"Full Stomach" Despite the Wait: Point-of-care Gastric Ultrasound at the Time of Procedural Sedation in the Pediatric Emergency Department

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ABSTRACT

Objectives: The objective was to use gastric point-of-care ultrasound (POCUS) to assess gastric contents and volume, summarize the prevalence of "full stomach," and explore the relationship between fasting time and gastric contents at the time of procedural sedation.

Methods: This was a prospective study of patients aged 2 to 17 years fasting prior to procedural sedation. A single sonographer scanned each patient's gastric antrum in two positions: supine with the upper body elevated and right lateral decubitus (RLD). Gastric content (empty, liquid, or solid) was noted, and the gastric volume (mL/kg) was estimated from antral cross-sectional area (CSA). "Full stomach" was defined as any solid content or >1.2 mL/kg of liquid gastric content.

Results: We enrolled 116 subjects, with a median fasting time of 5.8 hours. Of the 107 with evaluable images, 74 patients, 69% (95% confidence interval [CI] = 60%–77%), were categorized as having a full stomach. Each hour of fasting was associated with lower odds (odds ratio = 0.79, 95% CI = 0.65–0) of a full stomach. However, the knowledge of fasting time alone provides little ability to discriminate between risk groups (C-index = 0.66).

Conclusions: Gastric POCUS classified many patients as having a full stomach at the time of expected procedural sedation, despite prolonged fasting times. These findings may inform risk–benefit considerations when planning the timing and medication choice for procedural sedation.

There is a current lack of consensus regarding the need for a minimum period of fasting prior to nonelective sedation for urgent or emergent procedures in the pediatric emergency department (PED).[1–3] Recommendations from the American Academy of Pediatrics (AAP)[1] for children undergoing elective procedures mirror guidelines for general anesthesia from the American Society of Anesthesiologists[4] and recommend fasting prior to sedation for 2 or 6 hours after clear liquid or a light meal, respectively. For children

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requiring urgent/emergent sedation, the AAP guideline states that "the risks of sedation and possible aspiration are as-yet unknown and must be balanced against the benefits of performing the procedure promptly."[1] The 2014 clinical policy statement from the American College of Emergency Physicians (ACEP) summarized studies that found no association between the duration of preprocedural fasting and the risk of emesis or aspiration.[2] They recommended that "future research should focus on the identification of a potential high-risk population that might benefit from a fasting time . . . if such a delay is to be relevant in any ED procedural sedations."[2]

Prolonged fasting is not always benign. It can increase patient hunger and anxiety, reduce intravascular volume, prolong ED length of stay, cause hypoglycemia, and reduce parental and patient satisfaction.[5,6]

Unlike patients fasting prior to elective sedation, PED patients awaiting procedural sedation often have painful injuries, are frequently treated with opioids, and may have eaten large fatty meals immediately preceding injury, all of which can slow gastric emptying.[4,7,8] Large, multicenter studies are necessary to estimate the risk of pulmonary aspiration in any setting.[9] Gastric point-of-care ultrasound (POCUS), a technique developed by anesthesiologists, allows us to address a simpler question—what are the stomach contents and volume after a period of fasting prior in patients awaiting procedural sedation in our PED?

The terms "full stomach" and "empty stomach" are a convenient, albeit overly simplistic, shorthand to describe gastric contents and volume. As described by Kinsella, "the fullness of a stomach is different from the fullness of a glass. It can contain a variable amount of contents, which may comprise clear or particulate liquids and solids in various degrees of chunkiness."[10]

Prior studies in both adults and children have used POCUS to identify liquid or solid contents and to assess gastric volume.[11–15] We adopted the Perlas scale, which combines a qualitative description of stomach contents (empty, liquid, solids) and quantitative gastric volume estimated from antral cross-sectional area (CSA).[11,16–18] The Perlas category labels are ordered by "risk of aspiration," reflecting their intended application in the preoperative setting, as applied to healthy pediatric patients who have fasted for elective surgery. Patients with either an empty antrum ("low risk") or a negligible volume (typically ≤ 1.2 mL/kg) of gastric secretions ("suggests low risk") are classified as having an empty stomach. Conversely, patients with solid contents or higher volumes of clear fluid are considered to have a full stomach.

This study does not undertake the ambitious goal of determining whether procedural sedation can be safely performed in patients with full stomach. Rather, we aimed to: 1) use POCUS to describe gastric contents and volume, based on Perlas categories; 2) summarize the prevalence of full stomach; and 3) explore the relationship between fasting time and these measures of gastric content and volume in patients undergoing procedural sedation in the PED.

METHODS

Study Design and Setting

We performed a prospective observational study in the PED at an urban academic children's hospital with pediatric Level 1 trauma designation and an annual census of 55,000 patients, from June to December 2017. Approximately 800 patients undergo procedural sedation in our department each year. The study protocol was reviewed and approved by the hospital institutional review board.

Study Population

We enrolled patients aged 2 to 17 years who were fasting in anticipation of procedural sedation. We excluded patients with conditions likely to affect gastric emptying including gastrointestinal pathology, presence of an acute or chronic systemic illness, or multisystem trauma and those taking medications with gastrointestinal effects. Potential participants were identified by PED staff and research assistants. Patients were enrolled after obtaining informed consent if the primary investigator was available. Parents received a gift card of $10 value following participation.

Study Protocol and Measures

All POCUS evaluations were performed by a single sonographer (principal investigator JL) who had previously completed over 30 gastric POCUS scans supervised by the study site's pediatric POCUS director (coinvestigator EC). Patients were scanned using gastric POCUS at the time of "readiness for procedural sedation," defined in our PED as at least 2 hours since last liquid intake and 4 hours since last solid intake. The exact timing of this measurement varied based on the availability of the sonographer and the actual time

that each participant was sedated. Patient care was not delayed or interrupted by participation in this study, and no additional analgesic or sedative medications were administered to aid in obtaining images. Furthermore, the medical team managing the patient was blinded to ultrasound findings.

A Sonosite M-Turbo portable ultrasound machine was used to obtain a cross-sectional view of the antrum in the sagittal plane at the level of the liver and aorta using a 5–2 MHz curvilinear probe placed in the epigastrium. Scans were done in two positions: supine with the upper body elevated at 45° (SUBE) and right lateral decubitus (RLD), following the protocol described by Perlas and colleagues (Figure 1).[11] Antral contents were assessed qualitatively in the SUBE and RLD positions, and interpreted as empty, liquid, or solid (Figure 2). The sonographer then traced the antral circumference in the RLD position, in between antral contractions, using the manual caliper tool. From this, the machine calculated the antral CSA. Images were automatically uploaded to a password-protected database. The time required to complete each POCUS examination was recorded.

All study data were managed on REDCap (Research Electronic Data Capture), a secure, Web-based application designed to support data capture for research studies.[19] To evaluate inter-rater reliability, POCUS images were deidentified and retrospectively reviewed by the study site's pediatric POCUS director (coinvestigator EC), who was blinded to the clinical information and to the principal sonographer's interpretation.

At the time of enrollment, the researcher recorded baseline information from the patient and electronic medical record on a standardized data sheet. This included patient age, weight, height, race, ethnicity, time, and nature of the most recent oral intake, timing of injury, self-reported pain severity, and medications received. Adverse events were noted through retrospective chart review of the procedure note, as well as nursing notes that followed the patient's course through to discharge. Possible adverse events included retching/vomiting, oxygen desaturation, bradycardia, hypotension, allergic reaction, adverse behavioral reactions, and suspected or confirmed aspiration.

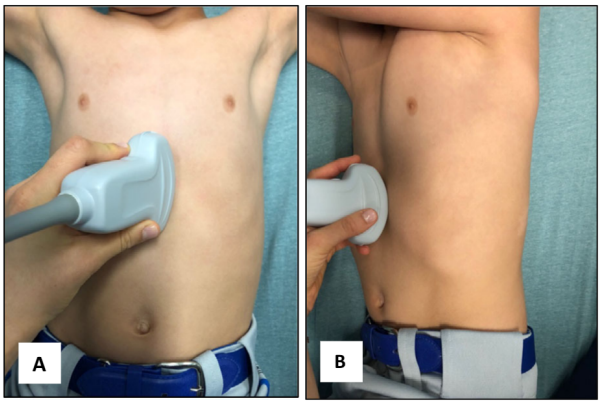

Figure 1. Patient positioning for gastric POCUS. Gastric POCUS is performed with a curvilinear probe in the epigastric location with a sagittal orientation in two positions: (**A**) right lateral decubitus and (**B**) supine with the upper body elevated, with the index marker pointing cephalad. POCUS = point-of-care ultrasound.

Data Analysis

We adopted the Perlas score, developed by anesthesiologists for preoperative aspiration risk assessment, as a metric to combine information about gastric content and volume into one of four ordinal categories (Figure 3).[11] Gastric volume (mL/kg) was estimated from CSA (cm^2) and age (months) using a previously developed prediction equation:[11,13]

$$\text{Volume} = -7.8 + (3.5 \times \text{CSA}) + (0.127) \times \text{age}.$$

We used 1.2 mL/kg as a cutoff of fasting gastric secretions based on estimates from prior studies, which range from 1.2 to 1.5 mL/kg in a pediatric patient.[11,13] Gastric contents were deemed "low risk" if the antrum qualitatively appeared empty (flat and collapsed or round and targetoid with a thick and prominent antral wall) in both SUBE and RLD positions. Contents were categorized as "suggests low risk" if liquid was present in either RLD or SUBE with a volume $\leq$ 1.2 mL/kg and as "suggests high risk" if liquid volume was > 1.2 mL/kg. "High risk" was defined as solid contents seen in either position. The former two categories (low risk and suggests low risk) were considered empty stomach and the latter two (suggests high risk and high risk) were considered full stomach (Figure 3).

Data were analyzed using R version 3.5.1.[20] The *zanthro* extension[21] for Stata (StataCorp, 2017, Stata Statistical Software, Release 15) was used to calculate body mass index categories. Categorical measurements were summarized as counts and percentages. Continuous data were summarized by mean and standard deviation (SD), and skewed data, by the median and 25th and 75th percentiles. We calculated that a minimum sample size of 93 patients was needed to ensure that the 95% Wilson score confidence interval (CI) for the proportion of patients with a full stomach was not

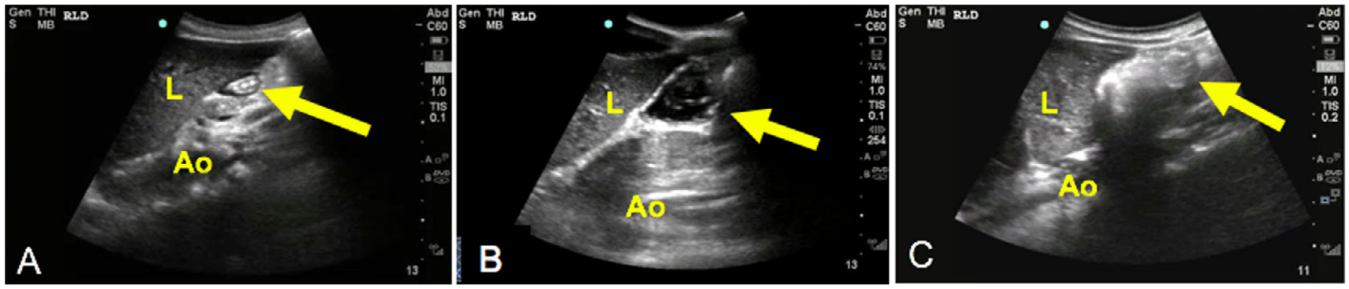

Figure 2. Gastric content as visualized by POCUS. Ultrasound images of the gastric antrum in the epigastric area obtained in a sagittal plane in the RLD position, representing (**A**) empty, (**B**) liquid, and (**C**) solid contents. An empty antrum appears flattened and devoid of contents. Liquid contents appear hypoechoic or anechoic, and solid contents appear hyperechoic, often with particulate content. *Yellow arrow* = antrum. Ao = aorta; L = liver; POCUS = point-of-care ultrasound; RLD = right lateral decubitus.

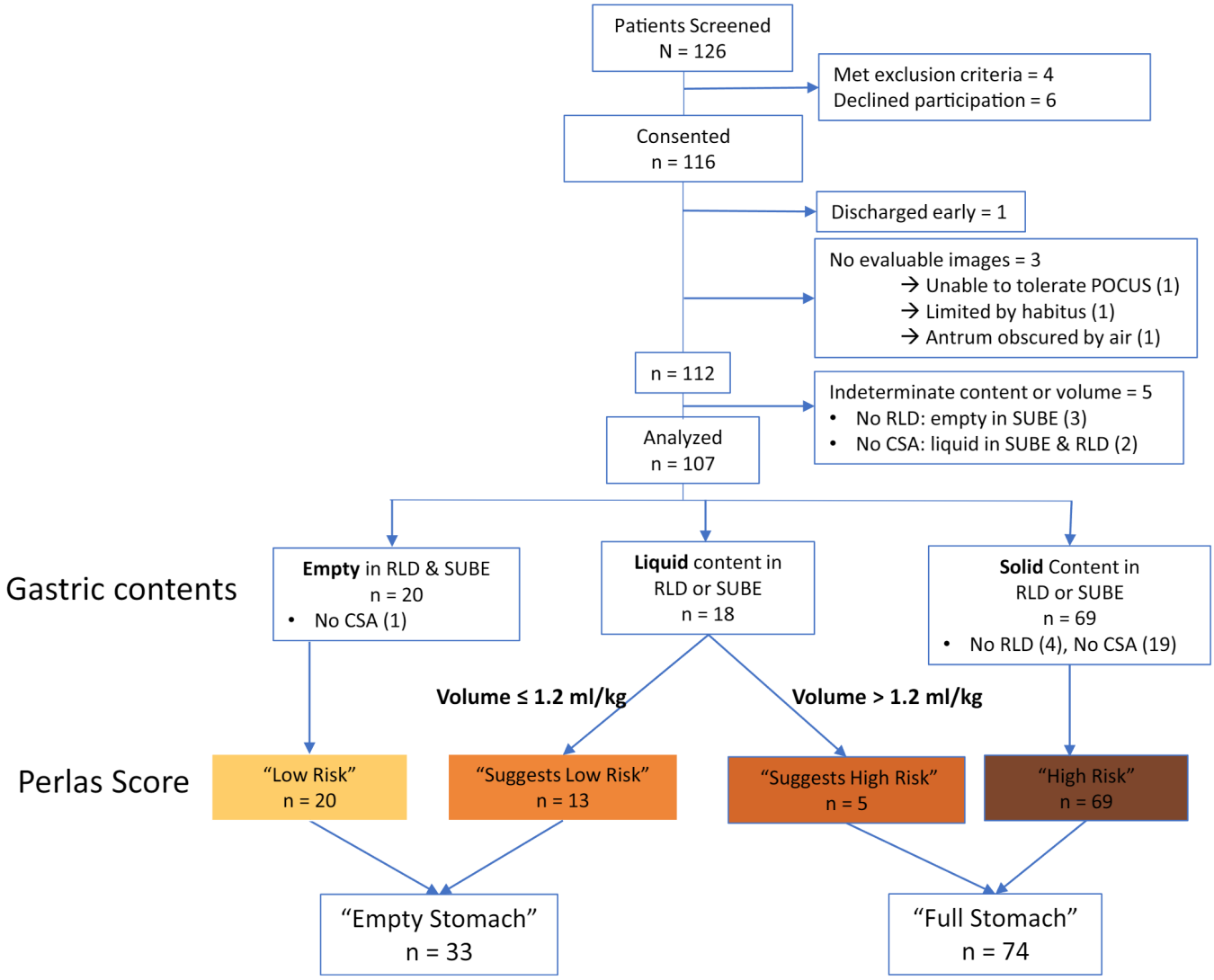

Figure 3. Patient flow diagram and classifications by Perlas category. *Bulleted lists* describe reasons for incomplete POCUS evaluation with counts in parentheses. *Arrows* indicate explanations for lack of evaluable images. No RLD = no POCUS images in right lateral decubitus position; No CSA = antral cross-sectional area could not be measured; N = total number of patients screened; n or (n) = number of patients in each category. CSA = cross-sectional area; POCUS = point-of-care ultrasound; RLD = right lateral decubitus; SUBE = supine with the upper body elevated.

wider than ±0.10.[22,23] The R package *ggplot2* was used to plot kernel density estimates for the distribution of patients in each Perlas category over the range of fasting times. This technique produces a continuous curve from the data located a small distance from each data point and then adds individual kernels to obtain

a smoothed histogram.[24] Logistic regression was used to estimate the effect of fasting time on the predicted probability of a full stomach. The concordance index (C-index), equivalent to the area under the receiver operating characteristic curve, was calculated. The C-index ranges between 0.5 and 1.0. A value of 0.5 indicates the model has no ability to discriminate between low- and high-risk subjects, whereas a value of 1.0 indicates the model can perfectly discriminate between these groups. Inter-rater agreement between the researcher and expert reviewer was summarized by weighted kappa coefficients, where the disagreements are weighted so as to be proportional to the square of the distance between the pair of measures.[25]

RESULTS

We enrolled 116 subjects, 115 of whom had a POCUS examination (Table 1). An unambiguous Perlas score was determined in 107 subjects. Of these, 74 subjects 69% (95% CI = 60%–77%) were categorized as having a full stomach (Figure 3). Figure 4A shows the number and percentage of subjects assigned to each category. For subjects in whom a CSA could be obtained and gastric volume estimated, Figure 4B illustrates the observed gastric volumes and the distributions of gastric volume in each group.

The stacked kernel density plot displays the number of subjects in each Perlas category over the observed range of fasting times, with a preponderance of subjects in the "high-risk" category (Data Supplement S1, available as supporting information in the online version of this paper, which is available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13651/full). The median fasting time was 5.8 hours. As illustrated in Figure 5, there is considerable overlap between the fasting times in each group. The predicted probability of a full stomach remains substantial despite prolonged fasting times. Although each hour of fasting was associated with lower odds (odds ratio = 0.79, 95% CI = 0.65 to 0.94) of having a full stomach, the knowledge of fasting time alone provides little ability to discriminate between risk groups (C-index = 0.66).

Point-of-care ultrasound assessments took a median of 4 minutes (IQR = 3 to 5 minutes) to complete. The weighted kappa for inter-rater agreement was 0.74 (95% CI = 0.68 to 0.79). Of 115 participants undergoing an ultrasound, 32 (28%) had their gastric POCUS scan a median of 44 minutes (IQR = 29 to 53 minutes) after, rather than before, the onset of procedural sedation (18 due to either lack of investigator availability prior to sedation or parental preference and 14 due to an inability of the patient to tolerate RLD positioning for a complete scan prior to sedation).

Table 1
Demographic and Clinical Characteristics of the 116 Enrolled Patients Fasting in Preparation for Procedural Sedation in a Pediatric ED: June–December 2017

Demographics	*n* = 116
Age (years)	8.4 (±4.0)
Sex	
Female	37 (31.9)
BMI classification	
Underweight	14 (12.1)
Healthy weight	60 (51.7)
Overweight	26 (22.4)
Obese	16 (13.8)
Race/ethnicity	
White	75 (64.7)
African American	8 (6.9)
Asian	4 (3.4)
Hispanic or Latino	24 (20.7)
Other/not reported	5 (4.3)
Fasting time (hours)	
Solids	5.8 (4.6–7.7)
Liquids	5.2 (4.1–6.8)
Maximum pain reported	
None/mild	2 (1.8)
Moderate	23 (19.8)
Severe	88 (75.9)
Not reported	3 (2.6)
Received opioid	
Yes	75 (64.7)
Received ondansetron	
Yes	24 (20.7)
Reason for sedation	
Fracture reduction	95 (81.9)
Laceration repair	9 (7.8)
Other	12 (10.3)
Recent fried/fatty food or meat	
Yes	75 (64.7)
No	40 (34.5)
Not reported	1 (0.9)
Procedural sedation agent used	
Ketamine	43 (37.1)
Ketamine + midazolam	58 (50.0)
Intranasal midazolam*	3 (2.6)
No medication	12 (10.3)

Data are reported as mean (±SD), n (%), or median (IQR).
BMI = body mass index; *n* = number of patients; IQR = interquartile range.
*Intranasal midazolam considered to be minimal sedation (anxiolysis).

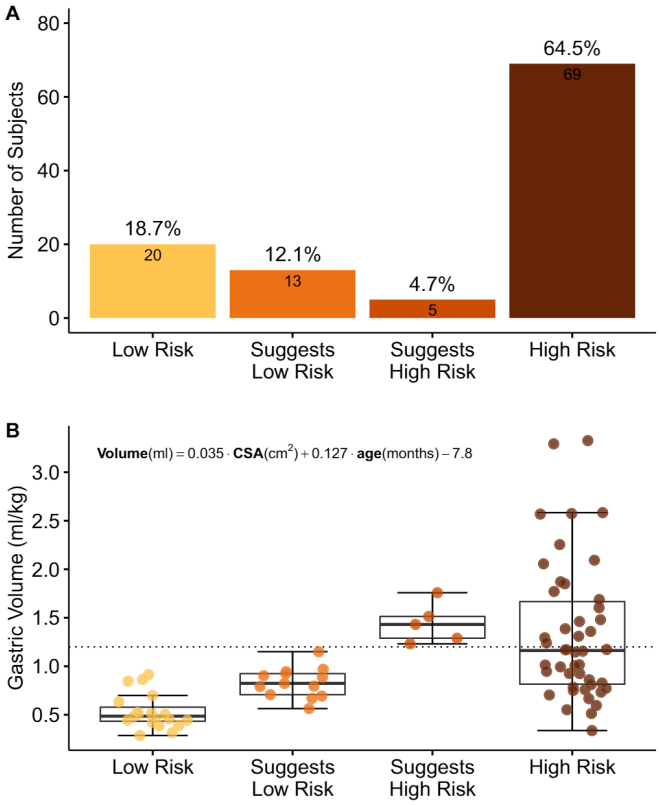

Figure 4. (**A**) Number (*inside bar*) and percent (*above bar*) of patients in each Perlas score category. (**B**) Gastric volume by Perlas score category. The *colored dots* (corresponding to Perlas score category) represent the estimated gastric volume (mL/kg) for each subject. The *middle line* in each box is the median. *Lower and upper hinges* correspond to the first and third quartiles. The *whiskers* extend from the hinge to the largest and smallest values no further than 1.5× IQR from each hinge. CSA = cross-sectional area.

Ultimately, 15 of 116 enrolled patients (19%) did not receive sedation. Of these, four were admitted for operative management, eight had injuries that were repaired or temporized without sedation, and three received only low-dose midazolam for anxiolysis. Medications used for sedation in those who did undergo procedural sedation are listed in Table 1. Of the 101 participants who ultimately received procedural sedation, four (4%, 95% CI = 1.6%–9.7%) vomited during the recovery period. Of the patients who vomited, three had been identified by gastric POCUS as high risk and one as suggests high risk. There were no other adverse events, including no suspected or confirmed aspiration events (0%, 95% CI = 0%–3.6%).

DISCUSSION

We found that a majority of enrolled PED patients would be considered as having a full stomach at the time of "readiness for procedural sedation" based on POCUS finding of residual solids or high-volume liquid contents. Moreover, fasting periods of 6 or more hours did not ensure an empty stomach. As summarized in Table 1, the majority of our patients had recently eaten fried/fatty food or meat, and the majority reported severe pain and received opioid analgesia, all of which can slow gastric emptying.[7,8,26] Our findings mirror those of Bouvet and colleagues,[7] who demonstrated that 56% of adults undergoing emergency surgical procedures had a full stomach at the time of anesthesia despite a mean fasting duration of 18 hours.

Two recent studies in the PED setting have evaluated the relationship between duration of preprocedural fasting and the risk of sedation-related adverse events.[27,28] In a multicenter prospective cohort study of sedation safety, 48.1% of the 6,166 children receiving procedural sedation did not meet fasting guidelines. There were no cases of clinically apparent pulmonary aspiration, and the authors found no association between fasting duration and any adverse event and concluded that "delaying sedation to meet established fasting guidelines does not improve sedation outcomes for children in the ED and is not warranted."[27] A nonrandomized before-and-after comparison of 2,188 children concluded that shortening preprocedural fasting from 6 to 3 hours did not result in increased vomiting and decreased ED length of stay.[28] These studies suggest that fasting prior to procedural sedation may be unnecessary, particularly in otherwise low-risk patients, when ketamine is the sedative agent.[27,28]

This study does not aim to determine whether procedural sedation can be safely performed in patients with a full stomach. Taken alone, our small sample provides scant additional information regarding the safety of procedural sedation of patients with high gastric volume or solid contents.

A methodologic criticism of studies of aspiration risk in children with fasting noncompliance has been that not all included children had full stomach.[29] To the extent that patients in these large cohorts are similar to our patients, the low observed risk of adverse outcomes may occur despite a high prevalence of patients with solid or large-volume gastric contents. Thus, as a research tool, gastric POCUS could augment future prospective studies, allowing risk estimates conditional on full stomach status. In our patients, fasting time alone is an imperfect predictor of gastric contents and volume. Since gastric POCUS provides an objective measure of gastric content, the technique

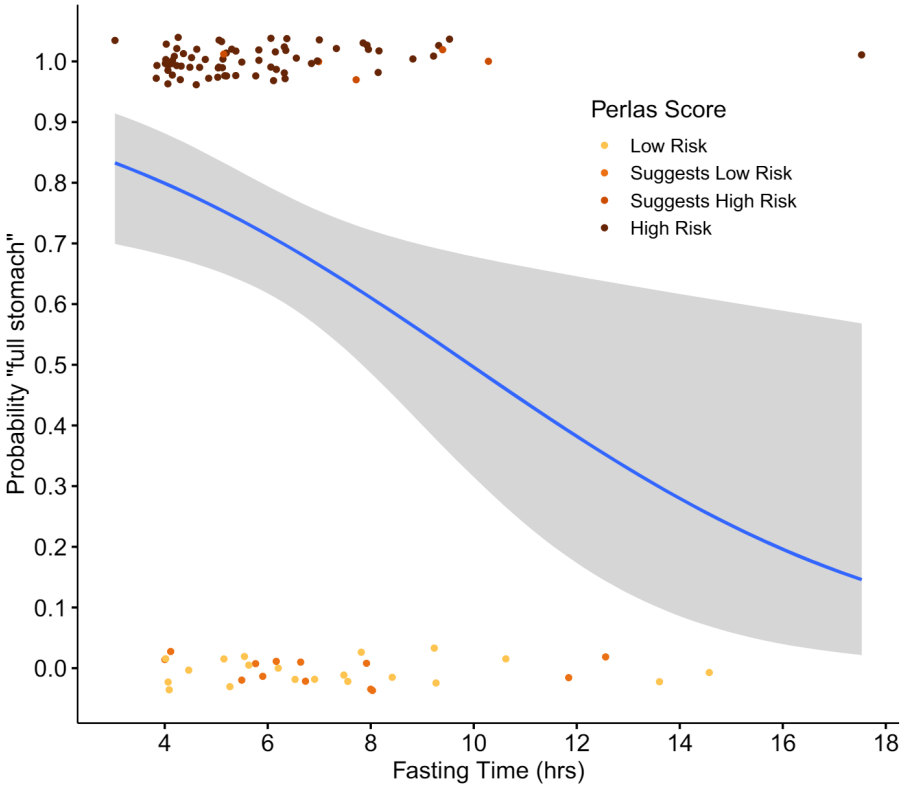

Figure 5. Predicted probability of a full stomach versus fasting time from logistic regression. The *shaded area* represents a 95% confidence envelope. The *dots* (colored by Perlas score category) indicate the fasting time for subjects with a full stomach (*upper row*) and those with an empty stomach (*lower row*).

could be used to develop and validate models to predict which patients have a full stomach from multiple predictors such as the time from intake to injury, pain severity, and/or opioid administration, in addition to fasting time.

As a clinical tool, gastric POCUS could be used to evaluate patients with risk factors for aspiration such as severe systemic illness, bowel obstruction, obesity, or obstructive sleep apnea; in patients with an anticipated need for airway manipulation; and in those undergoing deep sedation using agents likely to blunt airway reflexes.[30]

LIMITATIONS

We recruited a convenience sample of patients; therefore, our findings may not be representative of the population of patients undergoing procedural sedation in our ED. Also, parent and child reports of the timing and details of recent intake are likely not entirely reliable, but are consistent with a realistic clinical scenario in the PED.

Our choice of 1.2 mL/kg as the upper limit of baseline fasting gastric secretions represents a conservative estimate.[11,13] A variety of studies in adult patients have documented fasting baseline gastric volumes of up to 1.5 mL/kg in patients considered to be at negligible risk for aspiration.[18] For pediatric patients, the upper limit of normal fasting volume varies based on body size and habitus and has been reported to be approximately 1.2 to 1.5 mL/kg.[11,13]

There are some limitations associated with obtaining and interpreting gastric ultrasound findings. Gastric anatomy may be obscured by air or difficult to visualize due to patient habitus. In this study, no useful images could be obtained in three subjects, and an additional five patients could not be unambiguously assigned to a Perlas category (Figure 3). Also, a small amount of baseline air in the antrum may resemble solid content and lead to a false-positive identification of solid content.[31] While antral CSA can be measured with high intra- and inter-rater reliability,[32] the estimation of gastric volume based on available prediction equations introduces some degree of variability.

Some patients with painful injuries were unable to tolerate the RLD position required to estimate gastric volume from antral CSA. This may represent a practical limitation of the applicability of gastric POCUS in the PED to assist in decision making. In total, 30 patients (27.2%) were scanned after sedation, at a

median of 44 minutes after ketamine administration. An animal study demonstrated an inhibitory effect of ketamine on intestinal motility;[33] thus there is a potential that further delay in emptying of gastric contents occurred in those patients who were evaluated after sedation.

A single investigator performed all POCUS examinations. We assessed inter-rater reliability via a review of digital images only; hence, the reliability and repeatability of study results is uncertain. This study did not aim to determine the degree of training and/or prior experience required to be competent in gastric POCUS. Typically, ACEP requires 25 to 50 scans to achieve baseline competency in most modalities,[34] and we felt that 30 scans was sufficient in the case of our primary investigator. However, ultrasound competency, in general, is highly dependent on the user's prior sonography experience.

CONCLUSIONS

The majority of patients in this study had a full stomach at the time of expected sedation, many of whom had prolonged fasting times. Given the results of our study, providers should not feel confident or reassured that a fasted patient in the pediatric ED has an empty stomach. These findings may inform risk–benefit considerations when planning timing and medications for procedural sedation in the ED.

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Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13651/full

Data Supplement S1. Stacked kernel density plot (smoothed histogram) representing the number of patients in each Perlas score category over the range of fasting times.