

# Preprocedural Fasting State and Adverse Events in Children Undergoing Procedural Sedation and Analgesia in a Pediatric Emergency Department

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See editorial, p. 647.

**Study objective:** Assessment of preprocedural fasting is considered essential in minimizing the risks of procedural sedation and analgesia. Established fasting guidelines are difficult to follow in the emergency department (ED). We characterize the fasting status of patients receiving procedural sedation and analgesia in a pediatric ED and assess the relationship between fasting status and adverse events.

**Methods:** A prospective case series was conducted in a children's hospital ED during an 11-month period. All consecutive patients requiring procedural sedation and analgesia were included. Preprocedural fasting state and adverse events were recorded. The percentage of patients undergoing procedural sedation and analgesia who did not meet fasting guidelines was determined. Adverse events were analyzed in relation to fasting status.

**Results:** One thousand fourteen patients underwent procedural sedation and analgesia, and data on fasting status were available for 905 (89%) patients. Of these 905 patients, 509 (56%; 95% confidence interval [CI] 53% to 60%) did not meet fasting guidelines. Seventy-seven adverse events occurred in 68 (6.7%; 95% CI 5.2% to 8.4%) of the 1,014 patients. All adverse events were minor and successfully treated. Adverse events occurred in 32 (8.1%; 95% CI 5.6% to 11.2%) of 396 patients who met and 35 (6.9%; 95% CI 4.8% to 9.4%) of 509 patients who did not meet fasting guidelines. There was no significant difference in median fasting duration between patients with and without adverse events and between patients with and without emesis. Emesis occurred in 15 (1.5%) patients. There were no episodes of aspiration (1-sided 97.5% CI 0% to 0.4%).

**Conclusion:** Fifty-six percent of children undergoing ED procedural sedation and analgesia were not fasted in accordance with established guidelines. There was no association between preprocedural fasting state and adverse events.

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**Capsule Summary**

*What is already known on this topic*

It is controversial whether fasting guidelines for elective procedures should apply to emergency department (ED) procedural sedation and analgesia. Such guidelines are difficult to follow and are of unclear benefit in reducing adverse events.

*What question this study addressed*

This study prospectively characterized the fasting status of children sedated at an urban ED and compared adverse effects between those who were compliant with elective fasting guidelines and those who were not.

*What this study adds to our knowledge*

More than half of the 905 study children underwent procedural sedation and analgesia despite being noncompliant with elective fasting guidelines, and there was no difference between fasted and nonfasted children in airway complications, emesis, or other adverse events.

*How this might change clinical practice*

Compliance with elective fasting guidelines appears not to mitigate adverse effects typically noted during ED procedural sedation and analgesia in children, but institutional guidelines currently do not reflect this fact.

**INTRODUCTION**

The assessment of preprocedural fasting (defined as complete fasting, ie, neither solids nor liquids by mouth) is widely held to be essential in minimizing the risk of aspiration during procedural sedation and analgesia<sup>1</sup> in the emergency department (ED).<sup>2</sup> Age-based guidelines for preprocedural fasting for elective procedures (Table 1) have been published by the American Academy of Pediatrics (AAP)<sup>3,4</sup> according to similar guidelines set by the American Society of Anesthesiologists (ASA).<sup>5,6</sup> However, these consensus-based guidelines are difficult to follow for nonelective ED procedures and present a special challenge in the pediatric ED, where children are rarely fasted before their presentation and often require urgent or emergency procedures for acute injuries.

Previous studies have demonstrated the safety of procedural sedation and analgesia for children in the ED.<sup>2,7-17</sup> However, the fasting state of patients undergoing ED procedural sedation and analgesia has not been adequately

characterized, and data on optimal fasting times are lacking.<sup>2,5,6,18-21</sup> Furthermore, the relationship between fasting status and adverse events during procedural sedation and analgesia in the pediatric ED has not been studied.

The primary objective of our study was to characterize the fasting status of patients receiving procedural sedation and analgesia in a pediatric ED. Secondary objectives included assessing the relationship of preprocedural fasting state to observed adverse events.

**MATERIALS AND METHODS**

We conducted a prospective observational study in the ED of a large, urban, pediatric teaching hospital with a pediatric emergency medicine fellowship program.

All consecutive ED patients who required intravenous, intramuscular, oral, rectal, or inhalational agents for painful procedures or diagnostic imaging studies were included in 2 data collection intervals during an 11-month period (pilot study, August to October 2001; extended study, February to September 2002). Emergency attending physicians and fellows performed all sedations in this study, including sedations for diagnostic imaging. Procedural sedation and analgesia was performed in accordance with Joint Commission on Accreditation of Healthcare Organizations guidelines<sup>22,23</sup> and departmental procedural sedation and analgesia protocols.<sup>7,24</sup> This study was approved by the hospital's institutional review board.

**Table 1.**  
AAP/ASA guidelines for preprocedural fasting for elective procedures.

Age, mo	Solids and Nonclear Liquids,* h	Clear Liquids, h
<6	4-6 <sup>†</sup>	2
6-36	6	2
>36	6-8 <sup>‡</sup>	2

\*Infant formulas, breast milk, and nonhuman milk.

<sup>†</sup>Four hours according to the AAP guidelines.

<sup>‡</sup>Eight hours according to the AAP guidelines.

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Patients receiving procedural sedation and analgesia were tracked via the ED Pyxis machine (an automated medication storage and dispensing system; Pyxis Corporation, San Diego, CA). The computerized Pyxis logs were queried weekly for all patients who had received medications for procedural sedation and analgesia. Each query generated a report of patients for whom procedural sedation and analgesia medications had been withdrawn from the Pyxis machine. This list of medications consisted of sedative, dissociative, and analgesic agents, including midazolam, lorazepam, diazepam, fentanyl, ketamine, chloral hydrate, pentobarbital, and methohexital. Propofol, etomidate, morphine sulfate, and meperidine are not used for procedural sedation and analgesia in this ED. This process ensured complete identification of all patients undergoing ED procedural sedation and analgesia because these medications could be obtained only from the Pyxis machine.

For each patient identified in the Pyxis report, the computerized ED encounter sheet and the sedation monitoring record (a standardized, hospital-wide sedation scoring form required for every patient undergoing procedural sedation and analgesia) were obtained from the patient's medical record. For quality assurance, copies of the sedation monitoring records that were kept in the ED were reviewed weekly. Nitrous oxide sedations were identified during this review of the ED sedation monitoring records because nitrous oxide is not accessed through the Pyxis machine.

Cases in which medications were withdrawn from the Pyxis machine but never administered to the patient were excluded. Patients receiving medications for endotracheal intubation, muscle spasms, anxiolysis, rapid tranquilization for psychiatric agitation, seizure control, intractable vomiting, hiccups, or pain control without an associated procedure were also excluded. In cases in which it was unclear whether a drug was actually administered or for what indication a drug was given, the treating physician was contacted.

Record review was conducted in a standardized manner by 2 of the authors (DA, RG). Characteristics to be extracted from the medical record were identified and agreed on a priori. Fields were created on an SPSS (ver-

sion 11.0; SPSS, Inc., Chicago, IL) database for each of these variables. Demographic characteristics (eg, date of birth, weight, sex), comorbidities, dietary history, indications, medication doses, sedation depth, and adverse events were extracted from the patient's medical record. Patients were classified according to the ASA physical status classification (class 1, normal healthy patient; class 2, patient with mild systemic disease with no functional limitation; class 3, patient with severe systemic disease with definite functional limitation; class 4, patient with severe systemic disease that is constant threat to life; class 5, moribund patient not expected to survive without the procedure).

The dietary history section in the sedation monitoring record included assessment of the date and time of last solid and clear liquid intake. In keeping with established AAP/ASA guidelines,<sup>3-6</sup> solids were defined to include nonclear liquids such as infant formulas, breast milk, and nonhuman milk. Clear liquids included but were not limited to water, fruit juices, carbonated beverages, clear tea, and black coffee. Preprocedural fasting duration of the patients for solids and clear liquids was compared with the established AAP guidelines (Table 1) to determine the extent of compliance with these guidelines. Sedations were defined to be noncompliant with the guidelines if the fasting duration for either solids or clear liquids was less than the recommended duration. Patients with no dietary history documented were excluded from analysis of the relationship between fasting status and adverse events.

During procedural sedation and analgesia, the ED nurse scored sedation depth every 3 to 5 minutes on a standardized 6-point scale printed on the hospital-wide sedation monitoring record: 1, anxious, agitated, or restless; 2, cooperative, oriented, or tranquil; 3, asleep, brisk response to light stroke of cheek; 4, asleep, sluggish response to light stroke of cheek; 5, no response to light stroke of cheek but responds to painful stimuli; 6, no response to painful stimuli.

Adverse events were defined a priori and divided into 2 types. Type I adverse events included oxygen desaturation less than 90%, apnea, stridor, airway misalignment requiring repositioning, laryngospasm, broncho-

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spasm, cardiovascular instability, paradoxical reactions, emergency reactions, emesis, or pulmonary aspiration. Type II adverse events were defined as complications that negatively affected outcome, delayed recovery, or resulted in actual harm to the patient. These included reversal of sedation, hospital admission, endotracheal intubation, permanent neurological injury, or death. Inadequate sedation or prolonged sedation without associated complication was not considered an adverse event. Treating physicians and nurses were mandated by hospital-wide policy, instituted before the initiation of this study, to record all adverse events on the sedation monitoring record.

Data were analyzed by using descriptive statistics,  $\chi^2$  analysis (with Yates' correction or Fisher's exact test for dichotomous variables), independent-samples *t* test (for continuous, parametric data), and Mann-Whitney *U* test (for continuous, nonparametric data) performed on SPSS software. Fasting status was considered a dichotomous variable (compliant versus noncompliant), and fasting duration (in hours) was considered a continuous variable. Mean values are reported as mean $\pm$ SD. Median values are reported as median with interquartile range (IQR). For all tests, values of *P* less than .05 were considered statistically significant. Confidence intervals (CIs), odds ratios, power, and sample size calculations were performed on Stata software (version 6.0; Stata Corporation, College Station, TX).

Power and sample size calculations were based on interim analysis of the relationship between fasting status and adverse events from 284 patients in the 3-month pilot study. In this pilot study, 64% of sedations were noncompliant with fasting guidelines, adverse events occurred in 8.5% of patients, and fasting duration between patients with and without adverse events differed by 1 hour (6.5 versus 7.5 hours, respectively). We determined that with a final sample size of 907 sedations with dietary history available, we would have 90% power with an  $\alpha$  level of .05 to detect a difference in fasting duration of 1 hour between sedations with and without adverse events. With 907 sedations, we also calculated 85% power to detect a difference of 6% in adverse event rate between sedations compliant versus

those noncompliant with published fasting guidelines. Because dietary history was documented in 91% of sedations in the pilot study, a final sample size of 997 patients was required.

**RESULTS**

One thousand four hundred seventy patients were dispensed sedative, dissociative, or analgesic medications from the Pyxis during the study period. Of these patients, 456 were excluded because the medications were administered for purposes other than procedural sedation and analgesia, leaving 1,014 patients who received procedural sedation and analgesia. Ages ranged from 5 days to 31 years, with a median age of 5.4 years. Five hundred eighty (57%) were male patients. According to the ASA physical status classification system, 785 (77%) patients were class 1, 188 (19%) patients were class 2, and 41 (4%) patients were class 3. There were no ASA class 4 or 5 patients.

Medication regimens used for procedural sedation and analgesia are listed in Table 2. Of all sedations per-

**Table 2.** Medication regimens used for procedural sedation and analgesia.\*

Regimen	Subtotal, No.	Total, No. (%)	AE (Rate)
<b>Ketamine</b>		473 (46.7)	33 (7.0)
Ketamine and midazolam IV	238		
Ketamine and midazolam IM	71		
Ketamine IV	89		
Ketamine IM	75		
<b>Midazolam and fentanyl IV</b>		235 (23.2)	22 (9.4)
<b>Chloral hydrate PO/PR</b>		125 (12.3)	2 (1.6)
<b>Pentobarbital IV</b>		120 (11.8)	9 (7.5)
<b>Midazolam IV/PO</b>		41 (4.0)	
<b>Fentanyl IV</b>		7 (0.7)	1 (14.3)
<b>Nitrous oxide (50% inhaled)</b>		7 (0.7)	1 (14.3)
<b>Other</b>		6 (0.6)	
Midazolam and morphine IV	3		
Lorazepam and fentanyl IV	2		
Diazepam PO	1		
<b>Total</b>		1,014 (100.0)	68 (6.7)

AE, adverse event; IV, intravenous; IM, intramuscular; PO, oral; PR, rectal.  
\*The number of sedations associated with adverse event and the rate of adverse events for each regimen are also shown.

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formed, ketamine sedations accounted for 47% and the combination of fentanyl and midazolam accounted for 23%. Chloral hydrate and pentobarbital, used exclusively for diagnostic imaging, together accounted for 24% of all sedations. The most frequent indications for procedural sedation and analgesia (Table 3) were orthopedic procedures (40%), diagnostic imaging (25%), and laceration repair (17%).

**Table 3.**  
Indications for procedural sedation and analgesia.\*

Procedure	Subtotal, No.	Total, No. (%)	AE (Rate)
<b>Orthopedic procedures</b>		404 (39.8)	44 (10.9)
Fracture reduction	366		
Joint dislocation reduction	31		
Other orthopedic procedure	7		
<b>Diagnostic imaging</b>		254 (25.0)	10 (3.9)
Head CT	175		
Neck CT	44		
Body CT	32		
Ultrasonography	3		
<b>Laceration repair</b>		173 (17.1)	8 (4.6)
Facial laceration repair	138		
Other laceration repair	35		
<b>Lumbar puncture</b>		41 (4.0)	
<b>Abscess drainage</b>		37 (3.6)	2 (5.4)
<b>Arthrocentesis</b>		22 (2.2)	
<b>Bone marrow aspiration</b>		15 (1.5)	
<b>Gyneco-urological procedures</b>		15 (1.5)	
Inguinal hernia reduction	4		
Pelvic/gyneco-urological examination	3		
Foley catheter placement	2		
Foreskin caught in zipper removal	2		
Paraphimosis reduction	2		
Prolapsed urethra reduction	1		
Testicular detorsion	1		
<b>Wound debridement</b>		14 (1.4)	
<b>Chest tube placement</b>		10 (1.0)	1 (10.0)
<b>Dental procedures</b>		8 (0.8)	1 (12.5)
<b>Central venous line placement</b>		5 (0.5)	
<b>Miscellaneous procedures</b>		16 (1.6)	2 (12.5)
Ear foreign body removal	4		
ECG	2		
Manual disimpaction of stool	2		
Gastrostomy tube replacement	1		
Halo placement	1		
Nasal foreign body removal	1		
Nasogastric tube placement	1		
Ophthalmologic examination	1		
Peripheral IV line placement	1		
Rectal prolapse reduction	1		
Suture removal	1		
<b>Total</b>		1,014 (100.0)	68 (6.7)

\*The number of sedations associated with adverse event and the rate of adverse events for each indication are also shown.

**Adverse Events**

Of the 1,014 study patients, 68 patients (6.7%; 95% CI 5.2% to 8.4%) experienced 77 adverse events. Nine patients experienced more than 1 adverse event (Table 4). Sixty-six patients experienced 75 type I adverse events. The most common type I adverse event was oxygen desaturation less than 90%, which occurred during 32 sedations. There were 3 cases of hypotension associated with the intravenous administration of pentobarbital, each at a total dose of 3 mg/kg. One case resolved spontaneously, and the other 2 resolved with a normal saline solution intravenous fluid bolus of 20 mL/kg. There were no cases of clinically evident pulmonary aspiration (1-sided 97.5% CI 0% to 0.4%). All type I adverse events were minor and successfully treated with supplemental oxygen, bag-mask ventilation, stimulation, suctioning, airway repositioning, intravenous fluid administration, or simple observation.

There were 2 cases of type II adverse events (complications). Both patients were hospitalized after sedation,

**Table 4.**  
Adverse events associated with procedural sedation and analgesia.\*

Adverse Event	Subgroup	Subtotal	Total
<b>Type I adverse events</b>			75
O <sub>2</sub> desaturation <90%		32 <sup>†</sup>	
O <sub>2</sub> desaturation (alone)	23		
Emesis		15	
Emesis (alone)	14		
Emesis and O <sub>2</sub> desaturation <90%	1		
Apnea		13	
Apnea (alone)	6		
Apnea and O <sub>2</sub> desaturation <90%	7		
Paradoxical reaction		4	
Airway malalignment (requiring repositioning)		3	
Emergency reaction		3	
Hypotension		3	
Laryngospasm		2	
Laryngospasm (alone)	1		
Laryngospasm and O <sub>2</sub> desaturation <90%	1		
<b>Type II adverse events (complications)</b>			2
Hospital admission		2	
<b>Total</b>			77

\*Sixty-eight patients experienced 77 adverse events.

<sup>†</sup>Nine patients with O<sub>2</sub> desaturation <90% experienced a second type I adverse event: emesis (1), apnea (7), and laryngospasm (1).

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and both had uneventful hospital courses. The first was a 5-year-old boy with multiple medical problems, including CHARGE (coloboma, heart defects, atresia choanae, retarded growth and development, genital anomalies, ear anomalies) association, who had had tracheoesophageal fistula repair, complete atrioventricular canal repair, and gastrostomy tube placement. He presented with a chief complaint of headache and received pentobarbital (total 2 mg/kg intravenously) for head computed tomography (CT) scan. He was admitted overnight to the hospital after prolonged sedation. The other patient was a 4-year-old previously healthy boy who received ketamine (total 2 mg/kg intravenously) for removal of infected orthopedic pins. He experienced a generalized, afebrile seizure during his recovery period in the ED, which occurred 2 hours after the last administered ketamine dose. He was admitted to the hospital for uneventful observation after neurologic consultation and a negative head CT scan result. An electroencephalogram obtained the following day was interpreted as abnormal because of the presence of bifrontal sharp waves during sleep, suggesting a lowered threshold for seizures of generalized or frontal onset. This patient has been lost to long-term follow-up.

Adverse events were associated with older age (median age of patients with adverse events was 8.2

years versus 5.2 years for patients without adverse events;  $P=.001$ ) and deeper sedation (Table 5). The odds ratio for adverse events when maximum depth of sedation achieved was at least 5 compared with sedation depth less than or equal to 2 was 4.3 (95% CI 1.4 to 12.9;  $P=.008$ ). There was no association of adverse events to medication regimens (Table 2) or indications (Table 3) for procedural sedation and analgesia.

Emesis occurred in 15 (1.5%) patients (Table 6). One patient experienced O<sub>2</sub> desaturation and emesis (Table 4); however, the desaturation occurred during the procedure and emesis occurred during recovery. Only 1 patient vomited during the procedure; the remainder vomited after completion of the procedure and before discharge. None of the patients who vomited demonstrated clinical evidence of pulmonary aspiration. The occurrence of emesis was associated with older age (median age of patients with emesis was 11.1 years versus 5.3 years for patients without emesis;  $P=.03$ ) and sedation regimen (11 of the 15 patients with emesis were sedated with ketamine). The odds ratio for emesis with ketamine compared with nonketamine sedations was 3.2 (95% CI 1.1 to 9.6;  $P=.04$ ).

**Characterization of Fasting Status**

Of the 1,014 patients who underwent procedural sedation and analgesia, dietary history was not documented in 109 (11%) patients. Fasting status was thus available for 905 (89%) patients. Of these 905 patients, 396 (44%; 95% CI 39% to 49%) met published fasting guidelines and 509 (56%; 95% CI 53% to 60%) did not.

Median fasting duration increased with increasing age group. Median fasting duration for solids ranged from 4.2 hours (IQR 2.4 to 6.3 hours) for patients younger than 6 months ( $n=14$ ), to 6.1 hours (IQR 4.2 to 8.5 hours) for patients 6 to 36 months of age ( $n=247$ ), to 7.3 hours (IQR 5.5 to 9.7 hours) for patients older than 36 months ( $n=644$ ), with an overall median for all 905 patients of 6.8 hours (IQR 4.9 to 9.4 hours). Median fasting duration for clear liquids ranged from 4.1 hours (IQR 2.4 to 6.3 hours) for patients younger than 6 months, to 4.8 hours (IQR 3.2 to 6.8 hours) for patients 6 to 36 months of age, to 6.4 hours (IQR 4.4 to 8.6

**Table 5.**  
*Relationship between maximum depth of sedation achieved and occurrence of adverse events.*

Maximum Depth of Sedation*	Adverse Event Rate, No. (%)
1	0/6 (0.0)
2	4/95 (4.2)
3	18/284 (6.3)
4	28/365 (7.7)
5	13/92 (14.1)
6	1/1 (100.0)
Totals	64/843 (7.6)

\*Data on depth of sedation were available on 843 sedated patients, of whom 64 (7.6%) had associated adverse events. Maximum depth of sedation achieved during procedure: 1, anxious, agitated, or restless; 2, cooperative, oriented, or tranquil; 3, asleep, brisk response to light stroke of cheek; 4, asleep, sluggish response to light stroke of cheek; 5, no response to light stroke of cheek but responds to painful stimuli; 6, no response to painful stimuli.

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hours) for patients older than 36 months, with an overall median of 6.0 hours (IQR 3.9 to 8.2 hours).

Median fasting duration differed by approximately 4 hours between sedations for patients compliant versus those noncompliant with the fasting guidelines. For solids, median fasting duration was 9.6 hours (IQR 8.3 to 12.4 hours) for those compliant versus 5.2 hours (IQR 3.9 to 6.6 hours) for those noncompliant with fasting guidelines. For clear liquids, median fasting durations were 8.5 hours (IQR 6.2 to 10.4 hours) and 4.7 hours (IQR 3.3 to 6.2 hours), respectively.

**Fasting Status and Adverse Events**

Of the 68 patients who experienced adverse events, 67 had dietary history documented, and 1 patient (with a brief episode of apnea that resolved with stimulation) did not. There was no statistically significant difference in the adverse event rate in patients who met and in those who did not meet fasting guidelines. Adverse events occurred in 32 (8.1%; 95% CI 5.6% to 11.2%) of 396 patients who met and 35 (6.9%; 95% CI 4.8% to 9.4%) of 509 patients who did not meet fasting guide-

lines ( $P=.49$ ). In addition, there was no significant difference in fasting duration in patients with and without reported adverse events. Median fasting duration in patients with adverse events was 7.3 hours (IQR 5.9 to 9.4 hours) for solids and 6.6 hours (IQR 4.8 to 8.3 hours) for clear liquids versus 6.8 hours (IQR 4.8 to 9.4 hours;  $P=.34$ ) for solids and 6.0 hours (IQR 3.8 to 8.2 hours;  $P=.13$ ) for clear liquids in patients without adverse events (Table 7).

Likewise, there was no significant difference in fasting duration in patients with and without reported emesis. Median fasting duration in patients with emesis was 6.8 hours (IQR 5.1 to 9.5 hours) for solids and 5.8 hours (IQR 3.6 to 8.1 hours) for clear liquids versus 6.8 hours (IQR 4.9 to 9.4 hours;  $P=.78$ ) for solids and 6.0 hours (IQR 3.9 to 8.2 hours;  $P=.70$ ) for clear liquids in patients without emesis (Table 7).

A visual breakdown of fasting duration (for both solids and clear liquids) in 2-hour increments with associated numbers of cases of adverse events and emesis is depicted in the Figure. Cases of adverse events and emesis are distributed evenly throughout the different

**Table 6.**  
Description of patients who experienced emesis.

Age, y	Sex	ASA Class*	Sedation Indication	Sedation Regimen	Maximum Depth of Sedation	Fasting Duration, h		Compliant With Fasting Guidelines
						Solids	Liquids	
1.1	Male	2	Head CT	Chloral hydrate PO	NR	3.4	3.4	No
4.2	Male	1	Fracture reduction	Ketamine/midazolam IV	NR	8.1	8.1	Yes
4.8	Female	1	Facial laceration	Ketamine IV	4	0.8	0.8	No
5.8	Male	1	Fracture reduction	Ketamine/midazolam IV	4	5.9	5.9	No
6.2	Male	1	Facial laceration	Ketamine/midazolam IM	3	5.8	5.8	No
8.1	Female	1	Fracture reduction	Fentanyl IV	3	6.8	6.8	No
8.6	Male	1	Fracture reduction	Ketamine IV	3	8.8	5.3	Yes
11.1	Male	1	Fracture reduction	Ketamine/midazolam IM	4	9.9	9.9	Yes
11.3	Male	1	Fracture reduction	Ketamine/midazolam IV	3	6.8	4.8	No
11.5	Female	1	Fracture reduction	Ketamine/midazolam IV	4	9.6	3.1	Yes
11.6	Female	1	Joint reduction	Nitrous oxide	2	5.1	4.1	No
12.0	Male	1	Joint reduction	Midazolam/fentanyl IV	3	4.9	3.6	No
12.1	Female	2	Abscess drainage	Ketamine/midazolam IM	4	6.3	6.3	No
13.2	Male	1	Fracture reduction	Ketamine/midazolam IV	3	10.5	10.5	Yes
13.5	Female	1	Fracture reduction	Ketamine/midazolam IV	3	9.5	9.5	Yes

NR, Not recorded.  
\*ASA physical status classification.

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fasting durations, highlighting the observed lack of association between preprocedural fasting state and adverse events, including emesis.

**LIMITATIONS**

Our study has several limitations. Some adverse events may not have been captured by the present study design because we did not follow up patients once they were discharged from the ED. Adverse events, including emesis, could have occurred on the way home or at home. Given that all patients were required by ED protocol<sup>24</sup> to be at baseline (awake and alert) before discharge, we would not expect any significant adverse events to have occurred after ED discharge.

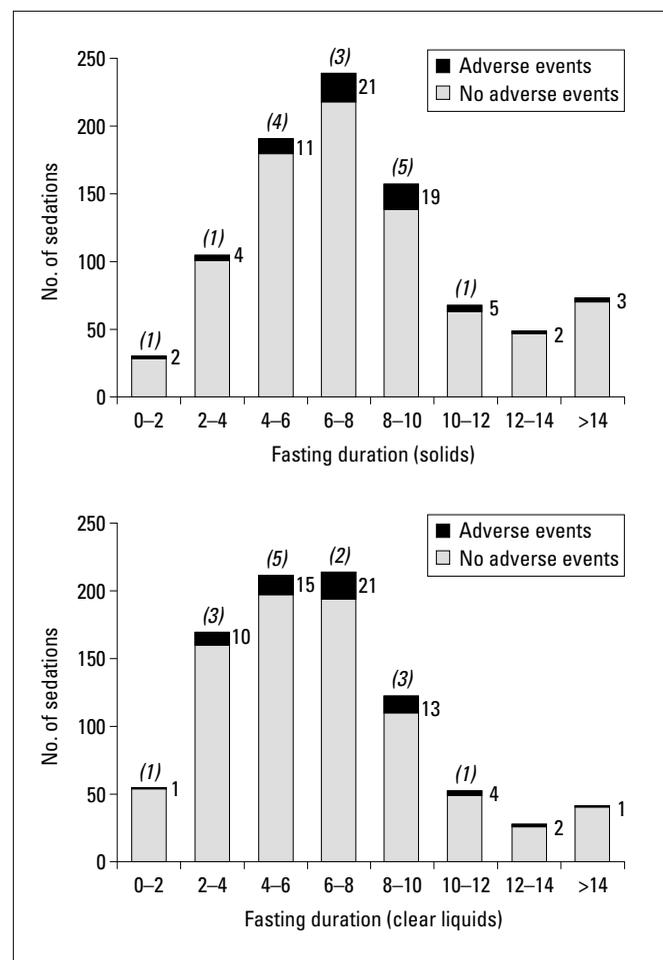
In addition, our study included few patients (n=14) younger than 6 months because these patients are routinely swaddled and not sedated for ED procedures and diagnostic imaging studies. Although there were no reported adverse events in this age group, it may be premature to extrapolate the results of the lack of relationship between preprocedural fasting state and adverse events from our study to this age cohort. However, the study by Ghaffar et al<sup>25</sup> had sufficient numbers of patients in this age group (n=138) to conclude that there was no improvement in safety when children younger than 6 months fasted longer.

The exact contribution of ED waiting times on the characterization of overall fasting status could not be determined by the current study design. It is possible

that waiting times were sufficiently long to contribute to a greater proportion of patients meeting fasting guidelines. However, this possibility is unlikely to affect the lack of association we observed between fasting status and adverse events.

In our study, dietary history was documented for 905 (89%) of the 1,014 patients sedated during the study period. Incomplete documentation of dietary history in the remaining 11% may have occurred for any number

**Figure.** Breakdown of fasting duration (for both solids and clear liquids) in 2-hour increments with associated numbers of cases of adverse events (located on the right side of the bars) and emesis (located above the bars in italics enclosed within parentheses).



**Table 7.** Median fasting duration (for both solids and clear liquids) for patients with (n=67) and without (n=838) adverse events and with (n=15) and without (n=890) emesis.

Dietary Intake	Adverse Event			Emesis		
	Yes, h (IQR)	No, h (IQR)	P Value	Yes, h (IQR)	No, h (IQR)	P Value
Solids	7.3 (5.9–9.4)	6.8 (4.8–9.4)	.34	6.8 (5.1–9.5)	6.8 (4.9–9.4)	.78
Clear liquids	6.6 (4.8–8.3)	6.0 (3.8–8.2)	.13	5.8 (3.6–8.1)	6.0 (3.9–8.2)	.70

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of reasons: urgency of the procedure, time constraints from other clinical demands, or physician's belief that ascertainment of fasting status may not be crucial in planning procedural sedation and analgesia with a level of sedation not expected to blunt airway reflexes. In their hospital-wide study of adverse events in 1,140 pediatric procedural sedations, Malviya et al<sup>26</sup> noted that complete documentation on their sedation quality assurance data form (similar to our sedation monitoring record) occurred less than 80% of the time. Additionally, in the study by Hoffman et al,<sup>27</sup> fasting status was not documented before sedation in 15% of the group of patients who did not meet AAP fasting criteria.

Although sufficiently powered to detect differences in overall adverse event rate in relation to fasting status, this study was underpowered to detect significant differences in the rate of emesis with or without aspiration. Of our 1,014 sedations, 15 (1.5%) cases of emesis were observed, none with evidence of aspiration. In their critical analysis of contributing factors to adverse sedation events in pediatrics, Cote et al<sup>28</sup> reported no cases of aspiration over their 27-year study period. Hoffman et al<sup>27</sup> describes 2 pediatric cases of aspiration occurring during sedation, but both were performed on patients outside of the ED setting (1 patient underwent bronchoscopy and the other a radiologic procedure). A recent review of aspiration during procedural sedation and analgesia<sup>2</sup> pooled the data on aspiration risk during general anesthesia and found the overall incidence of aspiration to be 1:3,420. Projecting data from the anesthesiology literature, one would need an extremely large denominator for adequate power to ascertain risk factors for aspiration during the practice of ED procedural sedation and analgesia.

### DISCUSSION

The difficulty of following established fasting guidelines during ED procedural sedation and analgesia has been discussed in the emergency medicine literature, but the percentage of ED patients not conforming to fasting guidelines has not been documented. Furthermore, the adverse event rate associated with appropri-

ately fasted versus nonfasted patients during ED procedural sedation and analgesia has not been characterized. Consensus-based AAP/ASA guidelines for preprocedural fasting for elective procedures have been widely disseminated and adopted by the medical community as a way of potentially increasing safety during procedural sedation and analgesia. Although these guidelines are intuitively appealing, data in the medical literature to support these guidelines are lacking.<sup>2,5,6,18-21</sup>

We studied the fasting status of 1,014 pediatric patients receiving ED procedural sedation and analgesia and found that 56% of the 905 patients who had dietary history documented were sedated even though they did not meet the established AAP/ASA preprocedural fasting criteria. We additionally found a lack of association between fasting status and observed adverse events.

Previous studies have demonstrated the safety of children undergoing procedural sedation and analgesia in the ED.<sup>2,7-17</sup> Our study characterizes procedural sedation and analgesia as practiced by pediatric emergency physicians and, in conjunction with a study by Pena and Krauss,<sup>7</sup> provides further evidence that this practice is safe and results in a low adverse event rate with no serious complications. We observed an overall higher rate of adverse events from procedural sedation and analgesia compared with that of the Pena and Krauss study, which was conducted between August 1997 and July 1998 in the same ED as our study and had a similar study design and adverse event criteria.<sup>7</sup> Of their 1,180 sedated patients, 27 (2.3%) were reported to have experienced adverse events. Five (0.4%) cases of emesis were observed, with no cases of aspiration. The required in-service training certification for all physicians and nurses administering procedural sedation and analgesia and the implementation of a hospital-wide sedation monitoring record with mandated documentation of adverse events may account for the differences in reporting of adverse events between the Pena and Krauss study and our study.

We found only 3 studies in the medical literature that address the relationship between fasting status and observed adverse events of pediatric procedural sedation and analgesia. Consistent with the results of our

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study, all 3 of these studies demonstrated a lack of association between fasting duration and adverse events. Kennedy et al<sup>17</sup> evaluated the safety and efficacy of different sedation regimens in 260 pediatric ED patients undergoing orthopedic fracture or joint reduction and found no association between fasting duration and the occurrence of emesis (mean fasting duration was  $4.4 \pm 2.5$  hours in those with emesis versus  $5.0 \pm 2.4$  hours in those without emesis;  $P = .40$ ). Ghaffar et al<sup>25</sup> evaluated preprocedural fasting guidelines for sedation for echocardiography in 324 children and found no significant difference in the rate of emesis for patients who fasted for more than 120 minutes versus those who fasted for less than 120 minutes (9 of 184 [4.9%] versus 8 of 140 [5.7%], respectively;  $P = .74$ ). A significantly higher proportion of children younger than 6 months who fasted for more than 120 minutes versus those fasted for less than 120 minutes failed to achieve adequate sedation (14 of 71 [19.7%] versus 5 of 67 [7.5%], respectively;  $P = .03$ ). They concluded that longer fasting times did not improve safety and may actually decrease efficacy of sedation in younger children. Hoffman et al,<sup>27</sup> in their study of 960 children sedated hospital-wide after implementation of a uniform sedation process, found that adherence to the AAP preprocedural fasting guidelines did not affect the overall risk of complications. However, the occurrence of sedation failures was significantly higher in patients who met preprocedural fasting criteria, which they suggested may be caused by added difficulty in sedating infants and young children when they are hungry.

In retrospect, potential variability in documentation and incomplete documentation by our ED staff may have been better controlled by using a trained research assistant who was blinded to the study's objectives. By being present for all sedations, the research assistant would ideally have collected complete data on adverse events and fasting status in a more standardized fashion, including assessment of the time, amount, and composition of last solid and clear liquid intake. In addition, telephone follow-up with the patients' families by the research assistant 72 hours after ED discharge would have ensured complete capture of post-discharge adverse events. Finally, other study

limitations could be addressed with a larger number of patients undergoing sedation, perhaps through a multicenter study design, which would provide additional power in analyzing the effect of fasting duration on occurrence of emesis and possible aspiration.

In summary, we performed a large-scale study of ED procedural sedation and analgesia that characterizes fasting status and assesses the relationship between preprocedural fasting state and adverse events. Our findings demonstrate that 56% of patients who were sedated had not fasted in accordance with established fasting guidelines for elective procedures. Despite the fact that these patients were not fasted for the appropriate duration (as defined by the fasting guidelines), they did not have any additional adverse events, including emesis. Noncompliance with the AAP/ASA preprocedural fasting guidelines does not appear to be a contraindication to ED procedural sedation and analgesia.

This study provides further evidence that procedural sedation and analgesia practiced by pediatric emergency physicians as described in this study (medication regimens [Table 2], indications [Table 3], standardized presedation assessment, standardized postsedation discharge criteria,<sup>21,24</sup> and lack of formal fasting guidelines) is safe and results in a low adverse event rate with no serious complications.

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