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ORIGINAL RESEARCH

Hard-Candy Consumption Does Not Have an Effect on Volume and pH of Gastric Content in Patients Undergoing Elective Gastrointestinal Endoscopic Procedures: A Randomized Controlled Trial

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Purpose: This study aimed to determine the effect of hard candies on gastric content volume and pH in patients undergoing elective esophagogastroduodenoscopy and colonoscopy. Additionally, the study evaluated the difficulty of the procedure, complications, and satisfaction levels of the endoscopist and patient.

Patients and Methods: A randomized controlled study equally recruited 108 outpatients to candy and control groups. The patients in the candy group could consume sugar-free candies within 2 hours before anesthesia, while the controls remained fasted. The endoscopic procedure began under topical pharyngeal anesthesia and intravenous sedation. A blinded endoscopist suctioned the gastric volume through an endoscope. A blinded anesthesia provider tested the gastric pH with a pH meter. The primary outcome variables were gastric volume and pH. The secondary outcome variables were complications, the difficulty of the procedure, and endoscopist and patient satisfaction.

Results: The characteristics of both patient groups were comparable. The mean gastric volume of the candy group (0.43 [0.27–0.67] mL/kg) was not significantly different from that of the control group (0.32 [0.19–0.55] mL/kg). The gastric pH of both groups was similar: 1.40 (1.10–1.70) for the candy group and 1.40 (1.20–1.90) for the control group. The procedure-difficulty score of the candy group was higher than that of the control group. The satisfaction scores rated by the endoscopist and the patients in both groups were comparable. In addition, most endoscopists and patients in the candy and control groups reported being "very satisfied". No complications were observed in either group.

Conclusion: Hard candies did not affect gastric volume or pH. Elective gastrointestinal endoscopic procedures in adult patients who preoperatively consume candies could proceed to prevent delays and disruption of workflows.

Keywords: gastric pH, gastric volume, gastrointestinal endoscopy, hard candy, preoperative fasting guidelines

Introduction

Preoperative fasting is a prerequisite in patients scheduled for procedures under anesthesia to mitigate the risk of pulmonary aspiration of gastric content, which could lead to severe complications such as aspiration pneumonitis or Mendelson's syndrome.[1–3] Several studies have reported that severe pulmonary complications are likely to occur if the pH of the gastric content is < 2.5[4–6] and the volume is ≥ 0.5 mL/kg.[5–7]

International guidelines recommend that patients refrain from consuming food or drinks for at least 6 to 8 hours before procedures are performed under anesthesia. Nevertheless, some patients admit to having refreshments, such as

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hard candies and chewing gum, during the fasting period. However, there are some discrepancies between established preoperative fasting guidelines. While the European Society of Anesthesiology allows chewing gum, candy, and smoking prior to procedures,[8] the American Society of Anesthesiologists (ASA) has not specified comparable exceptions to the recommended 6 to 8 hours of fasting.[1] As a result, some anesthesia providers may be unsure whether they should carry on anesthetizing patients for procedures or postpone the cases until an adequate fasting time is achieved. In the busy environment of the typical endoscopy unit, the postponement or even cancellation of cases where fasting requirements have not been met can delay patient management and disrupt workflows.

Based on direct observation of patients scheduled for esophagogastroduodenoscopy (EGD) at our institution (a tertiary-care, academic hospital), there have been times when patients have consumed hard candies before planned procedures. Cases involving the preprocedural chewing of gum have not yet been observed. This may be because chewing gum is not popular in the Asian population,[9] especially in elderly Thai individuals. However, information about the effects of hard-candy consumption before gastrointestinal endoscopic (GIE) procedures is limited. A study by Hamid et al demonstrated that patients who ate lollipops and those in a completely fasted control group had no differences in gastric content volume or the incidence of pulmonary complications resulting from aspiration.[10] Therefore, we hypothesized that procedures being performed under anesthesia could be allowed to proceed for patients who ingested some candies beforehand.

Our study primarily aimed to determine the effects of candy on the volume and pH of the gastric content of adult patients undergoing GIE procedures. The secondary outcome variables were complications, the difficulty of the procedures, and endoscopist and patient satisfaction.

Materials and Methods

Study Design

This rater-blinded, randomized, controlled study was conducted at a tertiary-care, university-affiliated teaching hospital. Before starting the research, its protocol was approved by the Siriraj Institutional Review Board, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand (approval number SI188/2564). The study was registered at the Thai Clinical Trial Registry (https://www.thaiclinicaltrials.org/show/TCTR20210625006). The recruited participants were outpatients scheduled for EGD and colonoscopy under anesthesia between October and December 2021. Patients were enrolled if they

1. were aged between 18 and 70 years,
2. had an American Society of Anesthesiologists (ASA) physical status classification of I to III,
3. had undergone fasting following the standard ASA guidelines, and
4. were able to comprehend spoken and written Thai.

Patients were excluded if they had a body mass index > 30 kg/m^2 or a full stomach condition (esophageal atresia, gastric outlet obstruction, intestinal obstruction, upper gastrointestinal bleeding, or ascites). Patients were informed of their enrollment by telephone the evening before the GIE procedure and were reminded of it in the preprocedural holding area. Written informed consent was obtained in the holding area before the start of the procedure.

The patients were randomly assigned to a "candy group" or a "control group" (full fasting) via computer-generated randomization (www.randomization.com). The patients in the candy group were allowed to consume 3 zero-calorie, sugar-free candies (ingredients: sorbitol, 97.36%; peppermint flavor, 2%; and sucralose, 0.05%) within 2 hours before the start of anesthesia for EGD. The control group received nothing by mouth (NPO). The endoscopists were board-certified gastroenterologists; each had several years of experience to avoid performance bias. The endoscopists were blinded to the patients' group allocations.

Topical pharyngeal anesthesia with 8 to 10 puffs of 10% lidocaine spray and moderate to deep sedation with 3 to 5 mg/kg/h of intravenous propofol infusion were performed to ensure adequate depth of anesthesia. Oral secretions were cleared by suctioning before endoscope insertion, while gastric content was aspirated under endoscopic visualization into a clean plastic container. Water flushing was prohibited before the gastric content was suctioned. The gastric volume was

measured in mL by an appropriate plastic syringe, and the gastric pH was measured by a pH meter (Hanna Instruments SRL, Nusfalau, Salaj, Romania). Normally, the elective patients were scheduled for both EGD and colonoscopy. Therefore, colonoscopy was performed just after the completion of EGD by the same endoscopist under moderate to deep sedation by intravenous propofol. However, no variables were measured during colonoscopy.

Immediately after the EGD procedure ended, the endoscopists rated their overall satisfaction. However, the patients were asked to report their satisfaction later once they had fully recovered in the postanesthesia care unit (indicated by a sedation score of 0) to avoid the delay of the procedure considering that there was a large volume of patients per day. The patients would give the scores based on their satisfaction of the overall procedure. The endoscopist and patient satisfaction scores were on a Likert scale of 1 to 5, where 1 denoted "very dissatisfied" and 5 represented "very satisfied".

Sample Size Calculation

The sample size was calculated by PASS sample size software (version 8.0; NCSS LLC, Kaysville, UT, USA). A previous report indicated that the gastric volume of patients who complied with standard preoperative ASA fasting guidelines was 20 ± 15 mL (mean ± SD).[11] As the average body weight of a Thai adult was approximately 60 kg according to a previous report,[12] the gastric volume that would cause pulmonary aspiration was ≥ 30 mL, given that the critical volume was ≥ 0.5 mL/kg.[5–7] Assuming noninferiority for gastric volume with a test power of 0.9, an equivalent margin of 10, an actual difference of 0, SD of 15, alpha error of 0.025, and beta error of 0.09, the calculated sample size was 49 per group. With the addition of a 10% dropout rate, the final sample size per group was 54.

Statistical Analysis

The participants' baseline characteristics were reported using descriptive statistics. The Kolmogorov–Smirnov test confirmed the normality of the data. Parametric data were reported as frequency (n), percentage, and mean ± standard deviation (SD) and compared using Student's unpaired *t*-test or Fisher's exact test for nominal and categorical data. Nonparametric data are reported as the median and interquartile range and were compared using the Mann–Whitney *U*-test. All data were demonstrated with an alpha error < 5%, and a probability (*P*) value < 0.05 was considered statistically significant. The statistical analyses were performed with PASW Statistics for Windows, version 18.0 (SPSS Inc, Chicago, IL, USA) and MedCalc Statistical Software, version 19.6.4 (MedCalc Software Ltd, Ostend, Belgium; https://medcalc.org; 2021).

Results

The study recruited 108 outpatients scheduled for EGD and colonoscopies. Of these, 54 patients were assigned to the candy group, and the remaining 54 patients were placed in the control group (Figure 1). The demographic characteristics of the groups were comparable. The mean age of the overall participants was 57.73 ± 9.53 years (mean ± SD), and most participants were female and classified as ASA II. The two groups had no statistically significant differences in their comorbidities (eg hypertension, type 2 diabetes mellitus, dyslipidemia, coronary artery disease, chronic kidney disease, and history of stroke). Approximately 40% of the participants in each group had been prescribed proton-pump inhibitors. The median NPO time was 11 hours. In the candy group, patients took some zero-calorie sugar-free candies within 2 hours (mean, 29.24 ± 21.66 min) before the start of anesthesia. There was no difference in the total procedural time of EGD and colonoscopy (Table 1).

All patients received topical pharyngeal anesthesia. The dosage was 8 to 10 puffs of 10% xylocaine spray; 4 to 5 puffs at a time; administered twice, with an interval of 3 to 5 min. Loss of gag reflex was ensured before applying intravenous sedation with propofol infusion. As the gastric content was visualized with the endoscope, it was entirely aspirated to the container. The median gastric volume of the participants was 23 (12.02–36.00) mL, with the volume of the candy group being significantly greater than that of the control group (28.5 vs 20.00 mL; $P < 0.05$). When adjusted to mL/kg, the median gastric volume of all participants was 0.36 (0.20–0.57) mL/kg. The medians of the candy and control groups were not significantly different (0.43 [0.27–0.67] mL/kg and 0.32 [0.19–0.55] mL/kg, respectively). The median difference in the gastric volume of the 2 groups was 6.00 (0.00–13.00) mL or 0.08 (–0.02–0.19) mL/kg (median [95% CI]). The overall gastric pH of the participants was 1.4, with the groups having similar values.

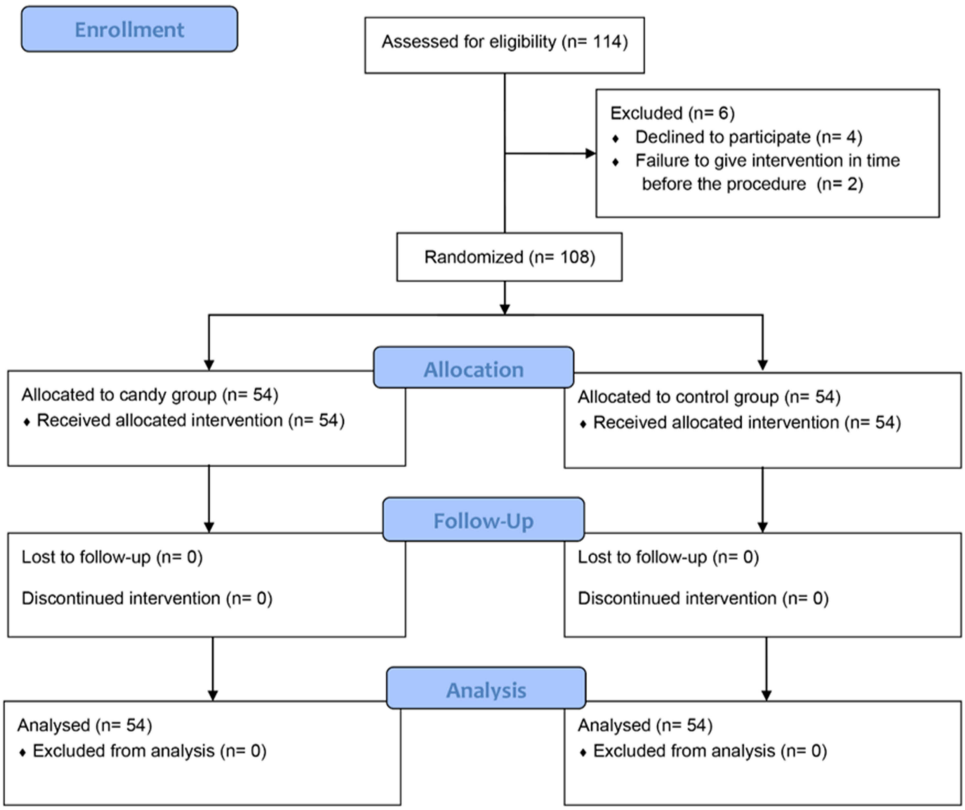

Figure 1 Flow diagram.

The endoscopists gave a rating of "very easy" to approximately three-quarters of the GIE procedures in the control group but to only around half of those in the candy group (Table 2). The patients with the history of PPI use (n = 44) had significantly higher gastric pH than the ones without PPI (n =64) (1.6 (13.-2.7) vs 1.3 (1.1–1.7), $P = 0.012$). Subgroup analysis was performed to determine the impact of PPI therapy on gastric pH. The gastric pH of non-PPI patients was not

Table 1 Patient Characteristics, Proton-Pump Inhibitor Use, Indications for Endoscopy, Procedural Time, and Total Anesthesia Time

Variables	Candy (n = 54)	Control (n = 54)	*P* value
Age (yr) (mean, SD)	59.7 (7.9)	55.8 (10.7)	0.059
Gender (n, %)			0.069
Male	24 (44.4)	14 (25.9)	
Female	30 (55.6)	40 (74.1)	
Body weight (kg) (mean, SD)	62.1 (11.9)	59.5 (11.1)	0.247
BMI (kg/m^2) (mean, SD)	23.5 (3.4)	23.2 (3.6)	0.628
ASA classification (n, %)			0.362
I	5 (9.3)	10 (18.5)	
II	40 (74.1)	37 (64.9)	
III	9 (16.7)	7 (12.9)	
Underlying diseases (n, %)			

(*Continued*)

Table 1 (Continued).

Variables	Candy (n = 54)	Control (n = 54)	*P* value
Hypertension	18 (33.3)	17 (31.5)	1.000
Diabetes mellitus type 2	8 (14.8)	9 (16.7)	1.000
Dyslipidemia	23 (42.6)	14 (25.9)	0.104
Coronary artery disease	5 (9.3)	1 (1.9)	0.205
Chronic kidney disease	5 (9.3)	2 (3.7)	0.437
Previous stroke	3 (5.6)	3 (5.6)	1.000
Others	30 (55.6)	34 (63.0)	0.557
Proton-pump inhibitor use (n, %)			0.557
No	30 (55.6)	34 (62.9)	
Yes	24 (44.4)	20 (37.0)	
NPO time (h) (median, IQR)	11 (5–14)	11 (4–14)	0.912
Indications for endoscopy (n, %)			
Gastroesophageal reflux disease	8 (14.8)	9 (16.7)	1.000
Dyspepsia	12 (22.2)	13 (24.1)	1.000
Abdominal pain	5 (9.3)	6 (11.1)	1.000
Gastric mass	0	1 (1.9)	1.000
Bowel habit change	4 (7.4)	4 (7.4)	1.000
Chronic diarrhea	0	3 (5.6)	1.000
Weight loss	7 (12.9)	3 (5.6)	0.320
Lower gastrointestinal bleeding	6 (11.1)	3 (5.6)	0.489
Anemia	11 (20.4)	11 (20.4)	1.000
Constipation	2 (3.7)	2 (3.7)	1.000
Colorectal cancer screening	13 (24.1)	12 (22.2)	1.000
Others	15 (27.8)	11 (20.4)	0.500
Procedural time (min) (median, IQR)			
EGD	11 (9–15)	11 (7–15)	0.219
Colonoscopy	31 (20–43)	24 (18–34)	0.058
Total anesthesia time (min) (median, IQR)	55 (45–70)	47 (40–60)	0.018*

Notes: Parametric data are presented as n (%) or mean (SD) and compared using Student's unpaired *t*-test. Non-parametric data are presented as median (interquartile range) and compared using Mann–Whitney *U*-test. *P* value < 0.05 is considered statistically significant. * Indicated *P* value < 0.05.
Abbreviations: BMI, body mass index; ASA, American Society of Anesthesiologists; NPO, nothing per oral; IQR, interquartile range; EGD, esophagogastroduodenoscopy.

different between the candy and control group (1.3 (1.1–1.6) vs 1.3 (1.1–1.7), $P = 0.909$). Also, the gastric pH was not different between the PPI users in candy and control groups (1.5 (1.3–2.3) vs 1.6 (1.3–2.8), $P = 0.363$) (Table 3). Neither group had intraprocedural complications (such as oxygen desaturation or pulmonary aspiration). The endoscopists and

Table 2 Patients' Gastric Volume and pH

Variables	Candy (n = 54)	Control (n = 54)	*P* value	Median Difference (95% CI)
Gastric volume (mL)	28.5 (15.0–38.0)	20.0 (11.0–32.0)	0.037*	6.00 (0.00–13.00)
Gastric volume (mL/kg)	0.4 (0.3–0.7)	0.3 (0.2–0.6)	0.120	0.08 (−0.02–0.19)
Gastric pH	1.40 (1.10–1.70)	1.40 (1.20–1.90)	0.739	0.00 (−0.20–0.10)

Notes: The data are presented as median (interquartile range) and compared using Mann–Whitney *U*-test. *P* value < 0.05 is considered statistically significant. *Indicated *P* value < 0.05.
Abbreviation: CI, confidence interval.

Table 3 The Impact of Proton-Pump Inhibitor on Gastric pH

Proton-Pump Inhibitor	n	Gastric pH	*P* value	Subgroup Analysis			*P* value
				Group	n	Gastric pH	
Yes	44	1.6 (1.3–2.7)	0.012*	Candy	24	1.5 (1.3–2.3)	0.363
				Control	20	1.6 (1.3–2.8)	
No	64	1.3 (1.1–1.7)		Candy	30	1.3 (1.1–1.6)	0.909
				Control	34	1.3 (1.1–1.7)	

Notes: The data are presented as median (interquartile range) and compared using Mann–Whitney *U*-test. *P* value < 0.05 is considered statistically significant. *Indicated *P* value < 0.05.
Abbreviation: PPI, Proton-pump inhibitor.

patients also rated overall satisfaction. The median satisfaction scores of the endoscopists and the patients in the candy and control groups did not differ. Most endoscopists and patients reported being "very satisfied" (Table 4). The endoscopist and patient satisfaction scoring sheet was provided in Supplementary Data.

Table 4 Complications, Difficulty of Procedure, and Endoscopist and Patient Satisfaction

Variables	Candy (n = 54)	Control (n = 54)	*P* value
Difficulty of procedure (n, %)			0.013*
Very easy	26 (48.1)	40 (74.1)	
Easy	24 (44.4)	10 (18.5)	
Moderate	4 (7.4)	4 (7.4)	
Endoscopist satisfaction (median, IQR)	5 (5–5)	5 (5–5)	0.542
Somewhat satisfied (n, %)	7 (13.0)	5 (9.3)	0.761
Very satisfied (n, %)	47 (87.0)	49 (90.7)	
Patient satisfaction (median, IQR)	5 (5–5)	5 (5–5)	0.416
Somewhat dissatisfied (n, %)	0	1 (1.9)	0.386
Neither satisfied nor dissatisfied (n, %)	1 (1.9)	0	
Somewhat satisfied (n, %)	3 (5.6)	1 (1.9)	
Very satisfied (n, %)	50 (92.6)	52 (96.3)	

Notes: Parametric data are presented as n (%) and compared using Student's unpaired *t*-test. Non-parametric data are presented as median (interquartile range) and compared using Mann–Whitney *U*-test. *P* value < 0.05 is considered statistically significant. Satisfaction scores: 1 very dissatisfied, 2 somewhat dissatisfied, 3 neither satisfied nor dissatisfied, 4 somewhat satisfied, 5 very satisfied. * Indicated *P* value< 0.05.

Discussion

There is no agreement between standard international guidelines about the time patients should refrain from consuming chewing gum or hard candies before procedures requiring anesthesia. Numerous studies have investigated the change in gastric content volume and acidity following chewing gum relative to the effects of standard fasting. However, the results of these investigations varied. Whereas some studies reported that gastric content volume increased due to chewing gum,[11,13,14] other researchers disagreed, finding that the volume was similar to that of NPO patients.[10,15–17] On the other hand, there is consensus among investigators regarding the acidity of gastric content. All studies agreed that gastric pH was not affected by chewing gum, with the pH after chewing being similar to that of NPO patients.[10,11,13–15,17]

Regarding preoperative hard-candy sucking, there are few studies on its effect on the characteristics of gastric content. Interestingly, 1 study that investigated this aspect with a particular type of sugar candy, lollipops, found no difference in gastric volume or pH compared with a standard fasting group.[10] However, the sample size in the study was small, and the result has yet to be confirmed.

Our study explored the effects of hard-candy consumption during the preoperative period. We focused on hard candies in the form of lozenges rather than lollipops or candy sticks, which are less culturally familiar and less commercially available in Thailand. The patients were allowed to suck and chew the candies to imitate the actual behavior of candy ingestion. A significantly greater gastric content volume was observed in the candy group than in the control group. This finding might be because hard candy can stimulate saliva production,[18] and candy chewing itself also encourages saliva production via the movement of the masticatory muscles.[19] This increased saliva was naturally swallowed into the stomach by the patients during their wait in the preoperative holding area.

We found that the gastric content volume of the standard fasting patients (20 mL) equaled that reported by another study.[11] Although the volume for the candy group was higher than that for the control group, it was still less than the presumed value for pulmonary aspiration risk that we had initially hypothesized (30 mL). Intriguingly, when the gastric volume was converted to mL/kg, the volumes of the candy and control groups were < 0.5 mL/kg each, indicating that the patients were safe from aspiration complications. Nevertheless, recent publications have suggested that pulmonary aspiration might occur when the gastric volume is larger than previously believed. The upper limit of the normal gastric volume in standard-fasted patients might be as high as 1.5 mL/kg.[20–22] Even in elective patients undergoing preoperative fasting according to recognized guidelines, 4.5% of the patients still had > 1.5 mL/kg of gastric volume in the stomach.[20] The gastric pH value was similar between groups and corresponded with previous reports.[10,15] Taken together, these data show that administering hard candies before endoscopic procedures under anesthesia is safe. The absence of adverse events in our study supports this conclusion.

Regarding the endoscopists' satisfaction, they rated a significantly smaller proportion of the GIE procedures in the candy group as "very easy" than in the control group. The endoscopists reported that the esophagus and stomach of the candy group patients appeared frothier than those of the control group patients.

Although international guidelines suggest that the fasting period should be 6 to 8 hours,[1,8] in practice, patients might fast much longer. The average fasting duration for adult elective operations was reported to be between 9 and 12 hours;[23] however, durations > 20 hours have been found at our institution. The disadvantages of prolonged fasting periods are thirst, hunger, anxiety, increased risk of postoperative nausea and vomiting, and patient dissatisfaction.[24–26] The current investigation demonstrated that most patients were very satisfied with the EGD process and anesthesia despite consuming candies to relieve thirst or possible unpleasant symptoms before the procedure. However, 1 patient in our control group reported being "somewhat dissatisfied" after experiencing postprocedural dizziness.

Our work had many strengths. For example, there were healthy patients and individuals with several comorbidities to generate generalizability. In addition, bias was reduced by using certified endoscopists who had a diversity of experience. From our results, the gastric pH was influenced by the use of PPI as the PPI users had significantly higher pH. In contrast, candy itself did not affect gastric pH because there was no difference between the gastric pH of the non-PPI patients who were in the candy and control groups. Furthermore, the patients with prescribed proton-pump inhibitors were equally stratified between the groups to minimize interference from gastric pH interpretation. Moreover, our study is the first to report endoscopist and patient satisfaction for intervention and control groups. Finally, compared with a previous report on

preoperative lollipop sucking where a gastric tube was placed for gastric volume measurement,[10] we used direct endoscopic visualization for better accuracy.

One of the limitations of our study was that we did not include sugar-containing candies for fear that they might alter the blood sugar levels of diabetic participants. Nonetheless, previous work demonstrated that sugar affects neither gastric volume nor saliva production.[15,19] Additionally, regarding patient satisfaction, we did not specifically ask whether they felt satisfied with having candies or maintaining a fasting state. Therefore, the satisfaction score might not directly reflect the benefits or drawbacks of preoperative candy consumption.

Conclusion

This study found that consuming hard candies did not affect the pH of gastric content and did not result in the accumulation of gastric content volume to the level of aspiration risk. Although not mentioned in the ASA guidelines for preoperative fasting, hard-candy consumption before elective EGD or other surgical procedures could be allowed. Scheduled operations should not be delayed or canceled if the patients have consumed hard candies during the nominal fasting period. Future directions would be to incorporate information regarding candy consumption into institutional and national guidelines for preoperative patient preparation.

Data Sharing Statement

The participant data are not publicly available. The data presented in this study are available on request from the Institutional Review Board and the corresponding author.

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Disclosure

The authors report no conflicts of interest in this work.

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