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Effects of a Preoperative Carbohydrate-Rich Drink Before Ambulatory Surgery: A Randomized Controlled, Double-Blinded Study

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Manuscript Preparation E
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Background: The guidelines recommend oral carbohydrates up to 2 hr before elective surgery. The objective of this study was to explore the safety and feasibility of preoperative carbohydrate drink in patients undergoing ambulatory surgery.

Material/Methods: Patients undergoing ambulatory surgery under general anesthesia were enrolled. They were fasted from midnight and randomly assigned to a study group (200 mL of a carbohydrate beverage) or the control group (pure water) and received the assigned drink 2 hr before surgery. Bedside ultrasonography was performed to monitor gastric emptying at T_0 (before liquid intake), T_1 (5 min after intake), T_2 (1 hr after intake), and T_3 (2 hr after intake). Subjective feelings of thirst, hunger, anxiety, and fatigue were assessed 1 hr after liquid intake using the visual analogue scale (VAS).

Results: In both groups, gastric antrum cross-sectional area, gastric content volume, and weight-corrected gastric content volume increased at T_1 and returned to baseline at T_3. These parameters were significantly higher in the study group at T_2 (6.28±1.38 *vs.* 4.98±0.78, 67.22±29.49 *vs.* 49.04±15.4, 1.10±0.51 *vs.* 0.85±0.37, P<0.05). Thirst and hunger VAS scores were reduced in both groups. The study group suffered significantly less hunger (28.44±10.41 *vs.* 36.03±14.42, P<0.05). Blood electrolytes (sodium, potassium, calcium) and glucose concentration levels were similar in both groups at T_2. No gastric regurgitation or pulmonary aspiration was recorded.

Conclusions: Administration of 200 mL of oral carbohydrate beverage 2 hr before ambulatory surgery is safe, effective, and can be used for preoperative management of fasting patients.

MeSH Keywords: Ambulatory Surgery • Carbohydrate-Rich Drink • Gastric Ultrasound • Patient Discomfort • Preoperative Fasting

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Background

Pulmonary aspiration during general anesthesia is a rare but serious event in healthy patients undergoing elective surgery. Since Mendelson reported a high incidence of pulmonary aspiration among obstetric patients receiving general anesthesia, preoperative fasting before elective surgery has been the most important measure for ensuring that a patient's stomach is empty at the time when anesthesia is induced [1]. Overnight fasting from midnight on the day of surgery is still standard practice in most hospitals in China. It has now been well established that this rule is excessively strict [2]. Patients who fast overnight before surgery may experience negative metabolic, physiological, and/or psychological effects [3]. The American Society of Anesthesiologists (ASA) recommends that patients without delayed gastric emptying should refrain from ingesting transparent liquids (water, fruit juice without pulp, carbonated beverages, clear tea, and black coffee) for at least 2 hr before elective procedures requiring general anesthesia [4]. Preoperative ingestion of carbohydrate-rich fluid has been widely advocated and adopted to facilitate enhanced recovery after surgery (ERAS) worldwide [5].

As a fast and safe mode for performing surgery, ambulatory operations are commonly performed in China. Ambulatory surgery refers to an operation in which the patient's admission, operation, and discharge occur within 24 hours (excluding emergency surgery or outpatient surgery performed at physician's clinic or hospital) [6]. The anesthesia requirements and management of patients undergoing ambulatory surgery differ from those used for inpatients undergoing elective surgery [7]. Integrating the concept of ERAS into the clinical pathway of ambulatory surgery can reduce postoperative complications and shorten the postoperative recovery time [5]. Several studies involving different surgeries have reported that preoperative carbohydrate drinks minimize postoperative adverse reactions [8–10]. The practice of administering an oral carbohydrate drink during the preoperative period has not yet been established in China.

The objective of this study was to explore the safety of administering a carbohydrate beverage to patients scheduled for ambulatory surgery. We determined the effects of ingesting a carbohydrate-rich drink on the gastric emptying and the risk of pulmonary aspiration.

Material and Methods

This study was approved by the Medical Ethics Committee of Xiangya Hospital Central South University, an academic medical center in China and registered at *http://www.chictr.org.cn* (ChiCTR1800018342).

Patients

Patients, aged 18 to 70 yr, with ASA score I or II and body mass index (BMI) 18 to 35 kg/m^2, who were scheduled for elective ambulatory surgery under general anesthesia, were recruited at the ambulatory surgery center at Xiangya Hospital of Central South University, Changsha, Hunan, China, during the period from October 1, 2018 to November 30, 2018.Written informed consent was obtained from each subject. We excluded pregnant women and patients who had diabetes mellitus, hyperglycemia, or hypoglycemia with blood glucose <2.8 mmol/L, gastroesophageal reflux, history of upper abdominal gastrointestinal surgery, or use of any medication that effects gastric secretion or emptying within the past 24 hours. Physical examination and laboratory tests were conducted 1 day before the operation. Patients were admitted on the day of surgery, after overnight fasting for at least 8 hr.

Randomization was performed using a computer-generated table. The opaque envelope method was used for allocation concealment. The patients and investigators were both blinded to group assignments. Two hours before the scheduled time of surgery, patients in the study group received 200 ml of Outfast (Renfu Farewell Pharmaceutical Company, China). The beverage contained 14.2% carbohydrate, vitamin B, organic zinc, taurine, electrolytes, and arginine. This drink did not contain any protein or fat. It had 56 kcal per 100 mL, 280–300 mOsm/kg, pH 3.8–4.3. Patients in the control group received 200 mL pure water. Both liquids were packed in the same bottle, and patients were asked to drink slowly, over the course of 2–3 minutes, to reduce the amount of air swallowed. No intravenous infusion or premedication was administered.

Outcome measurements

Primary outcome measurements included cross-sectional area (CSA), gastric volume (GV), and weight-corrected volume (cGV). All these parameters were measured by ultrasonography. The secondary outcome measurements included patient discomfort, blood electrolytes, and the incidence of aspiration.

Ultrasound assessment

Gastric ultrasound was performed at four timepoints: T_0 (baseline, before liquid intake), T_1 (5 min after intake), T_2 (1 hr after intake), and T_3 (2 hr after intake). Patients were placed in a 45° semi-recumbent, right lateral decubitus (RLD) position. A portable ultrasound device (SonoSite EDGE, Inc., Bothell, Washington, United States) equipped with a low-frequency convex array transducer (probe C60x, 2–5 Hz) was used to obtain a cross-sectional image of the gastric antrum. The gastric antrum was identified in the sagittal or sagittal oblique plane in the epigastrium, along the edge of the left lobe of the liver, and anterior to either the aorta or the inferior vena cava, according to the standard protocol [11].

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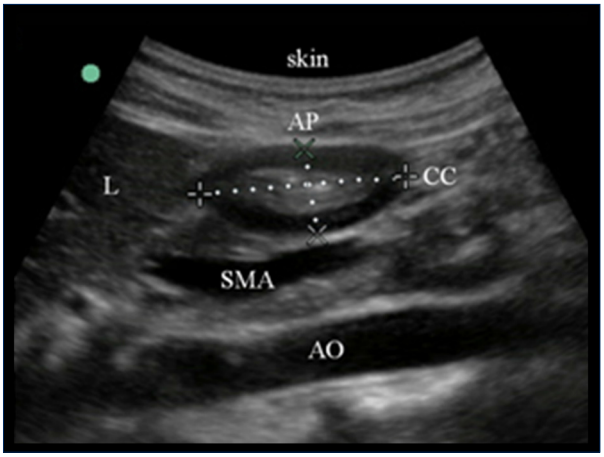

Figure 1. Measurement of the gastric antral area using transabdominal ultrasound. L – liver; AO – aorta; SMA – superior mesenteric artery; CC – cranio-caudal antral diameter; AP– antero-posterior diameter.

The cross-sectional area (CSA) of the gastric antrum was quantified by assuming it to be a perfect ellipse and using the following formula: CSA=ϖ×AP×CC/4, where AP and CC were two orthogonal diameters, representing antero-posterior and cranio-caudal diameter of the gastric antrum, respectively. To avoid underestimating antral area, all images were obtained with the antrum at rest (including the gastric wall), between peristaltic contractions. The average of three CSA calculations was recorded (Figure 1).

Antral CSA was used to estimate gastric content volume (GV) as proposed by a previously validated model, as follows: GV (ml)=27.0+14.6×right-lat CSA (cm^2)–1.28×age (yr), where right-lat CSA denotes antral CSA, as measured in the RLD position. cGV was calculated in ml/kg. If the calculated value was ≤0, GV was considered to be 0 mL. When GV was >1.5 mL/kg before the induction of anesthesia, the study was discontinued, and surgery was postponed.

Patient discomfort

The components of patients' discomfort included thirst, hunger, anxiety, and fatigue. The visual analog scale (VAS) was used to evaluate the subjective discomfort of patients at timepoints T_0 and T_2.

The scales are presented as 100-mm lines (horizontal), anchored by two verbal descriptors: (0=no discomfort; 100 mM=worst imaginable). Patients were asked to mark their intensity for the given parameter at a point between 0 and 100 mM.

Blood electrolytes

Changes in levels of blood electrolytes (sodium, potassium, calcium) and glucose after oral liquid intake were detected 2 hr after drinking and approximately 5 min before the induction of anesthesia. Blood samples were analyzed using a blood gas analyzer (GEM 3500, Instrumentation Laboratory Co., Massachusetts, United States).

Aspiration events

All patients underwent a standardized general anesthesia induction protocol with midazolam 0.05 mg/kg, sufentanil 0.5 μg/kg, cisatracurium 1.5 mg/kg, and etomidate 0.3 mg/kg (after endotracheal intubation). Any incident of regurgitation or aspiration was recorded by the anesthesiologist.

Statistical analysis

Bouvet et al. [4] reported that GV 2 hr after administration of a standard carbohydrate diet or water was approximately 0.45 mL/kg, with estimated standard deviation of 0.27 mL/kg. It was therefore assumed that GV of 0.2 mL/kg could be taken as evidence for non-inferiority of the carbohydrate-rich drink. With 1-β of 0.9 and an α-test level of 0.025, the required sample size for each group was ≥29 cases.

Values are expressed as mean ± standard deviation or as median and interquartile range. Intragroup comparisons were performed with a repeated-measures analysis of variance (ANOVA) or paired t-test. Intergroup comparisons were performed with Fisher's exact test, Pearson's chi-square test, Student's *t*-test, or the Mann-Whitney U-test. Statistical analyses were performed with SPSS 19.0 (SPSS, Inc., Chicago, IL). Differences with $P<0.05$ were considered statistically significant.

Results

During the study period, 66 patients were recruited, among whom 64 completed the study. In one case, the patient's participation was suspended because the planned surgery was unexpectedly cancelled. Another patient was excluded because presence of a large amount of gas in the antrum prevented measurement of the boundaries on ultrasonographic images. The oral beverage was tolerated well by all patients, with no report of adverse events such as allergic reaction or intolerance of the fluid. There were no significant differences between the study group and control group in terms of sex distribution, age, height, weight, or BMI (Table 1).

After oral intake of water or carbohydrate-rich liquid, there was a dramatic increase in CSA at T_1 in both groups. In both groups, CSA continued to remain high at T_2, compared to T_0. At T_3, CSA returned to baseline levels in both groups. There was no significant difference in CSA between groups at T_0, T_1, or T_3. At T_2, CSA was significantly higher in the study group than in the control group.

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Table 1. Patient demographics.

	Study group (n= 34)	Control group (n=30)	P value
Sex (male)	18 (52.94%)	13 (43.3%)	0.44
Age (year)	40.15±13.13	39.93±12.80	0.95
Height (m)	1.65±0.09	1.61±0.07	0.11
Weight (kg)	63.08±10.58	60.63±10.89	0.41
BMI (kg/m^2)	23.22±2.78	23.15±3.17	0.93

Values are presented as counts n (%) or mean ± standard deviation. BMI – body mass index.

Table 2. Ultrasonography findings.

	Time-point	Study group (n=34)	Control group (n=30)
CSA (cm^2)	T_0	4.20±0.87	4.18±0.62
	T_1	9.69±2.09*	9.00±2.11*
	T_2	6.28±1.38*#	4.98±0.78*
	T_3	4.42±0.74	4.27±0.58
GV (mL)	T_0	37.01±19.84	37.40±13.39
	T_1	117.32±36.08*	107.93±27.91*
	T_2	67.22±29.49*#	49.04±15.4*
	T_3	40.08±20.43	38.70±13.76
cGV (mL/kg)	T_0	0.60±0.34	0.65±0.29
	T_1	1.90±0.61*	1.85±0.66*
	T_2	1.10±0.51*#	0.85±0.37*
	T_3	0.65±0.34	0.67±0.31

CSA – cross-sectional area; GV – gastric volume; cGV – weight-corrected volume. Values are presented as mean ± standard deviation.
* P<0.05 *vs.* T0; # P<0.05 *vs.* control group.

Similar trends were observed for predicted GV and cGV. These findings suggest that the carbohydrate beverage had a gastric-emptying effect that was similar to that of pure water. None of the patients had GV >1.5 mL/kg before induction of anesthesia, which is considered to predict high risk for aspiration (Table 2).

Subjective feelings of thirst, hunger, anxiety, and fatigue, as measured by VAS at baseline, were similar between groups. One hour after intake (T_2), levels of thirst and hunger had significantly decreased in both groups. However, the ingestion of carbohydrate-rich liquid or water did not affect anxiety or fatigue. However, patients in the study group experienced significantly less hunger than patients in the control group at T_2 (Table 3).

There was no significant difference between the two groups in terms of levels of blood electrolytes (sodium, potassium, calcium) or glucose concentration. Blood glucose <3.9 mL (lower limit for normal glucose level) was observed in two patients in the control group and no patient in the study group. However, this difference between groups was not significant (Table 4).

No instance of gastric regurgitation or pulmonary aspiration was recorded by the attending anesthesiologist. Surgeries were performed successfully in all patients. There were no significant issues arising during or after surgery. All cases were discharged uneventfully the next day, after overnight observation.

Discussion

Administration of oral carbohydrate drinks before elective surgery has been proven to be safe with a positive influence on several clinical outcomes [10,12]. However, carbohydrate drinks are not routinely used in China due to the lack of sufficient clinical evidence in Chinese patients. We conducted this

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Table 3. VAS scores for subjective feelings of discomfort.

	Time-point	Study group (n=34)	Control group (n=30)
Thirst	T_0	51.06±14.18	49.40±16.87
	T_2	24.88±7.16*	23.73±6.80*
Hunger	T_0	45.38±16.18	44.83±15.69
	T_2	28.44±10.41*#	36.03±14.42*
Anxiety	T_0	26.53±14.63	28.90±15.79
	T_2	34.18±14.82*	35.93±16.69*
Fatigue	T_0	13.50 (9.75, 18.25)	10.95 (8.00, 13.8)
	T_2	11.80 (8.00, 15.00)	11.40 (5.00, 12.93)

Values are presented as mean ± standard deviation or median(range). * P<0.05 *vs.* T_0; # P<0.05 *vs.* control group.

Table 4. Assessment of blood electrolytes and glucose values.

	Study group (n=34)	Control group (n=30)	P value
Sodium (Na^+, mM)	136.57±3.12	136.80±3.24	0.777
Potassium (K^+, mM)	3.92±0.57	3.74±0.39	0.152
Calcium (Ca^{2+}, mM)	1.10±0.14	1.15±0.09	0.137
Glucose (mM)	5.97±1.50	5.83±0.87	0.635
No. of individuals with glucose 2.8–3.9 mM, n (%)	0 (0%)	2 (6.67%)	0.433

Values are presented as mean±standard deviation or counts [n (%)].

randomized controlled study to understand the effects of ingesting carbohydrate-rich before ambulatory surgery among patients in China. The current study demonstrated that patients who drank 200 mL of carbohydrate beverage 2 hr before ambulatory surgery had similar gastric emptying function, compared to those who drank 200 mL of pure water before ambulatory surgery. Compared with those who drank water, patients who drank the carbohydrate beverage had less discomfort and no significant changes in levels of blood electrolytes.

Appropriate water balance and patient nutritional status may be an important aspect of enhanced recovery after ambulatory surgery [13]. However, the fasting period of 6–8 hr before scheduled surgery is sometimes further prolonged to 10–16 hr due to unexpected delays in the initiation of surgery, which may be harmful for patients [14]. A prolonged fasting period is associated with a significant increase in incidence of adverse reactions such as thirst, hunger, anxiety, fatigue and hypoglycemia [15]. Notably, the recommended duration of preoperative fasting does not consider differences in the rate of gastric emptying for clear fluid, compared with solid food. In recent years, preoperative administration of a carbohydrate-rich drink was found to have an accelerated recovery from anesthesia and surgery [16]. However, preoperative use of a carbohydrate-rich drink has not been widely studied in China.

We provided patients with a carbohydrate beverage (Outfast, Yichang Human well FSMP CO., LTD, Yichang, China) designed specifically for perioperative use with fasting patients. Patients reported that the drink tasted good. Considering interindividual differences in tolerability, we decided to administer a dose of 200 mL. This volume was higher than the upper limit of a normal baseline fasting volume [11]. Bedside ultrasonography was used to measure cGV because it is non-invasive, convenient, rapid, and accurate. An RLD position was chosen for its sensitivity to detect small amounts of fluid moved by gravity to the antrum [17]. This was also the reason for the higher ultrasonic values used to evaluate patients in the 45° RLD position, compared with those in the supine position [18]. In agreement with previous reports, we also found that healthy fasting individuals often had low baseline levels of gastric juice secretions [19]. Usually we believe that if GV exceeds 1.5 mL/kg at the time of anesthesia induction, there is a risk of aspiration [20]. In this study, none of the patients in either group

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had GV >1.5 mL/kg at 2 hr after liquid intake. Patients given the carbohydrate beverage had a similar rate of gastric emptying to those given pure water, with no instance of regurgitation or aspiration in either group. These findings suggest that oral intake of 200 mL carbohydrate beverage 2 hr before ambulatory surgery is safe. Interestingly, in some patients, CSA was much lower at T_3 than it was at T_0.This is because clear fluid may accelerate gastric emptying and reduce CSA [21].

It is said that during fasting, patients develop subjective discomfort and symptoms of thirst and/or hunger prior to development of metabolic changes [22]. Although VAS scores are most frequently applied to measure pain intensity, in this study, we used them to evaluate other subjective feelings such as hunger and thirst [23]. Treatment with either the carbohydrate beverage or pure water effectively ameliorated the severity of thirst and/or hunger and decreased the amount of psychological stress. Carbohydrates stimulate the hypothalamic satiety center by modulating blood glucose levels and are thus more effective than pure water in relieving hunger.

The observed increase in VAS scores for anxiety likely reflects the fact that no medication was administered preoperatively; as the time for which the operation was scheduled drew closer, the patients became more anxious. The baseline VAS scores for fatigue were low, leaving little room for change. In our study, anxiety and fatigue VAS scores were similar between groups. No patient in either group exhibited signs of an electrolyte disturbance or hypoglycemia caused by long-term fasting; ingestion of 200 mL of a carbohydrate beverage had no impact on these measures. Notably, this finding may reflect our use of an intake dose of 200 mL, much smaller than that suggested in previous reports [24].

This study had some limitations. First, less carbohydrate beverage was used in this study (200 mL) compared with previous studies (approximately 400 mL). We used a low dose because it is recommended to take only ≤400 mL fluid within 2 hr prior to surgery. Notably, the volume of 400 mL used previously is greater than the upper limit of gastric secretion [11]. Second, the sample size of the current study was relatively small. Future large-scale studies are required to validate the findings of this study and to optimize dose and timing, as well as to examine the postoperative effects of administering such a carbohydrate beverage.

Conclusions

We conclude that 200 mL of the carbohydrate beverage tested in this study can be safely administered 2 hours before ambulatory surgery. This approach decreases the preoperative discomfort caused by thirst and hunger.

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