Published in final edited form as:

J Pediatr Nurs. 2017 ; 35: 129–133. doi:10.1016/j.pedn.2016.09.003.

Differences in Pediatric Non-Interventional Radiology Procedural Sedation Practices and Adverse Events by Registered Nurse and Physicians

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Abstract

Purpose—The purpose of this study was to determine differences in sedation-related adverse events according to the type of provider monitoring and delivering sedation.

Design and Methods—A retrospective, cross-sectional, correlational design using secondary data from the Pediatric Sedation Research Consortium database was used for this study.

Results—A sample of 36,352 cases (0 to 14 years of age) sedated for diagnostic radiology procedures by three types of providers (registered nurses [RNs] alone, physicians (MDs) alone, or registered nurse + physician [RN+MD sedation teams]) were compared. Patients sedated by RNs alone or MDs alone had lower odds of unanticipated adverse events (odds ratios 0.46 and 0.53, respectively; $p < 0.0001$) compared with RN+MD sedation provider teams.

Conclusions—Team skills may be an important competency for RN+MD sedation teams in the non-interventional radiology setting.

Practice Implications—This study can inform clinicians, administrators, and quality-improvement managers of the differences in adverse event outcomes of pediatric radiology procedures when RN+MD teams provide sedation compared with RNs or MDs alone.

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Disclosures: The authors have no disclosures

Presentation: This study was presented on January, 2014 at the American Association of Colleges of Nursing Doctoral Education Conference, Naples, FL.

Keywords

conscious sedation; patient safety; pediatrics; radiology; magnetic resonance imaging; nurses

BACKGROUND

Children require sedation more frequently and for different reasons than adults (Coté & Wilson, 2006). Children also require sedation for procedures more often than adults and at deeper levels; however, children also have the highest risk of and least tolerance for sedation complications, due to their anatomical and physiological differences in areas such as the respiratory system (Cravero & Havidich, 2011).

Traditionally, anesthesia providers administered sedation in operating rooms (ORs), but procedures are increasingly being performed elsewhere, increasing demand for sedation in other settings and by non-anesthesiologist providers, including registered nurses (RNs) (Cohen et al., 2006; Couloures, Beach, Cravero, Monroe, & Hertzog, 2011; Cravero et al., 2006).

Current research on RN-provided sedation is limited, primarily consisting of single-site studies describing the implementation and outcomes of RN-led sedation services, or outcomes of RN-administered medication protocols in a single setting such as a radiology or endoscopy unit (Crego, 2013). Outcomes of RN-provided sedation have not been compared to physician non-anesthesiologist sedation providers (MD), or to RN-MD teams that monitor and deliver sedation.

The Joint Commission (TJC)—an organization that accredits health care organizations and programs in the United States—sedation standards describe two provider roles for sedation, but they do not specify the type of provider. One provider performs the intervention or procedure (a physician non-anesthesiologist sedation provider [MD]) and can simultaneously deliver or direct the delivery of sedative medications by another competent provider (usually an RN) (Coté & Wilson., 2016; Joint Commission International, 2011). TJC and American Academy of Pediatrics (AAP) provide specific guidelines for intended level of sedation (moderate or deep) due to the increased risk of complications with deeper levels of sedation (JC, 2011; Coté et al., 2016). Most children receiving sedation are likely to achieve deep sedation at some point during the procedure, regardless of the intended level of sedation, the medication used or the route of administration (Couloures et al., 2011; Coté et al., 2016). Sedation level is a continuum, thus it is not always possible to predict how the patient will respond (ASA, 2002). The RN provider has the sole responsibility of continuously monitoring the patient throughout deep sedation procedures; if moderate sedation is performed, the second provider (usually the RN) can simultaneously assist with interruptible tasks during the sedation procedure and monitor the patient (Coté et al., 2016; JC, 2011). The influence of team factors, such as the use of an organization-wide sedation team with consistent membership, or individuals, who hold credentials in providing sedation and work in teams, may be important in comparing outcomes of sedation delivery systems. Preliminary studies by Blike, Cravero and Nelson, (2001) identified team-training skills used by airline crews as essential components in developing quality sedation care systems.

However, current TJC standards continue to highlight psychomotor skills, such as airway management, knowledge of sedative medications, and monitoring procedures, as essential to ensure safe sedation care, but there is little to no description of training or assessment of team (RN+MD) approaches (Joint Commission International, 2011; Blike, Cravero, & Nelson, 2001).

Several studies have documented that RNs provide sedation for procedures such as magnetic resonance imaging (MRI), computerized tomography (CT), and endoscopy as members of teams (Beebe et al., 2000; Lavoie, Vezina, Paul-Savoie, Cyr, & Lafrenaye, 2012; Woodthorpe, Trigg, Gurney, & Sury, 2007). In fact, one survey of gastroenterologists at United States endoscopy centers found that 89.5% of respondents included RNs as part of their endoscopy and sedation teams (Cohen et al., 2006). In addition, descriptive practice data from the Pediatric Sedation Research Consortium (PSRC, which contains multisite data on pediatric sedation, including adverse event rates and physiologic monitoring practices for non-anesthesiologist sedation providers [Langhan, Mallory, Hertzog, Lowrie, & Cravero, 2012]) have shown RNs as being solely responsible for delivering and monitoring sedation (Woodthorpe, et al., 2007). However, the AAP sedation guidelines describe the role of personnel like RNs to be purely assistive, providing monitoring and support if resuscitation is required, rather than as primary sedation providers (physicians or advanced practice providers) that order medication and maintain responsibility for the overall management of the patient throughout the sedation process (Coté et al., 2016). Several studies using PSRC data have examined outcomes according to sedation provider. In one study of 41,392 pediatric diagnostic radiology sedation cases, 31% received sedation and were monitored by only an RN during non-interventional diagnostic radiology procedures (Crego, 2013). An adverse event rate of 5.78% was reported for these patients; adverse events included minor complications (e.g., intravenous access) or major complications (e.g., unexpected need for bag-valve-mask ventilation) (Crego, 2013). In comparison, a prior study by Cravero et al. (2006) found a 5.3% incidence of minor and major complications in 30,037 sedation cases with MD and advanced practice sedation providers (physician assistants and nurse practitioners) for a variety of procedures. Cravero et al. (2006) did not examine RN-administered sedation. A third study investigated the impact of provider type on major complications during interventional and non-interventional procedural sedation (Couloures, et al., 2011). The study found no significant differences in the rates of major complications between the categories of providers studied (anesthesiologists, non-anesthesiologists [emergency physician, intensivists, and pediatricians]), and others; RN-specific results were not reported.

Research on the frequency of adverse events in children according to sedation provider type, including RNs alone, MDs alone, and RN+MD teams, has not been reported. Our study is the first to use the PSRC database to investigate this.

METHODS

A retrospective, cross-sectional, correlational design was used to determine differences in adverse events by provider type depending on sedation risk factors (age, weight, American Society of Anesthesia [ASA] score >2, number of comorbid conditions), MRI procedures,

number of medications provided, monitoring equipment (e.g., cardiac monitor, capnography), and the occurrence of adverse events (ASA, 2002).

PSRC Database

The primary data source was the PSRC database (Cravero, Blike, Beach, Gallagher, & Weiss, 2005; Cravero et al., 2006), which was developed to collect data on variables that are key to understanding sedation. Variables were originally included in the PSRC database after an extensive literature review and consensus by an expert panel of pediatric sedation specialists determined the importance of these variables in understanding pediatric sedation practices. PSRC data are collected from multiple sites to form a large sample of patients, providers, and procedures to better ascertain the incidence of and factors associated with adverse events in this population (Cravero et al., 2005). A large database is necessary to accurately assess sedation-related adverse events because of the low rate of occurrence, which has been estimated to be 5.3% (Cravero et al., 2006; Polaner et al., 2001).

The PSRC is an organization of more than 30 institutions in the United States, including general hospitals and children's hospitals that are both free-standing and housed within larger hospitals (Cravero et al., 2006). PSRC members may select specific departments (e.g., radiology) or specific groups (e.g., sedation service) within their institutions to collect and submit data to the database. Each member institution obtains approval from its own institutional review board prior to submitting data to the PSRC. Our study was exempted by our university's institutional review board.

PSRC sites use a standard web-based data-collection tool and share de-identified information with the rest of the consortium. The data-collection methods used by the PSRC have been detailed previously (Couloures et al., 2011; Cravero et al., 2006). Briefly, data collection is overseen at each PSRC member institution by a primary investigator who ensures that >90% of cases are reported to the database (Couloures et al., 2011). Processes are in place to minimize selection bias, including submission of an independent sedation case count and audits of at least 5% of cases (Couloures et al., 2011). Data include patient age, weight, ASA score, primary diagnosis, comorbid conditions, medications administered, procedure completed, and sedation procedure outcome. The database includes information on sedation providers, MDs by specialty, and on RNs. Data elements include the provider who monitored and administered sedation and outcomes of sedation (including adverse events) listed by the affected body system (Couloures et al., 2011).

Study Design

For the current study, evidence from prior sedation safety studies and the System Engineering Initiative for Patient Safety (SEIPS) framework guided the inclusion of study variables to compare outcomes of sedation by provider type. The SEIPS model considers how work system designs can affect patient safety and outcomes that could lead to system redesign (Carayon, et al., 2006). Study variables were organized into one of the three model components: 1) work systems—technology, care providers, patients, work environments, organization, and tasks that can affect how sedation is provided, 2) process—care processes used to provide sedation, and 3) outcomes—outcomes of sedation (Carayon, et al., 2006).

Work system variables included patient risk factors (age, weight, ASA score, and number of comorbid conditions), provider factors (RN alone, MD alone, and RN+MD team), and technology and tools (CT scan, MRI, and ultrasound). Process variables included the number of medications administered and the monitoring equipment used during sedation. Outcomes included sedation adverse events—an “unexpected and undesirable responses to medications(s) and medical intervention used to facilitate procedural sedation and analgesia that threaten or cause patient injury or discomfort” (Mason, Green & Piacevoli, 2012, p.15). Our study focused on the impact of work systems and processes on patient safety.

Sample

A sample of 41,392 cases met the study inclusion criteria: children up to and including 14 years of age sedated for diagnostic MRI, CT, or ultrasound from January 2005 to September 2007 for which RNs alone, MDs alone, or RN+MD teams delivered medications and monitored patients. Cases involving any advanced practice nurses, such as certified registered nurse anesthetists, were excluded. Physicians included in this study were emergency medicine physicians, house staff, intensivists, oral surgeons, pediatricians, radiologists, and surgeons. RN+MD team cases were defined as any in which an RN or MD already meeting study inclusion criteria delivered or monitored sedation in any combination; cases in which anesthesiologists, dentists, or fellows monitored or delivered sedation were excluded.

A total of 5040 cases were excluded from the study sample: 799 cases were missing ASA status; an advanced practice nurse monitored or delivered sedation in 2327 cases; and a fellow, medical technician, and/or other provider monitored or delivered sedation in 1914 cases. The resulting sample of 36,352 sedation cases was included in our study.

Analysis

All statistical analysis was completed using SAS version 9.1 (SAS Institute, Inc., Cary, NC). Assumptions included multicollinearity testing. The procedure-type variables CT scan (n=8343 cases) and ultrasound (n=85 cases) were removed from the model due to the high negative correlation between CT scan and MRI cases and the low number of ultrasound cases. Instead, a new dichotomous procedure-type variable “any MRI” (n=27,965 cases) was created so that any case that included an MRI was coded as 1 and cases with ultrasound or CT scans and no MRI were coded as 0.

Hierarchical logistic regression models with blocks of variables were used to explain the presence of an adverse event, depending on provider type (RN alone, MD alone, RN+MD team). The following blocks of variables were used: 1) age, weight, ASA score (1, 2, or >2), and number of coexisting medical conditions (none, 1, 2, or >2); 2) any MRI procedure; 3) number of medications administered (1, 2, >2, or propofol); 4) monitoring equipment used (any combination of monitoring equipment, including electrocardiogram, pulse oximetry, end tidal CO₂, blood pressure, impedance plethysmography, bispectral index monitoring, and inspired O₂); and 5) provider type (RN alone [only an RN was monitoring and delivering sedation], MD alone [only a non-anesthesia physician was monitoring and delivering sedation], and RN+MD team [an RN and MD were monitoring and/or delivering sedation]).

together], in which the referent category was the RN+MD team. Propofol was the most frequently administered medication in this sample. Propofol, is an anesthetic agent that can cause severe respiratory depression and is often administered alone to induce sedation (Mason, 2010). In order to control for the possible effect of propofol in cases in which one medication was administered, a second model was also completed that included propofol administration. The overall fit of each model was evaluated by examination of -2 log likelihood and chi-square.

RESULTS

In our study sample, 78% of the sedation cases were 5 years of age (Table 1). The majority (87%) had an ASA score of 1 or 2, regardless of provider type. There was at least one comorbid condition in 35% of sedation cases. The most common type of sedation provider was an RN+MD team (61%; n=22,060), followed by the RN-alone (34.5%; n=12,564) and MD-alone (4.7%; n=1,728). Most cases (75%) received only one medication. Propofol was administered in 57% of the cases; it was administered 1568 times by the MD-alone group, 23 times by the RN-alone group, and 19,245 times by RN+MD teams. RNs working in RN +MD teams administered propofol in 896 (3%) of cases. Propofol was administered in combination with >2 medications in only 1% of sample cases. The total number of adverse events was 2164 (6%).

In Model 1 (which controlled for age, weight, ASA score >2, number of comorbidities, MRI, number of medications administered, and monitoring equipment), sedation cases in the RN-alone and MD-alone provider groups had lower odds ($p<0.0001$) of adverse events (odds ratios [ORs] 0.46 and 0.52, respectively), compared with RN+MD teams (Table 2). Cases receiving >2 medications had the highest odds (OR 6.33, $p<0.0001$) of experiencing any adverse event, and constituted 4% of the study sample. Having any MRI generated a 2.76 ($p<0.0001$) OR of experiencing an adverse event, and these patients constituted 76.8% of the sample. Cases with high ASA scores also had higher odds of experiencing an adverse event (OR 1.44, $p<0.0001$).

Model 2 (which included the variables from Model 1 plus sedation with propofol) yielded similar results for the RN-alone and MD-alone providers (Table 2). In this model, cases in which >2 medications were administered had slightly higher odds of experiencing any adverse event (OR 6.39, $p<0.0001$) compared with Model 1 (OR 6.33, $p<0.0001$).

DISCUSSION

Sedation Providers

Our study demonstrated that the type of provider delivering sedation—RNs alone, MDs alone, or RN+MD teams—had an effect on rates of adverse sedation events. Our study found that cases sedated by RN+MD teams had a significantly higher likelihood of adverse events in diagnostic MRI procedures. However, we are not able to explain this difference in non-interventional sedation procedures. While there are TJC standards in place for RN+MD teams for interventional procedures (TJC, 2011), standards are unclear regarding sedation provider roles when the procedure is purely diagnostic (such as an MRI), so RN+MD teams

may operate differently during diagnostic versus interventional procedures. Differences may include whether the MD is present throughout the entire diagnostic procedure or just during the sedation-induction phase. In order to gain a better understanding of the RN+MD sedation team dynamic, clinically based investigations using quantitative and qualitative methods are necessary to develop sedation team training techniques, evaluate current organizational sedation policies, and evaluate the data-collection methods for assessing sedation quality.

MRI Procedure

In our study, MRI procedures were an important factor associated with sedation-related adverse events and may be an additional consideration when adjusting for sedation risk (Caperell & Pitetti, 2009). In children, MRI procedures raise different sedation concerns than in adults. Children are generally sedated more deeply than adults because, depending on developmental levels, they are less likely to cooperate during diagnostic procedures; this necessitates the administration of multiple sedative medications or use of anesthetic agents. Age may not fully account for developmental variations in children; the need for deeper sedation may be more related to the type of procedure and the amount of sedation needed in order to complete the procedure. Thus, especially a procedure like an MRI (which is lengthy, noisy, and requires long periods of stillness) may require a child to be more deeply sedated than would be required for a CT scan (Emrath, Stockwell, McCracken, Simon, & Kamat, 2014). Differences in the MRI environment—such as the need for MRI-compatible equipment and difficulty visualizing children once they are inside the machine—may also contribute to the complexity of sedation for this procedure and may require additional safeguards. Techniques that could help children avoid sedation altogether for MRI procedures—such as using child-friendly imaging equipment and engaging child life personnel who can assist in pre-procedural preparation, provide comfort, or introduce diversions, like video goggles—warrant additional consideration given the increased likelihood for adverse events associated with the procedure (Durand, Young, Nagy & Tekes, 2015; Baker, 2015).

Medication Administration

Our study found that the number of medications administered was also an important factor in the occurrence of adverse events, which is consistent with previous reports (Coté, Karl, Notterman, Weinberg, & McCloskey, 2000). Our study found that patients who received >2 medications had the highest odds of adverse events; however, most sedation regulations affecting RNs focus on the category of medication administered (e.g., anesthetic agents) rather than the number of medications. In our study, RNs working in RN+MD teams were administering propofol for diagnostic radiology procedures, which in some states is outside the scope of RN practice or is highly restricted (Crego, 2015). However, we found no association between administration of propofol and adverse events, which confirms findings from other studies (American Society for Gastrointestinal Endoscopy, 2009; Jensen, Moller, Hornslet, Konge, & Vilmann, 2015). Our study provides further evidence that restricting propofol administration by RNs working in RN+MD teams does not improve sedation outcome. Instead, rather than simply relying on high ASA scores to determine appropriate

referrals to anesthesia providers, specific guidance on administration of multiple sedative medications in organizational sedation policies should be considered.

Limitations

The availability of a large database on pediatric sedation is important for understanding provider practices and adverse events. However, there are limitations to the PSRC database, such as a lack of in-depth information on RN sedation providers (e.g., level of experience, provider specialty, credentials, knowledge, and training unique to RNs). Variation in experience, background, and specific roles for members of sedation teams were not accounted for in this study.

A second limitation is the lack of information on geographic locations and on organizational characteristics of the care setting. Therefore, it was not possible to compare RN sedation care practice according to location or state nursing board regulations. In addition, the number of pediatric sedation cases completed by an organization is not available in the PSRC.

A third limitation is that the intended or achieved level of sedation was not considered in model 1 or 2 of this study. Although the risk of sedation adverse events likely increases with the depth of sedation, the level of sedation varies throughout the procedure over a continuum and is not predictable (ASA, 2002). Additionally, the method of assessing depth of sedation relies on patient response to stimulation during the procedure, which is incongruous with the purpose of providing sedation to complete procedures such as MRI, thus limiting the value of using this variable in our models (Couloures, 2011).

A fourth limitation is the lack of data on possible delayed sedation adverse events. These events may require a higher level of care after discharge from sedation, such as emergency department or primary care provider visits or need for higher levels of care for inpatients. One way to overcome this limitation would be for the PSRC to develop processes that would allow researchers to access clinical and organizational data from contributing organizations. The addition of clinical data would allow greater understanding of the person-level factors that could contribute to adverse sedation outcomes.

Lastly, rather than being representative of sedation care at the national level, PSRC data may reflect best practices by organizations that are committed to providing high-quality sedation care.

Implications

This study can inform clinicians, administrators, and quality-improvement managers of the differences in adverse event outcomes of pediatric radiology procedures when RN+MD teams provide sedation compared with RNs or MDs alone. As team-based sedation care continues to develop, it is important to know what the contribution of each provider is and how provider teams should function. This type of research is necessary in order to improve sedation team performance.

Our findings can inform pediatric sedation policy development by quality-improvement managers, regulators, and policymakers. Our results can support organizations in developing evidence-based training that includes consideration of the procedure being completed, team communication, and use of multiple sedative agents. The team-based nature of sedation care requires improved collaboration amongst the providers involved. The PSRC provides useful data for examining organizational trends and factors that influence sedation adverse events. However, expanding the PSRC to include data on later adverse events and more explanatory factors, such as provider characteristics, is recommended in order to develop evidence on organizational and regulatory factors that affect pediatric sedation care delivery.

Acknowledgments

Funding: This work was supported by the National Institute of Nursing Research [grant number 1 F31 NR0104262-01A1]

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Highlights

- Secondary data can be used to improve understanding of pediatric sedation safety.
- Number of medications, MRI and type of provider are important measures of sedation safety.
- There are differences in sedation outcome depending on the type of sedation provider.

Table 1

Study Variable Descriptive Statistics (N=36,352)

Variable Name	N	%
Age		
0–12 months	8068	22.1
13–24 months	6706	18.4
25–60 months (5 years)	13,687	37.6
61–132 months (11 years)	6912	19.0
133–168 months (14 years)	979	2.6
High ASA (score greater than II)		
I or II	31,854	87.6
> II	4498	2.3
Comorbidity		
None	23,730	65.2
1	9388	25.8
2	2345	6.4
>2	889	2.4
Procedure		
Any MRI	27,965	76.81
No MRI	8387	23.07
Medications administered		
1	27,265	75
2	7808	21.4
>2	1279	3.5
Propofol administered	20,836	57.2
Monitoring equipment ^a	36,280	99.8
Providers		
MDs alone	1728	4.7
RNs alone	12,564	34.5
RN and MD teams	22,060	60.6

Abbreviations: ASA, American Society of Anesthesia; MD, medical doctor; MRI, magnetic resonance imaging; RN, registered nurse.

^aAny combination of monitoring equipment, including: ECG, pulse oximetry, end tidal CO₂, blood pressure, impedance plethysmography, bispectral index monitoring, inspired O₂.

Table 2

Logistic regression models for any unanticipated adverse sedation events

Variables		Model 1	Model 2 ^a
Block		Odds ratio (95% confidence interval)	
1	Age in months	0.999 (0.9–1.0)	0.999 (0.99–1.00)
	Weight	1.013 ^b (1.007–1.02)	1.013 ^b (1.007–1.02)
	High ASA score	1.441 ^b (1.2–1.6)	1.44 ^b (1.3–1.6)
	1 comorbidity	1.2 ^c (1.1–1.3)	1.2 ^c (1.09–1.33)
	2 comorbidities	1.328 ^c (1.1–1.6)	1.332 ^c (1.1–1.6)
	>2 comorbidities	1.45 (1.1–1.8)	1.45 (1.1–1.8)
2	Any MRI	2.76 ^b (2.4–3.2)	2.72 ^b (2.3–3.17)
3	2 medications	2.50 ^b (2.2–2.8)	2.52 ^b (2.3–2.8)
	>2 medications	6.33 ^b (5.4–7.4)	6.393 ^b (5.4–7.5)
	Propofol	Not included	1.179 (0.98–1.4)
4	Only pulse oximetry	3.32 ^b (2.7–4.2)	3.387 ^b (2.7–4.2)
	Inspired O ₂	2.087 ^b (1.6–2.8)	2.081 ^b (1.6–2.8)
	Only pulse oximetry, ECG	4.69 ^b (3.5–6.3)	4.758 ^b (3.6–6.4)
	Only pulse oximetry, end tidal CO ₂	1.335 ^c (1.1–1.6)	1.351 ^c (1.1–1.6)
	Only pulse oximetry, blood pressure, ECG	2.08 ^b (1.8–2.5)	2.156 ^b (1.8–2.6)
	Only pulse oximetry, blood pressure, ECG, end tidal CO ₂	0.841 (0.7–0.95)	0.833 (0.74–0.94)
	RN alone (ref RN–MD team)	0.456 ^b (0.4–0.5)	0.519 ^b (0.4–0.6)
	MD alone (ref RN–MD team)	0.521 ^b (0.4–0.6)	0.523 ^b (0.4–0.6)
5	RN alone	0.456 ^b (0.4–0.5)	0.519 ^b (0.4–0.6)
	MD alone	0.521 ^b (0.4–0.6)	0.523 ^b (0.4–0.6)
	RN–MD team	Referent variable	Referent variable
Chi-square		1105.6623 ^b	1109.0150 ^b
–2 log likelihood		15336.023	15332.67

Abbreviations: ASA, American Society of Anesthesia; MD, medical doctor; MRI, magnetic resonance imaging; RN, registered nurse.

^aThis model of any adverse event includes propofol administration.^bp<0.0001.^cp<0.01.