Propofol Sedation by Emergency Physicians for Elective Pediatric Outpatient Procedures

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Study objective: We describe the efficacy of propofol sedation administered by pediatric emergency physicians to facilitate painful outpatient procedures.

Methods: By using a protocol for patients receiving propofol sedation in an emergency department–affiliated short-stay unit, a prospective, consecutive case series was performed from January to September 2000. Patients were prescheduled, underwent a medical evaluation, and met fasting requirements. A sedation team was present throughout the procedure. All patients received supplemental oxygen. Sedation depth and vital signs were monitored while propofol was manually titrated to the desired level of sedation.

Results: There were 291 separate sedation events in 87 patients. No patient had more than 1 sedation event per day. Median patient age was 6 years; 57% were male patients and 72% were oncology patients. Many children required more than 1 procedure per encounter. Most commonly performed procedures included lumbar puncture (43%), intrathecal chemotherapy administration (31%), bone marrow aspiration (19%), and bone biopsy (3%). Median total propofol dose was 3.5 mg/kg. Median systolic and diastolic blood pressures were lowered 22 mm Hg (range 0 to 65 mm Hg) and 21 mm Hg (range 0 to 62 mm Hg), respectively. Partial airway obstruction requiring brief jaw-thrust maneuver was noted for 4% of patient sedations, whereas transient apnea requiring bag-valve-mask ventilation occurred in 1% of patient sedations. All procedures were successfully completed. Median procedure duration was 13 minutes, median sedation duration was 22 minutes, and median total time in the short stay unit was 40 minutes.

Conclusion: Propofol sedation administered by emergency physicians safely facilitated short painful procedures in children under conditions studied, with rapid recovery.

Capsule Summary

What is already known on this topic
Small trials have shown propofol administered by emergency physicians to be highly effective for procedural sedation, but there have not been large trials to profile its safety in this setting.

What question this study addressed
Adverse effects associated with 291 consecutive propofol sedations for elective (largely oncology) procedures in children, as managed by emergency physicians in a short-stay unit using a defined protocol and careful monitoring.

What this study adds to our knowledge
Hypoxia occurred in 5%, partial airway obstruction requiring airway repositioning in 4%, and apnea with assisted ventilation in 1%. All adverse effects were promptly identified and readily managed without further complication.

How this might change clinical practice
Emergency physicians can safely administer propofol for emergency department pediatric procedural sedation using a defined protocol with careful monitoring.

INTRODUCTION

Background

Many children have chronic illnesses requiring frequent procedures for diagnosis and management.[1] These procedures may be brief but are often painful and anxiety provoking. Sedatives are necessary routinely in the outpatient setting for these children requiring painful diagnostic and therapeutic interventions. Statements supporting the appropriate use of sedative agents for pain management in children have been issued by the American Academy of Pediatrics in conjunction with the American Society of Anesthesiologists (ASA)[2] and the American College of Emergency Physicians.[3] Appropriate pain management is now considered standard of care for the emergency physician.[4-6] Increasing numbers of painful pediatric medical procedures are being performed on an outpatient basis. Current opinion suggests that further study of some of the ultrashort-acting agents for use in the outpatient setting is advisable.[7]

The ideal agent for such sedations is safe and easy to administer, with rapid onset of action and easily controlled levels of sedation. It should allow rapid recovery with minimal adverse effects. Many of the sedation agents currently in use have the significant disadvantage of prolonged sedation.[7-14] A significant disadvantage of 2 commonly used emergency department (ED) sedative regimens, midazolam/fentanyl and ketamine,

is that both regimens frequently require 1 hour or more for recovery.[7,12-14] In contrast, children typically have recovered approximately 15 minutes after discontinuation of the ultrashort-acting sedative propofol.[15]

Propofol is a powerful sedative, characterized by rapid onset and short duration of action.[16] Propofol controls stress responses and has anticonvulsant and amnestic properties.[17,18] It does not itself have analgesic properties but may be used in combination with opioids.[17,18] These characteristics make propofol an attractive medication choice to facilitate short, painful procedures. Propofol adverse effects include transient hypotension and dose-dependant respiratory depression.[19-21]

Propofol's versatility as a sedative agent has resulted in its increasing use to facilitate minor procedures outside of the operating room setting. Propofol sedation has been studied for elective oncology procedures[22,23] and has been recommended for endoscopic retrograde cholangiopancreatography,[24] dermatologic procedures,[25] and magnetic resonance imaging.[26,27] Madan et al[28] describe propofol as a feasible option for pediatric diagnostic ophthalmic procedures. Similarly, Elitsur et al[29] have documented the use of propofol in 104 children undergoing pediatric gastrointestinal endoscopic procedures. A role is also seen for this agent in dentistry.[30]

Importance

Three prospective studies of propofol sedation in the ED suggest it may be safely administered by emergency physicians for short painful procedures in adult[31] and pediatric patient populations.[15,32] Although these were small case series, propofol was found to be a sedative agent with predictable efficacy, high patient satisfaction, and adverse effects that could be readily and safely managed by emergency physicians. There was no morbidity or mortality associated with short-term propofol use.

Goals of This Investigation

The objective of this study is to describe the efficacy and adverse effects of propofol sedation in a large case series administered by pediatric emergency physicians to facilitate outpatient pediatric procedures.

MATERIALS AND METHODS

Theoretical Model of the Problem

Brief and painful procedures are performed in the outpatient setting, requiring sedation provided by the

emergency physician. Propofol is an ideal sedative agent, with rapid onset of action and rapid recovery.[16] However, safety and efficacy when propofol is administered by emergency physicians has been inadequately studied.[15,31,32] Documentation of adverse effects, in particular, respiratory depression and hemodynamic instability, is warranted in this setting. In addition, documentation of the labor intensity required for physician administration and monitoring of the patient is necessary. The vigilance required for patient monitoring may, in fact, limit the use of this sedative by emergency physicians. This study was designed to document the safety profile of propofol, specifically as a sedative agent given by emergency physicians. We describe our approach to patient monitoring with this agent but did not collect data on physician or nursing time required for administration.

Setting/Selection of Patients

A prospective, consecutive case series of patients presenting to an ED-affiliated short-stay unit was performed from January to September 2000. Children who were sedated more than once during the study period were entered as discrete sedation events. We performed a focused, presedation medical and surgical history, including experiences with sedations or anesthetics and physical examination in accordance with standard recommendations.[2,7,33] A focused physical examination was performed, with special attention to the cardiopulmonary system and airway structures. Patients were required to fast 2 hours for clear liquids, 4 hours for breast milk, and 6 hours for all other intake in accordance with the ASA guidelines for elective procedures.[33] Exclusion criteria included ASA physical status classification 4 or 5; airway abnormalities; significant abnormalities of the cardiorespiratory, hepatic, renal, or central nervous systems; and history of adverse reaction to propofol, opioids, or eggs.

Study Design/Data Collection and Processing

A sedation protocol was established for all patients receiving sedation in an ED-affiliated short-stay unit. This protocol was based on data collected in a prospective study of pediatric patients in the ED.[32]

A 4-member sedation team was present throughout the procedure. Personnel on the team consisted of (1) a pediatric emergency attending physician or fellow, skilled in airway management and cardiopulmonary resuscitation, who was responsible only for propofol administration and monitoring the patient's vital signs, airway patency, level of consciousness and adequacy of

ventilation; (2) a registered nurse, present to record vital signs and other study data; (3) a respiratory therapist for airway assessment and support; and (4) a physician or nurse practitioner to perform the procedure.

Peripheral intravenous access was established in all patients without central access. Oxygen was administered at 5 L/min by using a funnel placed close to the patient's face before sedation in all patients.

Methods of Measurement

In accordance with published guidelines, we concurrently evaluated and recorded changes in pulse rate, respiratory rate, and oxygen saturations by means of continuous Marquette Eagle 4000 cardiorespiratory monitoring (GCX Corporation, Petaluma, CA), which printed these data at 2-minute intervals throughout the procedure until full patient recovery.[2,3,34] Blood pressure was measured every 2 minutes and recorded. The change in blood pressure caused by sedation administration was calculated by subtracting the minimum value obtained while the patient was sedated from the postsedation blood pressure. This method was chosen to minimize the confounding effect of preprocedural patient anxiety, which would increase starting blood pressure values to above-normal levels. Capnography was not performed.

One minute before the initial propofol dose, children received 1 to 2 µg/kg[35] of fentanyl (maximum 50 µg) to provide analgesia, except for those already receiving chronic opiates or those scheduled for nonpainful procedures (eg, diagnostic imaging). No patient was to receive more than a single dose of fentanyl.

An initial dose of 1 mg/kg of propofol[36,37] (maximum 40 mg) was then administered intravenously and supplemented with propofol doses of 0.5 mg/kg (maximum 20 mg) intravenously at the discretion of the sedating physician. Each propofol dose was either drawn up in an individual syringe or clearly labeled in 0.5 mg/kg increments to prevent inadvertent administration of additional medication. A 3-way stopcock allowed each propofol dose to be followed by a standard normal saline solution flush before the subsequent dose was given. The bolus was infused over 1 to 2 minutes, with a minimum interval of 60 seconds between each subsequent propofol dose. The dose of propofol was titrated to tolerance of noxious stimuli without patient complaint[38,39] and with sufficient compliance to perform the procedure. Nonpurposeful movements that did not interfere with the procedure and verbalizations, including moaning or minimal crying, were tolerated without additional medication administration. The use

of topical or local anesthesia during these procedures was not standardized and was left to the discretion of the medical provider performing the procedure.

In addition to vital sign monitoring, episodes of poor perfusion, oversedation, or emesis were recorded. Poor perfusion was defined as capillary refill time more than 3 seconds or weak peripheral pulses. Respiratory depression was defined as evidence of upper airway obstruction, the need for bag-valve-mask ventilation, or apnea with or without associated desaturation. Partial airway obstruction was defined as the presence of stridor, chest wall retractions, snoring respirations, or paradoxical abdominal breathing responding to brief jaw-thrust maneuvers. Necessary medical interventions for observed complications were documented in a standard fashion. These interventions included need for airway repositioning, bag-valve-mask ventilation, endotracheal intubation, intravenous fluid administration, or cardiopulmonary resuscitation. Sedation efficacy was defined as successful completion of the procedure without patient distress and lack of procedure interruption because of airway or hemodynamic complication. After completion of the procedure, when the child's cardiopulmonary functions were determined to be stable and adequate, documentation intervals of vital signs were increased to every 5 minutes until patient discharge.

Duration of procedure, duration of sedation, time from procedure completion to short-stay unit discharge, and total time in the short-stay unit were concurrently recorded. The duration of procedure was defined as the time allotted from the start of the first procedure to the end of the final procedure during a unique sedation event. Sedation duration was defined as that period beginning when the patient did not verbalize in response to questions and ending when he or she had regained that ability. Time in the short-stay unit was defined from admission to the short-stay unit until discharge, which included time to obtain informed consent, assent, and preparation time. Criteria for discharge included normal cardiopulmonary function, return to presedation level of responsiveness, and the ability to talk, drink, sit unaided, and walk with minimal assistance.

Primary Data Analysis

Measurements were reported by using descriptive statistics. Categoric data are presented as the percentage of frequency of occurrence. Continuous data are presented as means or medians with 95% confidence intervals and ranges. Statistics were performed with computer software (Excel X for Mac, Microsoft Corp-

oration, Redmond, WA). The University of Utah institutional review board reviewed and approved this study.

RESULTS

Characteristics of Study Patients

Thirteen pediatric emergency physicians administered propofol to 87 patients during the 9-month study period. Each patient received propofol once (n=41), twice (n=15), 3 times (n=3), 4 times (n=6), 5 times (n=5), 6 times (n=7), 8 times (n=1), 9 times (n=1), 10 times (n=1), 12 times (n=2), 13 times (n=3), or 15 times (n=2), for a total of 291 discrete sedation events for 550 procedures. Table 1 shows patient demographic characteristics.

Two or more procedures were performed in 263 (91%) of the encounters. The most commonly performed procedures were lumbar puncture with intrathecal chemotherapy administration. Other procedures performed are listed in Table 2.

Main Results

Fentanyl was used for premedication in 97% of the sedations. Of the 8 patients who did not receive fentanyl as premedication, 5 received a different narcotic before the procedure. No patient received more than 1 dose of fentanyl. Fentanyl and propofol doses are listed in Table 3. Table 3 also depicts the effect of propofol on the vital signs of the children in this study. Changes in pulse rate

Table 1.
Patient demographic characteristics (N=87).

Characteristic	Percentage of Patients (No.)
Age, y	
Median	6
Range	1–19
Sex	
Male	57 (50)
Female	43 (37)
Diagnosis	
Oncologic diagnosis	72 (63)
Rheumatoid arthritis	6 (5)
Blood dyscrasias	6 (5)
Pseudotumor cerebri	2 (2)
Closed fracture reduction	3 (3)
Other*	11 (9)
ASA classification	
ASA 1	4 (4)
ASA 2	6 (5)
ASA 3	90 (78)

*Cellulitis, periorbital cellulitis, septic ankle, seizure disorder, hypertension, ocular abnormalities, warts, pancreatitis, chronic otitis media.

were minimal. There was 1 occurrence of transient bradycardia to a minimum of 57 beats/min, which occurred in a 3-year-old female patient with acute lymphocytic leukemia, trisomy 21, tracheal stenosis, and pulmonary hypertension. Information not initially available to the study physicians revealed that this child had a history of bradycardia with general anesthesia. The patient was scheduled for a lumbar puncture and bone marrow aspiration. Her baseline pulse rate was 105 beats/min. She received fentanyl at 1 μg/kg and propofol at 1.5 mg/kg. No single apparent precipitant other than the sedation was appreciated. There was no associated oxygen desaturation, concomitant respiratory depression, apnea, change in peripheral pulses, or extremity perfusion documented with bradycardia. It resolved spontaneously without intervention in less than 1 minute. No other episodes of tachycardia or bradycardia were noted in the remaining study patients.

Propofol caused a transient decrease in systolic blood pressure in all but 4 sedation events. There was a mean decrease in the systolic blood pressure and diastolic blood pressure (Table 3, Figure 1). There was no evidence of poor perfusion recorded in any patients. Supplemental intravenous fluids were administered in 27% of the sedation events at the discretion of the sedating physician. The patients who received intravenous fluids had a median change of systolic blood pressure of 22 mm Hg compared with patients who did not, with a median change in systolic blood pressure of 21 mm Hg. Similarly, patients who received intravenous fluids had a median change of diastolic blood pressure of 21.5 mm Hg compared with patients who did not, with a median change in diastolic blood pressure of 21 mm Hg. All episodes of low blood pressure were transient. The median time from minimal blood pressure to a presedation blood pressure values was 4 minutes.

A slight decrease in respiratory rates and oxygen saturation was observed (Table 3). Of patients experiencing oxygen desaturation, 93% maintained saturations higher than 90% (Figure 2). Partial airway obstruction was noted in 4% of individual sedations, with no discernible relation to drug administration or patient characteristics. Apnea requiring bag-valve-mask ventilation occurred in 1% of sedations (3/291). Of the 3 encounters in which bag-valve-mask ventilation was required, 1 patient, a 5-year-old boy with acute lymphocytic leukemia, required bag-valve-mask ventilation for 2 separate sedations. He was sedated once with propofol for a bone marrow aspiration and, on a separate occasion, a second time for a lumbar puncture with intrathecal medication administration. For the bone marrow aspiration, the patient received fentanyl at 2 μg/kg and propofol at 7 mg/kg. His presedation oxygen saturation was 98%, with an oxygen desaturation to 90%. On the second occasion, the patient again received fentanyl at 2 μg/kg and propofol at 6.9 mg/kg. He desaturated from an initial oxygen saturation of 98% to a minimum of 65%. He regained an oxygen saturation of 95% within 40 seconds. The third case involved a 4-year-old boy with acute lymphocytic leukemia and a history of hypertension who was sedated for a bone marrow aspiration and a lumbar puncture with intrathecal medication administration. His presedation medications included dexamethasone and amlodipine. He received fentanyl at 2 μg/kg and propofol at 4.1 mg/kg. His initial oxygen saturation was 98%, with a desaturation to a minimum oxygen saturation of 93%. In each of these 3 cases, the patient required 45 to 60 seconds of bag-valve-mask ventilation as a result of apnea with associ-

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Table 2.
Procedures performed (N=550).

Procedure	Percentage of Patients (No.)
Lumbar puncture	43 (237)
Intrathecal medication administration	31 (168)
Bone marrow aspirate	19 (107)
Bone biopsy	3 (17)
Knee injections	1 (6)
Percutaneous central line placement	0.7 (4)
Closed fracture reduction	0.5 (3)
Other*	1 (8)

*Wart removal, staple removal, skin biopsy, broviac removal × 2, magnetic resonance imaging, spica cast placement, abscess incision and drainage.

Table 3.
Discrete sedation events (N=291).

Drug Doses and Vital Sign Changes	Results
Drug doses	
Mean fentanyl dose, μg/kg	1.2
Median fentanyl dose, μg/kg (range)	1.0 (0–2)
Mean propofol dose, mg/kg	3.9
Median propofol dose, mg/kg (range)	3.5 (0.8–15.3)
Vital sign changes	
Pulse rate, median decrease, beats/min (range)	4 (–31 to 52)
Systolic blood pressure, median decrease, mm Hg (range)	22 (–1 to 65)
Diastolic blood pressure, median decrease, mm Hg (range)	21 (–1 to 62)
Respiratory rate, median decrease, breaths/min (range)	7 (–20 to 78)
Oxygen saturation, median decrease, % (range)	3 (0 to 20)

ated desaturation. The apnea resolved and, in all cases, the procedures were successfully completed.

There was a single case of emesis in our study population. The episode of emesis occurred in the recovery period when the patient was sipping fluids. There was no evidence of aspiration, and no suctioning or other physical intervention was performed. No patient experienced an allergic reaction or cardiopulmonary arrest, and no patient required endotracheal intubation.

Propofol was effective in 100% of study procedures, and all procedures were successfully completed. Sedation duration data are presented in Table 4 and Figure 3.

LIMITATIONS

There were several limitations to this study. First, the level of sedation was not objectively scored in this study, making it difficult to quantify sedation depth. Objective measures of sedation depth may give more detailed information about safety and efficacy. Second, multiple physicians administered the propofol medication. Each physician may have had a different threshold for patient movement during the procedure, affecting the mean and median doses of propofol, which, however, may better reflect the diverse nature of a large emergency medicine practice, adding validity to the safety of propofol administration under these conditions. Third, intravenous fluid administration before or during the sedation event was not standardized, making it difficult to establish clear trends in blood pressure during propofol administration. However, there were no patients in the series who showed clinical evidence of poor perfusion. Fourth, end-tidal CO_2 monitoring was not performed in these patients. Hypercapnia may have

Figure 1.
Decrease in blood pressure (N=291).
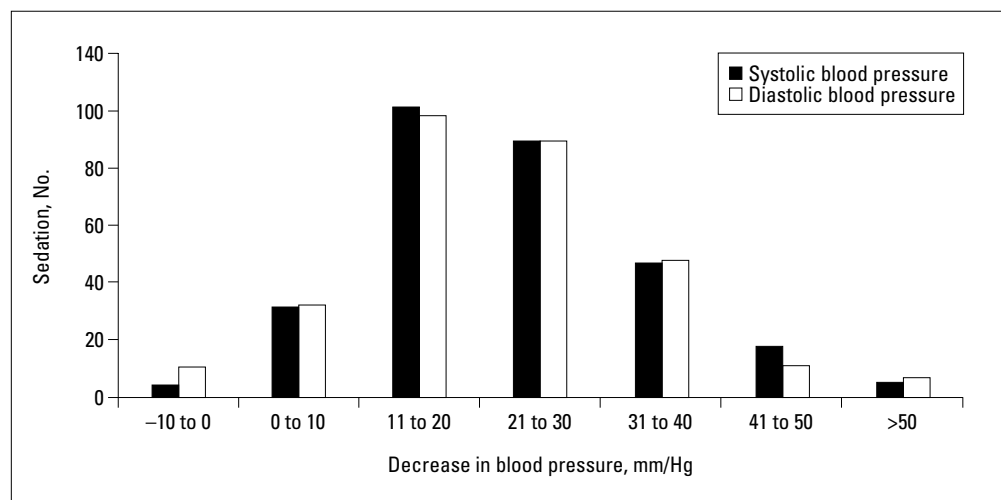
Figure 2.
Decrease in oxygen saturations (N=291).
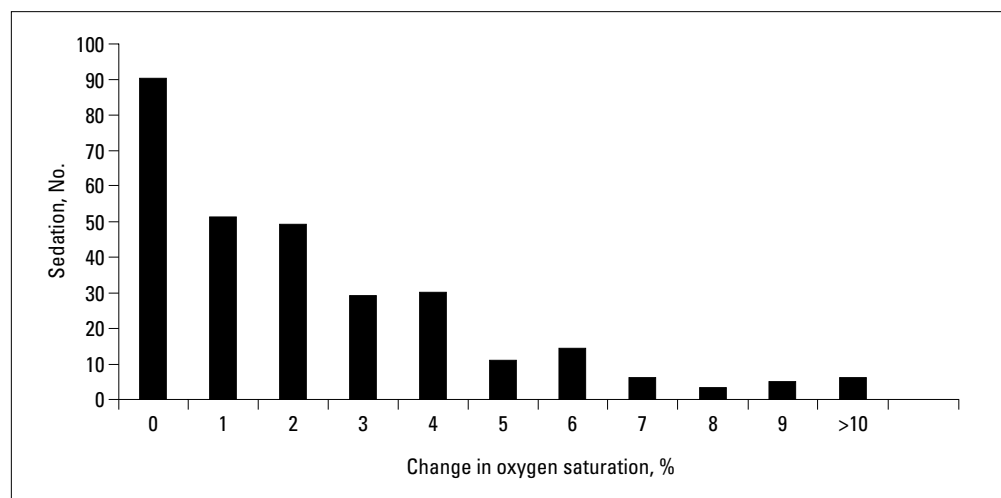
been present during propofol administration yet unsuspected clinically because of normal oxygen saturation. Finally, this study took place in a short-stay unit where children were scheduled for elective outpatient procedures. Thus, conservative fasting recommendations were followed, which may not be feasible in the ED.

DISCUSSION

Our data suggest that propofol, when administered by emergency physicians under the guidance of a sedation protocol, provides safe and effective sedation for short painful procedures in the outpatient setting. Although transient cardiopulmonary depression from propofol was not infrequent, all adverse events in this study were promptly identified and easily managed by pediatric emergency physicians. The ultrashort-acting attribute of propofol permitted continual titration to effect and prompt recovery on completion of the procedure, mini-

mizing overall short-stay unit duration, even for patients undergoing multiple procedures.

As shown in Table 1, there is a wide age range of children who received sedation for the noted procedures, reflecting the versatility of our practice. The majority of these children are known to have a disease process that requires treatment through repeated painful procedures such as those listed in Table 2. Because anxiety and discomfort may result in increased difficulty in performing the procedure itself and increased emotional duress to the patient, many of the children had required sedation in the operating room at greater inconvenience and expense before the introduction of the sedation service.

Bradycardia has been described as a possible adverse effect of propofol in combination with synthetic opioids.[19,20] We noted only one event of bradycardia. A transient decrease in blood pressure is a well-documented effect of propofol sedation.[19,20] We observed the same phenomenon, which was not associated with significant changes in peripheral perfusion, capillary refill time, or pulse rate.

Propofol can cause respiratory depression and apnea.[18] The occurrence of apnea appears to depend on the dose and the rate of medication administration, with a higher incidence of apnea reported in the larger doses.[18,40] Although potentially serious airway complications occurred in 5% of the patients overall, all such events were quickly identified and easily dealt with by emergency physicians. The majority of the patients simply required a jaw-thrust maneuver. In our study,

Table 4.
Time in minutes (N=291).

Duration	Minutes
Procedure duration, median (range)	13 (1–43)
Duration of sedation, median (range)	22 (1–46)
Time from procedure completion to short-stay unit discharge, median (range)	25 (2–90)
Total time in the short-stay unit, median (range)	40 (17–95)

Figure 3.
Procedure, sedation, and length-of-stay durations (N=291).
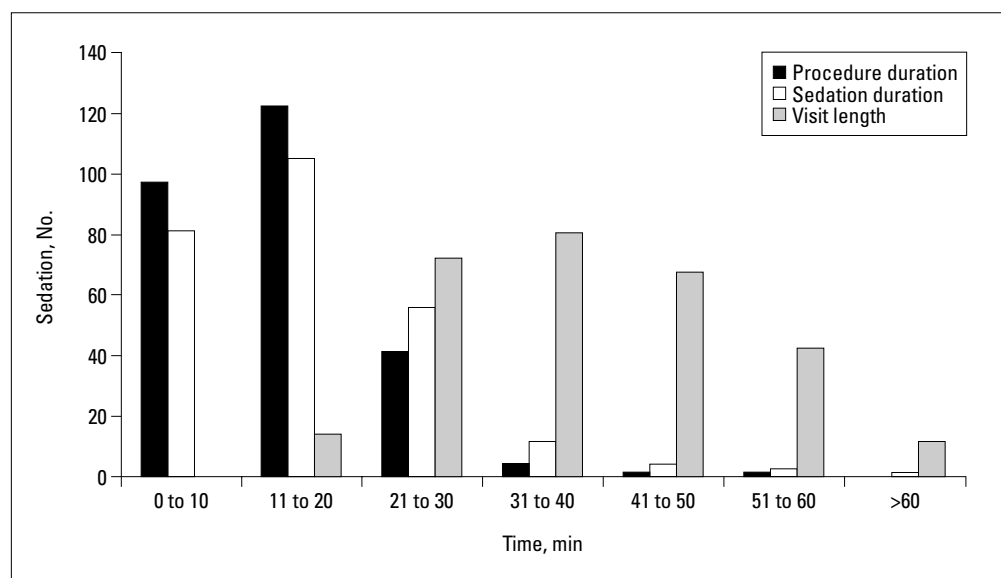
the few patients with apnea recovered rapidly and experienced no untoward effects as a result. Moreover, most recorded changes in oxygen saturation were minimal, which may be the result of high initial oxygen saturations in each of the patients because supplemental oxygen was administered before initial propofol delivery. Because patient oxygen saturation was nearly 100% before the first dose of propofol, a short duration of apnea was better tolerated without associated hypoxia. Fortunately, prolonged apnea was not observed. All procedures were successfully completed.

A significant advantage to propofol is the rapidity with which the patients reach full recovery. Patients receiving propofol reached their presedation level of consciousness within minutes of completion of the procedure. Additionally, they were largely free of certain adverse effects associated with the use of other common sedatives, including nausea, vomiting, and emergence reactions. A shortened duration of postsedation nursing care was needed, thereby allowing rapid disposition and patient discharge, an important consideration in the short-stay unit and ED settings.

Propofol use has been studied in children undergoing invasive and noninvasive procedures in a sedation unit staffed by pediatric intensivists and pediatric intensive care nurses.[27] In this study, Lowrie et al[27] concluded that safe sedation with propofol is best accomplished through careful presedation assessment and close monitoring by care providers not involved with the procedure. We agree with these suggestions; however, there are some important differences between the 2 studies. In contrast to our study, in which the 2 most common procedures were lumbar puncture with intrathecal medication administration and bone marrow aspiration, the 2 most common procedures done in the study by Lowrie et al were cardiac catheterization and magnetic resonance imaging, both procedures with relatively long sedation durations. This difference may have accounted for the need for propofol to be administered as a continuous infusion. Additionally, in the study by Lowrie et al, fentanyl was given during the procedure, not as a premedication. Finally, in our study a sedation physician was with the patient through the entire procedure, whereas that was not the case in the study by Lowrie et al. These study differences may have resulted in some of the differences in clinical outcome. In the study by Lowrie et al, for example, 2.4% of the procedures were cancelled because of complications, and one patient received endotracheal intubation. These complications were not encountered in our experience.

This protocol has been designed to allow safe administration of propofol to children in the outpatient setting but has implications useful for children in the ED setting. Many of the procedures required by children who present to the ED, such as closed fracture reduction, emergency lumbar puncture, joint reduction, or genitourinary evaluations for vaginal or rectal trauma, for example, are short but painful or anxiety provoking.

Use of propofol may improve patient flow through the ED. Nursing time and time in the ED are valuable commodities. We have demonstrated that propofol administration in these settings results in a short duration of sedation, short duration of close patient monitoring, and decreased time to discharge. It is of value to note that the elements of a comprehensive sedation team, premedication with fentanyl, bolus administration of the propofol, and median total doses and monitoring requirements may be easily translated to the ED setting. The safety of this protocol for acutely ill or injured children or those otherwise excluded from the current study remains uncertain.

In retrospect, it would have been valuable to objectively score the level of sedation caused by propofol, which would allow us to more accurately quantify the depth of sedation to allow accurate comparisons with other sedative medications. It would also have been helpful to perform end-tidal CO_2 monitoring to assess for hypercapnia as a possible adverse effect of propofol.

In conclusion, propofol maintains effective sedation for short painful procedures in children. When used as part of a standardized protocol with exclusion criteria, suggested titration schedule, and mandatory monitoring, pediatric emergency physicians may safely facilitate painful procedures in children by using propofol sedation. Although transient hypotension and respiratory depression may occur, they can be quickly recognized and easily managed under proper conditions. Recovery from propofol sedation is rapid, with brief total stay.

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