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Shortened preproceural fasting in the pediatric emergency department

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ABSTRACT

Background: There is no evidence of an association between fasting time and the incidence of adverse events during procedural sedation and analgesia. Pediatric and adult emergency medicine guidelines support avoiding delaying procedures based on fasting time. General pediatric guidelines outside emergent care settings continue to be vague and do not support a set fasting period for urgent and emergent procedures.
Objective: To describe shortened preprocedural fasting and vomiting event rates during the implementation of a shortened fasting protocol.
Methods: This was a prospective study of patients undergoing procedural sedation and analgesia (PSA) in an urban, tertiary care children's hospital emergency center from March 2010–February 2012. All consecutive patients had documentation of preprocedural fasting time and adverse events recorded on a standardized data collection form.
Results: PSA occurred in 2426 patients with fasting data available for 2188 (90.2%); 1472 were fasted ≥6 h for solids and 716 patients were in the shortened fasting group (<6 h). There is no evidence of an association between emesis at any time and shortened fasting time unadjusted (OR = 1.18 (95% CI 0.75–1.84) or adjusted for known risk factors including age >12 years, initial ketamine dose >2.5 mg/kg or total dose >5.0 mg/kg (OR = 1.14 (95% CI 0.74–1.75).
Conclusion: Analysis of a large prospective cohort study failed to find evidence of an association between emesis and shortened fasting time upon implementation of a shortened fasting protocol for procedural sedation and analgesia.

1. Introduction

Fasting time has been reported to have no association with the incidence of adverse events in procedural sedation and analgesia (PSA) [1-5]. The 2014 clinical policy for PSA in the Emergency Department by the American College of Emergency Physicians does not recommend delay of procedures based on fasting time as no decreased risk of emesis or aspiration has been shown [6]. However, guidelines from the American Academy of Pediatrics are less specific and do not support a set fasting recommendation for urgent and emergent procedures [7].

Stringent fasting guidelines, nil *per os* (NPO), from the American Society of Anesthesiology have been applied to the area of procedural sedation and analgesia (PSA) outside the operating room. These recommend at least 2 h from last clear liquid intake and 6 h from last solid intake before PSA [8]. Several studies have revealed increased adverse events such as hypoglycemia and dehydration with longer fasting periods in patients receiving PSA [8-11].

Ketamine is a widely used Emergency Department (ED) PSA agent with fewer associated airway and adverse event risks [2,6]. A consensus-based ED clinical practice advisory recommended a fasting time of 3 h for a light snack in patients undergoing dissociative sedation and non-extended moderate sedation for semi-urgent procedures in 2007 [12]. Our Evidence Based Outcomes Center and Sedation Oversight Committee amended our institutional clinical PSA guideline to move from a 6 h to 3 h solid fasting time for ED urgent procedures in February of 2011.

The goal of this study was to evaluate the vomiting rates in patients with shortened fasting in the ED compared to standard fasting.

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Secondary objectives included assessing the overall adverse event rate and the relationship of known PSA adverse event risk factors to the risk of emesis.

2. Materials and methods

2.1. Study design and population

We conducted a prospective cohort study of pediatric patients undergoing PSA in the ED of an urban, tertiary care children's hospital emergency center with an approximate annual volume of 85,000 patients from March 2010 to February 2012. Pre-sedation assessment forms were completed by the physician prior to PSA on a standardized paper data collection TeleForm® (Cardiff Software, Inc.; Vista, CA). This form included demographic data, procedure type, agent used and dosage, ED admit and discharge time, length of ED stay, NPO time for clear liquids and solids, and length of procedure. Airway risk using the American Society of Anesthesiologists physical status classification (ASA) was used [13]. In addition, physicians were asked to document any episodes of vomiting or adverse events during or after PSA. Sedation information was abstracted from the standard sedation nurse monitoring record and adverse events were recorded from nursing and physician documentation.

Data was entered by research assistants and 1 author (DRB) checked 100% of the charts for accuracy. Fifteen percent were additionally reviewed by the first author (CEC). PSA was performed in accordance with the Joint Commission guidelines and our hospital PSA guideline [14,15]. ED procedure management and sedation medication selection was at the discretion of the treating physician. This study was approved by the local Institutional Review Board.

2.2. Study protocol

Adverse events were defined *a priori* as follows: persistent oxygen desaturation to <93% on pulse oximetry and requiring supplemental oxygen or airway repositioning, bronchospasm, apnea, seizure, dizziness, hiccups, laryngospasm, stridor, arrhythmia, hypotension, rash, vomiting, aspiration, and behavioral reaction or any of the events recorded in the patient record [16].

2.3. Analysis

The primary outcome was defined as vomiting during or after the procedure. The intervention variable was a shortened fasting time defined as <6 h from last solid food intake or standard fasting ≥6 h. Baseline and clinical characteristics carrying an increased risk for vomiting were chosen *a priori*: including age <1 year or >12 years, initial ketamine dose >2.5 mg/kg, total ketamine dose >5.0 mg/kg, ASA classification III or higher, and ketamine use. The distribution of continuous variables (age, weight in kilograms (kgs), length of procedure, and length of stay) were assessed and found to be non-normally distributed, therefore non-parametric testing was utilized. Patient demographic and clinical characteristics were compared between the standard and shortened fasting times. For categorical variables, Pearson Chi-square test was utilized, and for continuous variables, the Mann–Whitney U (Wilcoxon rank sum) test was used. Frequencies and percentages along with median and interquartile ranges (IQR) were provided. Given a relatively low incidence of the primary outcome reported in the literature, published risk factors known to increase vomiting were chosen *a priori* according to the literature [2-5]. These potential confounders were evaluated when enough patients were present in each risk category. Odds ratios, 95% confidence intervals and p-values were calculated. Statistical significance was defined as a p-value < .05. All analyses were conducted using STATA, version 13 (StataCorp LP, College Station, TX).

3. Results

Procedural sedation was performed in the ED on 2426 patients; 2188 (90.2%) had fasting data available: 1472 (67.3%) in the standard fasting era and 716 (32.7%) in the shortened fasting era. Aspiration was not documented in any patients. Baseline characteristics were quite similar between groups (Table 1). Significant differences were found between groups for age and weight, yet those differences were not clinically relevant. The IQR for age in either group did not include the extremes of age for which the risk of vomiting has been reported to be increased. There was no evidence of an association between vomiting and a shortened fasting time of less than six hours (OR = 1.18 (95% CI 0.75–1.84); p-value = .44). Too few patients fell into the age <1 year category (4 patients), ASA class III category (4 patients), or received an initial ketamine dose ≥2.5 mg/kg (4 patients), and total dose ≥5.0 mg/kg (1 patient). Thus, age ≥ 12 years and medication type and dose were used in the adjusted binary logistic regression modeling however there was little difference between the unadjusted and adjusted effect estimates for shortened fasting time and emesis (aOR = 1.14 (95% CI 0.74–1.75). When considering any adverse event as an outcome, there was no significant association as a function of fasting times (aOR = 1.33 (95% CI 0.92–1.92). When ketamine was not administered, the odds of vomiting were reduced by 80% while controlling for shortened fasting time (aOR = 0.20 (95% CI 0.03–1.44).

Ketamine was the main agent used in the ED sedation cases. The mean dose of ketamine given was 1.1 mg/kg ± 0.38 and total dose 1.5 mg/kg ± 0.68. The initial dose of pentobarbital was 2.0 mg/kg ± 0.91 and a total dose 3.1 mg/kg ± 1.4. Midazolam (total) was typically given as a single dose 0.2 mg/kg ± 0.36. All were within the institution's pharmacy recommended doses. Patients who met standard fasting had a longer ED length of stay (p-value = .02). Patients with and without fasting data were very similar, the only difference was found in the ED length of stay which was 1.3 h less (95% CI 0.38–2.22) in the group with documented fasting (Table 2).

4. Discussion

Of the 2188 patients in this study, 98 patients (4.5%) experienced vomiting and there were no cases of aspiration. This matches the vomiting rate of 5.2% recently reported in a prospective, multicenter, observational ED cohort across Canada [2]. Other reported PSA vomiting rates range from 1.1–18.7% depending on medication type and route of administration [2,4,5,17-20]. In a large prospective multi-center study by Beach et al. with over 100,000 patients, NPO time was not shown to be an independent predictor of major complications or aspiration [3]. As expected, ketamine as a single agent increased the risk of vomiting (OR 2.32 (95% CI 0.93–5.78). Bhatt et al. reported similar results with ketamine as a single agent compared to other medications (OR, 1.3; 95% CI, 1.1–1.5) [2].

Given known risk factors for vomiting in PSA, a strength of our study lies in pre-selecting the known variables. We pre-identified six variables such that given the 98 episodes of vomiting, we had >10 events per variable to reduce the risk of model overfitting and potential to underestimate the vomiting risk in low PSA risk patients. Given that relatively low risk healthy children make up our ED sedation population, 4 of the risk factor categories did not have enough patients to make a meaningful assessment (age < 1 year, initial or total ketamine dose, and ASA class III status). By removing those predictor variables, we lose the ability to determine effect estimates for some of the high risk factor combinations. Patients <1 year of age that have an ASA class III status or greater would not be sedated in our ED. These patients are often excluded by published sedation policies and we caution against providing PSA for such patients in the ED setting. Especially in cases where higher ketamine doses are planned, our cohort does not have enough patients to provide accurate estimates for vomiting and adverse events. When excluding the high risk variables for which we had too few patients to

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