

Safe and Efficacious Use of Procedural Sedation and Analgesia by Nonanesthesiologists in a Pediatric Emergency Department

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Background: Children often require relief of pain and anxiety when undergoing diagnostic or therapeutic procedures in the emergency department (ED). Procedural sedation and analgesia (PSA) has become standard practice in the outpatient setting for such procedures. Few studies have looked at the overall success and incidence of complications of PSA as performed by nonanesthesiologists.

Objectives: To prospectively describe PSA as performed in a pediatric ED and to report the success of sedation and incidence of complications.

Design: Prospective descriptive study.

Setting and Population: Subjects aged 0 to 21 years presenting to the ED of an urban, tertiary care, children's hospital between May 1, 1997, and April 30, 1999, requiring PSA for a diagnostic or therapeutic procedure.

Methods: A PSA form was designed and used by ED personnel to record pertinent clinical and demographic characteristics of patients, information related to the procedure, vital signs, and occurrence of complications. *Success of sedation* was defined a priori as successful completion of the procedure in a minimally responsive subject. *Complications* were defined as apnea, hypoxia (sustained pulse oximetry, <93%), seizure, arrhythmia, laryngospasm, stridor, hypotension, rash, vomiting, disinhibition, or aspiration. Follow-up telephone calls were made to families within 24 to 48 hours of discharge from the ED to document further complications.

Main Outcome Measures: Rate of success of sedation and incidence of complications.

Results: Procedural sedation and analgesia was performed 1244 times in 1215 patients during the study. The

median age of the patients was 5.9 years (mean age, 6.9 years; range, 2 months to 19.4 years). There were 791 boys (65.1%) and 424 girls (34.9%). A little more than half of the patients (643 or 52.9%) required PSA for fracture reduction and 396 (32.6%) for laceration repair. Intravenous (IV) fentanyl citrate and midazolam hydrochloride was provided in 734 sedation events (59.0%); IV ketamine hydrochloride, midazolam, and atropine sulfate in 293 (23.6%); and intramuscular ketamine, midazolam, and atropine in 82 (6.6%). Procedural sedation and analgesia was successfully provided in 1177 (98.6%) of 1194 sedation events. Complications occurred in 207 (17.8%) of 1161 events. The most common complication was hypoxia (79.1% of patients), followed by vomiting (6.2% of patients). No patient required intubation. One patient had an oral airway placed, 3 patients received flumazenil, 3 patients received naloxone hydrochloride, and 1 patient received naloxone and bag-valve-mask ventilation. Seventy (9.8%) of 717 patients, following discharge from the ED, reported minor complications related to PSA. The most common complication was vomiting (76.7% of patients), followed by persistent dizziness (6.8% of patients). Patients who received IV fentanyl and midazolam were significantly more likely to experience a complication during PSA ($P < .001$), while patients sedated using IV ketamine, midazolam, and atropine ($P = .006$) or IV midazolam alone ($P = .005$) were less likely. No difference in success of sedation or incidence of complications at follow-up was found between the types of PSA provided.

Conclusions: Complications related to PSA occurred in 17.9% of patients, but most commonly consisted of hypoxia that was easily treated. Sedation was successful in 98.6% of patients. Procedural sedation and analgesia can be safely and effectively provided by nonanesthesiologists in a pediatric ED.

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CHILDREN OFTEN require relief of pain and anxiety when undergoing diagnostic or therapeutic procedures in the emergency department (ED). Despite adequate local anesthesia, distraction techniques, and reassurance, many children are un-

able to lie still during a procedure without being physically restrained. Physically restraining a child may facilitate the successful completion of a procedure but may result in psychological trauma for the child. As a result, procedural sedation and analgesia (PSA) has become standard practice in the outpatient setting to help fa-

cilitate care of such patients. *Procedural or conscious sedation* is defined as a pharmacologically induced state that allows patients to tolerate painful procedures while maintaining protective reflexes (ie, gag and cough) and adequate airway control.¹ In many outpatient settings, PSA is provided by nonanesthesiologists.

Procedural sedation and analgesia in children has been well studied. However, most investigations have evaluated individual pharmacologic agents available for use in PSA, including the incidence of complications for each agent, or have evaluated the use of PSA for specific procedures, such as performing a fracture reduction. Few investigators have looked at the overall use of PSA in a pediatric ED.²

On May 1, 1997, as part of a quality assurance program, a newly developed sedation record was instituted in the ED of Children's Hospital of Pittsburgh to be used for all patients who required PSA. The sedation record was designed to meet the recommendations advocated by the American Academy of Pediatrics for sedation and analgesia of pediatric patients and offered a unique opportunity for study.¹ Using the sedation record, we sought to prospectively describe PSA as performed in our ED and to report the incidence of complications that occurred during the procedure and after patients were discharged.

METHODS

All children who presented to the ED of Children's Hospital of Pittsburgh, a tertiary care pediatric hospital, between May 1, 1997, and April 30, 1999, requiring PSA were prospectively evaluated. The ED is a certified level I pediatric trauma center that evaluates and manages more than 50 000 patients each year. Patients who received sedative, dissociative, or analgesic agents for endotracheal intubation, pain control without an associated procedure, muscle relaxation, or seizure control were excluded. Patients were also excluded if they received medications orally, intranasally, or rectally. The treating physician in the ED was responsible for determining the agents used for PSA. The Children's Hospital of Pittsburgh Institutional Review Board approved this study. Informed consent was obtained for the purposes of PSA. However, informed consent was waived by the institutional review board for purposes of data collection and analysis.

Each patient who required PSA had a sedation record completed. This record included the patient's age, sex, race, American Society of Anesthesiologists (ASA) class, history of allergies, weight, medical history, number of hours since the patient's last oral or gastric intake (NPO), and current medications. In accordance with current ED policy, patients generally did not receive PSA until at least 3 hours had passed since their last oral or gastric intake. The use of analgesic medications before sedation was recorded.

Procedural sedation and analgesia was performed by a pediatric emergency medicine attending physician or fellow, a third-year pediatric resident, or a second- or third-year emergency medicine resident. All fellows and residents received extensive instruction in PSA and were directly supervised by attending physicians. A course in PSA is given by us to every pediatric emergency medicine fellow and third-year pediatric resident at Children's Hospital of Pittsburgh. The physician administering the medications was not the same physician performing the procedure. The training level of the provider of PSA was not recorded or analyzed.

During the sedation and procedure, the following vital signs were recorded at 5-minute intervals: oxygen saturation, heart rate, respiratory rate, blood pressure, and level of consciousness (using a 3-point scale: awake, drowsy or asleep but arousable, or asleep and unarousable). The type, route, and amount of medications given to the patient were recorded on the PSA form.

Success of sedation was defined a priori as the successful completion of the procedure in a minimally responsive subject. For example, in a patient who was to receive PSA for fracture reduction, the fracture would be manipulated before the procedure to determine if he or she was adequately sedated to allow for the procedure to proceed. During the sedation, the level of consciousness on a 3-point scale and responsiveness to the manipulation of the fracture during the procedure were noted. If the patient's level of consciousness did not change during the procedure or if the patient moved minimally during the procedure, PSA was considered successful.

Complications and adverse reactions were noted on the sedation records. *Complications* and *adverse reactions* were defined a priori as follows: persistent oxygen desaturation to less than 93% on pulse oximetry and requiring supplemental oxygen, bronchospasm, apnea, seizure, dizziness, hiccups, laryngospasm, stridor, arrhythmia, hypotension, rash, vomiting, aspiration, stridor, and disinhibition-dysphoria-agitation-emergence reaction. Other reactions perceived to be adverse events related to PSA by the physician performing PSA were noted and recorded.

Decisions made regarding interventions for adverse events were made by the physician conducting the sedation. The use of supplemental oxygen during PSA was not considered standard of care at our institution during the study. Therefore, supplemental oxygen was only applied when oxygen desaturation to less than 93% occurred for a period of time that was perceived by the treating physician as placing the patient at risk (generally 15 to 30 seconds) or if the pulse oximetry reading continued to decrease.

A postsedation discharge summary was included on the sedation record, as well as the results of a follow-up telephone call to the caretakers of children who had received PSA. Telephone calls were completed by a telephone nurse employed by the ED and trained in patient follow-up. The telephone nurse was blinded to the purpose of the study.

The ED record, nursing notes, and trauma sheets of all patients undergoing PSA were reviewed. The records were reviewed for adverse events that may not have been reported on the sedation record. In addition, these records were also reviewed for the extraction of data missing from the sedation records. A review of each record was conducted by 1 of 2 of us (R.D.P. or S.S.).

At monthly intervals during the study, all ED records were reviewed to ensure that no child who had received PSA was missed. In addition, the use of the PSA record was reviewed at the beginning of the study and at quarterly intervals with all physician and nursing personnel involved in PSA. This review was to ensure that the sedation record was used for all PSA and that ED personnel were familiar with its use. Physician and nursing personnel were not informed that the record would be used for study purposes.

Clinical and demographic data are presented as means (SDs) medians, ranges, and proportions. Success of sedation and incidence of complications are presented as proportions. For purposes of analysis, patients were arbitrarily divided into 3 groups based on age (<3, 3-12, and >12 years). Comparisons between groups of patients based on the occurrence of a complication during PSA or reported at follow-up were made using Mann-Whitney, χ^2 with Yates correction, or Fisher exact tests. $P \leq .05$ was considered significant. For each sedation regimen

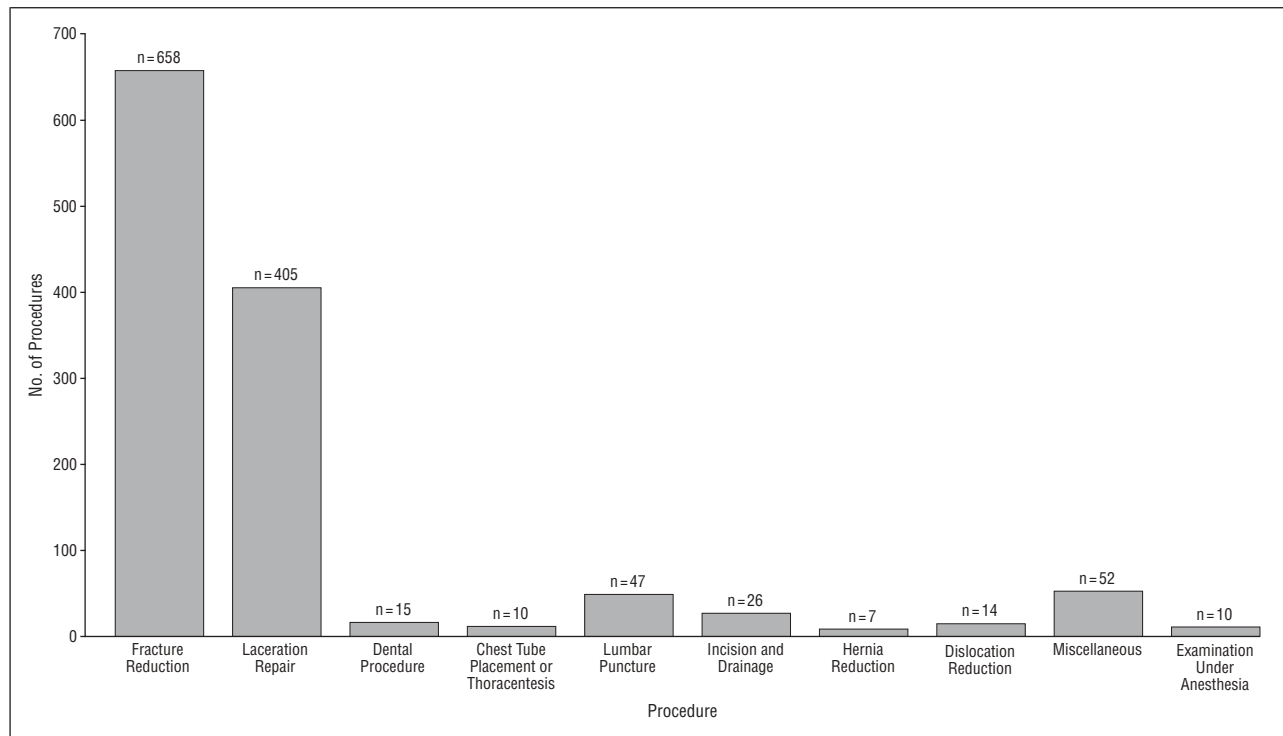


Figure 1. Type and frequency of procedures using procedural sedation and analgesia.

used, comparisons were made between those patients who experienced a complication during sedation and those who did not, and between those patients who noted a complication at follow-up and those who did not. Again, comparisons were made using Mann-Whitney, χ^2 with Yates correction, or Fisher exact tests, with $P \leq .05$ considered significant.

RESULTS

Procedural sedation and analgesia was performed 1244 times in 1215 patients during the study. The median age of the patients was 5.9 years (mean [SD], 6.9 [4.5] years; range, 2 months to 19.4 years). There were 791 boys (65.1%). Almost three quarters of the patients (74.8%) were white, 21.9% were African American, 0.2% were Asian, 0.1% were Hispanic, and 3.0% were "other." Slightly more than 81% (81.6%) of the patients were ASA class I; 17.0% were class II; 1.3% were class III; and 0.1% were class IV. Mean NPO for the patients was 5.0 ± 2.8 hours (range, 0-24 hours) before receiving sedation. The indications for PSA are shown in **Figure 1**. Most subjects (52.9%) required PSA to facilitate the reduction of a fracture. The type and frequency of use of various PSA regimens are shown in **Figure 2**. Intravenous (IV) fentanyl citrate and midazolam hydrochloride was most commonly used (59.0% of patients), followed by IV ketamine hydrochloride, midazolam, and atropine sulfate (23.6% of patients).

Procedural sedation and analgesia was successful in 1177 (98.6%) of 1194 sedation events. It was unsuccessful in 17 patients who did not become sufficiently sedated to allow for a procedure to be performed. The mean age of the 17 patients in whom sedation was unsuccessful was 8.0 ± 4.4 years (median, 7.4 years; range, 1.9-14.4 years). Of the 17 patients, 15 (88.2%) were boys and 7

(41.2%) were premedicated with analgesics. The mean (SD) NPO of the 17 patients before sedation was 5.7 (2.9) hours (median, 2.9 hours; range, 1-12 hours). Procedural sedation and analgesia was required for fracture reduction in 8 (47.1%) of 17 patients and for laceration repair in 4 (23.5%). **Table 1** describes the number of failed sedations and the mean dosing for each PSA regimen used.

During PSA, 65.0% of patients reached a level of consciousness of 3 (asleep and unarousable) on a 3-point scale, 31.4% reached a level of consciousness of 2 (drowsy or asleep but arousable), and 3.6% remained awake during PSA. A complication or adverse reaction occurred in 208 (17.9%) of 1161 sedation events. **Figure 3** describes the frequency and type of complications and adverse reactions noted. Seventeen patients had more than 1 complication. The most common complication was hypoxia (79.1% of patients), followed by vomiting (6.2% of patients). No patient required endotracheal intubation. One patient had an oral airway placed, 3 patients received flumazenil, 3 patients received naloxone hydrochloride, and 1 patient received naloxone and bag-valve-mask ventilation. The patient who received the oral airway was sedated using IV fentanyl and midazolam. The oral airway was placed for hypoxia resulting from an apparent upper airway obstruction. All 3 patients who were given flumazenil had been sedated using IV fentanyl and midazolam. Flumazenil was given for hypoxia alone in 2 patients and for hypoxia and agitation in a third patient. All 3 patients who were given naloxone were sedated using IV fentanyl and midazolam. One patient was given naloxone for hypoxia, a second for hypoxia and anxiety, and the third for prolonged sedation. The patient who received naloxone and bag-valve-mask ventilation had been sedated using IV fentanyl and midazolam and had experienced apnea and

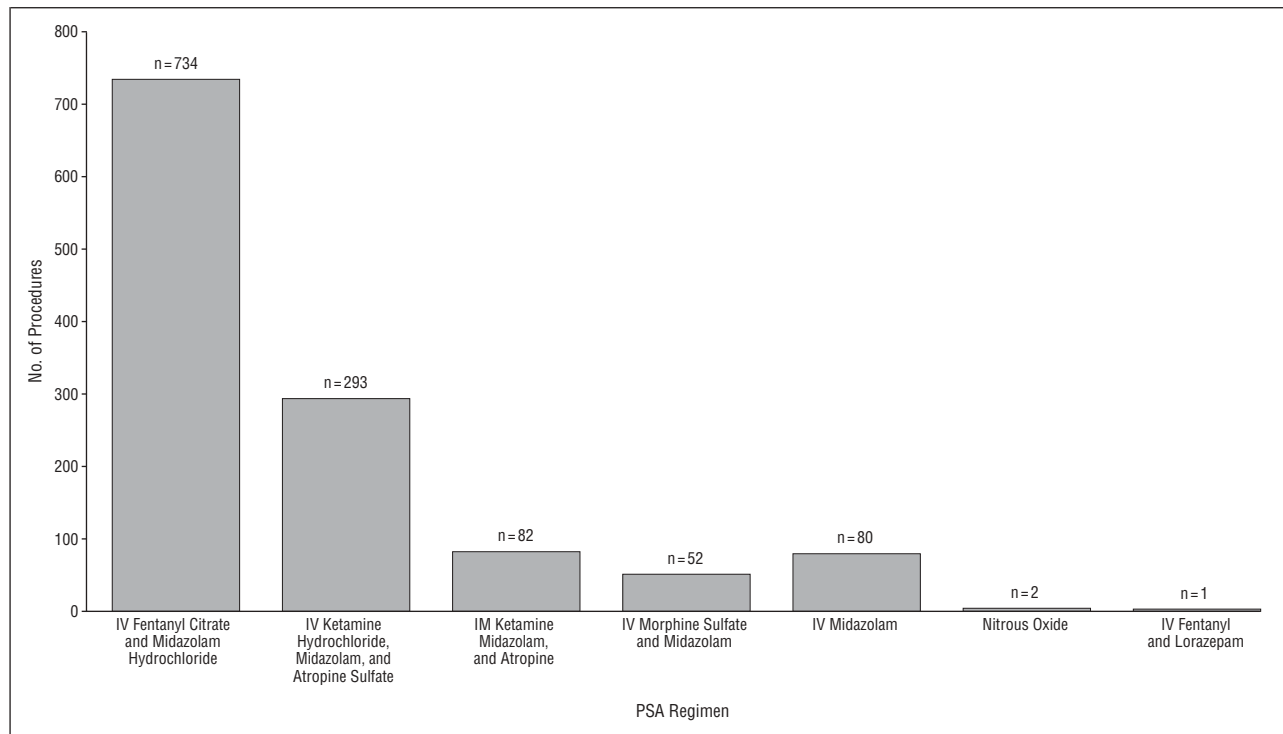


Figure 2. Type and frequency of use of procedural sedation and analgesia (PSA) regimens. IV indicates intravenous; IM, intramuscular.

Table 1. Failed Sedations by PSA Regimen*

Group	Total Sedations	Failed PSA (%)	Medication	Mean Dose	Medication	Mean Dose
IV fentanyl citrate and midazolam hydrochloride	706	12 (1.7)	Fentanyl*	2.7	Midazolam	0.1
IV ketamine hydrochloride, midazolam, and atropine sulfate	284	1 (0.4)	Ketamine	1.0	Midazolam	0.1
IM ketamine and midazolam	82	2 (2.4)	Ketamine	3.2	Midazolam	0.2
IV morphine sulfate and midazolam	50	0	NA	NA	NA	NA
IV midazolam	69	2 (2.9)	Midazolam	0.25	NA	NA
Nitrous oxide	2	0	NA	NA	NA	NA
IV fentanyl and lorazepam	1	0	NA	NA	NA	NA

Abbreviations: IM, intramuscular; IV, intravenous; NA, not applicable; PSA, procedural sedation and analgesia.

* Fentanyl dose is micrograms per kilogram of body weight; other doses are milligrams per kilogram of body weight.

hypoxia. Two patients who received IV fentanyl and midazolam were given diphenhydramine hydrochloride for persistent urticaria. One patient who received IV morphine sulfate and midazolam was given IV metoclopramide hydrochloride for persistent emesis. Finally, 1 patient who was sedated using IV fentanyl and midazolam received intramuscular dexamethasone sodium phosphate because of persistent hypoxia and stridor.

There was no significant difference between patients who experienced a complication or adverse reaction and those who did not based on sex, race, ASA class, premedication with analgesics, and level of consciousness achieved during PSA. Patients who experienced a complication or adverse reaction were more likely to be older (7.4 vs 6.6 years, $P = .02$). Patients who had sedation performed for laceration repair ($P = .04$) or lumbar puncture ($P = .02$) were less likely to experience a complication or adverse reaction. Patients who were sedated with IV fentanyl and midazolam were more likely

to experience a complication or adverse reaction (161/686, $P < .001$), while patients who were sedated using IV ketamine, midazolam, and atropine (24/277, $P = .006$) or IV midazolam alone (1/65, $P = .005$) were less likely.

Seventy (9.8%) of 717 patients reported minor complications and adverse reactions following discharge from the ED. The type and frequency of complications and adverse reactions noted following discharge from the hospital are shown in **Figure 4**. The most common complication or adverse reaction was vomiting (76.7% of patients), followed by persistent dizziness (6.8% of patients). Three patients reported more than 1 complication or adverse reaction at follow-up. No patient required a follow-up visit to his or her primary care physician or the ED. There were no significant differences between patients who experienced a complication or adverse reaction at follow-up and those who did not based on age, sex, race, ASA class, premedication, depth of sedation achieved, type of procedure, and type of sedation regimen.

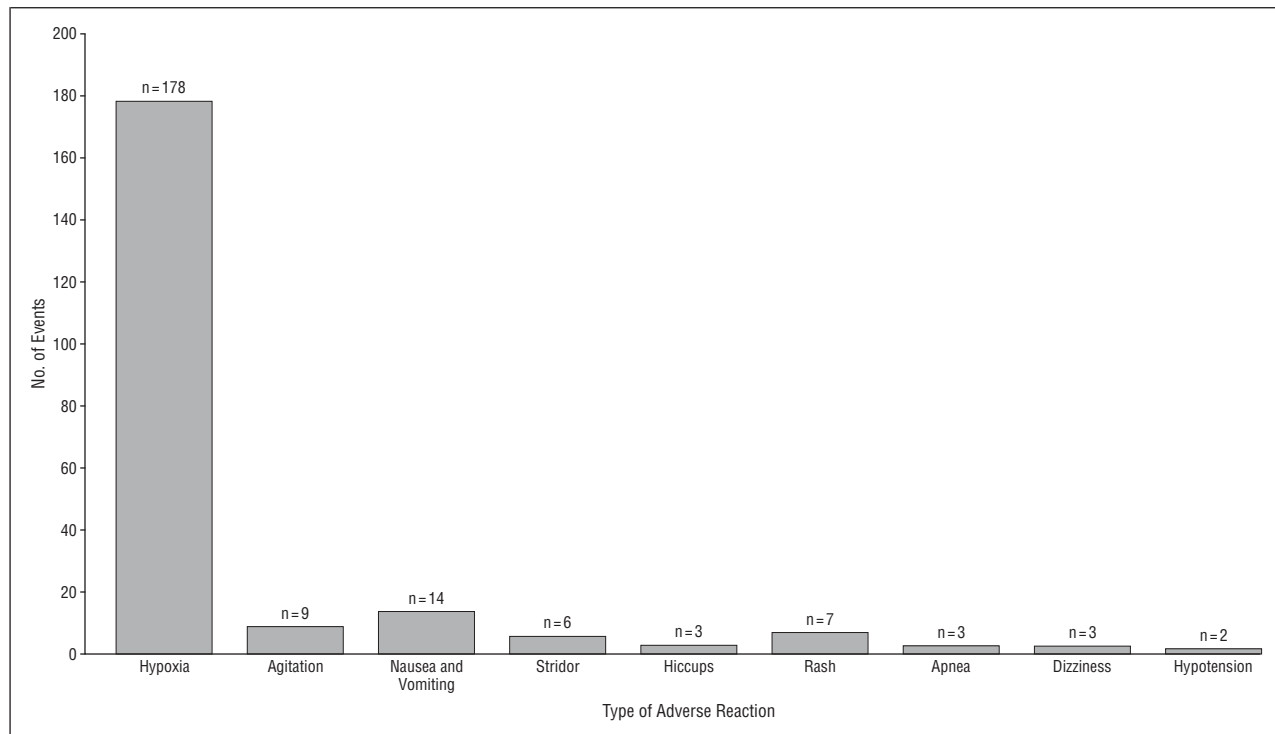


Figure 3. Number and type of adverse reactions noted during sedation.

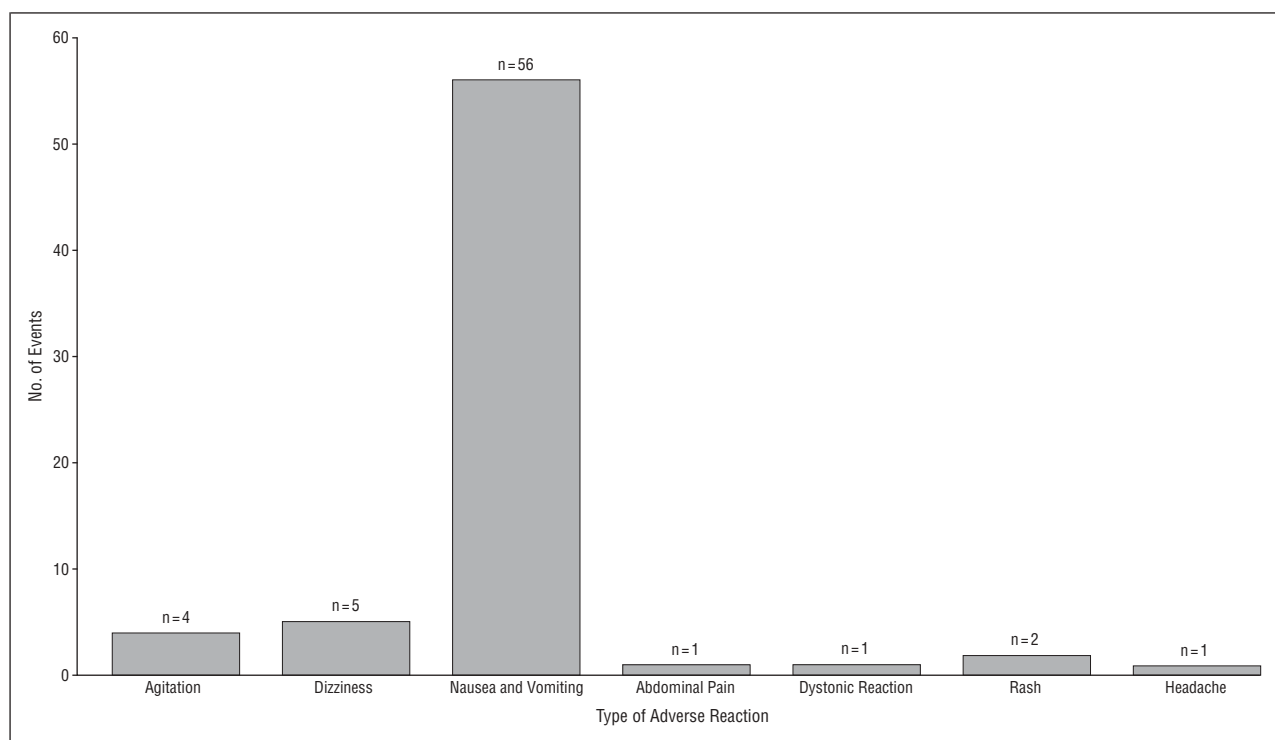


Figure 4. Number and type of adverse reactions noted at follow-up.

Three hundred eight subjects (25.3%) were younger than 3 years, 696 (57.3%) were between 3 and 12, and 211 (17.4%) were older than 12. There were no significant differences among age groups in regard to race, the likelihood of a failed sedation, or the incidence of adverse events following discharge from the hospital. Pa-

tients in the youngest age group had a significantly shorter mean NPO time than the oldest age group (4.6 vs 5.4 hours, $P=.01$), were more likely to be ASA class I than both other age groups (90.0% vs 80.0% and 74.9%, $P<.001$), and were less likely to be premedicated before receiving PSA than both other age groups (14.5% vs 32.8%

Table 2. Comparison of PSA Regimens and Incidence of Complications Noted During Sedation*

Group	Total Sedations	Complication	No.	Medication	Mean Dose (SD)	P Value	Medication	Mean Dose (SD)	P Value
IV fentanyl citrate and midazolam hydrochloride	686	Yes	161	Fentanyl*	3.0 (1.5)	.001	Midazolam	0.13 (0.08)	.01
		No	525		2.6 (1.4)			0.11 (0.07)	
IV ketamine hydrochloride, midazolam, and atropine sulfate	277	Yes	24	Ketamine	2.0 (1.2)	.83	Midazolam	0.09 (0.01)	.39
		No	253		2.0 (1.1)			0.11 (0.01)	
IM ketamine, midazolam, and atropine	82	Yes	13	Ketamine	3.3 (0.6)	.09	Midazolam	0.09 (0.04)	.94
		No	69		3.0 (0.8)			0.09 (0.04)	
IV morphine sulfate and midazolam	48	Yes	8	Morphine	0.2 (0.1)	.51	Midazolam	0.27 (0.14)	.03
		No	40		0.2 (0.1)			0.15 (0.09)	
IV midazolam	65	Yes	1	Midazolam	0.1 (NA)	.38	NA	NA	NA
		No	64		0.1 (0.1)			NA	

Abbreviations: IM, intramuscular; IV, intravenous; NA, not applicable; PSA, procedural sedation and analgesia.

*Fentanyl dose is micrograms per kilogram of body weight; other doses are milligrams per kilogram of body weight.

Table 3. Comparison of PSA Regimens and Incidence of Complications Noted at Follow-up*

Group	Total Sedations	Complication	No.	Medication	Mean Dose (SD)	P Value	Medication	Mean Dose (SD)	P Value
IV fentanyl citrate and midazolam hydrochloride	437	Yes	44	Fentanyl*	3.1 (1.7)	.35	Midazolam	0.12 (0.06)	.23
		No	393		2.7 (1.4)			0.12 (0.07)	
IV ketamine hydrochloride, midazolam, and atropine sulfate	176	Yes	17	Ketamine	2.1 (1.2)	.53	Midazolam	0.11 (0.07)	.74
		No	159		2.0 (1.1)			0.11 (0.06)	
IM ketamine, midazolam, and atropine	54	Yes	4	Ketamine	2.4 (1.2)	.31	Midazolam	0.08 (0.02)	.73
		No	50		3.1 (0.1)			0.09 (0.04)	
IV morphine sulfate and midazolam	19	Yes	4	Morphine	0.2 (0.1)	.80	Midazolam	0.24 (0.15)	.60
		No	15		0.2 (0.1)			0.21 (0.13)	
IV midazolam	29	Yes	1	Midazolam	0.1 (NA)	.62	NA	NA	NA
		No	28		0.1 (0.1)			NA	

Abbreviations: IM, intramuscular; IV, intravenous; NA, not applicable; PSA, procedural sedation and analgesia.

*Fentanyl dose is micrograms per kilogram of body weight; other doses are milligrams per kilogram of body weight.

and 49.3%, $P < .001$). Patients in the youngest age group were also less likely to experience a complication than patients in both other age groups (12.7% vs 19.2%, $P = .02$; and 12.7% vs 21.4%, $P = .01$). Patients between the ages of 3 and 12 years were more likely to reach a depth of sedation of 2 (drowsy or asleep but arousable) than both other age groups (41.8% vs 28.6% and 30.7%, $P = .02$). Patients in the oldest age group were more likely to be male than both other age groups (77.4% vs 61.4% and 63.4%, $P < .001$) and were more likely to be premedicated before PSA than patients between the ages of 3 and 12 years (49.3% vs 32.8%, $P < .001$).

Within each sedation regimen, no difference was found between patients who experienced a complication and those who did not in regard to mean age, sex, use of premedications, and mean NPO. **Table 2** describes the dose of each medication per kilogram of body weight used within a sedation regimen, stratified by occurrence of a complication during sedation. Significant findings noted for groups include the observation that patients who experienced a complication and were sedated with IV fentanyl and midazolam were given a higher dose of fentanyl (3.0 vs 2.6 $\mu\text{g}/\text{kg}$, $P = .001$) and a higher dose of midazolam (0.13 vs 0.11 mg/kg , $P = .01$) than those

who did not. Finally, among patients sedated using IV morphine and midazolam, those who experienced a complication received a higher dose of midazolam (0.27 vs 0.15 mg/kg , $P = .03$) than those who did not.

Similarly, no differences in clinical or demographic characteristics were found between patients who experienced a complication following discharge from the ED and those who did not within each sedation regimen. **Table 3** describes the dose per kilogram of body weight of each medication used within a sedation regimen, stratified by occurrence of a complication reported at follow-up. No significant findings were identified for any particular PSA regimen.

Patients who were sedated using IV fentanyl and midazolam were more likely to have a complication during sedation than those sedated using IV ketamine, midazolam, and atropine ($P < .001$) or IV midazolam ($P < .001$). Patients who were sedated using IV midazolam alone were also less likely to have a complication than patients who were sedated using intramuscular ketamine, midazolam, and atropine ($P = .008$) and IV morphine and midazolam ($P = .01$). There were no differences found between regimens in regard to the incidence of complications noted at follow-up.

Our study sought to document the success of sedation and the incidence of complications in subjects undergoing PSA in a pediatric ED where residents and pediatric emergency medicine fellows or attending physicians primarily perform PSA. In our study population, 98.6% of children were successfully sedated, 17.9% experienced a complication that was believed to be directly related to PSA, and 9.8% reported experiencing a complication following discharge from the hospital. Of those who experienced a complication, most experienced hypoxia that responded immediately to supplemental oxygen therapy, and only 11 children required an oral airway, bag-valve-mask ventilation, or the use of a reversal or other adjunctive agent. Many of the remaining complications were considered minor and were easily managed. Therefore, PSA was provided safely and efficaciously to our study population. It should be recognized, however, that the low number of complications noted in this investigation was achieved by trained physicians with advanced skills in assessing unstable vital signs and maintaining airways in emergencies.

Our complication rate is higher than that reported in other studies. Pena and Krauss,² in a large prospective evaluation of PSA in children, reported adverse events in 2.3% of children. Others have reported rates ranging from 0.6% to 7.8%.³⁻⁶ However, the medications used for PSA in these studies were different from those used in our study. Our higher complication rate may be due to the fact that we defined a sustained oxygen saturation of less than 93% as a complication. This may have led to an increase in the percentage of children experiencing a complication compared with previous studies. However, we believe that this definition is justified, as many of these children, if untreated, would likely have developed an even lower oxygen saturation rate.

Although statistically significant findings were found among patients who did and did not experience an adverse event during sedation, some findings were not considered clinically significant. Significant findings most likely occurred as the result of the large numbers of patients studied, allowing for small differences between groups to become statistically but not clinically significant.

The findings from this study may be limited by the fact that patients were sedated under controlled situations and by many different physicians with varying degrees and type of training. As a result, the incidence of complications may be higher in our ED than in others in which a limited number of physicians provide PSA.

Although PSA in children has been well studied, most investigators have evaluated individual pharmacologic agents used in PSA or have evaluated the use of PSA for specific procedures, such as performing a fracture reduction. Few investigators have looked at the overall use of PSA in a pediatric ED, especially when performed by nonanesthesiologists.

This study provides information that supports the idea that nonanesthesiologists can safely and effectively provide PSA to children in the outpatient setting. In addition, it provides information regarding the incidence of complications and adverse events that occur during PSA and immediately following.

A second limitation of this study is that patients were not randomized to receive the various sedation regimens used, potentially biasing comparisons among groups of subjects receiving differing regimens. Finally, variability among various physicians and nurses may have existed as to what constituted a complication, thereby inflating or deflating the reported rate.

In summary, we believe that PSA can be performed safely and effectively by nonanesthesiologists in a pediatric ED. Most complications experienced by subjects in our study were brief and not harmful to the patient.

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