Preprocedural Fasting and Adverse Events in Procedural Sedation and Analgesia in a Pediatric Emergency Department: Are They Related?

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Study objective: Fasting time before procedural sedation and analgesia in a pediatric emergency department (ED) was recently reported to have no association with the incidence of adverse events. This study further investigates preprocedural fasting and adverse events.

Methods: Data were analyzed from a prospectively generated database comprising consecutive sedation events from June 1996 to March 2003. Comparisons were made on the incidence of adverse events according to length of preprocedural fasting time.

Results: Two thousand four hundred ninety-seven patients received procedural sedation and analgesia. Four hundred twelve patients were excluded for receiving oral or intranasal drugs (n=95) or for receiving sedation for bronchoscopy by nonemergency physicians (n=317). A total of 2,085 patients received parenteral sedation by emergency physicians. Age range was 19 days to 32.1 years (median age 6.7 years); 59.9% were male patients. Adverse events observed included desaturations (169 [8.1%]), vomiting (156 [7.5%]), apnea (16 [0.8%]), and laryngospasm (3 [0.1%]). Fasting time was documented in 1,555 (74.6%) patients. Median fasting time before sedation was 5.1 hours (range 5 minutes to 32.5 hours). When the incidence of adverse events was compared among patients according to fasting time in hours (0 to 2, 2 to 4, 4 to 6, 6 to 8, >8, and not documented), no significant difference was found. No patients experienced clinically apparent aspiration.

Conclusion: No association was found between preprocedural fasting and the incidence of adverse events occurring with procedural sedation and analgesia.

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Editor's Capsule Summary

What is already known on this topic

Fasting guidelines for emergency department (ED) procedural sedation and analgesia are difficult to follow, and a recent study in *Annals* found no association between fasting and adverse events.

What question this study addressed

The researchers used a large, prospective, sedation database to stratify children on the basis of duration of fasting and assess the association of such fasting with adverse effects.

What this study adds to our knowledge

More than one third of the 1,555 study children underwent procedural sedation and analgesia despite 4 hours or less of fasting, and there was no difference between fasted and nonfasted children in respiratory complications, emesis, or other adverse events.

How this might change clinical practice

This independently confirms that compliance with elective fasting guidelines does not appear to mitigate adverse effects typically noted during ED procedural sedation and analgesia in children.

INTRODUCTION

Importance

A large number of pediatric patients receive procedural sedation and analgesia in emergency departments (EDs) across the country each year. Adverse events associated with ED sedation such as oxygen desaturations, apnea, laryngospasm, and vomiting have been observed and reported.[1,2] Specific practice guidelines for sedation, including recommendations about fasting time, have been published, although close adherence to these guidelines in the ED is difficult.[3-5] A recent study by Agrawal et al[6] found no association between the preprocedural fasting state and adverse events.

Background

The American Society of Anesthesiologists has published practice guidelines for sedation and analgesia by nonanesthesiologists.[3] For elective procedures, the American Society of Anesthesiologists recommends that patients fast for 2 hours after clear liquids, 4 hours after breast milk, and 6 hours after infant formula or a light meal before receiving sedation. For emergency procedures, the American Society of Anesthesiologists recommends that sedation be modified (ie, less sedation administered). No specific fasting-time guidelines are offered for emergency procedures. The American Society of Anesthesiologists also states that "the literature does not provide sufficient data to test the hypothesis that pre-procedural fasting results in a decreased incidence of adverse outcomes."

The American College of Emergency Physicians and the American Academy of Pediatrics have also published similar guidelines for monitoring and management of sedation for diagnostic and therapeutic procedures.[4,5] The relationship between preprocedural fasting time and incidence of adverse events has not been definitively defined. A limited number of pediatric sedation studies offer some analysis of preprocedural fasting and adverse events, and no association was found between the two in any of the studies.[7-9] The most recent study, designed specifically to investigate the relationship between the preprocedural fasting state and adverse events, also found no association.[6]

Goals of This Investigation

The purpose of this study is to further investigate the association between preprocedural fasting and the incidence of adverse events in pediatric patients receiving procedural sedation and analgesia in the ED.

MATERIALS AND METHODS

Study Design

This is a cohort study of consecutive patients receiving procedural sedation and analgesia. Data were analyzed from a prospectively generated database from June 1996 to March 2003. This study was approved as an exempt protocol by the Colorado Multiple Institutional Review Board.

Setting and Selection of Participants

The study was conducted in an urban tertiary care children's hospital ED.

All patients who received parenteral procedural sedation and analgesia in the ED, with sedation administered by emergency attending physicians, were included. Exclusion criteria were the following: (1) patients receiving sedation in the ED, performed by pulmonary physicians for bronchoscopy; and (2) patients who received oral or intranasal sedation because sedation sheets are not routinely generated in our ED for patients receiving sedation by the oral or intranasal route.

Data Collection and Processing

Sedation sheets, which are used hospital-wide and become part of the medical record, are automatically generated for all patients receiving parenteral procedural sedation and analgesia in our setting, that is, whenever ketamine, midazolam, lorazepam, diazepam, pentobarbital, fentanyl, morphine sulfate, or meperidine is dispensed to be used in sedation for a procedure. Propofol,

methohexital, and chloral hydrate are not used in our ED. Patient monitoring, presedation assessment, and readiness for discharge from the ED were performed in compliance with institutional and national guidelines.[10,11] Emergency attending physicians provided sedation for all patients. Nurses and physicians caring for the patients completed these sedation sheets.

Sedation sheets are collected and reviewed quarterly as a hospital quality-assurance initiative. For the purpose of this study, data pertaining to fasting time, procedure type, drugs used, and adverse events were abstracted solely from the sedation sheet. Fasting time is listed on the sedation sheet, with fill-in blanks for time of last oral intake, one blank for food and milk and a second for clear liquids. Other sections of the sedation sheet include areas for documentation of complications, numeric vital signs and oxygen saturations, and patient responses or interventions (eg, apnea/bag-mask ventilations). Data were abstracted from the sedation sheets by a nurse who functions as an ED research coordinator and who was not a contributing author.

No further medical record review occurred except for any patients who were intubated. This practice is performed routinely for all intubated patients as part of an ED quality monitor.

Outcome Measures

Adverse events abstracted solely from the sedation sheets and recorded were respiratory and vomiting. Respiratory adverse events were apnea, laryngospasm, desaturations (pulse oximetry <90% in room air at the elevation of the study site, 5,280 feet), and aspiration. The presence or absence of an adverse event was treated as a dichotomous variable.

Primary Data Analysis

These data were collected with the primary intent of investigating the safety and efficacy of parenteral procedural sedation and analgesia. As part of the safety analysis, we investigated the association of fasting time with the incidence of adverse events. Patients were divided into groups according to the following fasting times: 0 to 2 hours, 2 to 4 hours, 4 to 6 hours, 6 to 8 hours, greater than 8 hours, and not documented.

Statistical analysis was performed using SPSS software (version 11.5, SPSS, Inc., Chicago, IL). We calculated simple odds ratios (ORs) with 95% confidence intervals (CIs) to compare the incidence of adverse events among the fasting time groups using the 0- to 2-hour group as the reference.

Data Presentation

The incidence of adverse events among groups is shown in table format and as bar graphs. ORs with 95% CIs are presented.

RESULTS

Characteristics of Study Subjects

Two hundred sixty-nine subjects have been reported on previously as part of an earlier sedation study that compared the incidence of emergency reactions in patients receiving ketamine and midazolam to those receiving ketamine alone.[12]

During the study period, from June 1996 to March 2003, a total of 2,497 patients received sedation in the ED. Four hundred twelve patients were excluded. Of these, 317 patients received sedation in the ED, performed by pulmonologists for bronchoscopy. Ninety-five patients received sedation drugs by the oral or intranasal routes of administration. A total of 2,085 patients received parenteral procedural sedation and analgesia by emergency physicians. Age range was 19 days to 32.1 years (median age 6.7 years). Three patients, aged 23, 28, and 31 years, with congenital heart disease who continue to receive care at our facility received sedation for cardioversion; 59.9% were men.

Three-hundred nine patients (14.8%) experienced a respiratory adverse event or vomiting. Adverse events observed were desaturations 165 (8.1%), vomiting 156 (7.5%), apnea 16 (0.8%), and laryngospasm 2 (0.1%). Fasting time was documented in 1,555 (74.6%) patients. Median fasting time before sedation was 5.1 hours (range 5 minutes to 32.5 hours). Characteristics of patients for whom fasting time was and was not documented are listed in Table 1.

Drugs administered for sedation were ketamine (1,199 [57%]), ketamine/midazolam (295 [14%]), midazolam/fentanyl (284 [14%]), midazolam alone (225 [11%]), and a variety of other combinations (82 [4%]). Drugs administered with incidence of adverse events are listed in Table 2. The incidence of adverse events observed by procedure performed is listed in Table 3.

Main Results

Patients were divided into groups according to fasting time in hours: 0 to 2, 2 to 4, 4 to 6, greater than 8, and not documented. No significant difference in the incidence of adverse events was detected among these groups (Table 4 and the Figure).

One patient was intubated. This patient, with new-onset leukemia, pulmonary infiltrates with effusion, and pericardial effusion, received midazolam and fentanyl for thoracostomy tube placement. A review of the entire

medical record was performed to further describe this patient's course. The patient was intubated 115 minutes after the administration of sedation drugs for respiratory insufficiency and impending respiratory failure thought to be a result of progression of underlying pulmonary disease and pericardial effusion. Pericardiocentesis was also performed. This patient's preprocedural fasting time was 185 minutes. The patient also experienced oxygen desaturation, which was recorded and included as an adverse respiratory event.

No patients experienced clinically apparent aspiration.

LIMITATIONS

This study has several limitations. Fasting time was not documented in one fourth of our patients, which could affect the internal validity of this study, especially if a large number of these patients had short (ie, <2 hours) fasting times. However, we did compare the incidence of adverse events between patients according to whether fasting time was documented and found no differences.

Despite the fact that the sedation sheet contains blanks for material consumed (solids versus liquids), this distinction was not consistently documented and therefore not included in our results. Not knowing the type of

Table 1.

Characteristics of patients receiving sedation with fasting time documented and those without (N=2,085).

Characteristic	Fasting Time Documented (N=1,555) (74.6%)	Fasting Time Not Documented (N=530) (25.4%)
Age, y, median (range)	6.8 (20 days to 32.1 years)	6.2 (19 days to 18.6 years)
Male sex, %	60.2	59.1
Procedure, No. (%)		
Fracture reduction	876 (56.3)	220 (41.5)
Laceration repair	285 (18.3)	126 (23.8)
Lumbar puncture	80 (5.1)	50 (9.4)
Radiology	64 (4.1)	31 (5.8)
Other	250 (16.2)	103 (19.5)
Sedation drugs, No. (%)		
Ketamine	979 (63)	220 (41.5)
Midazolam	130 (8.4)	95 (17.9)
Midazolam/fentanyl	188 (12.1)	96 (18.1)
Midazolam/ketamine	199 (12.8)	96 (18.1)
Other	59 (3.7)	23 (4.4)

Table 2.

Incidence of adverse events by parenteral sedation drugs used.

Sedative Drugs/Combinations	No.	Respiratory Adverse Events (Rate)	Vomiting (Rate)
Ketamine	1199 (1,022 IV 177 IM)	70 (5.8)	129 (10.8)
Midazolam/ketamine	295 (283 IV 12 IM)	28 (9.5)	16 (5.4)
Midazolam/fentanyl	284	54 (19)	4 (1.4)
Midazolam	225 (224 IV 1 IM)	13 (5.8)	2 (0.9)
Midazolam/morphine	29 (27 IV 2 IM)	3 (10.3)	0
Other*	53	4 (7.5)	5 (9.4)
Total	2,085	172 (8.2)	156 (7.5)

IV, Intravenous; *IM*, intramuscular.

*Pentobarbital (n=9), ketamine/fentanyl (n=8), midazolam/fentanyl/ketamine (n=7), ketamine/morphine (n=6), fentanyl (n=5), morphine/midazolam/fentanyl (n=4), ketamine/midazolam/pentobarbital (n=3), morphine/midazolam/fentanyl (n=3), midazolam/pentobarbital (n=2), lorazepam (n=1), meperidine/ketamine (n=1), midazolam/pentobarbital/fentanyl (n=1), midazolam/morphine/diazepam (n=1), fentanyl/morphine (n=1), midazolam/fentanyl/diazepam (n=1).

Table 3.

Incidence of adverse events by procedure type (N=2,085).

Procedures	No.	Respiratory Adverse Events (Rate)	Vomiting (Rate)
Fracture or dislocation reduction	1,096	78 (7.1)	101 (9.2)
Laceration repair	411	37 (9)	40 (9.7)
Lumbar puncture	130	8 (6.2)	0
Radiology	95	6 (6.3)	1 (1.1)
Incision and drainage	66	5 (7.6)	1 (1.5)
Genitourinary procedure	37	3 (8.1)	1 (2.7)
Joint aspiration	25	2 (8)	0
Chest tube/thoracentesis	37	10 (27)	2 (5.4)
Burn dressing	22	4 (18.2)	1 (4.5)
Dental procedure	17	1 (5.9)	1 (5.9)
Foreign body removal	15	2 (13.3)	2 (13.3)
Gastrointestinal tract procedure	16	4 (25.0)	0
Central venous catheters	14	4 (28.6)	1 (7.1)
Eye examination	16	1 (6.3)	1 (6.3)
Wound care	24	1 (4.2)	1 (4.2)
Ear-nose-throat procedure	8	2 (25)	0
ECG	7	1 (14.3)	0
Cardiac procedure	7	1 (14.3)	1 (14.3)
Ortho/other	31	2 (6.5)	2 (6.5)
Other	11	0	0
Total	2,085	172 (8.2)	156 (7.5)

material ingested limits the external validity (generalizability) of these results. Also, we are unable to make comparisons within our population according to whether patients met current fasting guidelines for nonemergency sedation.

Omission of fasting times and incomplete documentation of sedation records occurred in 11%, 15%, and greater than 20% of patients enrolled in the studies mentioned previously, which address preprocedural fasting and adverse events.[6,7,13] Explanations given for this incomplete documentation are varied but similar to the ones we believed affected our study: we believe that documenting nurses and physicians may have omitted fasting times because of the perceived urgency of the procedure, time constraints as a result of high ED patient volumes, and the belief that the information was not vital to patient safety, given the depth of sedation anticipated (midazolam administered alone had the highest rate of undocumented fasting times in our study). Additionally, the fact that the nursing staff completing this form was not aware that the information would be used for a research study may have resulted in less-complete documentation than would otherwise be expected for a prospective study.

Observers recording data were not blinded to the fasting times of the patients enrolled, which could lead to a bias in reporting. However, observers were also unaware of the study objective.

Despite the fact that sedation sheets are generated for all parenteral sedation in our ED and that this document is part of a hospital-wide quality standard, we cannot be absolutely sure that all patients receiving sedation also received a sedation sheet. Although unlikely, some patients may have been missed.

Finally, preprocedural fasting guidelines have been established mainly to prevent the potential adverse event of pulmonary aspiration; however, aspiration has never been reported in the medical literature to occur during ED sedation.[14] Clinically apparent pulmonary aspiration events did not occur in our patient population of more than 2,000. A substantially larger number of patients may be required to detect this rare event.

DISCUSSION

In Retrospect

This study would be strengthened by documentation of fasting times for all patients, with close attention being paid to whether solids or liquids (clear or otherwise) were ingested. It would also be desirable, although impractical in the clinical setting, to blind observers who documented results to fasting time, type of drug administered, and
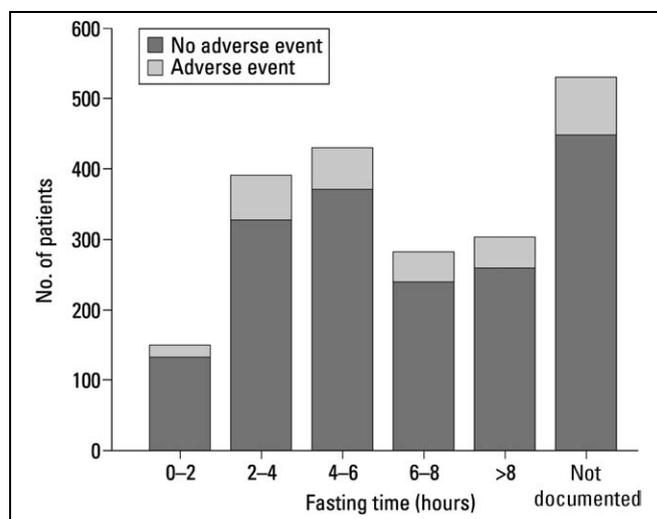
Figure.
Fasting time versus any adverse event.

Table 4.
Adverse events by fasting time.

Fasting Time (No.)	Respiratory Adverse Events		Vomiting		Any Adverse Event	
	No. (%)	OR (95% CI)	No. (%)	OR (95% CI)	No. (%)	OR (95% CI)
0–2 h (150),*	11 (7.3)	1	10 (6.7)	1	18 (12.0)	1
2–4 h (391)	30 (7.7)	1.05 (.51–2.15)	40 (10.2)	1.60 (.78–3.28)	64 (16.4)	1.44 (.82–2.51)
4–6 h (430)	31 (7.2)	.98 (.48–2.00)	30 (7.0)	1.05 (.50–2.20)	60 (14.0)	1.19 (.68–2.09)
6–8 h (281)	27 (9.6)	1.34 (.65–2.79)	18 (6.4)	.96 (.43–2.13)	41 (14.6)	1.25 (.69–2.27)
>8 h (303)	19 (6.3)	.85 (.40–1.80)	27 (8.9)	1.37 (.65–2.91)	44 (14.5)	1.25 (.69–2.24)
Not documented (530)	54 (10.2)	1.43 (.73–2.82)	31 (5.8)	.87 (.42–1.82)	82 (15.5)	1.34 (.78–2.32)

*Reference group.

procedure performed. Another significant improvement to this study would be to enroll a large enough study population to detect and comment on the incidence of clinically apparent pulmonary aspiration. Undoubtedly, a multicenter study would be required to obtain a large enough number of patients to detect the rare event of aspiration.

Our results support the findings of Agrawal et al[6] that the incidence of adverse events does not appear to be affected by length of preprocedural fasting. This study has the benefit of studying a larger number of patients (2,085 versus 1,014) with a higher incidence of any adverse event (14.8% versus 6.7%), as well as vomiting (7.5 versus 1.5%). Given the larger sample size and higher incidence of adverse events, a greater opportunity to detect any association between preprocedural fasting time and incidence of adverse events would be expected. However, no such association was found.

The higher rate of adverse events in this study compared to that by Agrawal et al[6] may be explained by the fact that all of our patients received parenteral sedation. Although adverse events associated with oral or intranasal sedation are well documented,[15] recent studies have reported a higher rate of adverse events when sedation is administered by the parenteral route.[1,2,6] The higher rate of vomiting in our study may, in part, be explained by the fact that a larger percentage of our patients received ketamine (71.6% versus 46.7%). We also had a larger number of patients with shorter fasting times; however, once again, no association between fasting time and vomiting was detected.

Published guidelines for preprocedural fasting exist despite lack of data to support their impact on patient safety. These guidelines are also difficult to implement and impractical in an ED setting. Our data support previously reported conclusions that emergency physicians provided safe procedural sedation and analgesia for pediatric procedures, regardless of preprocedural fasting times.

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REFERENCES

1. Newman DH, Azer MM, Pitetti RD, et al. When is a patient safe for discharge after procedural sedation? The timing of adverse effect events in 1,367 pediatric procedural sedations. *Ann Emerg Med.* 2003;42:627-635.
2. Pena BMG, Krauss B. Adverse events of procedural sedation and analgesia in a pediatric emergency department. *Ann Emerg Med.* 1999;34:483-491.
3. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology.* 2002;96:1004-1017.
4. Jagoda AS, Campbell M, Karas S Jr, et al, for the Clinical Policies Subcommittee on Procedural Sedation and Analgesia. Clinical policy for procedural sedation and analgesia in the emergency department. *Ann Emerg Med.* 1998;31:663-677.
5. Committee on Drugs. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics.* 1992;89:1110-1115.
6. Agrawal D, Manzi SF, Gupta R, et al. Preprocedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department. *Ann Emerg Med.* 2003;42:636-646.
7. Hoffman GM, Nowakowski R, Troshynski TA, et al. Risk reduction in pediatric procedural sedation by application of an AAP/ASA process model. *Pediatrics.* 2002;109:236-243.
8. Kennedy RM, Porter FL, Miller JP, et al. Comparison of fentanyl/midazolam with ketamine/midazolam for pediatric orthopedic emergencies. *Pediatrics.* 1998;102:956-963.
9. Ghaffar S, Haverland C, Ramaciotti C, et al. Sedation for pediatric echocardiography: evaluation of preprocedural fasting guidelines. *J Am Soc Echocardiogr.* 2002;15:980-983.
10. Joint Commission of Accreditation of Healthcare Organizations. *Revisions to Anesthesia Care Standards: Comprehensive Accreditation Manual for Hospitals.* Oakbrook Terrace, IL: Joint Commission of Accreditation of Healthcare Organizations, Department of Publications; 2001.
11. Zaritsky AL, Nadkarni VM, Hickey RW, et al, eds. *PALS Provider Manual.* Dallas, TX: American Academy of Pediatrics and American Heart Association; 2002:379-396.
12. Wathen J, Roback MG, MacKenzie T. Does midazolam alter the clinical effects of intravenous ketamine sedation in children? A double-blind, randomized, controlled emergency department trial. *Ann Emerg Med.* 2000;36:579-588.
13. Malviya S, Voepel-Lewis T, Tait A. Adverse events and risk factors associate with sedation of children by nonanesthesiologists. *Anesth Analg.* 1997;85:1207-1213.
14. Green SM, Krauss B. Pulmonary aspiration risk during emergency department procedural sedation: an examination of the role of fasting and sedation depth. *Acad Emerg Med.* 2002;9:35-42.
15. Coté CJ, Karl HW, Notterman DA, et al. Adverse sedation events in pediatrics: analysis of medications used for sedation. *Pediatrics.* 2000;106:633-644.