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Signa Vitae

ORIGINAL RESEARCH

Gastric point-of-care ultrasound evaluation in pediatric emergency department procedural sedation patients; is the stomach empty at the point of scheduled revisit?

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Abstract

Objectives: This study aimed to use gastric point of care ultrasound (POCUS) to estimate the prevalence of an "empty stomach" among patients undergoing procedural sedation and analgesia (PSA) in the emergency department (ED) after observing the requisite fasting time at home.
Methods: A prospective observational study was conducted with children with facial lacerations who made a scheduled revisit to the ED after completion of the recommended fasting time. Their stomach contents were assessed with a sagittal view of the gastric antrum by POCUS in the right lateral decubitus position. The characteristics of gastric contents were described as empty, solid, and liquid with an estimated gastric volume. "Empty stomach" was defined as a collapsed gastric antrum or calculated a gastric fluid volume of less than or equal to 1.25 mL/kg on POCUS.
Results: Gastric POCUS was performed in 125 patients, and the final analysis included 122 patients. For 95 patients who had followed the recommended fasting time, the median fasting time was 7 hours for solids and 6 hours for liquids, and 78 (82%) patients had an empty stomach. Conversely, seven of 27 patients (26%) who did not have an adequate fasting time had an empty stomach. The optimal cut-off value of fasting time to predict an empty stomach was 6.5 hours based on a receiver operating characteristic (ROC) analysis (sensitivity = 0.767, specificity = 0.811).
Conclusions: Most scheduled revisiting children had an "empty stomach" at the time of sedation after the recommended fasting. However, providers should be aware that one in five children still had stomach residue, although they had more than 6 hours of fasting.

Keywords

Ultrasonography; Gastric emptying; Pediatrics

1. Introduction

Procedural sedation and analgesia (PSA) is a common intervention in the pediatric emergency department (PED) [1, 2]. PSA relieves patient pain and anxiety, improves the procedure quality, and ensures safety. However, close observation of the patient is essential since serious adverse events (SAE) such as pulmonary aspiration can occur [3, 4]. Pulmonary aspiration is a critical complication that might trigger serious morbidity and mortality. However, there have been no report of PSA related aspiration in ketamine use, and 0.9 aspiration events were reported per 10,000 pediatric PSA with propofol [5–7].

When performing general anesthesia, the risk of aspiration may increase further, with 2–10 events occurring per 10,000 elective surgery procedures [8–11]. The American Society of Anesthesiologists (ASA) provided fasting times before elective procedures. However, there is controversy over whether nil per os (NPO) time is required prior to PSA in PEDs. The largest cohort of prospectively by the Pediatric Sedation Research Consortium, database on 139,142 patients of PSA practice, revealed little association between NPO status and aspiration or major adverse outcomes [5, 12–17].

Generally, PSA does not require a long fasting time since it only lasts for a short duration and is less likely to inhibit the protective airway reflex. The American Academy of Pediatrics 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" [18]. The American College of Emergency Physicians (ACEP) clinical policy also stated that nonscheduled procedural sedation is excluded from fasting requirements [17]. However, it is also argued that even in the PED, if the patient is expected to receive airway-related treatment or has a severe systemic disease, it is necessary to consider fasting before procedural sedation unless an urgent procedure is required [19].

Apart from the discussion of the appropriate duration of fasting for patients undergoing PSA, it is necessary to determine whether fasting actually results in an empty stomach in PED patients. The reason for fasting is to ensure gastric emptying, and it has been reported that patients undergoing unscheduled procedures have significantly delayed gastric emptying times, unlike patients undergoing elective surgery [20]. Recently, studies that confirmed "full stomach" using a gastric POCUS in children undergoing PSA in PED have been reported, and these studies found that the frequency of an empty stomach even after 6 hours of fasting as called for by the ASA recommendation is quite low [21, 22].

We questioned whether delayed gastric emptying in the PED was similar in patients with a scheduled revisit. It was thought that the frequency of an empty stomach would be different from previous studies because if children were sent home, the patient's anxiety would be reduced during fasting than while staying in an unfamiliar PED [23]. The primary goal of this study was to evaluate the frequency of an empty stomach after fasting in pediatric patients with a scheduled revisit through gastric POCUS.

2. Methods

2.1 Study design and setting

We conducted a prospective observational study on pediatric patients visiting the PED at a tertiary hospital with an annual census of 50,000 patients from January to October 2020. Approximately 500 pediatric PSA are performed in our department annually. The study protocol was reviewed and approved by the hospital institutional review board (2020-01-039).

2.2 Study population

This is a convenience sample of revisiting pediatric patients who were fasting for PSA in anticipation of the repair of a facial laceration. Patients were excluded if they needed urgent procedures, or they had conditions likely to affect their gastric emptying, including gastrointestinal diseases, systemic illness, and multi-organ trauma. Those taking medications with gastrointestinal effects, cases in which sedation was performed with a medication other than intramuscular ketamine, were excluded as well. Patients were enrolled after obtaining informed consent from their parents.

2.3 The study protocol and data collection

We ran a pediatric wound care program in our PED in which plastic surgeons did facial wound repair under PSA twice a day. When the patient participated in that program, they were instructed to return home after wound dressing and to revisit the PED after the recommended NPO time. The recommended fasting time in our program was more than 2 hours after a clear liquid diet and more than 6 hours for milk, dairy, or solid food. Patient care was not delayed by participation in this study, and no additional sedatives were administered for the POCUS examinations.

If sufficient NPO time was not able to be achieved until the last available schedule of the plastic surgeon, wound closure would be delayed more than 12 hours, which can increase risk of wound infection and of poor aesthetic outcome. In such cases, despite the insufficient fasting time, PSA was performed.

A single sonographer (principal investigator) conducted all of the ultrasound scans. This investigator had experience with more than 30 gastric POCUS scans supervised by the research director, the POCUS director of the site's PED. Patients were scanned by gastric POCUS immediately after sedation. A LOGIQ S8 (General Electric Healthcare, Chicago, IL, SA) ultrasound machine and a 2.5–8.0 MHz linear transducer were used. The gastric POCUS exam was performed on the patient's upper abdomen in a right decubitus (RLD) position [24, 25]. The ultrasound images were acquired under the sagittal view using the abdominal aorta, superior mesenteric artery, liver, and pancreas as anatomical indicators [26]. The characteristics of the stomach contents were described by the Perlas scale, which combines a qualitative description of stomach contents as "empty", "liquid", "solid", and a quantitative gastric volume estimated from the antral cross-sectional area (CSA) [27–30]. The CSA of the gastric antrum was evaluated by tracking the serous layer's periphery using a manual caliper (Fig. 1). The gastric volume was estimated from the CSA and age by an equation previously developed and validated by comparing with volume of gastric aspirate suctioned under anesthesia: Gastric Volume (mL/kg) = –7.8 + (3.5 $\times$ CSA (cm^2)) + (0.127) $\times$ Age (months) [31]. The upper limit of the normal baseline gastric volume is, still controversial, reported to be from 1.0 to 1.5 mL/kg in children [27, 31–33]. We defined a cut-off of physiologic gastric secretion as 1.25 mL/kg on the basis of the value derived by Cook-Sather. In their study, 95% of 611 pediatric patients who fasted at least 8 hours for solid food and 2 hours for liquid food had a gastric fluid volume less than 1.25 mL/kg before elective surgery [33]. "Empty stomach" was defined as an empty antrum or a physiologic amount of gastric secretion ($\leq$1.25 mL/kg) with gastric POCUS. Patients with solid contents or higher volumes of clear fluid were defined as not having an empty stomach.

After enrollment, we gathered information regarding age, sex, height, weight, underlying diseases, current medication, time of the last meal, and the nature of the most recent oral intake as reported by parents. The result of the gastric POCUS and any adverse events associated with the PSA were obtained from the patients' electronic medical records.

2.4 Data analysis

At the beginning of this study, there was no reference to guide sample size calculation to assess the presence of a sonographic empty stomach in PED patients with a scheduled revisit. We assumed an empty stomach ratio of 50% in patients presenting for a schedule revisit, based on prior studies of unscheduled PSA patients in the PED and nonelective pediatric surgery patients [19, 20, 22]. We calculated that enrollment of more than 93 patients from approximately 500 annual cases of PSA, would allow a 95% confidence interval for the proportion of empty stomach with a width of $\pm$10%.

Descriptive statistics were used for the demographic and clinical characteristics. Categorical variables were described using frequency and proportions, and continuous variables

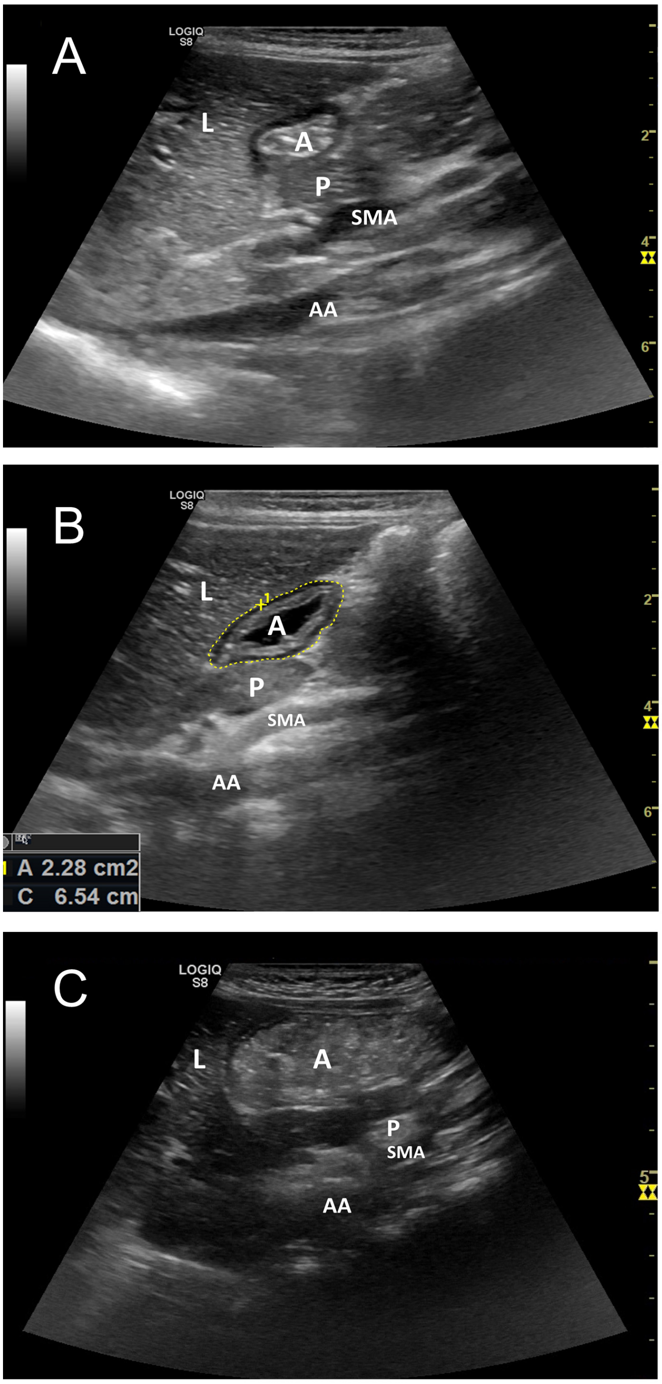

FIGURE 1. Interpretation of ultrasound images. Gastric contents were assessed as empty (A), liquid (B), and solid (C). Cross-sectional area (CSA) of the antrum can be evaluated by tracing the circumference of the antrum following the serosal layer (yellow dotted line). The gastric volume can be estimated from the CSA and age by using the following equation: Gastric Volume (mL/kg) = –7.8 + (3.5 × CSA (cm^2)) + (0.127) × Age (months) = –7.8 + (3.5 × 2.28) + (0.127 × 16) = 1.2 mL/kg. L, liver; A, antrum of the stomach; P, pancreas; SMA, superior mesenteric artery; AA, abdominal aorta.

were described using either means with standard deviations (SD) or medians with interquartile ranges (IQR), as appropriate. To evaluate the diagnostic value of solid food fasting time to determine an empty stomach, we used receiver operating characteristic (ROC) analysis and area under the curve (AUC) calculations.

The inter-rater agreement between the researcher and an expert reviewer was summarized by weighted kappa coefficients. Analyses were conducted in IBM SPSS Statistics for Windows, version 20.0 (IBM Corp., Armonk, NY, USA).

3. Results

During the study period, 150 patients were screened, and 129 children were enrolled. One patient was excluded because of an underlying gastrointestinal disease, 11 patients for taking gastrointestinal medications, five patients for systemic illness, four patients for other sedative agents than intramuscular ketamine injection, and four patients declined consent. Gastric POCUS was performed on 125 patients, of which 122 were included in the final analysis and three were excluded due to uninterpretable images (Fig. 2). Among the 122 patients, 95 patients had more than 6 hours NPO as recommended. The median fasting time was 7 hours for solid food and 6 hours for a liquid diet. Of these 95 patients, 78 (82%) showed an empty stomach on gastric POCUS, and 17 (18%) did not. Conversely, among the other 27 patients who had a shorter NPO time than recommended, only seven patients (26%) had an empty stomach.

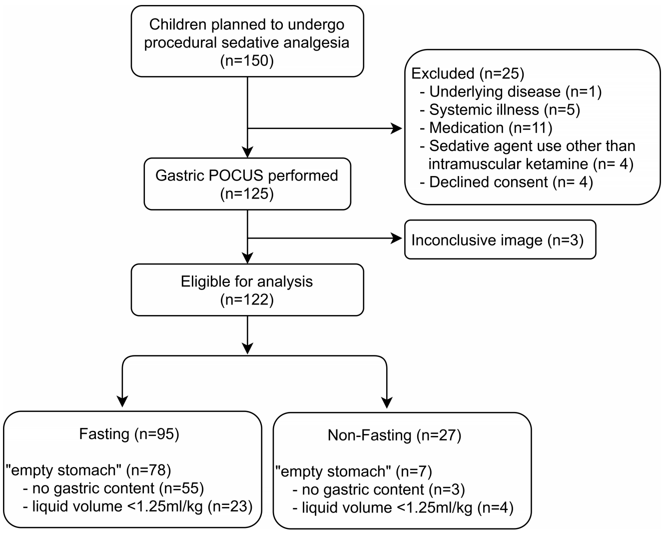

FIGURE 2. Flow chart outlining the study design.

The baseline characteristics of the children are shown in Table 1. The odds of a sonographic empty stomach gradually increased with longer fasting duration (Fig. 3), while the proportion of solid food and the residual gastric volume by POCUS decreased over time (Fig. 4). The diagnostic value of the fasting time in the case of solid food was evaluated using a ROC curve with 112 patients who had more than 2 hours of liquid fasting. The diagnostic value was high (AUC = 0.801, $p < 0.01$) and the optimal cut-off value of the solid food fasting time was 6.5 hours (sensitivity = 0.767, specificity = 0.811) (Fig. 5). The weighted kappa for inter-rater agreement was 0.75 (95% CI = 0.69 to 0.78), suggesting good agreement.

In this study, a total of 4 adverse events occurred. Two transient episodes of hypoxia occurred in patients with gastric

TABLE 1. Baseline characteristics of the children.

Characteristics	All patients		Fasting		Non-fasting	
	N	%	N	%	N	%
All	122	100.0	95	100.0	27	100.0
Age, months	37.9 ± 16.1		37.0 ± 15.5		41.0 ± 18.0	
Sex						
Male	89	73.0	69	72.6	20	74.1
Height, m	0.94 ± 0.13		0.93 ± 0.14		0.98 ± 0.12	
Weight, kg	15.1 ± 3.51		14.9 ± 3.37		15.8 ± 3.85	
BMI, kg/m^2	16.6 ± 3.29		16.8 ± 3.09		15.7 ± 3.79	
Obese	17	13.9	14	14.7	3	11.1
Fasting time, hours						
Solids	7.0 (6.0–9.0)		7.5 (6.0–9.0)		3.0 (2.0–3.0)	
Liquids	6.0 (4.0–8.0)		6.0 (5.0–8.0)		3.0 (2.0–4.0)	
Empty stomach	85	69.7	78	82.1	7	25.9

residue, and two episodes of post-PSA emesis occurred in patients with a sonographic empty stomach. Two patients with hypoxia were recovered with stimulation and nasal oxygen supplementation only. There were no instances of aspiration, hypotension, or severe hypoxia.

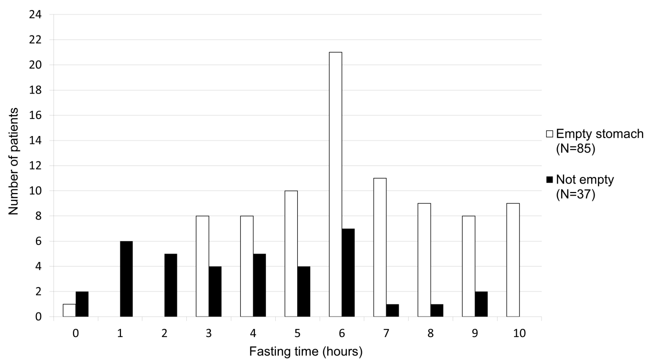

FIGURE 3. Number of patients with "empty stomach" per fasting duration.

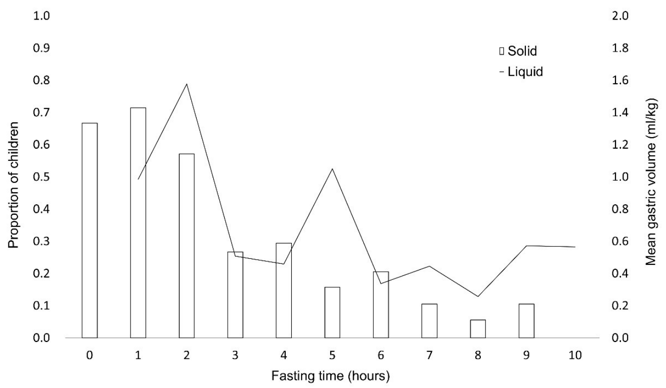

FIGURE 4. The proportion of solid food remnant and the residual gastric volume per unit body weight over fasting time. The two values decrease over time.

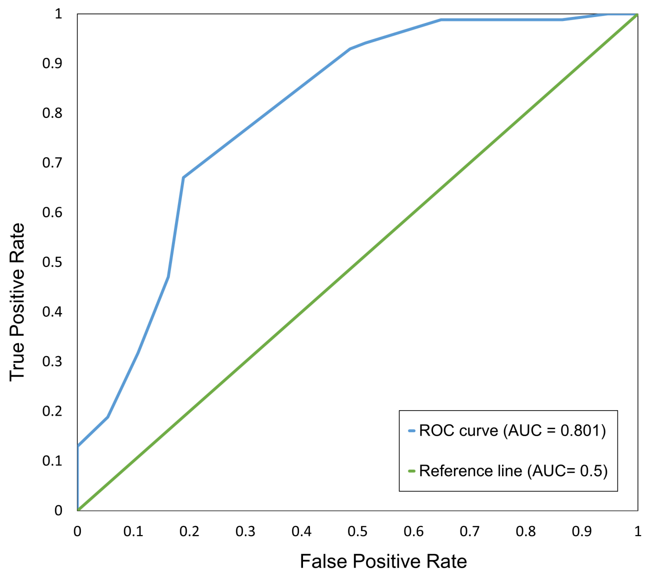

FIGURE 5. Receiver operating characteristic (ROC) curve for prediction of "empty stomach" based on fasting time. Area under the curve (AUC) was 0.801 ($p < 0.01$), and the optimal cut-off value was 6.5 hours (sensitivity = 0.767, specificity = 0.811).

4. Discussion

In this study, we used gastric POCUS to determine the presence and nature of gastric content after patients have been returned home to complete a six hour fast. In our study, 82% of patients showed an empty stomach after a median NPO time of 7.5 hours for solid intake and 6 hours for clear liquid intake. This study included a population with lower age group, weight, and height but similar body mass index than in other studies [20–22, 34]. The ROC analysis suggested the optimal cut-off of solid food NPO duration for gastric emptying was 6.5 hours when the patients had more than 2 hours of liquid fasting. However, even if the fasting time was more than 10 hours, there were cases where the stomach was not empty.

Our study differs from others in that we targeted patients who are scheduled to revisit the PED. "Waiting at home" was originally designed to reduce PED crowding and length of stay but is thought to be a factor that promotes gastric emptying in pediatric patients. Another notable point is the futuristic design of fasting. Therefore, we can obtain a more accurate NPO duration than the memory of parents or patients, which is commonly adopted in other studies.

Recent studies have investigated the prevalence of an empty stomach on gastric POCUS in pediatric patients requiring PSA in the PED. Leviter *et al*. [21] reported that only 31% of patients had an empty stomach after 5.8 (4.6–7.7) hours of solid fasting and 5.2 (4.1–6.8) hours after liquid fasting. Moake *et al*. [22] conducted a study on 93 patients with PSA, and reported that gastric emptying could be confirmed in only 20% of patients fasting more than 6 hours and in less than 40% of patients fasting for more than 8 hours. In our study, empty stomach was confirmed in 82% of patients fasting more than 6 hours and 87% of patients fasting of solid food more than 8 hours, which is higher than previous studies in the PED mentioned above.

In contrast to studies on PED PSA, empty stomach in the patients hospitalized for elective procedures had been identified with a high probability. In a study of 200 hospitalized pediatric patients by Bouvet *et al*. [34], 99% of patients showed an empty stomach on gastric POCUS after 13.5 hours of solid food fasting. In addition, a study of 75 children hospitalized for elective ear, nose, and throat surgery reported that 100% of patients had an empty stomach after fasting for more than 6 hours [35]. However, non-elective surgery patients were shown to have an empty stomach at rates similar to PED patients. Gagey *et al*. [20] reported that only 54% of 143 children before non-elective surgery had an empty stomach even after 11 hours of fasting time.

These differences in gastric emptying time may be because of the difference in the degree of pain and stress that the injured patient is experiencing and may also be an effect of medication for pain control or of ileus due to trauma [23]. These factors may be less likely to present in a patient presenting for elective surgery. In contrast with other PED PSA studies, our study population had a simple facial wound, and the degree of pain felt by our patients may have been lower than that of patients in the studies involving orthopedic trauma. Furthermore, we believe that keeping children waiting in their own home before revisiting may have promoted gastric emptying because stress from fear and discomfort inherent to the PED environment can be a factor in delayed gastric emptying [36, 37].

In our study, the frequency of sonographic gastric residual was reduced compared to previous studies, but it was still detected in 18% despite a more prolonged fasting time than the ASA suggests. For twenty years, there have been authors arguing that ASA fasting requirements are not relevant in PSA and demonstrating that the occurrence of adverse events related to PSA has no relationship with fasting status [5, 19]. Since it is difficult to ensure gastric emptying in children fasting in the PED, despite prolonged fasting times, the current practice recommends that an ASA guideline-based prolonged fasting time is not required when PSA is performed for a short duration in healthy children [19].

Nevertheless, in some PED patients, it may be necessary to consider fasting prior to a PSA procedure. In particular, children with severe systemic illness or receiving medications that inhibit the protective airway reflex may require longer fasting times prior to PSA [6, 19]. However, it should be remembered that an extended fasting time itself cannot guarantee an empty stomach. In this case, it may be helpful to evaluate the risk of SAE through gastric POCUS [20].

This study has several limitations. We enrolled a convenience sample of patients with a facial laceration at a single institution. Therefore, this study may not be representative of the population of patients undergoing PSA for other procedures, or those at other institutions. Moreover, the physician was not blinded to the patient's fasting status prior to the POCUS examination; thus, there may be a possible detection bias in the POCUS interpretation.

We relied on parental reports to identify patient's fasting time and recent intake details that may be incorrect. However, this is standard of care for operative anesthesia and is consistent with a real-world clinical scenario. And in our study, fasting was asked prospective and therefore it could be more accurate than usual recollection.

We performed gastric POCUS only in the RLD position, but the original Perlas scale was classified by both supine and RLD positions [27]. However, for the assessment of low aspiration risk category by Perlas, supine POCUS exam is not essential because the CSA should be measured in the RLD position eventually. Additionally, we assumed that a single RLD examination might reduce the scan time and distress of the patients.

In some cases, there was a difference between the time when the fasting time was recorded and the time at which the POCUS exam was performed, but the difference did not exceed 30 minutes.

One physician performed all of the POCUS examinations, and the interrater reliability was assessed via reviewing digital images. However, considering that ACEP requires 25 to 50 scans to achieve baseline competency in most POCUS modalities, we believe that our results based on 30 scans under supervision are acceptable.

Finally, as this was an observational study, the fasting time, the nature of the last meal and the patients' physical environment while fasting could not be controlled.

5. Conclusions

Our study showed that most patients who came back to the PED as a scheduled revisit with fasting had an "empty stomach" at the time of sedation. However, one in five children had stomach content despite a longer fasting time than suggested in the ASA guidelines. These findings may provide information about risk-benefit considerations when planning procedural sedation timing of children in the PED.

AUTHOR CONTRIBUTIONS

The conception and design of the study: HHD, SL. Acquisition, analysis, or interpretation of data: HN, HHD. Drafting of the manuscript: HN. Critical revision of the manuscript for

important intellectual content: JSS, YWK. Statistical analysis: SL, CHK. Study supervision: HHD, SCL, JHL. Final approval of the version to be submitted: All authors.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was reviewed and approved by the hospital institutional review board of Dongguk University Ilsan Hospital, Dongguk University (2020-01-039).

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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