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Association of Preprocedural Fasting With Outcomes of Emergency Department Sedation in Children

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IMPORTANCE It is not clear whether adherence to preprocedural fasting guidelines prevent pulmonary aspiration and associated adverse outcomes during emergency department (ED) sedation of children.

OBJECTIVE To examine the association between preprocedural fasting duration and the incidence of sedation-related adverse outcomes in a large sample of children.

DESIGN, SETTING, AND PARTICIPANTS We conducted a planned secondary analysis of a multicenter prospective cohort study of children aged 0 to 18 years who received procedural sedation for a painful procedure in 6 Canadian pediatric EDs from July 2010 to February 2015. The primary risk factor was preprocedural fasting duration. Secondary risk factors were age, sex, American Society of Anesthesiologists classification, preprocedural and sedation medications, and procedure type.

MAIN OUTCOMES AND MEASURES Four outcomes were examined: (1) pulmonary aspiration, (2) the occurrence of any adverse event, (3) serious adverse events, and (4) vomiting.

RESULTS A total of 6183 children with a median age of 8.0 years (interquartile range, 4.0-12.0 years), of whom 6166 (99.7%) had healthy or mild systemic disease (American Society of Anesthesiologists levels I or II), were included in the analysis. Of these, 2974 (48.1%) and 310 (5.0%) children did not meet American Society of Anesthesiologists fasting guidelines for solids and liquids, respectively. There were no cases of pulmonary aspiration. There were 717 adverse events (11.6%; 95% CI, 10.8%-12.4%), of which 68 (1.1%; 95% CI, 0.9%-1.3%) were serious adverse events and 315 (5.1%; 95% CI, 4.6%-5.7%) were vomiting. The odds ratio (OR) of occurrence of any adverse event, serious adverse events, and vomiting did not change significantly with each additional hour of fasting duration for both solids (any adverse event: OR, 1.00; 95% CI, 0.98 to 1.02; serious adverse events, OR, 1.01; 95% CI, 0.95-1.07; vomiting: OR, 1.00; 95% CI, 0.97-1.03) and liquids (any adverse event: OR, 1.00; 95% CI, 0.98-1.02; serious adverse events: 1.01, 95% CI, 0.95-1.07; vomiting: OR, 1.00; 95% CI, 0.96-1.03).

CONCLUSIONS AND RELEVANCE In this study, there was no association between fasting duration and any type of adverse event. These findings do not support delaying sedation to meet established fasting guidelines.

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Supplemental content

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Approximately 1 of every 100 children who visit an emergency department (ED) for care receives sedation for common medical procedures, such as fracture reduction and complex laceration repair.[1] Conservatively, this translates to 25 000 ED sedations in Canada, 60 000 in the United Kingdom, and 250 000 in the United States each year.[2-4] Although procedural sedation is regarded as safe, approximately 1% of children experience a serious adverse event.[1] Arguably the most feared, potentially life-threatening adverse event is pulmonary aspiration, which is defined as the inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory tract.[5,6]

With the goal of reducing the occurrence of pulmonary aspiration in sedated patients, preprocedural fasting guidelines were developed using consensus opinion by organizations such as the American Society of Anesthesiologists (ASA) and American Academy of Pediatrics.[7-9] These guidelines specify a minimum fasting period of 2 hours for clear liquids, 4 hours for breast milk, 6 hours for infant formula and light meals, and 8 hours for solids containing meat or fatty foods.[7]

However, some clinical experts contend that preprocedural fasting guidelines, which were originally intended for patients undergoing elective procedures, are not directly applicable to ED procedural sedation, because the risk of clinically important pulmonary aspiration is thought to be significantly less as a result of differences in baseline patient risk, sedation medications used, and procedures performed in this setting.[10-13] Consistent with this view, several relatively small, single-center cohort studies of children undergoing procedural sedation have not shown an association between fasting duration and adverse events such as oxygen desaturation, vomiting, and apnea.[13-16] Furthermore, prolonged fasting has been associated with less-favorable outcomes in some patients, and it consumes finite human and physical ED resources during periods of extended waiting.[10,17,18] As a result, adherence to preprocedural fasting guidelines is highly variable in emergency medicine.[14,16,19]

Given these limitations, the American Academy of Pediatrics has concluded that the true association of preprocedural fasting duration with serious adverse events such as pulmonary aspiration remains unknown for children undergoing sedation for emergency procedures, and they advocate further research "in many thousands of patients"[20(pe6)] to better define relationships, be they any adverse event, fasting intervals, and sedation complications. To address this gap, we performed a planned secondary analysis of what we believe is the largest, prospective cohort study of children to date who have received emergency procedural sedation.[1] Our broad objective was to examine any association between the incidence of sedation-related adverse outcomes and preprocedural fasting duration.

Key Points

Question Does the duration of preprocedural fasting alter the risk pulmonary aspiration and associated adverse outcomes in children undergoing emergency department procedural sedation?

Findings In this study of 6183 healthy patients undergoing sedation in 1 of 6 geographically separate and nationally representative Canadian emergency departments, 2974 (48.1%) did not meet fasting guidelines prior to sedation. Data analysis failed to identify an association between preprocedural fasting of any duration and any type of adverse event, and there were no cases of clinically apparent pulmonary aspiration.

Meaning Delaying sedation to meet established fasting guidelines appears not to improve sedation outcomes for children in the emergency department.

Methods

We performed an a priori planned secondary analysis of a multicenter prospective cohort study conducted in 6 Canadian pediatric EDs from July 10, 2010, to February 28, 2015.[1] All sites are members of Pediatric Emergency Research Canada, a national collaborative research network. Study methods have been previously described in detail.[21]

The study received approval from the research ethics board at each participating institution (the IWK Health Centre in Halifax; Montreal Children's Hospital in Montreal; Children's Hospital of Eastern Ontario in Ottawa; The Hospital for Sick Children in Toronto; Stollery Children's Hospital in Edmonton; and Alberta Children's Hospital in Calgary). Informed verbal or written consent, according to site-specific ethics regulations, was obtained from parents or guardians, and assent was obtained from children 7 years and older.

Study Setting and Population

Children aged 0 to 18 years who were undergoing parenteral procedural sedation for painful procedures were eligible for enrollment in the study. Children were excluded if they received a drug purely for anxiolysis or analgesia without the intent of sedation or if there was a language barrier present, as determined by the health care professional obtaining informed consent. Sedations with missing clinical data about the timing of last oral intake for solids or liquids were excluded from this substudy.

Definitions

Standardized definitions from the Quebec Guidelines, a consensus-based document developed by North American experts in pediatric procedural sedation, were used to determine time intervals and adverse events.[6] Adverse event definitions require both the specific clinical event to have occurred (eg, oxygen desaturation) and 1 or more appropriate interventions to be performed with the intention of treating or managing it (eg, airway repositioning, oxygen administration or increase in oxygen delivery, or positive pressure ventilation). Specific definitions from the Quebec Guidelines for adverse events reported in this study are documented in eTable 1 in the Supplement.

Outcome Measures

Four outcomes were examined for our primary objective: (1) clinically apparent pulmonary aspiration, (2) the occurrence of any adverse event, (3) serious adverse events, and

(4) vomiting. Clinically apparent pulmonary aspiration was defined as the suspicion or confirmation of oropharyngeal or gastric contents in the trachea during the sedation or physiologic recovery phase and the appearance of respiratory signs and symptoms that were not present before the sedation. Any adverse event, an aggregate measure, was defined as the occurrence of any 1 of the 15 adverse events under surveillance in our study (eTable 1 in the Supplement). Serious adverse events were defined as the occurrence of apnea, laryngospasm, hypotension, bradycardia, complete airway obstruction, clinically apparent pulmonary aspiration, permanent neurologic injury, or death. Vomiting was defined as the expulsion of gastric contents through the nose or mouth during sedation induction or maintenance or ED recovery. Study outcomes were chosen to encompass events that are direct precursors to pulmonary aspiration (vomiting) and those that have a higher probability of requiring positive pressure ventilation, thus increasing the risk of aspiration (serious adverse events).

Risk Factors

The primary risk factor of interest was fasting duration for solids and liquids. Fasting duration was analyzed both as a continuous variable (in number of hours prior to sedation) and as a dichotomous variable with the cut point determined by the ASA preprocedural fasting guidelines as 6 or more hours for solids and 2 hours or more for liquids. Other risk factors and potential confounders for adverse sedation outcomes were chosen a priori, based on clinical knowledge and literature review.[6] These included age, sex, sedation medication, ASA physical status classification,[22] use of preprocedural opioids (any opioid administered with the intent of treating pain prior to the administration of the first sedation medication), and procedure type. For the outcome of vomiting, preprocedural antiemetic administration was also examined. Risk factors were measured using patient or parental report, review of the medical record, and physical examination findings.

Statistical Analysis

Demographic characteristics and risk factors were summarized using descriptive statistics (median and interquartile range for continuous variables; frequency and percent for categorical variables) and compared between guideline compliant and noncompliant groups. Differences between groups were tested for statistical significance using Pearson χ^2 or *t* tests as appropriate. Observed fasting durations for solids and fluids were described using frequency distributions after categorization at clinically meaningful cut points (2, 4, and 6 hours). The incidence of sedation-related adverse events was described across fasting durations using frequency and percentage with 95% CIs adjusted for clustering by site. Variances were estimated using the Taylor series linearization method. Using box plots, we compared observed fasting durations for solids and liquids of patients who experienced any adverse event, a serious adverse event, or vomiting with patients who did not experience these outcomes. To examine the statistical association between fasting duration and outcomes, we included fasting duration as a continuous variable in a multivariable logistic regression analysis and modeled its association with the outcomes using restricted cubic splines. To identify the optimal number of knots, we fit separate models with 5 knots (located at the fifth, 27.5th, 50th, 72.5th, and 95th percentiles), 4 knots (located at the fifth, 35th, 65th, and 95th percentiles), or 3 knots (located at the 10th, 50th, and 90th percentiles). We used visual inspection of the resulting spline plots for each number of knots, as well as Akaike information criterion and Wald tests for nonlinearity to determine the functional form of the association that provides the best fit to the data. To adjust for potential confounders and risk factors, the identified covariates were included in the models. To reduce the risk of bias as a result of small numbers of events and sparse distributions of covariates, the logistic regression models were estimated using penalized likelihood with the Firth adjustment.[23,24] Results from the model were expressed as odds ratios, 95% profile-likelihood CIs, and *P* values, with statistical significance assessed at the 5% level. The goodness of fit of each model was evaluated using the Hosmer-Lemeshow test. The regression models were used to obtain plots of predicted probabilities of each outcome as a function of fasting duration for solids and liquids respectively, with categorical and continuous confounders held constant at the mode and median respectively. Statistical analyses for this article were performed from January 2016 to June 2017 using SAS, version 9.4 (SAS Institute Inc) and R, version 3.0.2 (R Foundation for Statistical Computing).

Results

Patient Characteristics

Of the estimated 9650 eligible sedations, 6295 (65.2%) were included in the final analysis of the parent study.[1] We excluded 112 sedations that were missing information regarding the time of last solid or liquid intake prior to sedation, leaving 6183 sedations (98.2% of the original cohort) in the current analysis. Of the 6183 patients, 6166 (99.7%) were classified as ASA physical status classification I or II, 4124 (66.7%) were male, and the median age was 8.0 years (interquartile range, 4.0-12.0 years). Ketamine alone was the most commonly used sedation medication (n = 3847; 62.2%) and orthopedic reduction was the most common procedure (n = 4076; 65.9%) (**Table 1**).

A total of 2974 children (48.1%) and 310 children (5.0%) did not meet ASA fasting guidelines for solids and liquids, respectively. Comparison of baseline characteristics of patients who did and did not fulfill fasting guidelines are shown in Table 1. For solids and liquids, there were a number of statistically significant differences between compliant and noncompliant groups; however, the only clinically significant differences between groups were age (solids) and sedation medication (solids and fluids).

Incidence of Sedation-Related Adverse Events

Overall, there were 717 adverse events (11.6%; 95% CI, 10.8%-12.4%). There were no cases of clinically apparent pulmonary aspiration. Oxygen desaturation (n = 340; 5.5%;

Table 1. Baseline Comparison of Children Who Met and Did Not Meet ASA Fasting Guidelines for Solids and Liquids

Characteristic	No. (%)						
		Fasting From Solids (≥6 h)			Fasting From Liquids (≥2 h)		
	Total (n = 6183)	No (n = 2974)	Yes (n = 3209)	*P* Value	No (n = 310)	Yes (n = 5873)	*P* Value
Age, median (IQR)	8.0 (4.0-12.0)	6.0 (3.0-12.0)	9.0 (5.0-12.0)	<.001	7.0 (3.0-13.0)	8.0 (4.0-12.0)	.62
Male	4124 (66.7)	1926 (64.8)	2198 (68.5)	.002	197 (63.6)	3927 (66.9)	.23
Procedure type							
Foreign body removal	219 (3.5)	141 (4.7)	78 (2.4)	<.001	16 (5.2)	203 (3.5)	<.001
Incision and drainage of abscess	318 (5.1)	176 (5.9)	142 (4.4)		35 (11.3)	283 (4.8)	
Laceration repair	1010 (16.3)	608 (20.4)	402 (12.5)		47 (15.2)	963 (16.4)	
Lumbar puncture	148 (2.4)	55 (1.9)	93 (2.9)		25 (8.1)	123 (2.1)	
Orthopedic reduction	4076 (65.9)	1804 (60.7)	2272 (70.8)		148 (47.7)	3928 (66.9)	
Other	412 (6.7)	190 (6.4)	222 (6.9)		39 (12.6)	373 (6.4)	
Sedation medication							
Ketamine only	3847 (62.2)	2017 (67.8)	1830 (57.0)	<.001	203 (66.5)	3644 (62.1)	<.001
Ketamine and midazolam	235 (3.8)	93 (3.1)	142 (4.4)		16 (5.2)	219 (3.7)	
Ketamine and propofol	849 (13.7)	291 (9.8)	558 (17.4)		18 (5.8)	831 (14.2)	
Propofol and fentanyl	719 (11.6)	350 (11.8)	369 (11.5)		38 (12.3)	681 (11.6)	
Ketamine and fentanyl	201 (3.2)	62 (2.1)	139 (4.4)		5 (1.6)	196 (3.3)	
Propofol alone	240 (3.9)	122 (4.1)	118 (3.7)		21 (6.8)	219 (3.7)	
Other	92 (1.5)	39 (1.3)	53 (1.7)		9 (2.9)	83 (1.4)	
Preprocedural opioid use	1780 (28.8)	765 (25.7)	1015 (31.6)	<.001	61 (19.7)	1719 (29.3)	<.001
ASA physical status classification							
Class I or II	6166 (99.7)	2966 (99.7)	3200 (99.7)	.93	308 (99.3)	5858 (99.7)	.21
Class III or IV	17 (0.3)	8 (0.3)	9 (0.3)		2 (0.7)	15 (0.3)	

Abbreviations: ASA, American Society of Anesthesiologists; IQR, interquartile range.

Table 2. Characteristics of Patients Who Vomited During Sedation[a]

Patient No./ Sex/Age, y	Fasting Duration, h		Procedure	Preprocedural		Ketamine Dose,[b] mg/kg	Duration of Procedure, min
	Solids	Liquids		Opioid	Antiemetic		
1/M/5	1.7	3.7	Foreign body removal	No	No	4	37
2/M/5	5.7	3.2	Burn debridement	Yes	Yes	2.5	25
3/M/7	17.5	3.0	Lumbar puncture	No	No	1.6	20
4/M/0	4.6	5.3	Laceration repair	No	No	1.9	54
5/M/11	10.0	10.0	Burn debridement	Yes	No	1.5	32
6/M/4	13.9	13.9	Orthopedic reduction	No	No	4	43

[a] No other adverse events occurred in any patient in this Table.

[b] All patients were sedated with ketamine only.

95% CI, 5.0%-6.1%) and vomiting (n = 315; 5.1%; 95% CI, 4.6%-5.7%) were the most common events. Of the 315 vomiting events, 6 events (1.8%) occurred during sedation, while the remainder occurred during recovery. Details of these 6 patients are shown in **Table 2**; all met fasting guidelines for fluids, while only half met fasting guidelines for solids. All patients who met fasting guidelines had a fasting duration of at least 10 hours. Serious adverse events occurred in 68 patients (1.1%; 95% CI, 0.9%-1.3%).

Association of Fasting Duration With Adverse Events

Table 3 presents the observed incidence of any adverse event, serious adverse events, and vomiting across fasting intervals for solids and liquids that are classified by duration: short (≤2 hours), intermediate (2 to 4 hours and 4 to 6 hours) and long (>6 hours). Box plots comparing fasting times for patients with and without events are presented in **Figure 1**. The results show no visible differences in distributions of fasting times between those with and without any adverse event, serious adverse events, or vomiting.

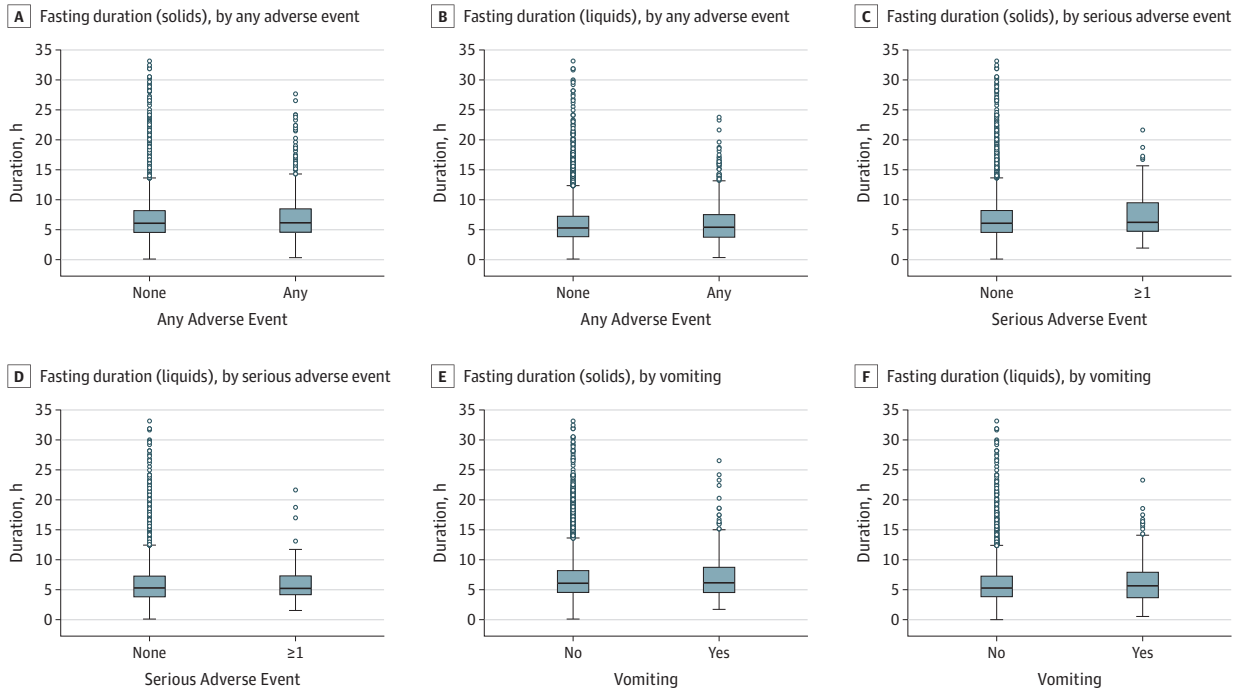
The restricted cubic spline plots, Akaike information criterion statistics, and tests for nonlinearity for the 5-knot, 4-knot, and 3-knot splines are presented in eFigures 1, 2, and 3 in the Supplement. For all outcomes, the Akaike information criterion statistic reached a minimum when fasting duration was modeled as a simple linear term and all tests for nonlinearity were nonsignificant, indicating that a simple linear term for the association between fasting duration and outcomes fit the data the best. There was no evidence of lack of fit in any of the models. The detailed results from the multivariable logistic regression analysis

Table 3. Observed Incidence of Sedation Outcomes for Short, Intermediate, and Long Fasting Durations for Solids and Liquids

Duration[a]	Any Event		Serious Event		Vomiting	
	No. (%)	95% CI of Percentage	No. (%)	95% CI of Percentage	No. (%)	95% CI of Percentage
Solids						
≤2 h (n = 112)	11 (10.3)	6.0-17.1	10 (0.9)	0.2-4.7	4 (3.4)	1.3-8.4
2-4 h (n = 888)	105 (11.8)	9.8-14.0	10 (1.1)	0.6-2.0	50 (5.6)	4.2-7.2
4-6 h (n = 2007)	223 (11.1)	9.8-12.5	20 (1.0)	0.7-1.5	94 (4.7)	3.8-5.7
>6 h (n = 3176)	378 (11.9)	10.9-13.1	38 (1.2)	0.8-1.6	168 (5.3)	4.6-6.1
Liquids						
≤2 h (n = 310)	32 (10.3)	7.5-14.2	2 (0.6)	0.1-2.2	15 (5.0)	3.1-8.0
2-4 h (n = 1405)	174 (12.4)	10.8-14.2	14 (1.0)	0.6-1.7	79 (5.6)	4.5-6.9
4-6 h (n = 2056)	222 (10.8)	9.5-12.2	25 (1.2)	0.8-1.7	88 (4.3)	3.5-5.3
>6 h (n = 2412)	287 (11.9)	10.7-13.3	29 (1.2)	0.8-1.7	133 (5.5)	4.6-6.4

[a] Fasting durations of 2 hours or less were considered short; durations of 2 to 4 hours and 4 to 6 hours, intermediate; and durations of more than 6 hours, long.

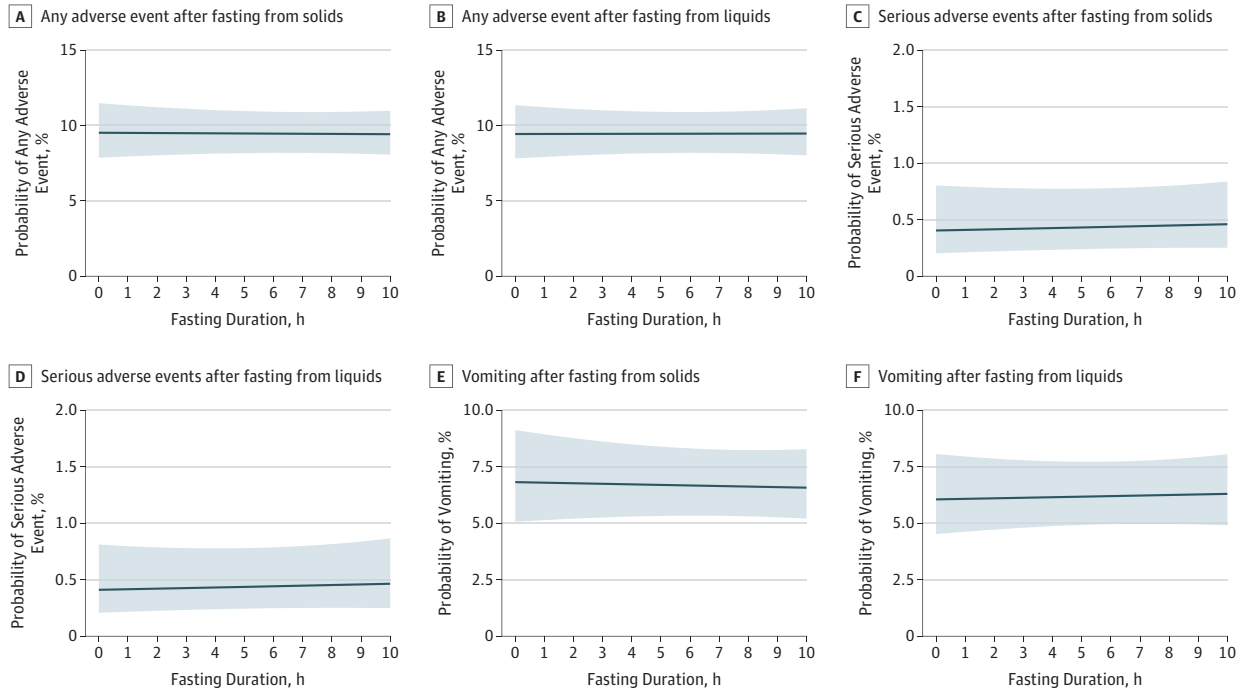
Figure 1. Fasting Duration (Solids and Liquids) for Patients Who Did and Did Not Experience Any Adverse Event, Serious Adverse Events, and Vomiting



A and B, Fasting duration for solids and liquids, respectively, for patients who experienced or did not experience any adverse event; C and D, Fasting duration for solids and liquids, respectively, for patients who experienced or did not experience serious adverse events; E and F, Fasting duration for solids and liquids, respectively, for patients who experienced or did not experience vomiting.

are presented in eTable 2 in the Supplement. These results show that, when adjusted for age, sex, sedation medication, and procedure type, the odds of an adverse event did not change significantly with each additional hour of fasting duration for both solids (odds ratio [OR], 1.00; 95% CI, 0.98-1.02; P = .91) and liquids (OR, 1.00; 95% CI, 0.98-1.02; P = .97). Similarly, the odds of vomiting (solids: OR, 1.00; 95% CI, 0.97-1.03; P = .79; liquids: OR, 1.00; 95% CI:, 0.96-1.03; P = .81) and the odds of a serious adverse event (solids: OR, 1.01; 95% CI, 0.95-1.07; P = .64; liquids: OR, 1.01; 95% CI, 0.95-1.07, P = .69) did not increase with decreased fasting duration. The modeled associations, together with 95% CIs, are depicted graphically in **Figure 2.**

Figure 2. Association of Preprocedural Fasting Duration for Solids and Liquids With the Probability of Sedation-Related Adverse Events



Point estimate probabilities of adverse events were obtained from the fitted logistic regression models for the association of fasting duration for solids and liquids and any adverse event (A and B), serious adverse events (C and D), and vomiting (E and F), after adjusting for age (1-year intervals), sex, preprocedure opioid administration, sedation medication, procedure type, and preprocedure ondansetron administration (vomiting model only) by setting categorical covariates to their modal category and continuous covariates to their median.

Discussion

The overall incidence of adverse events in our population was 11.6% (95% CI, 10.8%-12.4%). Serious adverse events occurred in 68 patients (1.1%; 95% CI, 0.9%-1.3%), and vomiting occurred in 315 patients (5.1%; 95% CI, 4.6%-5.7%). There were no cases of clinically apparent pulmonary aspiration. When fasting duration was modeled as a continuous variable using the best-fitting function form (a simple linear term), we did not observe an association between the duration of preprocedural fasting and any type of sedation-related adverse event.

Our study findings provide support to the idea that strict adherence to ASA fasting guidelines does not improve patient outcomes for children undergoing procedural sedation in the ED. Delaying sedation to meet fasting guidelines does not appear to decrease adverse event rates but has the potential to lengthen ED length of stay and impede patient flow. These findings support the recommendation from the American College of Emergency Physicians not to delay ED procedural sedation based solely on fasting time.[25]

Previous studies of ED procedural sedation have shown no association between fasting duration and adverse events. However, because of the small sample sizes (range, 218-1555 patients)[13-16] and limited statistical power of these studies, the ASA has stated, "The literature does not provide sufficient evidence to test the hypothesis that preprocedure fasting results in a decreased incidence of adverse outcomes in patients undergoing either moderate or deep sedation."[9(p1007)] Furthermore, previous studies did not model fasting duration optimally but rather categorizes fasting duration at arbitrary cut points, which assumes the relationship between fasting duration and adverse events is flat within intervals and results in a loss of power and precision.[13-16] From the previous literature, the best risk estimate for aspiration was 15 cases in 10 000 sedations.[16] Although we also did not observe any cases of pulmonary aspiration, this large sample allows us to conclude that the risk is no more than 3.1 in 10 000 sedations.[1] It is important to note that, to our knowledge, there have never been any reported cases of pulmonary aspiration in children undergoing parenteral sedation in the ED setting, despite widespread nonadherence with fasting guidelines.[14,16,19,26]

It is generally thought the risk of aspiration in ED procedural sedation is less than the risk in elective sedation and general anesthesia. Beach and colleagues[24] from the Pediatric Sedation Research Consortium recently published evidence of the association of fasting duration with the incidence of major complications in 139 142 children undergoing procedural sedation outside of the operating room. In this population of sicker children (of whom 17% had an ASA classification of III or greater), who were undergoing longer elective sedations (53% for magnetic resonance imaging or computed tomography) and were primarily sedated with

propofol (76%), there were 10 cases of aspiration, all of which occurred in children who fasted from solids for longer than 6 hours. The authors also found no association between fasting duration and aspiration or other major complications. Furthermore, they concluded the risk of aspiration was 0.7 cases per 10 000 sedations, which was approximately one-half to one-third the risk associated with general anesthesia. In this context, the estimated risk of aspiration of no more than 3.1 cases per 10 000 sedations in our population of healthy children undergoing short, painful procedures is conservative and likely an overestimate.

Limitations

Our study has several important limitations. First, given the observational nature of our study design, direct causal inferences cannot be made. Second, though approximately half of the patients did not fulfill fasting guidelines for solids, only 112 of 6183 patients (1.8%) consumed solids within 2 hours of their sedation. This makes it difficult to draw firm conclusions about the association of shorter fasting durations with adverse events. Third, despite a large sample size, we did not observe any cases of clinically apparent pulmonary aspiration. However, this is not surprising, given that the literature contains no reported cases of aspiration in ED parenteral sedation. Fourth, all study sites were tertiary care academic children's hospitals, which may limit the generalizability of our results to practice in general hospitals. Finally, a large proportion of our patients (62.2%) received ketamine alone, which is consistent with the literature indicating it is the most commonly used medication in ED sedation for children.[1,14,16,27,28] Unlike other sedatives, ketamine has been shown to maintain airway protective reflex properties and may result in a decreased risk of aspiration. In our cohort, ketamine alone was used more frequently in the group of patients who did not meet fasting guideline recommendations for elective sedation (2017 patients [67.8%]) compared with those who did (1830 patients [57.0%]). It is possible our results could be confounded by indication. We did adjust for all known risk factors, including sedation medication, in our multivariable analysis; however, it is possible that there were unmeasured factors for which we were unable to account.

To address these limitations, future research should focus on compilation of much larger data sets using rigorous methodology and standardized outcome measurements,[6,29] which would allow for accurate determination of the actual aspiration rate associated with ED procedural sedation. Cohorts including larger numbers of patients who have short preprocedural fasting durations would add to our understanding of aspiration risk in the ED population.

Conclusions

To our knowledge, our study is the largest prospective ED procedural sedation cohort, with the most complete documentation of fasting status and outcome ascertainment and most robust statistical analyses conducted to date. In this study population, we failed to identify an association between fasting duration and any type of adverse event. These results indicate that delaying sedation to meet established fasting guidelines does not improve sedation outcomes for children in the ED and is not warranted.

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Correction: This article was corrected on July 3, 2018, to correct an omission of 4 numbers and portions of 4 accompanying percentages from Table 1. The values and correct percentages for sedation medication combinations ketamine and midazolam, ketamine and propofol, propofol and fentanyl, and ketamine and fentanyl have been added for patients who met fasting guidelines from liquids.

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Author Contributions: Dr Bhatt had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
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