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Review

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

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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.

What is already known about the topic?

- Nurse-administered procedural sedation and analgesia is increasingly common practice for procedures performed in the cardiac catheter laboratory.

What this paper adds

- The reported rates of respiratory complications for nurse-administered procedural sedation and analgesia in the cardiac catheter laboratory range from 2.4 to 9.4%.
- A higher percentage of deeply sedated patients were reported to experience complications than moderately sedated patients.
- Clinical guidelines are inconsistent regarding administration of deep sedation without an anaesthetist present in the cardiac catheter laboratory.

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- Capnography has not been researched as a parameter to monitor respiratory status when nurse-administered procedural sedation and analgesia is used in the cardiac catheter laboratory.

1. 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 Anesthesiologists (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) has developed a set of guidelines for PSA for electrophysiology procedures (Bubien et al., 1998). As yet, 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.

1.1. 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 (Fox et al., 2007) and intravenous sedation (Kezerashvili et al., 2008). 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).

2. Method

2.1. 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?

3. Design

Initial searching of the literature by the corresponding author 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 (Whittemore and Knafl, 2005), and as such, was selected as an appropriate structure for the review.

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 flowchart of studies from search to inclusion is provided in Fig. 1. Articles that met the inclusion criteria were critically analysed using the Health Care Practice Development Unit's (2003) evaluation tool for quantitative studies and the level of evidence of each study was determined using the (NHMRC, 1998) "Designation of Level of Evidence" (p. 56) framework. Data extracted from each study were developed into a summary table by the corresponding author. The process for categorising data for the summary table was reviewed by JXR, KP & LW-C.

4. Results

Nineteen articles and three clinical guidelines met the inclusion criteria. Table 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".

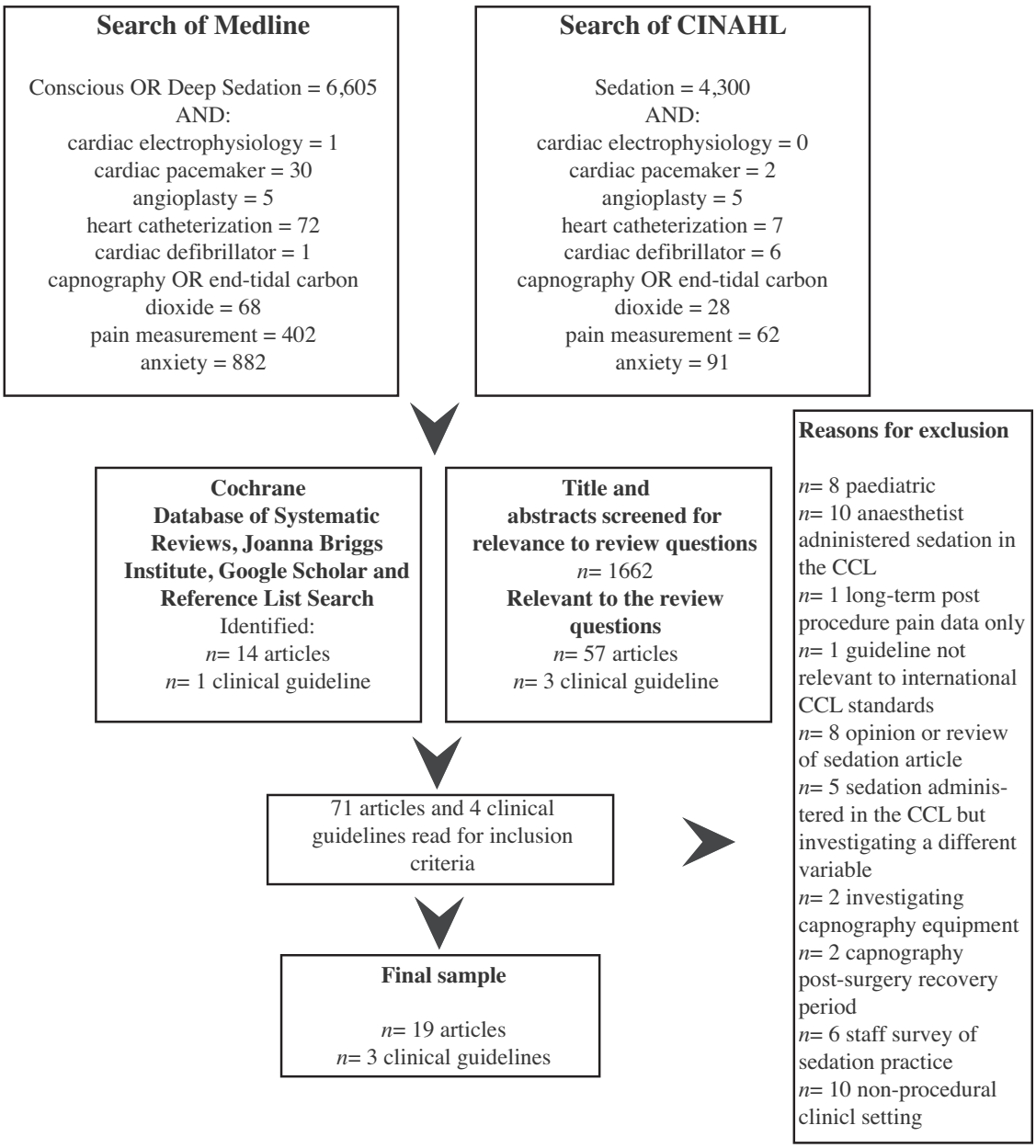

Fig. 1. Search strategy.

4.1. 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 catheterization, 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

Table 1
Summary of identified 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 to 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 to 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

Table 1 (*Continued*)

Author	Year	Design	Sample	Relevant findings	Level of evidence
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 SpO_2 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 and II
Koniaris et al.	2003	Retrospective review of endoscopic procedures to determine benefits of capnography	$n = 4846$ 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

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).

Table 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 ($SpO_2 > 80\% < 90\%$)	$n = 17$ (2.4%)
Geiger et al. (1997)	5% reduction from baseline SpO_2 requiring sedation reversal	$n = 14$ (2.6%)
	5% reduction from baseline SpO_2 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 SpO_2 requiring:	$n = 5$ (9.4%)
	Sedation reversal	$n = 3$ (5.6%)
	Airway adjuncts	$n = 2$ (3.7%)

SpO_2 = Peripheral oxygen saturation.

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 maneuvers, 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 ICDs. 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 3819 catheterisations, 260 transoesophageal echocardiograms and 5479 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 presents the respiratory complications for each of the CCL studies.

Other procedural areas, which used PSA, classified respiratory complications differently. Table 3 presents studies that investigated PSA in emergency departments (ED) and endoscopy suites.

Respiratory complications were expanded in the ED and endoscopy studies to include measurements derived from capnography and end-tidal carbon dioxide ($ETCO_2$) monitoring that indicate respiratory depression.

4.2. 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 et al., 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

Table 3
Respiratory complications for PSA in emergency and endoscopy.

Author	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%)
		$SpO_2 < 93\%$	Capnography group $n = 17$ (25%); Blinded group $n = 27$ (42%)
		$ETCO_2 > 50$ mmHg	Capnography group $n = 9$ (23%); Blinded group $n = 8$ (22%)
		Change in $ETCO_2$ value of 10 mmHg 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 ($SpO_2 < 90\%$ for >15 s)	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 s)	Blind arm $n = 77$ (62.6%); Open arm $n = 51$ (41.1%) $p = <0.001$
		Abnormal ventilation (loss capnography waveform: >5 s, <15 s, $>75\%$ decrease in waveform amplitude for > 5 s)	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 $ETCO_2$ by 20% and one of the following:	$n = 32$ (56%) one event and $n = 5$ two events (8.7%)
		$SpO_2 < 90\%$	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 the presence of at least one of the criteria below:	Oxygen group $n = 30$ (53%); Room air group $n = 22$ (40%)
		$SpO_2 < 90\%$	Oxygen group $n = 10$ (18%); Room air group $n = 15$ (28%)
		$ETCO_2 > 50$ mmHg	Oxygen group $n = 1$ (0.02%); Room air group $n = 2$ (0.04%)
		Change in $ETCO_2$ value of 10 mmHg 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 ($SpO_2 < 95\%$)	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%)
		$SpO_2 < 90\%$	Oxygen group $n = 5$ (11%); Room air group $n = 2$ (6%)
		$ETCO_2 > 50$ mmHg	Oxygen group $n = 12$; Room air group $n = 8$ (22%)
		Change in $ETCO_2$ value of 10 mmHg 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%)
		$SpO_2 < 92\%$	$n = 19$ (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 $ETCO_2$ level >10 mmHg from baseline	Not specified
		$ETCO_2 < 30$ mmHg or >50 mmHg	Not specified
Miner et al. (2002)	Emergency	Respiratory Depression noted by findings below:	$n = 33$ (44%)
		$ETCO_2 > 50$ mmHg	$n = 24$ (32%)
		$ETCO_2 < 50$ mmHg but $SpO_2 < 90\%$	$n = 5$ (14.8%)
		$ETCO_2 < 50$ mmHg 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
		Disordered respiration	Not reported
		Acute respiratory event defined by presence of at least one of the criteria below:	30 episodes detected
		Hypoxia ($SpO_2 < 90\%$)	Identified 27 episodes (50%) of respiratory depression
		Alveolar hypoventilation ($ETCO_2$ 25% > baseline)	Identified 3 episodes (5.5%) of respiratory depression

$ETCO_2$ = End-tidal carbon dioxide; SpO_2 = peripheral oxygen saturation.

(Burton et al., 2006; Deitch et al., 2010; Miner et al., 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 et al., 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 to 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 (Rozario et al., 2008) 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. 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 et al., 2004).

4.3. 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 et al., 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).

4.4. Economic impact

The savings associated with using PSA in the CCL were reported in a study of a consecutive series of 9558 patients (Kezerashvili et al., 2008). US$ 5,365,691 was saved over a decade, which was attributed to forgoing anaesthetic services. No other study reported cost considerations of PSA in the CCL.

4.5. 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.

4.6. 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.

5. 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.

5.1. 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.

5.2. 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., 2001), 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.

5.3. 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.

6. 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 (Geiger et al., 1997; Kezerashvili et al., 2008; Pachulski et al., 2001), and, there were cost-savings associated with forgoing anaesthetic services (Kezerashvili et al., 2008). 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.

Conflict of interest

None declared.

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Ethical approval

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References

Australia and New Zealand College of Anaesthetists (2010). Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical or Surgical Procedures. From http://www.anzca.edu.au/resources/professional-documents/professional-standards/pdfs/PS9.pdf.

Beddoes, L., Botti, M., Duke, M., 2008. Patients' experiences of cardiology procedures using minimal conscious sedation. Heart & Lung 37 (3), 196–204.

Bubien, R.S., Fisher, J.D., Gentzel, J.A., Murphy, E.K., Irwin, M.E., Shea, J.B., et al., 1998. NASPE expert consensus document: use of i.v. (conscious) sedation/analgesia by nonanesthesia personnel in patients undergoing arrhythmia specific diagnostic, therapeutic, and surgical procedures. Pacing & Clinical Electrophysiology 21 (2), 375–385.

Burton, J., Harrah, J., Germann, C., Dillon, D., 2006. Does end-tidal carbon dioxide monitoring detect respiratory events prior to current sedation monitoring practices? Academy of Emergency Medicine 13 (5), 500–504.

Deitch, K., Chudnofsky, C.R., Dominici, P., 2007. The utility of supplemental oxygen during emergency department procedural sedation and analgesia with midazolam and fentanyl: a randomized, controlled trial. Annals of Emergency Medicine 49 (1), 1–8.

Deitch, K., Chudnofsky, C.R., Dominici, P., 2008. The utility of supplemental oxygen during emergency department procedural sedation with propofol: a randomized, controlled trial. Annals of Emergency Medicine 52 (1), 1–8.

Deitch, K., Miner, J., Chudnofsky, C.R., Dominici, P., Latta, D., 2010. Does end tidal CO_2 monitoring during emergency department procedural sedation and analgesia with propofol decrease the incidence of hypoxic events? A randomized, controlled trial. Annals of Emergency Medicine 55 (3), 258–264.

Fox, D.J., Davidson, N.C., Bennett, D.H., Clarke, B., Garratt, C.J., Hall, M.C.S., et al., 2007. Safety and acceptability of implantation of internal cardioverter-defibrillators under local anesthetic and conscious sedation. Pacing & Clinical Electrophysiology 30 (8), 992–997.

Fu, E.S., Downs, J.B., Schweiger, J.W., Miguel, R.V., Smith, R.A., 2004. Supplemental oxygen impairs detection of hypoventilation by pulse oximetry. Chest 126 (5), 1552–1558.

Geiger, M., Wase, A., Kearney, M., Brandon, M., Kent, V., Newby, K., et al., 1997. Evaluation of the safety and efficacy of deep sedation for electrophysiology procedures administered in the absence of an anesthetist. Pacing & Clinical Electrophysiology 20 (7), 1808–1814.

Gross, J., Farmington, C., Bailey, P., Connis, R., Cote, C., Davis, F., et al., 2002. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 96 (4), 1004–1017.

Health Care Practice Research and Development Unit, 2003. Evaluation Tool for Quantitative Studies. University of Salford, Salford. , Retrieved March 22, 2010, fromIn: http://www.fhsc.salford.ac.uk/hcprdu/tools/quantitative.htm.

Kezerashvili, A., Fisher, J.D., DeLaney, J., Mushiyev, S., Monahan, E., Taylor, V., et al., 2008. Intravenous sedation for cardiac procedures can be administered safely and cost-effectively by non-anesthesia personnel. Journal of Interventional Cardiac Electrophysiology 21 (1), 43–51.

Koniaris, L.G., Wilson, S., Drugas, G., Simmons, W., 2003. Capnographic monitoring of ventilatory status during moderate (conscious) sedation. Surgical Endoscopy 17, 1261–1265.

Lipscomb, K., Linker, N., Fitzpatrick, A., 1998. Subpectoral implantation of a cardioverter defibrillator under local anaesthesia. Heart 79 (3), 253–255.

Malamed, S., 2003. Sedation A Guide to Patient Management. Mosby, St Louis, MO.

Marquie, C., Duchemin, A., Klug, D., Lamblin, N., Mizon, F., Cordova, H., et al., 2007. Can we implant cardioverter defibrillator under minimal sedation? Europace 9 (7), 545–550.

Miner, J., Heegaard, W., Plummer, D., 2002. End-tidal carbon dioxide monitoring during procedural sedation. Academy of Emergency Medicine 9 (4), 275–280.

Natale, A., Kearney, M., Brandon, M., Kent, V., Wase, A., Newby, K., et al., 1996. Safety of nurse-administered deep sedation for defibrillator implantation in the electrophysiology laboratory. Journal of Cardiovascular Electrophysiology 7 (4), 301–306.

National Health Medical Research Council, 1998. A Guide to the Development Implementation and Evaluation of Clinical Practice Guidelines. Commonwealth of Australia, Canberra.

Pachulski, R., Adkins, D., Mirza, H., 2001. Conscious sedation with intermittent midazolam and fentanyl in electrophysiology procedures. Journal of Interventional Cardiology 14 (2), 143–146.

Qadeer, M., Vargo, J., Dumot, J., Lopez, R., Trolli, P., Stevens, T., et al., 2009. Capnographic monitoring of respiratory activity improves safety of sedation for endoscopic cholangiopancreatography and ultrasonography. Gastroenterology 136 (5), 1568–1576.

Rozario, L., Sloper, D., Sheridan, M., 2008. Supplemental oxygen during moderate sedation and the occurrence of clinically significant desaturation during endoscopic procedures. Gastroenterology Nursing 31 (4), 281–285.

US Preventative Services Taskforce, 1989. In: Fisher, M. (Ed.), Guide to Clinical Preventative Services: An Assessment of the Effectiveness of 169 Interventions. Williams and Williams, Baltimore.

Vargo, J.J., Zuccaro Jr., G., Dumot, J.A., Conwell, D.L., Morrow, J.B., Shay, S.S., 2002. Automated graphic assessment of respiratory activity is superior to pulse oximetry and visual assessment for the detection of early respiratory depression during therapeutic upper endoscopy. Gastrointestinal Endoscopy 55 (7), 826–831.

Whittemore, R., Knafl, K., 2005. The integrative review: updated methodology. Journal of Advanced Nursing 52 (5), 546–553.

Yarchi, D., Cohen, A., Umansky, T., Sukhotnik, I., Shaoul, R., 2009. Assessment of end-tidal carbon dioxide during pediatric and adult sedation for endoscopic procedures. Gastrointestinal Endoscopy 69 (4), 877–882.