencing a serious adverse event, classified as either death or severe clinical instability during the procedure (Geiger et al., 1997; Kezerashvili et al., 2008; Pachulski et al., 2001). The authors of these

observational studies argued that the use of nurse-administered PSA in the CCL is safe because sedation-related complications such as hypoxaemia and hypotension are infrequent and reversible with simple interventions. Early detection of complications can lead to timely management reducing the likelihood of serious adverse events, such as the need for tracheal intubation and mechanical ventilation. Therefore, the weight of evidence from these studies suggests that nurse-administered PSA is safe when performed in a setting with adequately trained practitioners and clear protocols for patient monitoring.

Practice is also likely to be influenced by guidelines that have been published on the administration and monitoring of PSA without an anaesthetist present (ANZCA, 2010; Gross et al., 2002). In Australia and New Zealand specifically, the Australia and New Zealand College of Anaesthetists provide recommendations for the type of patients and the sedative and analgesic medications that are suitable, as well as education, staffing and patient monitoring requirements for PSA that is administered without an anaesthetist present (ANZCA, 2010). These guidelines are meant to apply whenever PSA is administered without an anesthetist present, regardless of the practice setting.

To date though, there is limited research into current real-world practice specifically looking at the: degree to which current practice is consistent with recommendations in existent guidelines; the extent of education and training for nurses who administer PSA in the CCL; and the degree to which local hospital policy or protocols are utilised. The one review of real-world practice emerged from the United States. The results of this study suggested the management of

PSA in the CCL varies between institutions (Gaitan et al., 2011). In their survey of cardiac electrophysiology laboratories in the United States, Gaitan et al. found considerable variability in the depth of induced sedation, medications administered, the amount of direction and medical supervision for medication titration and the application of airway interventions by nurses during nurse-administered PSA.

As previous research has identified considerable practice variation in the northern hemisphere, and no review has been undertaken in other regions, a study of contemporary nurse-administered PSA practice in Australian and New Zealand CCLs was indicated. Furthermore, it was hoped that establishing current trends would provide important insights into how to improve practice. Therefore, this study was undertaken to characterise current nurse-administered PSA practice, education and competency/credentialing standards in Australian and New Zealand CCLs.

Methods

Research design

A quantitative, descriptive survey design was used for this cross-sectional study, using a snow-ball sampling method. Snowball sampling is an effective type of convenience sampling method that can be used when probability sampling is unrealistic (Wright & Stein, 2005).

Population, Sampling and data collection

One nurse from each CCL in Australia and New Zealand was sought to complete the survey in order to describe practice at their institution. Currently there is no readily accessible register or database containing the number and location of CCLs in Australia and New Zealand. Industry sources indicate that there are currently 101 CCLs operating in Australia and 14 CCLs operating in New Zealand. For this reason, a snowball sampling strategy was used. An email invitation to participate in the survey was sent by the chair of the Australia and New Zealand Interventional Nurses' Council, which is a nursing body representing CCL nurses in Australia and New Zealand, to CCL contacts. Recipients of this email were asked to forward the link to their own personal contacts to increase the number of nurses invited to participate in the survey. Three follow-up reminders were sent by the chair of the nursing body to the group of initial contacts via email to enhance the response rate. Postcodes and IP addresses were used to ensure there was only one survey completed from a particular CCL.

Survey instrument

A questionnaire was purposefully developed for this study to survey Australian and New Zealand CCLs. The survey was undertaken as one phase within a program of research aimed at establishing educational standards, competencies and clinical practice guidelines for both nurse-administered PSA specifically, and more broadly, for nursing practice within Australian and New Zealand CCLs. A total of 33 items were used to determine which procedures nurses are required

to administer PSA, the activities nurses perform to manage PSA in the CCL, the hospital policies that are available to direct nursing practices related to PSA, on the knowledge or skill-base requirements that exist for nurses who administer PSA in the CCL and on the level of education about PSA that is being provided to nurses in Australian and New Zealand CCL's. The majority of the items (*n*=31) were either fixed-choice options (eg. Yes/No) or were multiple choice with an option for free text. An ordinal scale (always, most of the time, some of the time, rarely, never) was used to determine the frequency with which nurse-administered PSA was used for the variety of procedures and also to determine the frequency that different types of sedative and analgesic medications were used.

The three sections of the questionnaire that specifically focused on PSA practice were informed by the literature and published guidelines on sedation. These sections of the questionnaire contained items to determine which procedures nurses are required to administer PSA, the activities nurses perform to manage PSA in the CCL, as well as items on the hospital policies that are available to direct nursing practices related to PSA, on the knowledge or skill-base requirements that exist for nurses who administer PSA in the CCL and on the level of education about PSA that is being provided to nurses in Australian and New Zealand CCL's.

The questionnaire was pilot tested by two nurse unit managers at separate hospitals. As some changes were made to increase the clarity of some questions

prior to the survey being conducted, the results of the pilot test are not included in the final results.

Data Analysis

Following the data collection period, data was downloaded into SPSS v19. Descriptive statistics (frequencies & percentages) were used to summarise the categorical data.

Ethical considerations

It was decided to gather information about PSA practice in Australian and New Zealand CCLs in the same questionnaire as the broader study because it would facilitate an efficient use of resources, and, at the same time, considerably reduce participant burden. Ethical approval to conduct the survey in this format was received from a university human research ethics committee (HREC Register Number V2011 46).

As the results of the survey that focused on nurse-administered PSA addresses a distinct research objective within the broader program of research, it was considered that it was ethical to report the results in a separate paper. This decision is supported by requirements for separate publication of results of a large survey that have previously been noted in the nursing literature, and it is also consistent with statements produced by the Committee on Publication Ethics (COPE) (COPE; Norman & Griffiths, 2008). To facilitate transparency

though, specific details and findings of the concurrent study will be reported elsewhere (Under review).

Results

There were 79 responses to the larger survey, of these 62 (76%) respondents completed the items focused on procedural sedation and analgesia, which represents a response from 54% of the estimated total number of CCLs in operation in Australia and New Zealand. Participant demographic characteristics are shown in Table 5.1.

Table 5.1 Demographics

Demographic characteristics	Completed questionnaire *n* (%)
Australia	55 (89)
New Zealand	7 (11)
Urban area	43 (69)
Regional area	19 (31)
Public hospital	30 (48)
Private hospital	32 (52)

Sedation administration practices

Responses indicate that nurses commonly administer PSA in Australian and New Zealand CCLs. Of the 62 respondents who answered questions related to PSA, only two (3%) indicated that PSA or anaesthesia was not ever used in their CCLs. Of the remaining 60 respondents, two (3%) indicated that nurses were never

required to administer PSA, implying that either an anesthetist or another medical practitioner was always present to administer PSA as required.

Procedures

Respondents were asked to indicate the frequency with which a nurse or an anaesthetist would administer PSA for each type of procedure performed in the CCL. If their CCL did not perform a particular procedure, participants were asked to leave the section blank. The results presented in Figure 5.1 demonstrate that practice varies considerably between institutions in terms of whether an anaesthetist or a nurse administers PSA. The majority of respondents indicated that nurse-administered PSA is more commonly used than anaesthetist-administered PSA for angiography, percutaneous coronary intervention, electrophysiology studies, permanent pacemaker (PPM) implants, temporary pacing lead insertions, vascular procedures and paediatric cases. Whereas respondents indicated that an anesthetist was more often used to administer PSA for cardiac ablation procedures, implantable cardioverter-defibrillator (ICD) procedures, implant of cardiac resynchronisation therapy devices and structural heart procedures.

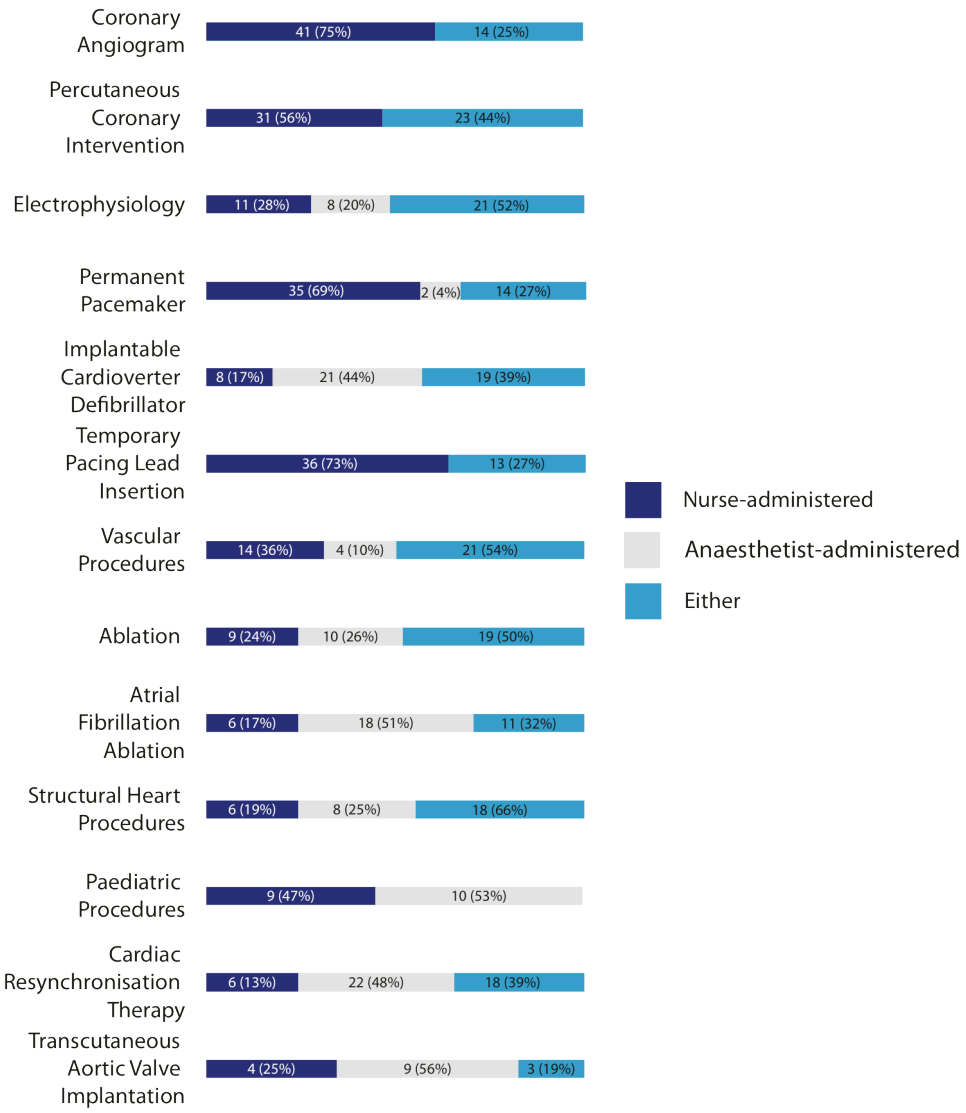

Figure 5.1 Mode of PSA per procedure

Depth of sedation

Deep sedation, which is the point at which the patient is not responsive to verbal commands, is required for defibrillation threshold testing and cardioversion. 67% (*n*=39) of respondents indicated that sedation for these aspects of procedures were always administered by a medical officer (either anaesthetist or intensivist), 10% (*n*=6) indicated that the sedation was always administered by a

nurse and 10% (*n*=6) indicated that sedation was administered by a nurse when access to a medical officer could not be arranged (13% did not reply to this question).

Medications

All respondents indicated that the cardiologist performing the procedure prescribed nurse-administered PSA verbally, as opposed to being titrated according to a pre-specified order. All respondents indicated that a combination of benzodiazepines and opioids were used to induce sedation and analgesia. One respondent indicated that propofol was also used for nurse-administered PSA. No other sedative and analgesic medications were reported to be used in respondents' CCLs.

Sedation monitoring and intervention practices

Nurse staffing

A majority of respondents (*n*=37; 64%) indicated that in their CCLs, if nurse-administered PSA was used, the nurses' primary responsibility was to monitor sedation throughout the procedure. In the CCLs of the remaining 36% (*n*=21) of respondents, the nurse is responsible for duties other than monitoring the sedation status of the patient during the procedure.

Observations

A majority of respondents (*n*= 34; 59%) indicated that their unit had a policy outlining the type of observations that nurses should record during nurse-

administered PSA. A similar number of respondents (*n*=30; 52%) indicated that their unit had a policy outlining the frequency with which observations should be recorded during nurse-administered PSA.

Oxygen supplementation

The decision to apply supplemental oxygen was reported by 34% (*n*=20) of respondents to lie with the nurse who administers sedation. A further 16 (28%) respondents indicated that either the nurse or the cardiologist performing the procedure would decide when supplemental oxygen was required. There was a policy on the use of supplemental oxygen at 38% (*n*=22) of respondents' CCLs. No respondents indicated that the decision to apply supplemental oxygen was only ever made by the cardiologist performing the procedure.

Application of airway interventions

A majority of the respondents (*n*=35; 60%) indicated that nurses are at times required to perform an airway intervention during sedation (jaw thrust, oro/nasopharyngeal airway, mask ventilation). The decision to apply an airway intervention is made predominantly by the nurse performing the procedure (*n*=31; 53%). A further 41% (*n*=24) of respondents indicated that either a nurse or the cardiologist performing the procedure would make the decision for a nurse to apply an airway intervention and 6% (*n*=3) indicated that the decision to apply and airway intervention was made according to criteria outlined in a policy.

Extra medical assistance during sedation

Only two (4%) respondents indicated that their CCL had a policy which outlined the criteria for situations where extra medical assistance for sedation should be acquired. Other respondents indicated that the decision to acquire extra medical assistance was either made only by the nurse (*n*=1; 2%), only by the cardiologist performing the procedure (*n*=12; 20%), or by the nurse or the cardiologist (*n*=41; 71%). Mostly, extra medical assistance was provided by an anesthetist (*n*=41; 71%). However, respondents also indicated that sometimes the hospital medical emergency (Code Blue) team (*n*=31; 53%) or medical officers not performing the procedure, who happen to be present at the time (*n*=11; 19%), were also utilised for extra medical assistance.

Training in sedation

While 57% (*n*=33) of respondents indicated that some degree of education about PSA is provided to nurses who administer PSA in their CCLs, only 31% (*n*=18) reported covering all aspects of the education that is recommended by the Australia and New Zealand College of Anaesthetists (Table 5.2). Similarly, a minority of respondents (*n*=26; 45%) indicated that nurses who administer PSA are required to undergo a competency/credentialing assessment in the administration and monitoring of PSA. 55% (*n*=32) of respondents indicated that nurses are required to be certified in ALS if they are to administer PSA. Sixteen of the respondents (28%) indicated that nurses are required to undergo competency assessment in PSA and be certified in ALS before permitted to

administer PSA. Ten respondents (17%) indicated that nurses are required to undergo competency assessment in PSA, yet do not have to be certified in ALS. Fourteen respondents (24%) indicated that nurses did have to be certified in ALS but did not have to undergo competency assessment in PSA.

Table 5.2 Key components of PSA nursing education

Component	*n* (%)
Education (any)	33 (57)
Pharmacology	23 (40)
Level of consciousness	28 (48)
Cardiorespiratory status	29 (50)
Identification of sedation-related complications	28 (48)
Interventions to treat sedation-related complications	27 (46)
All aspects	18 (31)

Discussion

The following trends identified in this study, which together broadly characterise nurse-administered PSA in Australian and New Zealand CCLs, are discussed in relation to the literature below.

Nurse-administered PSA is common

It is clear from the results of this study that nurse-administered PSA is very commonly utilised in nearly all Australian and New Zealand CCLs across various procedures. This finding is in line with the only previous review of PSA practice in the CCL setting. Gaitan et al (2011) reported that nurse-administered PSA was also used in the vast majority of institutions.

A combination of benzodiazepines and opioids are used to induce sedation and analgesia.

In the present study, the medications used for nurse-administered PSA were remarkably similar between institutions. A combination of benzodiazepines and opioids was used in all the institutions surveyed. The popular use of benzodiazepines and opioids is not surprising, though, considering the majority of research conducted on the safety and effectiveness of nurse-administered PSA in the CCL have used these types of medications (Lipscomb et al., 1998; Marquie et al., 2007).

In addition to benzodiazepines and opioids, propofol was reported to be used for nurse-administered PSA by one of the respondents. This finding is important, even though it can be inferred from the survey that use of propofol for nurse-administered PSA in Australian and New Zealand CCLs is likely to be few. It is important because of the contention between physicians who use propofol in procedural areas without an anesthetist present and the broader anaesthetic community. The guidelines for sedation and analgesia without an anaesthetist present, which were developed by the Australia and New Zealand College of Anaesthetists, state that propofol should not be administered without an anaesthetist present due to the high risk of unintentional loss of consciousness (ANZCA, 2010).

However, it should also be noted that the infrequent use of medications other than benzodiazepines and opioids for nurse-administered PSA in the CCL is in

distinct contrast to findings in the survey conducted in the United States, where nurse-administered propofol is more commonly used. (Gaitan et al., 2011) The use of cardiologist-directed, nurse-administered propofol in the United States is likely gaining traction because the evidence that it is a safe and effective method to induce PSA is emerging from large observations studies (Salukhe et al., 2012; Sayfo et al., 2012). That being said, editorials accompanying these publications have called for more research to be conducted in order to explicate the type of patients that are suitable, the degree of patient monitoring that is required and specific education, training and accreditation requirements before the administration of propofol without an anaesthetist present is broadly recommended for use in the CCL setting (de Bono, 2012; Hummel & Awad, 2011). Therefore, further research is indicated as a prelude to the development of evidence-based guidelines, which outline which procedures and the patients for which propofol is appropriate to be used as well as the standards for specialised training and credentialing programs.

Deep sedation is used without a second medical practitioner present.

For the majority of procedures, moderate sedation is targeted. However, during ICD procedures, sometimes defibrillation threshold testing needs to be performed. Also, during electrophysiology procedures, sometimes cardioversion needs to be performed. These aspects of procedures are likely to be painful (Marquie et al., 2007). In order to ensure patient comfort, a purposeful, yet

transient, increase in the level of sedation, such that the patient no longer responds to verbal stimulation, is required. This level of sedation is defined in the contemporary literature on PSA as “deep” sedation. In this study, a considerable number of respondents (*n*=12; 20%) indicated that deep sedation was used without an anaesthetist present for these particularly painful aspects of procedures.

The administration of “deep” sedation during defibrillation threshold testing and cardioversion is another contentious issue regarding nurse-administered PSA in the CCL. According to clinical guidelines developed by the ANZCA, deep sedation is not recommended to be used without an anesthetist present (ANZCA, 2010). However, it should be noted that contradictory to the guidelines, the evidence actually suggests the administration of deep sedation without an anaesthetist present in the CCL is safe because serious adverse events are extremely rare (Conway et al., 2011). As a considerable proportion of respondents indicated that deep sedation is used for defibrillation threshold testing and cardioversion, it is recommended that the guidelines are updated, or new guidelines developed, which take into consideration the evidence demonstrating that this practice is safe and effective when administered by trained practitioners with clear protocols for patient selection and monitoring within the CCL setting.

Sedation monitoring practices vary between institutions

There were a considerable number of respondents (*n*=21; 36%) who indicated that tasks other than monitoring sedation are performed by the nurse who

administers sedation. This is an important finding because guidelines developed by the ANZCA recommended that one person's primary responsibility should be to monitor the sedation status of the patient (ANZCA, 2010). While this is the recommended practice, there is no evidence to suggest that being responsible for other duties actually results in worse patient outcomes. Therefore, the appropriateness of this recommendation remains uncertain. Furthermore, financial considerations associated with the increased cost associated with the necessity for allocating an extra staff member to a procedure if PSA is used, are likely to influence this practice. As such, more research needs to be undertaken to determine if nurses who administer PSA in the CCL should be permitted to perform duties other than monitoring the patient and this research needs to include an evaluation of the cost implications of differing staffing ratios.

Furthermore, in the research that has been conducted on nurse-administered PSA in the CCL, the authors noted that strict protocols for patient monitoring were followed (Fox et al., 2007; Pachulski et al., 2001; Sayfo et al., 2012). Strict concordance with these protocols contributed to the low incidence of sedation-related serious adverse events. This is because frequent monitoring facilitated early detection of decline in cardiopulmonary function, leading to prompt corrective interventions, such as application of an airway adjunct or administration of sedation-reversal medication (Geiger et al., 1997; Pachulski et al., 2001). For this reason, it is concerning that a considerable number of CCLs in Australia and New Zealand do not have protocols for patient monitoring during PSA in the CCL. As such, the development and implementation of protocols for

patient monitoring during nurse-administered PSA in the CCL setting is one area of practice in Australia and New Zealand that can be improved.

Education and training for nurses who administer sedation is not comprehensive

Results of the survey indicate that education about PSA in Australian and New Zealand CCL is generally poor. This is a concerning and important finding as studies that demonstrated the safety of nurse-administered PSA in the CCL stated that nurses received education about PSA and were assessed for competency by the anaesthetic departments of their institutions (Conway et al., 2011; Kezerashvili et al., 2008; Pachulski et al., 2001). Also, research from other clinical settings has demonstrated that implementing comprehensive education and credentialing programmes results in improved safety (Priestly et al., 2006). Therefore, it is recommended that comprehensive PSA education programmes be established for CCL nurses in Australia and New Zealand.

While education and training in PSA needs to be improved in most Australian and New Zealand CCLs, this study identified one important area that should specifically be targeted. The specific area of PSA education that was particularly deficient, and should therefore be targeted by CCL nurse educators, involves the detection and treatment of sedation-related complications. This is because (1) a minority of respondents indicated that education is provided on interventions to treat sedation-related complications, (2) a majority of respondents indicated that nurses must determine the circumstances in which they should administer

interventions to support or restore cardiac or respiratory function during nurse-administered PSA and (3) only 55% of respondents indicated that nurses must be certified in ALS to administer PSA (If specific training in PSA is not provided, ALS training is the other avenue where nurses could be trained to manage the airway of patients with depressed consciousness).

Limitations

While this survey provides the first information about PSA practice patterns in Australian and New Zealand CCLs, only 54% of the target population responded to all the items focused on PSA in the questionnaire. Therefore, the results of this survey need to be interpreted with caution, as they may not generalise to the population (Shih & Fan, 2008). The length of the questionnaire likely contributed to the low completion rate (Dillman, Smyth, & Christian, 2009). As stated in the methods section though, it was deemed necessary to include items focused on PSA in the same survey as the broader study for an efficient use of resources and to reduce participant burden.

It is possible that selection bias and non-response bias have an impact on the extent to the which the results from this study can be generalised.(Saks & Allsop, 2007) Selection bias cannot be ruled out because it is not known whether one clinical nurse leader from each CCL in Australia and New Zealand was invited to participate. Also, no information was able to be gathered about the characteristics of non-responders. Therefore, it is possible there could have been underlying reasons why clinical nurse leaders who were invited chose not to

participate in the study. However, as there is no publicly accessible database of CCLs to access, these limitations could not be overcome.

Finally, personalised contact with non-responders could potentially have improved the response rate (Saks & Allsop, 2007). Unfortunately though, personal reminders could not be sent because there was no way to determine who had completed the survey, with all the responses being kept completely anonymous in accordance with ethical requirements (NHMRC, 2006).

Conclusion

Nurse-administered PSA is very commonly utilised in Australian and New Zealand CCLs. It was also identified that deep sedation is administered by nurses without an anesthetist present in the CCL, that protocols for patient monitoring are lacking and that nurse education about PSA is not comprehensive in many CCLs, and in others, is not provided at all. Establishing these current trends in nurse-administered PSA practice in Australian and New Zealand CCLs has provided important insights into strategies, which potentially could improve the safety and effectiveness of PSA in this setting. Areas of particular importance to address include setting up protocols for patient monitoring and establishing comprehensive PSA education programs for CCL nurses in Australia and New Zealand.

CHAPTER SIX

Risk factors for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory: A matched case-control study

Aaron Conway, Karen Page, John X Rolley & Paul Fulbrook

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Preamble

In the studies that have reported on the safety of nurse-administered PSA in the CCL, respiratory complications, such as respiratory depression and airway obstruction, occurred in 2.4-9.4% of patients (Conway et al., 2011). These complications pose considerable risk to patient safety as they can lead to inadequate oxygenation and ventilation. To expand understanding of the conditions that contribute to the onset of impaired respiratory function during nurse-administered PSA in the CCL, a matched case-control study was conducted and is presented in this chapter.

Abstract

Background

Side effects of the medications used for procedural sedation and analgesia in the cardiac catheterisation laboratory are known to cause impaired respiratory function. Impaired respiratory function poses considerable risk to patient safety as it can lead to inadequate oxygenation. Having knowledge about the conditions that predict impaired respiratory function prior to the procedure would enable nurses to identify at risk patients and selectively implement intensive respiratory monitoring. This would reduce the possibility of inadequate oxygenation occurring.

Aim

To identify pre-procedure risk factors for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory.

Design

Retrospective matched case-control.

Methods

21 cases of impaired respiratory function were identified and matched to 113 controls from a consecutive cohort of patients over 18 years of age. Conditional

logistic regression was used to identify risk factors for impaired respiratory function.

Results

With each additional indicator of acute illness, case patients were nearly two times more likely than their controls to experience impaired respiratory function (OR=1.78; 95%CI=1.19-2.67; *p*=0.005). Indicators of acute illness included emergency admission, being transferred from a critical care unit for the procedure or requiring respiratory or haemodynamic support in the lead up to the procedure.

Conclusion

Several factors that predict the likelihood of impaired respiratory function were identified. The results from this study could be used to inform prospective studies investigating the effectiveness of interventions for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory.

Keywords:

Conscious sedation, Deep sedation, Heart catheterisation, Artificial cardiac pacing, Cardiac electrophysiology.

Introduction

Procedural sedation and analgesia (PSA) is very often used during procedures performed in the cardiac catheterisation laboratory (CCL) to provide pain relief and to reduce feelings of discomfort and anxiety. When an anaesthetist is not assigned to the CCL, it is common for nurses to administer sedative and analgesic medication via the intravenous route, according to direction from the cardiologist performing the procedure (Gaitan et al., 2011).

As recommended in guidelines developed by anaesthetic professional organisations, if there is no anaesthetist present, the nurse administering PSA must focus particular attention to monitoring respiratory function (ANZCA, 2010; Gross et al., 2002). This is because side effects of intravenous sedative and analgesic medications can cause respiratory depression and partial obstruction of the patient's airway (Odom-Forren & Watson, 2005). Depression of respiratory drive manifests clinically as hypopnoeic hypoventilation, bradypnoea or periods of apnoea (Becker & Casabianca, 2009). Relaxation and consequent displacement of the pharyngeal musculature is the mechanism by which the sedated patient's airway becomes obstructed (Odom-Forren & Watson, 2005). For convenience, respiratory depression and partial airway obstruction will be defined in this paper using the collective term, "impaired respiratory function".

Impaired respiratory function is a problem, because it causes inadequate ventilation. As a consequence of inadequate ventilation, the amount of oxygen inhaled and the amount of carbon dioxide exhaled are reduced (Becker &

Casabianca, 2009). If inadequate ventilation is undetected, and corrective interventions are not actioned, within a short space of time oxygenation can become inadequate for physiologic requirements. In the most severe of consequences, the failure to identify inadequate ventilation and oxygenation leads to serious adverse events, such as disability or death (Robbertze et al., 2006). Due to the iatrogenic and preventable nature of PSA-related adverse events, timely identification of impaired respiratory function facilitating the swift implementation of corrective interventions is essential whenever nurse-administered PSA is used in the CCL setting. In this context, the identification of specific factors that are associated with impaired respiratory function would be of considerable assistance in clinical practice, because it would aid nurses to identify groups of patients who would potentially benefit from even closer observation of respiration than is typically applied.

The incidence of impaired respiratory function related to nurse-administered PSA in the CCL is reported to range between 2.4-9.4% (Conway et al., 2011). In the previous research though, only a few factors associated with impaired respiratory function during PSA have been identified. These include induction of deep sedation during defibrillation threshold testing or cardioversion, administration of propofol, and high doses of benzodiazepines and opioids (Geiger et al., 1997; Pandya et al., 2009; Sayfo et al., 2012). However, it is important to note that these factors only become apparent after a procedure has commenced. Demographic and clinical risk factors, which potentially can be screened by CCL nurses prior to commencement of the procedure, have not yet

been identified. Advance indication of those at risk of impaired respiratory function would provide nurses the opportunity to devise a plan of care that ensures intensive respiratory monitoring can be applied from the onset of the procedure.

In other clinical areas that also frequently utilise PSA, such as the emergency department and endoscopy unit, studies have identified that certain demographic and clinical risk factors potentiate the effects of sedative and analgesic medications on respiratory function. In these studies, to identify demographic and clinical risk factors for impaired respiratory function during PSA, comprehensive lists of potential factors were investigated, typically using multivariable logistic regression models. For example, in previous research investigators have examined whether age, body mass index, *American Society of Anesthesiology Physical Classification* scores (indicator of the patient's present health status and comorbidities), and smoking history are significantly associated with PSA-related complications (Qadeer, Rocio Lopez, Dumot, & Vargo, 2009; Taylor et al., 2011). The previous research conducted in the CCL setting has not utilised multivariate statistics to investigate these potential demographic and clinical risk factors for impaired respiratory function during PSA. Therefore, further research is required to gain a better understanding of the conditions that are related or contribute to the onset of impaired respiratory function during nurse-administered PSA in the CCL.

Aim

The aim of this study was to identify pre-procedural demographic and clinical risk factors for impaired respiratory function during nurse-administered PSA in the CCL setting.

Methods

Design

A retrospective matched case-control design was used.

Sample and setting

The sample consisted of consecutive patients over 18 years of age who underwent a procedure in any one of the three CCLs within one private hospital and electrophysiology procedures in the Cardiac Investigation Unit of a public hospital. The study hospitals are both situated in the same metropolitan region of Australia, each servicing over 500 in-patients. In both hospitals, during procedures when anaesthetic services are not deemed necessary, nurses administer and monitor PSA. It is important to note, though, that there may be differences in nursing roles, staffing ratios and regulatory frameworks internationally. Nevertheless, the literature suggests similar practices to those described in this paper are most commonly employed (Gaitan et al., 2011).

Data from 573 procedures were analysed. These included 194 electrophysiology procedures and 378 coronary, vascular or structural heart procedures. Most of

the procedures took place in the private hospital (n = 473). There were four procedures performed for private patients excluded due to age (< 18 years). None were excluded from the public hospital. Nurses administered PSA during 169/473 (36%) procedures at the private site and 80/100 (80%) procedures at the public hospital (total *n*=249).

Matching procedure

Cases for matching were specified as patients who experienced impaired respiratory function, classified as SpO2 less than 95%; 8 respirations or less per minute; or intervention to maintain a patent airway. These criteria were chosen because they have been used to define respiratory complications in other studies, are readily available in the patient's medical record and also because SpO2 <95%, corresponds to a PaO2 of less than 80mmHg (generally accepted as the cut-off point for hypoxia) (Becker & Casabianca, 2009; Langhan, Chen, Marshall, & Santucci, 2011; Lightdale et al., 2006).

Also, it is suggested to match as many controls per case possible, even though there is only incremental benefit to matching more than 4 controls (Breslow, 1996). Therefore, we matched as many controls as possible to the 21 cases of impaired respiratory function that were identified in this study. As a result, some of the cases have more controls than others.

Controlling known intra-procedural confounders was a central concern for this study. Therefore, cases were matched with controls that did not have impaired respiratory function from the consecutive cohort based on the type of

procedure, age (+/- 5 years) and gender. Age was controlled because, during initial analysis of the data, a significant inverse correlation was found between age and the total amount of sedative and analgesic medications used during the procedures. This indicated that cardiologists prescribed fewer medications for older patients than younger patients. Similarly, gender was controlled because previous research has shown that females require higher medication doses to induce sedation and analgesia (Yen et al., 2011). By controlling for the type of procedure performed, this would also control for other intra-procedural confounders, such as the requirement for defibrillation threshold testing or cardioversion during the procedure, the use of supplemental oxygen and the duration of the procedure.

Data collection

Retrospective data were retrieved from a two-month period (1 May-30 June 2010) at the private hospital and for a one-month period at the public hospital (1 August-31 August 2011), using an electronic database to identify subjects. A data extraction tool was developed specifically for this study for the researchers to manually abstract data from the medical records. This tool was pilot tested on five medical records. Minimal changes were required and the tool was found to be efficient and easy to use. One researcher audited all the medical records to ensure data collection was consistent. The following data were retrieved: demographics, patient characteristics, procedural and sedation characteristics, nursing practices associated with PSA, and patient outcomes.

Data analysis

Data were transferred from the data extraction tool into SPSS v19 for analysis. Descriptive statistics (frequencies and percentages) were used to summarise categorical data while means and standard deviations or median and inter-quartile range was calculated to describe the continuous data. Demographics, admission status, health status, physiologic data and risk factors known to predict sedation-related complications in other populations were compared between matched cases and controls in order to identify potential risk factors to include in a multivariable model. Conditional logistic regression was used to estimate the odds ratios (ORs) and 95% confidence intervals (CIs) for univariate and multivariate analysis. In order to avoid unnecessary deletion of potentially important factors from the multivariate regression model, variables with statistical significance of $p<0.10$ on univariate analysis were selected.(Hosmer & Lemeshow, 2000) It is also important to note, that matching a different number of controls to cases did not influence the results because paired rather than independent statistical tests have been used (Niven, Berthiaume, Fick, & Laupland, 2012). Multicollinearity was assessed by regressing each factor in the model on each other and considered present if $R^2 > 0.6$. Principal component analysis was conducted to determine if the factors that showed evidence of multicollinearity were measuring the same construct. Factors with Eigenvalue over 1 were combined into an overall score for further multivariate analysis. Backward stepwise multivariate conditional logistic regression based on the likelihood ratio was used. The final model was determined using an entry

probability of 0.5 and removal probability of 0.10. As there was only a small amount of missing data, specifically related to the baseline blood pressure and baseline heart rate variables, no attempt was made to account for this missing data.

Ethical considerations

Approval for the study was obtained from the Human Research Ethics Committees of both hospital sites and from the university (2011.14.36, v2011 84 and HREC/12/QPCH/34). The investigation conforms with the principles outlined in the Declaration of Helsinki (Rickham, 1964).

Results

Impaired respiratory function occurred during 8.3% (95%CI=4.9%-11.7%) of the procedures (n=21) that nurses administered PSA. Table 1 summarises the demographic characteristics of the cases of impaired respiratory function that were identified in this study. Only two of the cases could not be matched successfully for age within five years. Despite this, none of the potential intra-procedural confounders was statistically significant (Table 2). Five of the 15 potential risk factors were statistically significant at $p<0.10$ (Table 3). These factors were retained for entry in a multivariable model.

Table 6.1 Characteristics of cases of impaired respiratory function during nurse-administered PSA

Age	Gender	Type of procedure	Type of impaired respiratory function	Matched controls
71	Female	Coronary angiogram	SpO2<95%	4
69	Male	Coronary angiogram	SpO2<95%	12
82	Male	Coronary angiogram	SpO2<95%	1
64	Female	Percutaneous coronary intervention	SpO2<95%	6
52	Male	Percutaneous coronary intervention	SpO2<95%	13
76	Female	Percutaneous coronary intervention	SpO2<95%	9
81	Male	Percutaneous coronary intervention	SpO2<95%	5
83	Female	Percutaneous coronary intervention	SpO2<95%	4
44	Male	Percutaneous coronary intervention	SpO2<95%	2
67	Female	Radiofrequency ablation not for atrial fibrillation	Respiration rate less than 8	1*
42	Male	Radiofrequency ablation not for atrial fibrillation	SpO2<95%	1*
70	Female	Cardiac pacemaker implant, lead revision or generator change	Respiration rate less than 8	7
87	Male	Cardiac pacemaker implant, lead revision or generator change	SpO2<95%	9
65	Male	Cardiac pacemaker implant, lead revision or generator change	SpO2<95%	7
73	Male	Cardiac pacemaker implant, lead revision or generator change	SpO2<95%	11
86	Female	Cardiac pacemaker implant, lead revision or generator change	SpO2<95%	10
78	Male	Implantable cardioverter defibrillator implant, lead revision or generator change	SpO2<95%	4
73	Male	Implantable cardioverter defibrillator implant, lead revision or generator change	SpO2<95%	2
46	Male	Implantable cardioverter defibrillator implant, lead revision or generator change	SpO2<95%	1
62	Male	Implantable cardioverter defibrillator implant, lead revision or generator change	SpO2<95%	3
65	Male	Peripheral vascular intervention	SpO2<95%	1

*Control has more than 5 years difference in age

Table 6.3 Univariate analysis of intra-procedural confounders

	β	Odds ratio	95% CI	*p*-value
Procedure duration	0.01	1.01	.99-1.03	.148
Total midazolam	.063	1.06	.74-1.54	.735
Total fentanyl	0.001	1.00	.99-1.01	.850
Defibrillation threshold testing or cardioversion performed during the procedure	-.712	.49	.03-7.79	.491
Oxygen supplementation	.472	1.60	.39-6.63	.515

Table 6.4 Univariate analysis of potential risk factors

	β	Odds ratio	95% CI	*p*-value
Emergency admission to hospital	1.75	5.75	1.57-21.01	.008*
Smoking history	-.89	.41	.14-1.17	.096*
Transferred from critical care unit for procedure	-1.22	.30	0.10-.92	.035*
Chronic pulmonary disease	-.20	.82	.24-2.85	.759
Chronic heart failure	-.82	.44	.13-1.54	.201
Moderate to severe renal failure	-.141	.87	.22-3.39	.839
Charlson comorbidity index total	.03	1.03	.80-1.34	.811
Moderate to severe comorbidity	.30	1.34	.36-5.00	.660
Respiratory support	-1.257	.29	.08-.99	.049*
Hemodynamic support	-1.15	.32	.08-1.24	.098*
Baseline systolic blood pressure out of normal range (<90mmHg>140mmHg)	.679	1.97	.664-5.86	.221
Baseline heart rate out of normal range (<40bpm>100bpm)	3.28	26.53	.001-688452	.527
Baseline respiration rate out of normal range (<12 per minute>20 per minute	.176	1.19	.133-10.70	.875
Sleep apnea	.76	2.14	.62-7.37	.229
BMI>35	-.81	.45	0.99-2.01	.293

*$p<0.10$

Respiratory support scored 'yes' if required supplemental oxygen, invasive ventilation or Bi-PAP prior to the procedure; Hemodynamic support scored 'yes' if inotropic or chronotropic, anti-arrhythmic, vasodilator, diuretic medication infusion, requirement for cardiac pacing or IABP prior to the procedure.

Moderate to severe comorbidity = Charlson comorbidity index total >4.

Multivariate analysis found that only one risk factor was independently associated with impaired respiratory function during nurse-administered PSA. According to the multivariable model, patients with impaired respiratory function during nurse-administered PSA in the CCL were 5.8 times more likely than their controls to have been admitted to the hospital as an emergency (OR=5.8; 95% CI=1.6-21.0; *p*=0.008) (Table 4). However there was evidence of multicollinearity between the emergency admission (patients admitted to hospital through the emergency department), transfer from critical care unit for procedure, requirement for respiratory support prior to the procedure and requirement for haemodynamic support prior to the procedure factors (R^2>0.6). Principal component analysis revealed these four factors were in fact measuring the same construct (one component with Eigenvalue>1). The new factor, "acute illness", was input in a further multivariable regression model with the remaining factor with statistical significance *p*<0.10, "smoking history", and backward stepwise conditional logistic regression analysis was again performed. According to the regression model, with each additional indicator of acute illness, patients were 78% more likely than their controls to experience impaired respiratory function during nurse-administered PSA in the CCL (OR=1.78; 95%CI=1.19-2.67; *p*=.005) (Table 5).

Table 6.5 Backward stepwise multivariable logistic regression model

Step	Factor	β	Odds ratio	95% CI	*p*-value
5	Emergency admission	1.75	5.8	1.6-21.0	0.008

Likelihood Ratio X^2 (1df) =8.87; *p*=0.0029; McFadden's Pseudo R2=0.1313.

Table 6.6 Backward stepwise multivariable logistic regression model

Step	Factor	β	Odds ratio	95% CI	*p*-value
1	Acute illness	.574	1.78	1.18-2.67	.006
	Smoking history	-.843	.43	.14-1.31	.137
2	Acute illness	.579	1.78	1.19-2.67	.005

Likelihood Ratio X^2 (1df) =8.29; *p*=0.004; McFadden's Pseudo R2=0.1228.

Discussion

The aim of this study was to identify pre-procedural demographic and clinical risk factors for impaired respiratory function during nurse-administered PSA in the CCL setting. Results indicate that with each additional indicator of acute illness, patients were nearly two times more likely to experience impaired respiratory function. These results have considerable face validity, as it is probable that patients with acute illness had underlying conditions that impacted on their cardiopulmonary function, which could have mediated impaired respiratory function.

The incidence of impaired respiratory function in the present study (8.3%; 95%CI=4.9%-11.7%) is in line with previous research (Fox et al., 2007; Geiger et al., 1997; Natale et al., 1996; Pachulski et al., 2001). As such, the results are likely also applicable to other CCLs in Australia and in overseas institutions that employ similar processes for the administration and monitoring of PSA. Although evidence in this area is limited, the finding that patients with acute illness were most likely to experience impaired respiratory function during nurse-administered PSA in the CCL is consistent with previous research. In the endoscopy setting, patients with higher *American Society of Anesthesiology Physical Classification* (Gross et al., 2002) scores (indicating poorer health status and greater comorbidities) were at greater risk of PSA-related cardiopulmonary complications during procedures, and inpatients were more likely to have unforeseen cardiopulmonary events when PSA was used (Sharma et al., 2007).

As the results from our study are valid from a clinical viewpoint and are consistent with previous research, we recommend that further studies be conducted to shed light on the effectiveness of interventions to improve patient outcomes. There are many potential areas to focus this research. For example, while guidelines for monitoring respiratory function during PSA without an anaesthetist present recommend that one practitioner's primary responsibility must be to perform patient monitoring, in real-world practice, it is most common for the nurse who administers PSA to also be responsible for acquiring equipment during the procedure (ANZCA, 2010; Gaitan et al., 2011; Gross et al., 2002). Therefore, in many circumstances, yet especially for patients with acute

illness who often undergo interventional rather than diagnostic procedures, the nurse may be absent from the procedure room for short periods of time. One potential alternative course of action would be to allocate two nurses to the procedure for patients with acute illness. This would permit one nurse to continually monitor respiratory function with another nurse available to organise any equipment that may be required during the procedure. This may result in earlier detection and treatment of impaired respiratory function. However, it would be particularly important for the effectiveness of this intervention to be evaluated both in terms of patient outcomes and the extra costs associated with utilising greater nursing resources.

Another intervention that could potentially improve outcomes for patients at risk of impaired respiratory function is to use capnography to monitor ventilation. Capnography may be of particular benefit when used for these patients because previous research has shown that practitioners are eighteen times more likely to detect respiratory depression when utilising this technology (Waugh, Epps, & Khodneva, 2011). As such, we recommend that further studies be conducted to ascertain the added benefit of using capnography during PSA for patients with acute illness.

Strengths and limitations

A strength of this study is the methods used to address multicollinearity between potential risk factors. The first backward stepwise conditional logistic regression model identified only one independent risk factor for impaired respiratory

function: emergency admission. Due to multicollinearity, the impact of being transferred from the critical care unit and requiring respiratory or hemodynamic support were not appreciated statistically. Various methods have been employed in epidemiological studies to address issues associated with multicollinearity in logistic regression models. Using principal component analysis to combine factors is a preferred method to deal with multicollinearity, rather than deleting factors that are intercollinear from the model (Dohoo, Ducrot, Fourichon, Donald, & Hurnik, 1997). While using principal component analysis to combine factors did not improve the goodness-of-fit of the model, (R^2=0.12 compared with 0.13) the final model is stronger than the first presented in this paper from a clinical viewpoint, as the implications for clinical practice are greater. The final model identifies considerably more people who are at risk of impaired respiratory function. For example, the patients who were not an emergency admission, yet deteriorated during their stay, were admitted to a critical care unit, and required either respiratory or hemodynamic support.

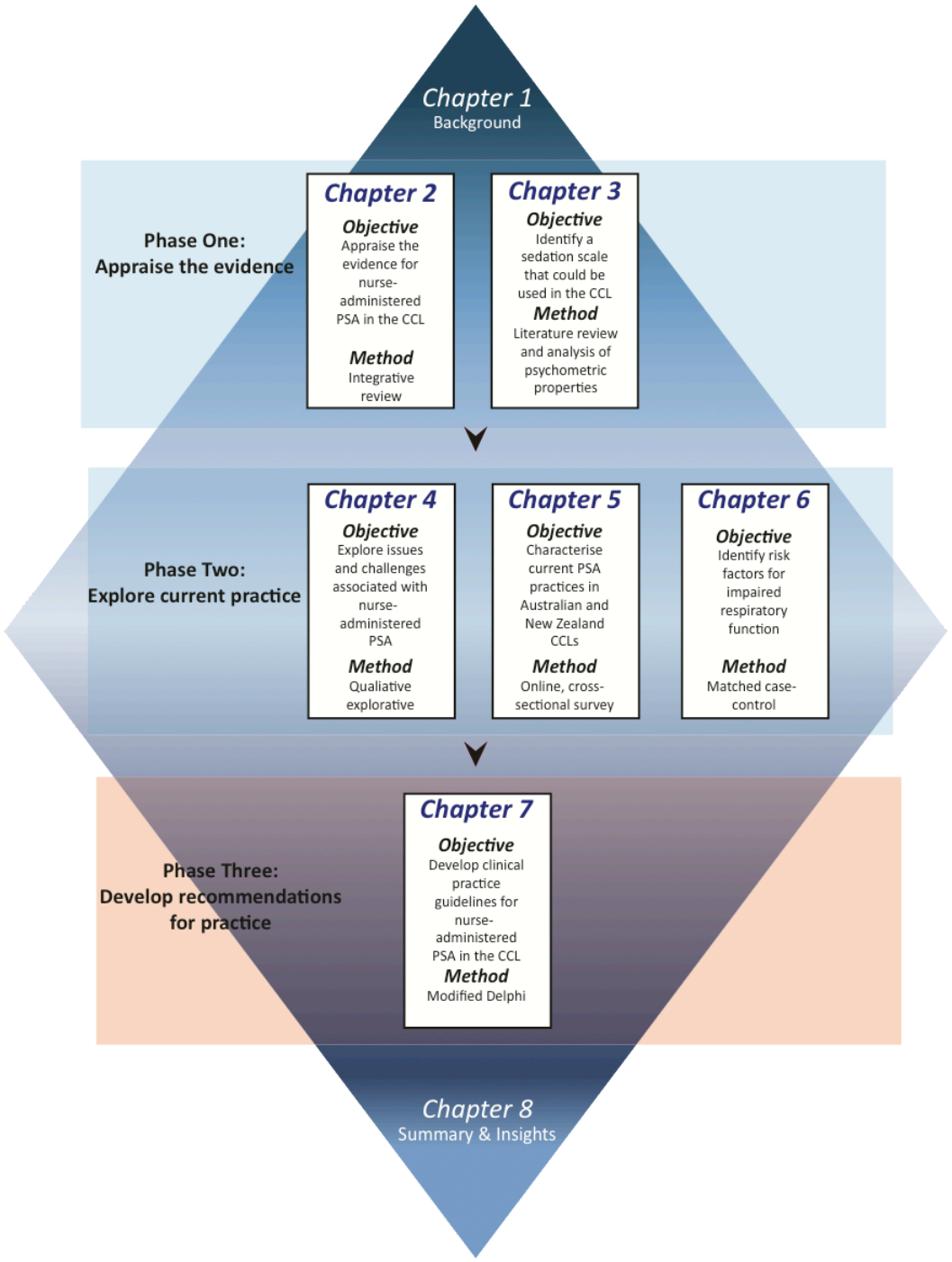
There are limitations, though, that should be considered in the interpretation of results. First of all, although intra-procedural confounders can be controlled using multivariate statistics, a matched case-control design was utilised because the sample size was relatively small. Using a matched case-control design permitted greater power to examine the effect of pre-procedural risk factors than if multivariate statistics were used to control the intra-procedural confounders (Hosmer & Lemeshow, 2000).

Also, the accuracy and consistency of the information about practices and patient data associated with the use of nurse-administered PSA in the CCL could not be checked due to the retrospective nature of the data. Therefore, further prospective studies in this field are recommended, so that a researcher can directly observe impaired respiratory function (Shaver, Weiss, & Braude, 2010).

Conclusion

The objective of this study was to identify pre-procedural demographic and clinical risk factors for impaired respiratory function during nurse-administered PSA in the CCL. We found that patients with acute illness were more likely to experience impaired respiratory function. These results have considerable face validity, as it is probable that patients with acute illness had underlying conditions that impacted on their cardiopulmonary function, which could have triggered impaired respiratory function. Also, the results are consistent with previous research in this field. As such, the results from this study could be used to inform prospective studies investigating the effectiveness of interventions for impaired respiratory function during nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory.

PHASE THREE


Chapter 1
Background
Phase One:
Appraise the evidence
Chapter 2
Objective
Appraise the evidence for nurse-administered PSA in the CCL
Method
Integrative review
Chapter 3
Objective
Identify a sedation scale that could be used in the CCL
Method
Literature review and analysis of psychometric properties
Phase Two:
Explore current practice
Chapter 4
Objective
Explore issues and challenges associated with nurse-administered PSA
Method
Qualiative explorative
Chapter 5
Objective
Characterise current PSA practices in Australian and New Zealand CCLs
Method
Online, cross-sectional survey
Chapter 6
Objective
Identify risk factors for impaired respiratory function
Method
Matched case-control
Phase Three:
Develop recommendations for practice
Chapter 7
Objective
Develop clinical practice guidelines for nurse-administered PSA in the CCL
Method
Modified Delphi
Chapter 8
Summary & Insights

Clinical practice guidelines for nurse-administered procedural sedation and analgesia in Australia and New Zealand cardiac catheterisation laboratories: A modified Delphi study

Aaron Conway, John X Rolley, Karen Page & Paul Fulbrook

Australian Critical Care (Draft Version)

Preamble

The previous chapters presented in this thesis have provided an in-depth exploration of the contemporary issues associated with nurse-administered PSA in the CCL setting by conducting a systematic appraisal of the evidence, qualitative interviews with senior CCL nurses and a cross-sectional survey of practice. It was identified in these studies that a very critical issue facing the discipline is that the existing clinical practice guidelines for the administration of sedation without an anaesthetist present, which are meant to apply regardless of the clinical setting, do not address the unique circumstances in which nurse-administered sedation is currently being used in the CCL setting. In response to this finding, in the final study included within this thesis, a modified Delphi method was used to develop a set of clinical practice guidelines specifically for nurse-administered PSA in the CCL.

Abstract

Background

As part of their role in the cardiac catheterisation laboratory (CCL), nurses administer and monitor procedural sedation and analgesia (PSA) without an anaesthetist present. As such, nurses' decisions regarding how they manage sedated patients have an impact on clinical outcomes. It is therefore important for CCL nurses to have a resource to help them consider which intervention will produce the best possible outcome.

Objective

To formulate consensus-derived, evidence-based recommendations for nursing interventions performed for patients who are sedated during procedures in the CCL.

Design

Sequential mixed methods incorporating a modified Delphi study.

Methods

An initial draft of recommendations was developed through a synthesis of findings from the initial exploratory phase of the project, which consisted of an in-depth literature review, a qualitative study and a national practice survey. This draft was revised over two Delphi rounds, first by a group of senior CCL nurses, then, more broadly by the discipline.

Results

The first survey round was completed by nine participants. All but one of the draft recommendations met the pre-determined cut-off point for inclusion. 42 participants completed the second Delphi survey round. Consensus was reached on 24 recommendations for nursing practice across 6 domains.

Conclusion

The guidelines presented in this paper will aid nurses to apply evidence in their clinical decision-making regarding PSA within the CCL and also provide institutions with a guide as to the resources nurses require to be able to provide safe and effective care to adults undergoing procedures within this setting.

Introduction

As part of their role in the cardiac catheterisation laboratory (CCL), nurses administer and monitor procedural sedation and analgesia (PSA) without an anaesthetist present. As such, nurses' decisions regarding how they manage sedated patients have an impact on clinical outcomes. It is therefore important for CCL nurses to have a resource to help them consider which action will produce the best possible outcome. This project aimed to produce this resource by developing nursing clinical practice guidelines, which in effect, attempt to translate best evidence into practice. It is intended these guidelines will ultimately help registered nurses apply evidence in their clinical decision-making regarding sedation within the CCL and also to provide institutions with a guide as to the resources nurses require to be able to provide safe and effective care to adults undergoing procedures under sedation within this setting.

Background

As stated previously, nurses take on responsibility for PSA in the CCL. Minimal, moderate or deep sedation may be used according to procedural requirements, cardiologist's preferences and patient characteristics including their co-morbidities, level of pain and anxiety, and their sensitivity to sedative medications (Kezerashvili et al., 2008; Natale et al., 1996). The risk of adverse complications becomes greater in the presence of acute comorbidities that are common in cardiac patients and also as the level of sedation is increased (Odom-

Forren & Watson, 2005). Despite recommendations from the Australia and New Zealand College of Anaesthetists that an anaesthetist should be present to administer sedation in these circumstances, evidence suggests that in the CCL setting, nurses are required to administer and monitor PSA in increasingly complex circumstances without an anaesthetist present (ANZCA, 2010; Gaitan et al., 2011; Trentman et al., 2009).

It has been reported that lack of access to anaesthetic services is one factor driving the use of nurse-administered PSA in the CCL (Gaitan et al., 2011). Another factor is the cost-savings associated with forgoing anaesthetic services. Kezerashvili et al (2008) reported that one healthcare institution in the U.S. saved $5,365,691 as a result of not using anaesthetists for routine CCL procedures over a 10-year period. In response to these anaesthetic service access issues, a number of studies have investigated sedation-related complications for deeply sedated CCL patients. In a recent integrative review we conducted on nurse-administered PSA in the CCL, we found that there were higher percentages of patients who experienced respiratory complications in the investigations of deep sedation in the CCL compared with patients who were only moderately sedated (Conway et al., 2011). In spite of this, each author of the deep sedation studies advocated for its safety in the CCL setting (Fox et al., 2007; Natale et al., 1996).

Due to the workforce constraints and economic advantages, along with the safety data that has been reported, it is anticipated that sedation practice in the CCL will continue along its current course with nurses required to practice

beyond the recommendations within clinical guidelines developed by anaesthetists. As such, further consideration of the evidence available to drive safe practice for all forms of PSA that are used by nurses in the CCL is urgently required to ensure optimal patient outcomes. For this reason, the current project was designed to supplement existing guidelines by developing evidence-based recommendations for the unique circumstances in which nurse-administered PSA is currently being used in the CCL setting. Moreover, by producing an easy-to-use reference of the evidence-base behind these interventions, the guidelines aim to help nurses to make informed choices when caring for patients who are sedated in the CCL.

Objective

The objective was to formulate consensus-derived, evidence-based recommendations for nursing interventions that have the potential to maximise outcomes for patients who are sedated during procedures in the CCL.

Methods

Research design

A sequential mixed method design was used to develop the guidelines for nurse-administered PSA in the CCL (Creswell & Plano Clark, 2007). The guiding principles for the development of clinical practice guidelines outlined by the National Health and Medical Research (NHMRC) informed the design of this study (NHMRC, 1998). As such, the project first involved an in-depth exploratory

phase, consisting of a literature review (Conway et al., 2011), a qualitative study of nurses' perceptions of the issues and challenges associated with nurse-administered PSA in the CCL (Conway, Rolley, Fulbrook, & Page, Accepted 24th October 2012) and a survey of nurse-administered PSA practice in Australia and New Zealand CCLs (Conway, Rolley, Page, & Fulbrook, Under Review). This initial phase was followed up with a subsequent phase, consisting of a modified Delphi study. The modified Delphi study was utilised to achieve consensus for recommendations lacking in evidence from patient outcome data. This technique is a valid and reliable method used to achieve consensus (Powell, 2003). The modified Delphi study used in this project consisted of two rounds. Figure 8.1 illustrates the process used to develop the guidelines.

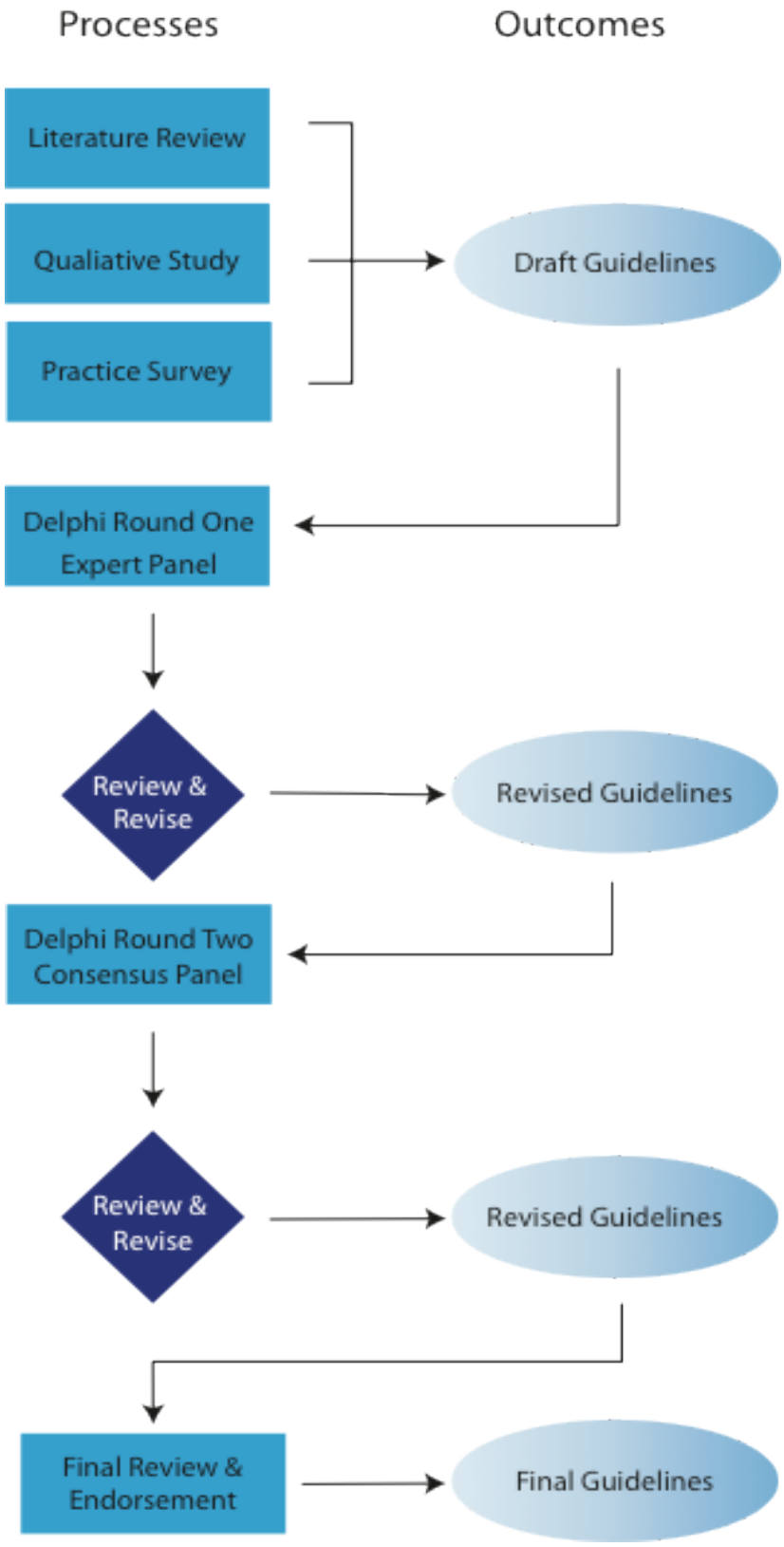


Figure 8.1 Guideline Development Method

Procedure

Phase One - Literature Review, Qualitative Study & Survey

Literature Review

A comprehensive review of research regarding nurse-administered PSA in the CCL and in other clinical areas as well as of related clinical practice guidelines was undertaken in the initial phase of this project. Limitations in the evidence regarding patient monitoring practices and inconsistencies in existent clinical practice guidelines regarding the level of sedation that can be induced without an anaesthetist present were identified (Conway et al., 2011).

Qualitative Study

A qualitative study was undertaken to explore the issues and challenges associated with nurse-administered PSA in the CCL from nurses' perspectives. A total of 23 nurses from 16 CCLs across four states in Australia and also New Zealand participated in the study. While the results of the qualitative study are reported elsewhere (Conway et al., Accepted 24th October 2012), the most critical issue identified was that current guidelines, which are meant to apply regardless of the clinical setting, are not practical for the CCL due to a lack of access to anaesthetists. Furthermore, this study demonstrated that nurses hold concerns about the legitimacy of their practice in situations when they are required to perform tasks outside of clinical practice guidelines.

Survey

A quantitative study, utilising a cross-sectional, descriptive survey design was conducted to characterise current practice as well as education and competency standards regarding nurse-administered PSA in Australian and New Zealand CCLs. A full report of this study is reported elsewhere (Conway et al., Under Review). The survey represented practice at 54% of the estimated total number of CCLs in Australia and New Zealand. While nurse-administered PSA was reported to be used in nearly all CCLs (*n*=58; 94%), clinical practice was found to be diverse. It was identified that sedation-monitoring practices vary considerably between institutions, that only 31% of respondents indicated that comprehensive education about PSA is provided and that only 45% of respondents indicated that nurses who administer PSA must undergo competency assessment.

Phase Two – Modified Delphi Study

A number of issues were identified from a synthesis of findings from the previous phase. The issues included:

1. The administration of deep sedation for defibrillation threshold testing or cardioversion without an anaesthetist or second medical practitioner present.

2. Nurse staffing ratios during nurse-administered PSA.

3. The processes that need to be in place in order to arrange for anaesthetic support in the case that a nurse considers the patient's PSA requirements to fall outside of their scope of practice.

4. The circumstances in which capnography should be used to monitor ventilation during nurse-administered PSA.

5. The routine administration of supplemental oxygen.

6. The need to investigate new medication regimens that have the potential to improve the safety and effectiveness of PSA.

A draft set of guideline recommendations was developed to address these issues. Then, as is recommended for a Delphi study, an expert panel was recruited for the first survey round (Hasson, Keeney, & McKenna, 2000). Previous research indicates the views of a small group with expert knowledge can be representative of a target population (Vella, Goldfrad, Rowan, Bion, & Black, 2000). Also, there are only small improvements in reliability produced with more than 15 participants in a Delphi study (Ayanian, Landrum, Normand, Guadagnoli, & McNeil, 1998). An expression of interest to participate in the expert panel was sent by email to known contacts from the chair of the Australia and New Zealand Interventional Nurses' Council. The following inclusion criteria for the expert panel were applied:

- Currently employed within the CCL setting as either:
- Nurse Unit Manager/Clinical Nurse Manager;
- Clinical nursing educator (or similar role); or

- Senior nurse in terms of clinical practice experience (more than 3 years); and have a
- Special interest in procedural sedation and analgesia in the CCL.

Next, a survey was distributed to the expert panel. It consisted of 6 items for each of the recommendations as well as free text space to allow for suggestions about wording, content and missing recommendations (Table 8.1). The items asked participants to rate their agreement on a 10-point Likert scale. A hierarchy, which was used in a previous cardiovascular nursing clinical practice guideline development process, was used to grade each recommendation. Nursing interventions supported by high-level research evidence were accorded the strongest recommendation, while those without research evidence to support their use in practice were graded according to the level of consensus reached (Table 8.2) (Rolley, Salamonson, Dennison, & Davidson, 2011). Recommendations in the draft of the guidelines were refined through descriptive and content analysis of the survey data.

Table 8.1 Recommendation Assessment Items

Item	Response Type
I agree with this recommendation	10-point Likert
I agree with the grade of this recommendation	10-point Likert
I agree with the level of evidence for this recommendation	10-point Likert
This recommendation is relevant to interventional cardiovascular nursing practice	10-point Likert
Is this recommendation already adopted within your practice setting?	Yes/No
This recommendation could easily be adopted within my practice setting	10-point Likert
If you disagree with the wording of this recommendation, please provide an alternative.	Qualitative response

Table 8.2 Grading system for evidence and recommendations

Level of evidence	Study design	Grade of recommendation	Description
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.	A	Body of evidence can be trusted to guide practice.
II	Evidence obtained from at least one properly designed randomised controlled trial.	B	Body of evidence can be trusted to guide practice in most circumstances.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).	C	Body of evidence provides some support for recommendations but care should be taken in application.
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case—control studies, or interrupted time series with a control group.	D	Evidence is weak and recommendation should be applied with caution. Consensus based on expert opinion only.
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time	N	Consensus was not achieved for this recommendation. Clinicians should follow local policy and procedures.

	series without a parallel control group.	
IV	Evidence obtained from case series, either post-test or pre-test and post-test.	

Following development of a revised set of guidelines, a broader sample of CCL nurses, intended to be more representative of the population, was sought to determine the degree of consensus on the recommendations. As such, for the second Delphi survey round, we broadened the inclusion criteria in order to recruit a larger number of participants (Shaw, Southwood, & McDonagh, 2004). While this is not typical of a Delphi study, we considered that the final recommendations put forward in the guidelines would be more representative of the views of the population if a larger sample were drawn. Moreover, it seemed especially important to maximise the chances that the guidelines were representative of the views of practicing CCL nurses because, due to the limitations in the evidence-base, many of the recommendations had to be made by consensus rather than from patient outcome data.

An expression of interest to participate in a consensus panel was sent by email to known contacts of the chairperson of the Australia and New Zealand Interventional Nurses' Council. In addition, a snowball sampling method was utilised in order to increase the number of participants (Wright & Stein, 2005). The following inclusion criteria for the consensus panel were applied:

- Registered Nurse; and
- Currently practicing in the Cardiac Catheterisation Laboratory.

A similar survey used for the expert panel was distributed to the consensus panel. In this survey, though, there were 24 recommendations. Again, a 10-point Likert scale was used for participants to rate their agreement with each recommendation.

Review

For final validation before endorsement, a further revision of the guidelines was sent for review by an interdisciplinary panel of reviewers consisting of senior cardiovascular nurses, cardiologists, an anaesthetist and a cardiovascular researcher.

Data Analysis

Quantitative data from the surveys were analysed using SPSS v19. Only descriptive statistics (Median and IQR) were used.

Ethical considerations

Ethical approval to conduct this study was received from a university human research ethics committee (HREC Register Number V2011 46). All data collection was anonymous with no identifying information collected. Participation was voluntary and participants were free to withdraw from the study at any time.

Results

Expert panel

An invitation was sent to a panel consisting of 28 senior CCL nurses to participate in refining the draft set of guidelines. Nine with a special interest in this particular topic chose to participate directly in the deliberations about the PSA guidelines. Two participants practiced in New South Wales, two in South Australia, three in Western Australia and two in New Zealand.

There were 27 recommendations submitted to this expert panel for evaluation. Only one of the recommendations scored below the median cut-off score of 7.5 to indicate consensus. For this reason, the recommendation was excluded from the revised set of guidelines. This recommendation related to the need for research into medications other than midazolam and fentanyl for nurse-administered PSA in the CCL (median=7; IQR=2). In light of suggestions from the consensus panel, two further recommendations were combined and minor changes were made to the wording of other recommendations in order to increase clarity. As such, there were 24 recommendations in the revised set of guidelines sent for consideration by the consensus panel.

Consensus panel

An invitation was sent to a panel of 56 CCL nurses. A response was received from 42 nurses (75%). Six (25%) recommendations scored a median of 10, eight (33%) recommendations scored a median of 9 and the remaining 10 (42%)

recommendations scored a median of 8. As such, all 24 of the recommendations reached the pre-determined cut-off point for consensus (Median >7.5).

Discussion

As described above, the modified Delphi study produced a total of 24 recommendations across 6 domains. These recommendations are discussed in relation to the literature below.

Pre-procedural assessment

Suitability for nurse-administered PSA. Some medical conditions have been shown to increase the risk of PSA-related complications (Qadeer et al., 2009; Taylor et al., 2011). Therefore, appropriate patient selection is vital for ensuring a safe PSA encounter. Moreover, it was noted by participants in the qualitative study from Phase One of this project that it was important for processes to be in place to ensure that patients who may not be suitable for nurse-administered PSA are identified at a time that will ensure the procedure does not have to be delayed in order to arrange anaesthetic support. As such, it is recommended that a checklist should be used in the pre-admission clinic setting to screen patients scheduled to undergo procedures without an anaesthetist present. The cardiologist should be alerted and the suitability of nurse-administered PSA considered if patients exhibit the risk factors displayed in Table 8.3.

Recovery. It was identified in the qualitative study, that nurses' perceive patients who receive large doses of sedative and analgesic medications during long

electrophysiology-based procedures require longer periods of close observation in the recovery area (Conway et al., Accepted 24th October 2012). This finding is not supported by patient outcome data. As such, further research is required. Nonetheless, it is recommended by consensus that, in order to ensure adequate staffing is available, the potential for extended duration of sedation recovery should be identified in the pre-admission clinic setting.

Risk for complications. Recent evidence indicates that patient with acute illness are more likely to experience impaired respiratory function during nurse-administered PSA (Conway, Page, Rolley, & Fulbrook, Accepted 16th November 2012). Also, the induction of deep sedation is associated with higher rates of PSA-related respiratory complications compared with moderate sedation (Conway et al., 2011). Therefore, it is recommended that patients should be screened prior to the procedure in order to identify patients at risk of impaired respiratory function so that intensive respiratory monitoring can be applied.

Risk of increased pain and discomfort. High levels of pre-procedural anxiety and pre-existing musculoskeletal injuries contribute to increased pain and discomfort during procedures (Beddoes et al., 2008). Therefore, screening for these conditions is recommended to be part of pre-procedural assessment (Gallagher et al., 2010).

Table 7.3 Pre-procedural assessment

Recommendation	Grade of recommendation
A checklist should be used in the pre-admission clinic setting to screen patients scheduled to undergo EPS, ICD, CRT or Cardioversion without an anaesthetist or second medical practitioner present. The cardiologist should be alerted and the suitability of nurse-administered PSA considered if patients exhibit the following: • BMI>35 • Prior difficulty with sedation/anaesthesia • Substance abuse • Expected length of procedure > 6 hours • Sleep apnoea, undiagnosed but high-risk for sleep apnoea (assessed using Berlin questionnaire) or obesity hypoventilation syndrome (assessed using serum venous bicarbonate) • Significant respiratory disease, SpO2 <94% on room air • Significant renal/hepatic impairment • Low ejection fraction Using the checklist in the pre-admission clinic setting will facilitate the time required to make arrangements for anaesthetic support if deemed required.	D
The potential for extended duration of sedation recovery should be identified in the pre-admission clinic setting in order to facilitate adequate staffing ratios.	D

Risk factors of impaired respiratory function during nurse-administered procedural sedation and analgesia should be screened for prior to the procedure in order to tailor appropriate strategies for intensive respiratory monitoring. • Emergency admission • Transfer from a critical care unit (ICU, CCU, ED) • On haemodynamic support in lead up to the procedure (temporary pacing, IABP, inotropes, anti-arrhythmics, vasodilators) • On respiratory support in lead up to the procedure (supplemental oxygen, bipap) • Potential requirement for deep sedation during defibrillation threshold testing or cardioversion.	C
Risk factors of increased pain and discomfort during the procedure should be identified prior to commencement of the procedure in order to tailor appropriate comfort measures. • Previous muscloskeletal injuries (Beddoes et al., 2008). • High levels of anxiety (Faces Anxiety Scale is a simple tool that can be used to identify high levels of anxiety) (Gallagher et al., 2010).	C

Pre-procedural patient and family education

Previous guidelines have recommended that patients should be provided with information about the risks of sedation and preparation requirements (ANZCA, 2010; Gross et al., 2002). However, a major challenge associated with nurse-administered PSA in the CCL that was noted by nurses in the qualitative study, was the difficulty in managing patients' who experienced a greater degree of pain or discomfort than they anticipated (Conway et al., Accepted 24th October 2012). Therefore, it was recommended by consensus that information about the anticipated degree of pain and discomfort during the procedure should also be provided (Table 7.4). Integrating this patient education into existing pre-procedural information that is already routinely provided would be the most optimal method of delivering this education (Astley et al., 2008).

Table 7.4 Pre-procedural patient and family education

Recommendation	Grade of recommendation
Information should be made available to patients and their families, which clearly outlines the proposed method of sedation and analgesia. If the proposed method is nurse-administered procedural sedation and analgesia rather than a general anaesthetic, a clear description of the anticipated degree of pain and discomfort associated with the procedure	D

should be provided and consent signifying the patient's understanding and willingness to undergo the procedure with this mode of sedation.	

Pre-procedural patient comfort

In the most recent and largest randomised controlled trial, patients who received premedication for cardiac catheterisation were not, as anticipated, less anxious than the control group (Woodhead, Harding, Simmonds, Dee, & McBride-Henry, 2007). As there is limited evidence for administration of oral benzodiazepines to reduce anxiety, it is recommended pre-medication is used on a patient-specific basis only (Table 7.5).

Table 7.5 Pre-procedural patient comfort

Recommendation	Grade of recommendation
The use of pre-procedural sedation with oral medications should be administered on a patient-specific basis only (Woodhead et al., 2007).	B

Intra-procedural patient comfort

Medications for PSA. Serious adverse events associated with the administration of midazolam and fentanyl for nurse-administered PSA in the CCL are rare (Kezerashvili et al., 2008). As such, a combination of midazolam and fentanyl is recommended to be used for nurse-administered PSA in the CCL. It's important to note though, that other sedative and analgesic agents, such as propofol, dexmedetomidine, ketamine and remifentanil, have several desirable properties including a rapid onset of action and short half-life (Behan et al., 2008; Hayman, Forrest, & Kam, 2012; Mandel, Hutchinson, & Marchlinski, 2011). Also, evidence demonstrating their safety in the CCL setting is emerging (Kottkamp et al., 2011; Tang et al., 2007; Wutzler et al., 2012). However, more evidence is required in order to explicate the type of patients that are suitable, the degree of patient monitoring that is required and specific education, training and accreditation requirements (de Bono, 2012; Hummel & Awad, 2011). Therefore, the use of these agents for nurse-administered sedation in the CCL is not recommended for clinical practice (Table 7.6).

Complementary therapies. Investigations into the use of complementary therapies, such as music therapy, have found these interventions were simple to apply in practice, did not disrupt procedures and induced relaxation during cardiac procedures (Nilsson, Lindell, Eriksson, & Kellerth, 2009; Norgaard et al., In press). Therefore, it is recommended these therapies should be offered to patients.

Table 7.6 Intra-procedural patient comfort

Recommendation	Grade of recommendation
The proceduralist may prescribe a combination of benzodiazepines and opioids for a registered nurse to administer intravenously, either pre-emptively for procedures known to induce a considerable degree of pain and discomfort, or in response to either patient self-report, or clinical signs of anxiety, pain and discomfort associated with the procedure. The proceduralist must be present when sedation is administered by the registered nurse.	B
Other sedative and analgesic agents, such as propofol, dexmedetomidine, ketamine and remifentanil, have several desirable properties over the opioid and benzodiazepine combination that is most commonly used for PSA including rapid onset of action and short half-life. Also, evidence demonstrating their safety is emerging. However, more evidence is required in order to explicate the type of patients that are suitable, the degree of patient monitoring that is required and specific education, training and accreditation requirements. Therefore, the use of these agents for nurse-administered sedation in the CCL is not recommeded outside of the research setting.	C

Complementary therapies, such as music therapy, should be offered for patients who choose to utilise this relaxation technique to reduce anxiety during procedures in the CCL.	B

Intra-procedural patient assessment and monitoring

Supplemental oxygen. It is widely recognised, and already recommended in previous clinical guidelines for PSA without an anaesthetist, that supplemental oxygen should be used because it reduces the occurrence of hypoxia secondary to respiratory depression (ANZCA, 2010). Therefore, it is recommended that nurses apply supplemental oxygen to all patients who receive nurse-administered PSA in the CCL (Table 7.7).

Pulmonary ventilation and oxygenation. Sedative and analgesic medications can depress respiratory drive, resulting in reduced tidal volume, reduced respiratory rate and periods of apnoea (Malamed, 2003). Also, a common side effect of PSA is relaxation and consequent displacement of the pharyngeal musculature leading to partial obstruction of the airway (Odom-Forren & Watson, 2005). These side effects can lead to inadequate ventilation and oxygenation if corrective interventions are not applied promptly. Therefore, it is recommended that nurses continuously monitor pulmonary ventilation and oxygenation of sedated patients with pulse oximetry and clinical observation of respiration. In addition, capnography should be used to monitor patients who are more likely to experience respiratory depression. Such patients include those undergoing defibrillation threshold testing, cardioversion, long electrophysiology-based

procedures and also those receiving continuous infusions of sedative and analgesic medications (Waugh et al., 2011).

Cardiovascular function. It is recommended that nurses utilise an ECG to monitor heart rate and rhythm and either invasive or non-invasive blood pressure monitoring during PSA (ANZCA, 2010; Gross et al., 2002). Furthermore, while impaired cardiovascular function related to nurse-administered PSA in the CCL is rare, evidence suggests corrective interventions such as intravenous fluid bolus and administration of sedation reversal medications are effective treatments (Geiger et al., 1997; Pachulski et al., 2001). As such, it is recommended that nurses promptly report to the proceduralist any indication of compromise in cardiac function.

Goal of PSA. In order to facilitate optimal titration of PSA, it is recommended that nurses report any signs of pain, discomfort, anxiety and agitation as well as any unintended depression in level of consciousness to the proceduralist.

Monitoring during deep sedation. While moderate sedation is targeted for the majority of procedures, a transient increase in the level of sedation is required for defibrillation threshold testing (DTT) and cardioversion, as these are particularly painful and distressing aspects of procedures (Timperley et al., 2008). In the survey of nurse-administered PSA practice in Australian and New Zealand CCLs that was conducted as part of this project, it was identified that 20% of CCLs do utilise nurse-administered PSA for defibrillation threshold testing and cardioversion (Conway et al., Under Review). Also, previous research has

demonstrated the safety of nurse-administered PSA for DTT and cardioversion (Natale et al., 1996). As such, it is recommended nurse-administered PSA can be used.

However, as there is a more pronounced impact on respiratory physiology at the level of deep sedation, it is recommended that capnography should be used (Waugh et al., 2011). In addition, nurses should increase the frequency of their assessment and documentation of the adequacy of cardiac and respiratory function. Also, any indication of compromise in respiratory or cardiac function should be promptly reported to the proceduralist and corrective interventions implemented immediately.

Staffing. Nurse staffing for procedures performed with nurse-administered PSA in the CCL differs between institutions (Conway et al., Under Review). Furthermore, In the previous phases of this project, it was identified that nurses generally deemed that one scout nurse was suitable for diagnostic and interventional coronary and vascular procedures, yet they noted that excluding a sedated patient from their direct vision in order to gather equipment was not optimal during electrophysiology-based procedures. The reason noted was that usually higher doses of PSA medications were used (Conway et al., Accepted 24th October 2012). It's important to note though, that research has not yet been undertaken to compare the effectiveness of different staffing ratios for nurse-administered PSA in the CCL on either patient outcomes, or on costs. As such, further research is required. Nonetheless, it was recommended by

consensus that if nurses-administered PSA is to be used for an electrophysiology-based procedure, two scout nurses should be allocated.

Anaesthetic service support. In the qualitative study, it was identified that, due to the unpredictable nature of the effects of PSA on cardiac and respiratory function, situations arise where the patient requires more specialised care than can be supplied by a registered nurse (Conway et al., In press). This finding is supported by a study of PSA during electrophysiology-based procedures, where the investigators found that PSA needed to be converted to a general anaesthetic in 11% of cases (Trentman et al., 2009). Therefore, it is recommended by consensus, that each institution should establish a system that facilitates support from an anaesthetic service for situations that the nurse deems the administration or monitoring of PSA fall outside their scope of practice, even if this means the procedure must be delayed or abandoned.

Table 7.7 PSA administration and monitoring

Recommendation	Grade of recommendation
Nurses should administer supplemental oxygen for all patients who receive intravenous sedative and analgesic medications.	B
If sedation and analgesia is administered, nurses should continuously monitor pulmonary ventilation and oxygenation using pulse oximetry combined with clinical observation of respiration in order to detect potential complications including: -Hyponpoeic hyopventilation (reduced tidal volume) -Bradypnoea (reduced respiratory rate) -Apnoea (absence of respiration) -Partial airway obstruction Adequacy of ventilation and oxygenation should be recorded before and after sedative and analgesic titration and at least every 10 minutes by documenting the oxygen saturation value and respiratory rate. Any indication of respiratory compromise needs to be promptly reported to the proceduralist and corrective interventions implemented immediately.	D

Corrective interventions for impaired respiratory function may include repeated physical stimulation, airway realignment or placement of airway adjuncts, increasing supplemental oxygen or administration of sedation-reversal medications.	
Capnography should be used in addition to pulse oximetry and clinical observation of respiration for all patients at higher risk of impaired respiratory function during procedural sedation and analgesia. Risk factors for impaired respiratory function include: 1. Deep sedation for cardioversion or defibrillation threshold testing. 2. Electrophysiology procedures with prolonged duration. 3. For any procedures during which continuous infusions of sedative or analgesic medications are administered Adequacy of ventilation and oxygenation when capnography is being used should be recorded by documenting the oxygen saturation value, respiratory rate, characteristics of the capnographic waveform and end-tidal carbon dioxide value.	D

Nurses should monitor cardiovascular function using invasive or non-invasive blood pressure measurement and an ECG to monitor heart rate and rhythm in order to detect potential complications related to sedation including hypotension and bradycardia. Any indication of compromise in cardiac function needs to be promptly reported to the proceduralist and corrective interventions implemented immediately. Corrective interventions for impaired cardiac function related to sedation may include intravenous fluid bolus or administration of sedation-reversal medications. Adequacy of cardiovascular function should be recorded before and after sedative and analgesic titration and at least every 10 minutes by documenting the blood pressure, heart rate and heart rhythm.	D
The goal for nurse-administered procedural sedation and analgesia in the CCL should be for the patient to retain the ability to respond to verbal stimulation and maintain normal cardiopulmonary function while providing as much comfort as possible.	D

Nurses should report any signs of pain, discomfort, anxiety and agitation to the proceduralist in order to facilitate titration of sedation and analgesia. While patients can self-report feelings of distress, nurses should also monitor for clinical signs of pain, discomfort, anxiety and agitation, as well as the effectiveness of sedation and analgesia in reducing or alleviating these distressing experiences. **Clinical signs of pain/discomfort/anxiety include:** -Increasing heart rate and blood pressure -Frequent readjustment of body position -Facial grimacing -Groaning **Clinical signs of agitation include:** -Uncontrolled leg movements -Reaching for groin or oxygen mask	D

Nurses should regularly monitor level of consciousness during procedural sedation and analgesia. The level of consciousness should be documented before and after sedative and analgesic titration as well as at least every 10 minutes. Consciousness should be assessed by determining the degree of stimulation required to elicit a PURPOSEFUL response. The stimulation should begin as verbal, then progress to increasing levels of physical stimulation. Careful attention should be focused on distinguishing reflex withdrawal from a "purposeful" response to stimulation, such as the ability to follow simple commands (eg. establishing eye contact or responding with comprehensible words) If there is an unintended further depression in the level of consciousness, such that the patient does not respond to verbal stimulation, nurses should first implement a simple corrective intervention, such as repeated physical stimulation. Also, it is essential that the depressed level of consciousness is reported to the proceduralist so that further doses of sedative and analgesic medications can be witheld or infusions of sedative medications can be discontinued until such a time that the patient responds purposefully to verbal stimulation.	D

Scales can be used to assess level of consciousness during sedation (Observer's assessment of alertness/sedation OAA/S).	D
At the cardiologist's discretion, a purposeful increase in the level of sedation, to the point that the patient does not respond to verbal stimulation, may be used to facilitate defibrillation threshold testing and cardioversion.	C
In the case that nurse-administered procedural sedation and analgesia is used for defibrillation threshold testing or cardioversion, nurses should use capnography to monitor ventilation and increase the frequency of their assessment and documentation of the adequacy of cardiac and respiratory function. Any indication that cardiac or respiratory compromise has occurred should be promptly reported to the proceduralist and corrective interventions implemented immediately. After defibrillation threshold testing or cardioversion, level of consciousness and adequacy of cardiac and respiratory function needs to be monitored continuously until the patient is responsive to verbal stimulation. If the patient remains unresponsive to verbal stimulation, nurses should	D

first implement a simple corrective intervention, such as repeated physical stimulation. Also, it is essential that the prolonged depressed level of consciousness is reported to the proceduralist so that further doses of sedative and analgesic medications can be withheld or infusions of sedative medications can be discontinued until such a time that the patient responds purposefully to verbal stimulation. In the case that the patient remains unresponsive to verbal stimulation, airway adjuncts can be used in order to protect the patient's airway and administration of sedation-reversal medications may be required.	
For diagnostic and interventional coronary and vascular procedures, the registered nurse can be responsible for duties other than sedation administration and monitoring provided there is another registered nurse or cardiac technician/physiologist allocated to the procedure who is performing the advanced cardiac monitoring role.	D

For electrophysiology procedures (including pacing, ICD, CRT, EPS, Ablation), renal denervation procedures and structural heart procedures during which nurse-administered procedural sedation and analgesia is intended to be used, two registered nurses need to be allocated to the case. The primary duty of at least one of the registered nurses is to administer and monitor sedation and implement any interventions required to support or restore respiratory or cardiac function, while the other can be responsible for other duties.	D
Systems should be in place so that if at any time before or during the procedure the nurse considers the patient's procedural sedation and analgesia requirements to fall outside of their scope of practice, support from an anaesthetist must be arranged, even if this means the procedure must be delayed or abandoned.	D

Post-procedural patient assessment and monitoring

To prevent post-procedural complications related to PSA, patients require close, specialised monitoring by a nurse either in the procedural area, or in another appropriately staffed recovery unit, for a period of time after the procedure has finished (ANZCA, 2010; Gross et al., 2002). It is recommended that patients remain monitored until they are oriented, are able to move all limbs on command, are able to maintain a normal oxygen saturation level without oxygen supplementation and also until their vital signs have returned to baseline level (Table 7.8) (ANZCA, 2010; Gross et al., 2002). A standardised approach to determining suitability for discharge from the recovery area can be achieved with the use of a validated sedation recovery score (Aldrete & Kroulik, 1970).

Table 7.8 Post-procedural patient assessment and monitoring

Recommendation	Grade of recommendation
Patients who receive nurse-administered procedural sedation and analgesia are to remain in the procedural area or another clinical area where close, specialised monitoring of the patient's sedation status can be provided until the patient is oriented, able to move all limbs on command, is able to maintain their oxygen saturations without oxygen supplementation and vital signs have either returned to	D

baseline or are within acceptable limits.	
A validated standardised assessment tool, such as the Post Anaesthetic Recovery Score (PARS), should be used to document the patient's progress to recovery from sedation at regular intervals and prior to being discharged from the clinical area in which they are being recovered.	C

Strengths and Limitations

The guidelines presented in this paper were developed from evidence in the literature and also from expert opinion, which is the process typically used to develop guidelines in healthcare (NHMRC, 1998; Shekelle, Woolf, Eccles, & Grimshaw, 1999). However, to ensure the recommendations were applicable to current clinical practice, we also incorporated a qualitative study, a quantitative survey of practice and a modified Delphi study. By undertaking an in-depth, exploratory phase, which consisted of the literature review, qualitative study and quantitative survey, several aspects of practice that could not be appreciated from the existent literature or previous guidelines were identified. Therefore, many of the recommendations put forward in the guidelines we developed have not been articulated previously (ANZCA, 2010). As such, this document provides important new information for CCL nurses to consider in their provision of patient care. Similarly, there is important new information for institutions to

consider regarding the facilities, equipment and support that they should make available for their nurses.

It's important to note, though, that the recommendations based on consensus need to be interpreted with caution (Tricoci, Allen, Kramer, Califf, & Smith, 2009). Moreover, further research is needed for their justification. Accordingly, revisions to the guidelines will be necessary as new evidence arises to inform practice. Also, implementation projects will be required for evaluation of the effectiveness of the guidelines in improving patient and health service outcomes (Grimshaw, Eccles, & Russell, 1995).

Conclusion

The existent clinical practice guidelines for the administration of PSA without an anaesthetist present, which are meant to apply regardless of the clinical setting, do not address the unique circumstances in which nurse-administered PSA is currently used in the CCL setting. The guidelines presented in this paper were developed in light of the existent literature and guidelines, yet were also informed by a comprehensive exploration of the issues specifically related to the administration and monitoring of PSA in the CCL setting. As such, they will aid registered nurses to apply evidence in their clinical decision-making regarding PSA within the CCL and also to provide institutions with a guide as to the resources nurses require to be able to provide safe and effective care to adults undergoing procedures within this setting.

CHAPTER EIGHT

Summary and insights

Overview

This chapter synthesises the findings of the proceeding six chapters by highlighting the original contributions to the knowledge base from the program of research. Key findings from each of the studies will be summarised and recommendations for future research proposed. The overall aim of the program of research was to establish an evidence base for nurse-led sedation practices in the CCL context. The diagram of the thesis structure presented in Chapter One is repeated below to demonstrate how each of the studies undertaken as part of the doctoral program of research contributed to the thesis as a whole (Figure 8.1).

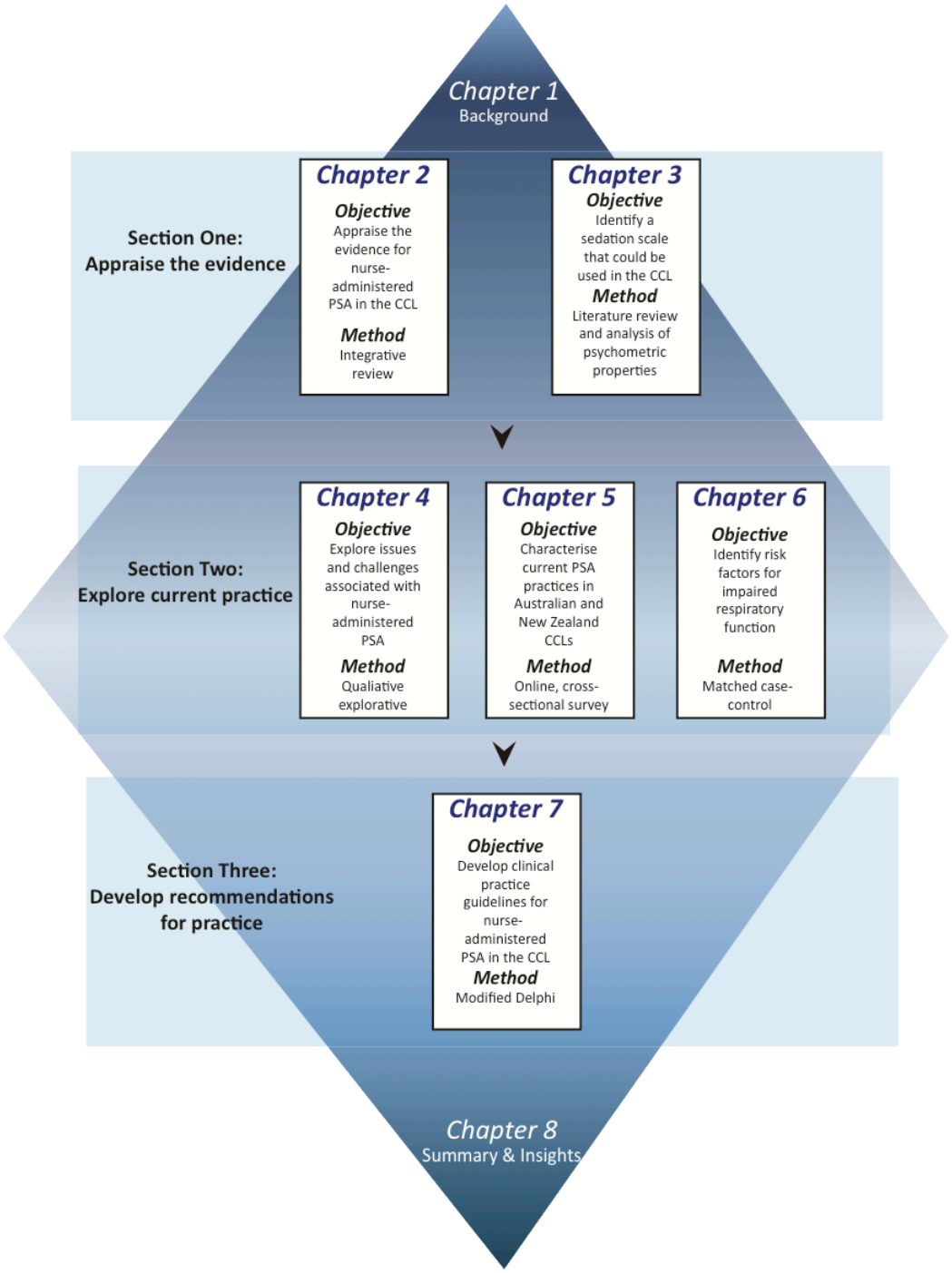


Figure 8.1 Thesis Structure

Contribution to new knowledge

In summarising the research objectives and key findings of the individual studies Table 8.1 highlights the significant and original contributions to the body of knowledge regarding nurse-administered PSA in the CCL setting that have been derived from this thesis.

Table 8.1 Summary of new knowledge

Research Objective	Chapter	Key Findings
Appraise the existing evidence	2	• Evidence indicates that nurse-administered PSA in the CCL is safe • Respiratory complications range 2.4-9.4% • Deep sedation associated with higher frequency of complications • Management of PSA in the CCL is varied and only somewhat informed by the existent clinical practice guidelines
	3	• New scale is needed because psychometric testing of existent scales is deficient
Explore current practice	4	• New guidelines needed which incorporate the unique aspects of nurse-administered PSA in the CCL setting • Several challenges identified that impact on nurses' ability to monitor for adverse effects of PSA
	5	• Nurse-administered PSA is used in almost all CCLs in Australia and New Zealand • Protocols for patient monitoring have not been developed in many CCLs • Education for nurses about PSA is not comprehensive in most CCLs and is not provided at all in many others
	6	• Patients with acute illness are nearly two times more likely to experience impaired respiratory function during PSA
Develop recommendations for practice	7	• A set of clinical practice guidelines were developed which include 24 recommendations for practice covering pre, intra and post-procedural domains

Research Objective 1 – Appraise the existing evidence

As displayed in Figure 8.1, this research objective was addressed in Phase One of the thesis, in Chapter 2 and Chapter 3. The study presented in Chapter 2 was the first review to systematically appraise the available evidence supporting the use of nurse-administered PSA in the CCL. A major finding was that, overall, nurse-administered PSA in the CCL was generally deemed to be safe. However, it was concluded from the analysis of the studies and the guidelines that were included in the review, that there were deficiencies in the evidence base precluding the formation of clear recommendations for practice. Also, the management of sedation in the CCL was impacted by a variety of contextual factors including local hospital policy, workforce constraints and cardiologists' preferences for the type of sedation used. As a result, sedation practice in the CCL was varied and only somewhat informed by the existent clinical practice guidelines.

In addition to comprehensively reviewing the literature on sedation, which was specific to the CCL setting, studies focused on nurse-administered PSA that had been conducted in other clinical settings were also extensively reviewed in order to identify evidence-based practices that were applicable to the CCL setting. A key finding from research on sedation in other clinical areas was that sedation scales were frequently utilised to track the patient's level of sedation over time. Moreover, this standardised assessment of level of sedation has actually led to improved clinical outcomes in ICU patients. For this reason, It was hypothesised that sedation scales could also facilitate effective titration of PSA in the CCL

setting and potentially also improve outcomes for patients. A sedation scale that is suitable for use in the CCL needs to be identified.

Therefore, the manuscript presented in Chapter 3 focused on identifying potential sedation scales that could be used in the CCL and appraising their psychometric properties in order to determine their suitability for application to clinical practice. Only one scale was found that was developed specifically for the CCL, the NASPE SED scale (Bubien et al., 1998). Unfortunately, this scale had not undergone psychometric testing and several weaknesses were identified in its item structure. Other identified sedation scales were developed for the ICU. While these scales have demonstrated validity and reliability in the ICU, weaknesses in their item structure preclude their use in the CCL (De Jonghe et al., 2003; Ramsay et al., 1974; Sessler et al., 2002). It was not within the scope of this research program to develop and test a sedation scale, however recommendations for the development and psychometric testing of a new sedation scale were presented.

Research Objective 2 - Explore current practice

Building on the findings of the literature review presented in Chapter 2, this research objective was addressed in Phase Two of the thesis, in Chapter 4, Chapter 5 and Chapter 6. In the literature review presented in Chapter 2, it was identified that the majority of research undertaken on the topic of nurse-administered PSA in the CCL had focused on ascertaining the safety of this practice by determining the rate of serious adverse events and sedation-related

respiratory complications. While this research provides the discipline with reassurance that serious adverse events related to sedation are unlikely to occur, it provided little insight into the specific issues and challenges that nurses faced on a daily basis in order to consistently deliver these optimal outcomes for patients.

The qualitative study presented in chapter 4 was undertaken to explore these issues and challenges. A total of 23 nurses from 16 CCLs across four states in Australia and also New Zealand participated in the study. Semi-structured interviews were used and data were analysed using thematic analysis.

Major themes emerged from analysis regarding the lack of access to anaesthetists, the limitations of sedative medications, the barriers to effective patient monitoring and the impact that the increasing complexity of procedures had on patients' sedation requirements. The most critical issue identified in the study was that current guidelines, which are meant to apply regardless of the clinical setting, are not practical for the CCL due to a lack of access to anaesthetists. Furthermore, this study demonstrated that nurses held concerns about the legitimacy of their practice in situations when they were required to perform tasks outside of clinical practice guidelines. In order to address nurses' concerns, it was proposed that new guidelines should be developed, which address the unique circumstances in which sedation is used in the CCL.

Also, several recommendations with the potential to improve clinical practice were proposed. First, the findings emphasised that CCL nurses should possess

advanced knowledge and skills in monitoring for the adverse effects of sedation. Second, it was identified that it was often difficult for CCL nurses to observe respiration due to environmental barriers. Therefore it was suggested that consideration should be given to the use of capnography in such situations. Third, findings indicated that a team-based approach was predominantly used to monitor patients. Although participants agreed this was suitable for coronary procedures, concerns were expressed about the adequacy of this model for electrophysiology-based procedures. Thus, regarding the latter procedure, it was suggested that consideration should be given to the allocation of two 'scout' nurses. Finally, the findings highlighted the importance of ensuring patients are aware that although sedative and analgesic medications will be administered, it is likely they will remain awake during the procedure. And, while all efforts will be made to ensure pain relief is provided, some aspects may be uncomfortable.

While anecdotal evidence suggested that nurse-administered PSA was frequently utilised in CCLs, the study presented in Chapter 5 was the first to quantify the frequency with which it was actually used and characterise associated nursing practices. A cross-sectional, descriptive survey design was used to characterise current practice as well as education and competency standards regarding nurse-administered PSA in Australian and New Zealand CCLs.

A sample of 62 nurses, each from a different CCL, completed the questionnaire that focused on PSA practice. Thus, the survey represented practice at a majority (54%) of the estimated total number of CCLs in Australia and New Zealand.

Nurse-administered PSA was reported to be used in 94% (*n*=58) of respondents CCLs. Importantly, by characterising nurse-administered PSA in Australian and New Zealand CCLs, several strategies to improve practice were also identified. Areas of particular importance to improve included setting up protocols for patient monitoring and establishing comprehensive PSA education for CCL nurses in Australia and New Zealand.

In Chapter 2, it was identified that PSA-related respiratory complications occurred in 2.4 to 9.4% of patients who receive nurse-administered PSA in the CCL. Increasing understanding of the conditions that are related or contribute to the onset of impaired respiratory function would be likely to aid nurses identification of at-risk patients that would benefit from close observation. Two factors had already been identified in previous research. These factors included induction of deep sedation during defibrillation threshold testing and cardioversion, and administration of propofol. However, demographic and clinical risk factors for impaired respiratory function that are apparent prior to commencement of the procedure had not been identified in previous research. Therefore, a matched case-control study was conducted to identify pre-procedural risk factors for impaired respiratory function during nurse-administered PSA in the CCL. This study was presented in chapter 6.

Results indicated that patient with acute illness were nearly two times more likely to experience impaired respiratory function. Further, four clinical indicators can easily be assessed to identify the patients with acute illness, who are at increased risk. These include: 1) Emergency admission; 2) Transfer from a critical

care unit for the procedure; 3) Requiring respiratory support prior to the procedure; and 4) Requiring haemodynamic support prior to the procedure.

These significant findings can now be used to inform prospective studies investigating the effectiveness of interventions for impaired respiratory function during nurse-administered PSA in the CCL.

Research Objective 3 – Develop recommendations for practice

This research objective was addressed in Phase Three of the thesis, in Chapter 7. The previous phases of the program of research identified that the existent clinical practice guidelines for the administration of PSA without an anaesthetist present, which are meant to apply regardless of the clinical setting, do not address the unique circumstances in which nurse-administered PSA was being used in the CCL setting. To address this problem, a modified Delphi study was conducted to develop a set of clinical practice guidelines specifically for nurse-administered PSA in the CCL. First, the information from previous studies in the program of research was used to inform the initial phase of the Delphi study. A draft set of recommendations was developed from a synthesis of findings from the literature review, qualitative study and practice survey, which were presented in Chapters 2, 4 and 5 respectively. This was then sent for consideration by an expert panel consisting of nine members. As such, the guidelines were developed in light of the existing literature and guidelines, as well as rigorous research evidence from this program of research.

The initial 27 recommendations were refined down to 24. A further 42 nurses completed the second Delphi round. Each of the 24 recommendations met the pre-determined cut-off point for consensus. A consensus process was used to derive recommendations in areas where there was little to no evidence available to inform practice. It is anticipated that the guidelines produced from this Delphi study will support registered nurses to apply evidence in their clinical decision-making regarding PSA within the CCL.

Recommendations for research

Throughout the manuscripts presented within this thesis, several areas that would benefit from further research have been identified. These are summarised below:

1. Validity and reliability testing of a new sedation scale for the CCL.
2. Identification of predictors for prolonged length of recovery time.
3. Identification of predictors for paradoxical excitation.
4. Clinical trials of novel PSA medications for electrophysiology-based procedures, such as propofol, dexmedetomidine, ketamine and propofol.
5. Clinical trial comparing pre-procedural oral benzodiazepine with intra-procedural intravenous sedation and analgesia.
6. Evaluation of the benefits and costs of allocating two scout nurses to electrophysiology-based procedures.
7. Evaluation of the added benefit of using capnography to monitor respiration.

8. Clinical trial to evaluate the effectiveness of patient education about PSA.
9. Development of an audit tool to evaluate implementation of guidelines.
10. Evaluation of the impact that implementation of the guidelines that were developed as part of this doctoral program of research have on patient outcomes.

Figure 8.1 provides a graphical representation of how these research studies link up with their intended outcomes, thereby explaining the mechanism by which they could improve nurse-administered PSA in the CCL. Furthermore, as displayed in the diagram, it is anticipated that these studies could be performed either in isolation as discrete projects or grouped together into programs of research.

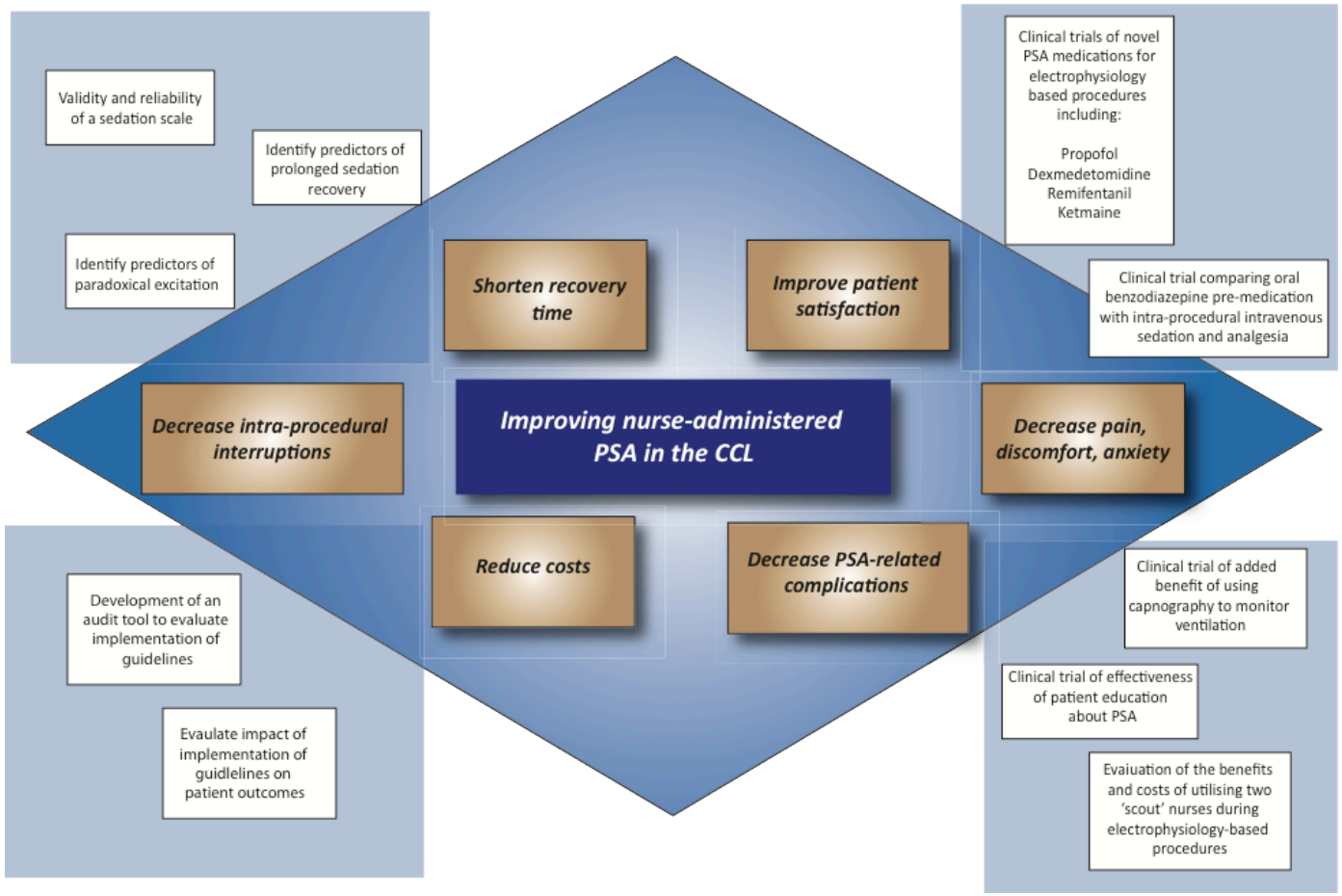


Figure 8.1 Recommendations for research

Conclusion

The overall aim of the program of research was to establish an evidence base for nurse-led sedation practice in the CCL context. This aim was achieved by systematically appraising the existing evidence, broadly exploring current practice patterns as well contemporary issues and challenges faced by CCL nurses who use PSA and then synthesising this information in order to develop recommendations for practice.

Furthermore, it is important to note that the mixed methods approach clearly enabled the research objectives to be comprehensively addressed in an informed sequential manner. Through this process, the thesis has generated a substantial amount of new knowledge to inform and support nurse-led sedation practice in the CCL context. The notable example of the effectiveness of the sequential mixed methods design was that by undertaking several initial in-depth exploratory research studies, several issues that could not be appreciated from the existent literature were able to be identified and then considered further in subsequent phases of the program of research. Consequently, many of the recommendations put forward in the guidelines had not been articulated previously. In addition, the sequential mixed methods approach enabled the guidelines to address issues unique to nursing practice in the CCL context. As such, the research presented in this thesis not only provided vital new information for CCL nurses to consider in their provision of patient care, yet also simultaneously produced a set of clinical practice guidelines that are readily

applicable to the clinical setting, thereby increasing the prospect of implementation. The guidelines, as a result, outline best practice standards for the pre-procedural patient assessment and risk screening practices as well as the intra and post-procedural patient monitoring practices that nurses who administer PSA in the CCL should undertake in order to deliver safe, evidence-based and consistent care to the many patients who undergo procedures in this setting.

The main limitation of the research to note is that the comprehensive appraisal of the evidence conducted, combined with the guideline development process, highlighted that there were numerous deficiencies in the evidence base regarding nurse-administered PSA in the CCL. As such, rather than being based on high-level evidence, many of the recommendations for practice were produced by consensus. For this reason, further research is required in order to ascertain which specific practices result in the most optimal patient and health service outcomes. Therefore, along with necessary guideline implementation and evaluation projects, post-doctoral research is planned to follow up on the research gaps identified, which are planned to form part of a continuing program of research in this field.

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Mr Aaron Conway
Nursing Research
The Prince Charles Hospital

Human Research Ethics Committee
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Administration Building, Lower Ground
Rode Road, Chermside QLD 4032
Executive Officer Research & Ethics Ph: **(07) 3139 4500**
Office Ph: **(07) 3139 4691**
Our Ref: **PL/JL/ Low Risk Approval**

12 March 2012

Dear Mr Conway,

Re: HREC/12/QPCH/34: Restrospective medical record audit of nurses' monitoring and management of patients who receive cardiologist-directed, nurse-administered procedural sedation and analgesia in the cardiac catheterisation laboratory. A.Conway

I am pleased to advise that The Prince Charles Hospital Human Research Ethics Committee reviewed your submission and upon recommendation, the Chair has granted final approval for your low risk project.

I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved include:

Document	Version	Date
Low Risk Application		
Low Risk Site Specific Assessment		
Protocol	1	22 February 2012

Approval of this project is subject to the same confidentiality and privacy requirements as apply to other research projects and research subjects are not recognisable in publications or oral presentations.

Please complete the Commencement Form before starting your study and return to the office of the Human Research Ethics Committee. http://www.health.qld.gov.au/tpch/documents/form_notification.dot

If you intend to publish the results of your work, it is advisable to ascertain from prospective journal editor/s the actual requirements for publication e.g. some journals may require full ethical review of all studies. When results are published, appropriate acknowledgment of the hospital should be included in the article. Please forward copies of all publications resulting from the study for inclusion in the Internet website list.

On behalf of the Human Research Ethics Committee, I would like to wish you every success with your research endeavour.

Yours truly,

Dr Russell Denman
Chair
HUMAN RESEARCH ETHICS COMMITTEE
METRO NORTH HEALTH SERVICE DISTRICT

UnitingCare Health

Human Research Ethics Committee

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Document Submission and Approval Form

Please quote our reference: 2011.14.36

Correspondence: from Aaron Conway dated 24th June 2011

Study Title: *Strengthening cardiac catheter laboratory nurses' leading role in procedural sedation and analgesia*

Investigator: Aaron Conway

Details of documents reviewed:

- Application to conduct abovenamed research
- Sedation Chart Review Version 3

The document/s listed above were received, reviewed and approved.

Douglas Killer MBBS FRACP
Executive Officer

24th June 2011

Human Research Ethics Committee
Committee Approval Form

Principal Investigator/Supervisor: John Rolley Melbourne Campus

Co-Investigators: Melbourne Campus

Student Researcher: Aaron Conway Melbourne Campus

Ethics approval has been granted for the following project:
Delivering best practice nursing in the cardiac catheterisation laboratory environment through the development of practice standards, competencies and nursing clinical practice guidelines

for the period: 24/08/2011-31/03/2012

Human Research Ethics Committee (HREC) Register Number: V2011 46

Special Condition/s of Approval
Prior to commencement of your research, the following permissions are required to be submitted to the ACU HREC:

The following standard conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (2007) apply:

(i) that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
- security of records
- compliance with approved consent procedures and documentation
- compliance with special conditions, and

(ii) that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
- proposed changes to the protocol
- unforeseen circumstances or events
- adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

Signed: ..... Date: .....24/08/2011.....
(Research Services Officer, Melbourne Campus)