Oral carbohydrate 2 hours before surgery doesn’t increase the risk of reflux and aspiration—A randomized controlled trial in volunteers

Gang Zhang (mzzhanggang@hotmail.com)
Sichuan provincial orthopedic hospital

Xiaoyan Huang
Chengdu Third People’s Hospital

Ji Feng
Sichuan provincial orthopedic hospital

Lan Zhang
Sichuan provincial orthopedic hospital

Research Article

Keywords: Ultrasound, risk stomach, reflux, aspiration pneumonia

Posted Date: January 11th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-2361859/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License
Abstract

Background: Due to concerns of both physicians and patients about aspiration, the duration of fasting before surgery is far beyond the recommended guideline, which will bring a series of adverse reactions. It still remains to be controversial that patients drink carbohydrate before operation.

Methods: Volunteers were randomly divided into Group C and D. After 6 hours of fasting, the subjects in group C drank carbohydrate less than 400ml, and the subjects in group D continued fasting without any beverage. The subjects in both groups received ultrasound evaluation every hour thereafter. The primary outcomes were the incidence of risk stomach, and the secondary outcomes were gastric volume and the visual analogue scale of hunger, thirst, and anxiety.

Results: There were no significant differences in general data. The total incidences of risk stomach in group C and D were 100% vs 13%, 70% vs 10%, 13.3% vs 6.6%, 10% vs 6.6% at T0,T1,T2,T3, respectively. There were no significant differences in the primary outcome between the two groups at T2 and T3. The gastric volume of group C and D were 36.08±16.90 vs 1.01±16.89, 25.67±20.67 vs 0.54±18.10, 6.89±18.32 vs -1.70±15.32, 2.74±16.48 vs -0.70±17.57 at T0, T1, T2, T3. The VAS of hunger and thirst and the VAS of anxiety in the two groups were 0.60±0.62 vs 1.00±0.70 and 0.70±0.70 vs 1.13±0.51, respectively.

Conclusion: Compared with non-beverage subjects, oral carbohydrate more than 2 hours before surgery not only did not increase the incidence of risk stomach, but also reduced preoperative hunger, thirst, and anxiety.

Trial registration: Registration date: 7/2/2021; Registration number: ChiCTR2100043166;

Introduction

Reflex aspiration is a rare but serious complication of general anesthesia. According to previous studies, the incidence of reflux aspiration under anesthesia ranges from 0.1–19%.[1] A prospective multicentre observational study conducted at 261 hospitals in Europe showed that the overall incidence of reflux aspiration in children during the perianaesthesia period was 0.1–0.4%.[2] Perioperative mortality caused by aspiration accounted for 9% of the total anesthesia-related mortality.[1, 3]

After anesthesia, especially after the use of muscle relaxants, the relaxation of lower cardiac sphincter and the disappearance of laryngeal protective reflex, will lead acidic gastric contents regurgitate into the lung with spontaneous or positive pressure ventilation, complicated with aspiration pneumonia, ARDS or other serious complications.[4] Once aspiration occurs, the fatality rate is very high. At present, there is no specific rescue means, so clinical prevention is emphasized.[5] Strict adherence to preoperative fasting is the main clinical measure to prevent reflux aspiration. However, long-term abstinence from fasting will bring unbearable thirsty and hungry, which leads anxiety and mental tension, aggravates stress response and increases the endocrine disorders and occurrence of postoperative insulin resistance. It will
eventually affect the postoperative recovery of patients, and even increase the incidence of postoperative complications.\[6\] The 2017 ASA Guidelines for Fasting before surgery call for clear liquids to be consumed 2 hours before surgery.\[7\] Chinese guidelines also agree and recommend 200–400 ml of carbohydrates 2 hours before surgery.\[8\] Water or carbohydrate intake 2 hours before surgery is also an important component in ERAS.\[9, 10\] A large number of studies have shown that shortening the duration of fasting and drinking before surgery can improve the comfort level of patients, reduce the incidence of complications and promote the recovery of patients.\[11–14\]

Although drinking beverages within the recommended time before surgery has obvious advantages, the clinical practice is not satisfactory. First of all, it is still controversial that the patients are recommended to drink beverages before surgery. It has also been demonstrated in numerous studies that significant residual gastric volume will be found in patients who ingested fluids within 2 hours before surgery. The studies above don’t seem to support the protocol of shorten fasting time by drinking beverages before surgery.\[13, 15, 16\] Although various countries have successively issued corresponding preoperative guidelines for fasting and drinking, for safety reasons, both doctors and patients in clinical practice are afraid of reflux aspiration and still adhere to the inherent concept that the longer the fasting time, the lower the risk of reflux aspiration and the safer the patient.

In order to verify the safety of preoperative beverage consumption and answer this controversial question, we conducted this experiment.

**Methods**

This study was a prospective, randomized controlled trial, which has been approved by the Medical Ethics Committee of Sichuan Orthopaedic Hospital, and all the enrolled subjects signed informed consent. It was also registered prior to patient enrollment at Chinese Clinical Trial Registry (http://www.chictr.org.cn; Registration number: ChiCTR2100043166; Scientific title: Safety Evaluation by Gastric Ultrasound for Drinking Glucose Beverages on Demand at 3 Hours Before Surgery; Principal investigator: Gang Zhang).

Inclusion criteria: Aged 18–60 years old, previously healthy, ASA grade I, BMI 18-25kg/m2. Exclusion criteria: Subjects with pregnancy, diabetes, metabolic disease, kidney disease, organic digestive disease, no use of drugs affecting the digestive system within one week before the examination. In order to better approach the patients with elective surgery, all subjects began fasting and abstaining strictly adherence to guidelines before ultrasound evaluation. After at least 6 hours of fasting and drinking, the subjects were randomly divided into group C (Oral carbohydrate less than 400ml as needed) and group D (continue fasting and abstaining).

**Several Important Time Points In This Study Were Defined As Follows**

T0: the time the subjects in group C drank water immediately after 6 hours of fasting and abstinence, or the time the subjects in group D have been fasting and abstinence for 6 hours. T1: the time 1 hours after
subjects in group C drinking water, or the time the subjects in group D have been fasting and abstinence for 7 hours; T2: the time 2 hours after subjects in group C drinking water, or the time the subjects in group D have been fasting and abstinence for 8 hours; T3: the time 3 hours after subjects in group C drinking water, or the time the subjects in group D have been fasting and abstinence for 9 hours

Gastric ultrasound was performed at T0, T1, T2, T3.

**Ultrasound Scan Of Stomach**

Antral antrum ultrasound examination was performed by an anesthesiologist with more than three years of ultrasound experience to observe gastric empties. The subjects were asked to lie on their backs and fully expose their abdomen. Ultrasound scans of the gastric antrum were performed in the supine position and the right supine position respectively. The specific scanning method was as follows: the abdominal low frequency convex probe with the frequency set at 2-5HZ was placed slightly to the right under the xiphoid. After slightly pressing down the probe, the left lobe of liver can be clearly seen in the scanning window, and the gastric antrum is usually located on the left side of the liver. At the same time, the superior mesenteric artery and abdominal aorta should be scanned in the ultrasound section, and this section was defined as the standard section. (Fig. 1)

**Assessment Of Gastric Contents By Ultrasound**

First, Perlas A semi-quantitative scale was used to evaluate reflux aspiration: Perlas 0, no stomach contents were found in neither supine or right lateral decubitus. Perlas 1: no stomach contents were found in supine position, but on the right side. Perlas 2, stomach contents were visible in both positions. Secondly, antero posterior diameter (AP) and CC craniocaudal diameter (CC), the long and short diameters of the gastric antrum in the patient's right lateral position, were measured in the standard interface at the end of expiration. The mean values of AP and CC were calculated after three measurements. The next step was to calculate the cross-sectional area of the gastric antrum (CSA) with the elliptic area calculation formula, namely CSA = π × D1×D2/4. Finally, the following mathematical models can be established to calculate gastric volume (GV) according to the cross-sectional area of the antrum (CSA): GV = 27.0+(14.6×right lateral antral CSA)-(1.28×age). This model is suitable for non-pregnant adult patients and the gastric volume can be reliably predicted to 500 ml. (Fig. 1)

According to the Perlas grading standard,[17] if the gastric antrum scan of both supine position and right decubitus position showed empty stomach, it was Perlas 0 of gastric antrum, indicating no gastric contents. If the supine position was empty, the gastric contents could be seen in the right decubitus position, it was Perlas 1 of the gastric antrum. If the gastric contents were visible in both positions, it was grade 2 of the gastric antrum. Based on this classification, the evaluation criteria of risk stomach is as follows: if the antrum is grade 0 or grade 1 with antrum area less than 340 mm², it indicates an empty
stomach. If it was grade 2 of antrum with an area larger than 340 mm\(^2\), indicating moderate gastric contents. If the antrum is grade 2, no matter how much the antrum area is, it indicates risk stomach.

At the same time, it is considered reliable to define a risk stomach with a volume greater than 1.5ml/kg. [13, 18] Based on this, dangerous stomach was defined in this study as Perlas grade 2, Perlas grade 1 with antral transsection area of 340mm\(^2\), or a gastric volume greater than 1.5ml/kg.

**Measurement of outcomes**

1. Primary outcome measures: incidence of risk stomach:

Definition of dangerous stomach (meeting any of the following): Perlas semi-quantitative grade 2; Perlas semi-quantitative grade 1 with CSA greater than 340mm\(^2\); GV greater than 1.5ml/kg.

2. Secondary outcome measures

The gastric volumes: The gastric volumes calculated by formula GV = 27.0+(14.6×right lateral antral CSA)-(1.28×age) at different time points;

Visual Analog Scale (VAS): In this study, 0–3 scale was used to evaluate hunger and thirst;

Hunger score: 0 indicates no hunger; A score of 1 indicates mild hunger; A score of 2 indicates obvious but tolerable hunger; A score of 3 is very hungry, can not stand or even appear dizzy, cold sweat and other symptoms;

Thirst score: 0 indicates no thirst; A score of 1 is slightly thirsty; A score of 2 indicates a significant but tolerable thirst; 3 points represents severe thirst.

**Statistical analysis**

SPSS20.0 statistical software was used for statistical processing and analysis of data. Measurement data conforming to normal distribution were expressed as mean ± standard deviation (x ± S), and Independent sample t test was used for comparison between groups. The statistical data were represented by the number of cases (percentage) n(%)), and the χ\(^2\) test was used for comparison. Non-parametric test was used to compare measurement and counting data that did not conform to normal distribution. α = 0.05 was used as the test level, P < 0.05 was considered to be statistically significant.

**Results**

A total of 60 volunteers were recruited from March 15, 2021 to May 25, 2022. (Fig. 2) There were no significant differences between the two groups in age, height, weight and time of fasting and abstinence before ultrasound examination. (Table 1)
The total incidences of risk stomach in group C and group D were 100% (P2: 91%; P1: 9%) vs 13% (P2: 13%; P1: 0%) at T0, respectively. The total incidences in group C and group D of risk stomach were 70% (P2: 66.7%; P1: 13.3%) vs 10% (P2: 6.6%; P1: 3.3%) at T1, respectively. The total incidences in group C and group D of risk stomach were 13.3% (P2: 10.0%; P1:6.6%) vs 6.6% (P2: 6.6%; P3.3%) at T2, respectively. The total incidences in group C and group D of risk stomach were 10% (P2: 6.6%; P1: 3.3%) vs 6.6% (P2: 6.6%; P1:0%) at T3, respectively. (Table 2)

Although all of the gastric volumes were less than 1.5ml/kg at different time points calculated by the formula, at the time of T0 and T1, the differences of gastric volume between group C and group D were statistically significant. (Fig. 3, Table 2)

The VAS of hunger and thirst and the VAS of anxiety in the two groups were 0.60 ± 0.62 vs 1.00 ± 0.70 and 0.70 ± 0.70 vs 1.13 ± 0.51, respectively, and the differences between the two groups were statistically significant. (Table 2)

Discussion

Although it is a small probability event that gastric contents are mistakenly inhaled into the lungs during anesthesia, once it occurs, it will lead serious complications and even death.[19] Survivors often have complications including pneumonia, acute respiratory distress syndrome, multiple organ dysfunction and brain injury, etc.[20] Therefore, fasting from midnight before surgery has become an important part of preoperative preparation. However, through literature review, it is found that the problem of prolonging the time of fasting and drinking before surgery exists both at home and abroad.[21–23]

First of all, due to the uncertainty of the operation time, the medical staff could not inform the patients about the specific time before the operation. Therefore, in order to ensure the safety of patients, they prefer patients to follow the traditional regimen of abstaining from food and drink from midnight the day before surgery. Secondly, medical staff’s insufficient study and practice of the new guidelines limited the development of preoperative time management of fasting.[24] In addition, medical staff did not provide adequate information to patients about preoperative fasting. As a result, patients have insufficient understanding about fasting program.[25] Prolonged fasting and drinking may cause a lot of harms, including increasing preoperative insulin resistance,[26–28] enhancing preoperative stress response[29], increasing the incidence of intraoperative hypotension,[30, 31] and postoperative nausea and vomiting.[32–34]

At present, aspiration risk is mainly assessed by fasting duration, but preoperative fasting duration cannot be used as a indicator for gastric volume.[35]

Recent studies have found that gastric volume of different populations can be quickly and accurately assessed by ultrasound.[36] It can guide anesthesiologists to prepare for anesthesia and manage the airway to minimize the risk of reflux aspiration.[37] Its effectiveness in evaluating gastric emptying is comparable to that of “gold standard” gastric nuclide imaging.[38]
Ultrasonic evaluation of indicators related to gastric reflux aspiration is the main research method in this study.

There was no significant difference in the primary outcome (incidence of risk stomach) between the two groups at T2 and T3. It indicated that drinking a certain amount of beverage 2 hours before surgery did not increase the risk of patients' adherence to guidelines. While fasting guidelines vary from country to country, the time limit on drinking water before surgery is usually two to three hours. The ASA Guidelines for preoperative Fasting in 2007 stipulate that clear liquids can be consumed 2 hours before surgery[7], and Chinese guidelines also agree and recommend 200-400ml of carbohydrates 2 hours before surgery. [8] Due to concerns about reflux aspiration, both physicians and patients adhere to the belief that the longer the period of fasting and abstaining, the better the safety of patients during the perioperative period can be guaranteed. At the same time, many studies have found that a large amount of gastric residual volume can still be found in the stomach after drinking water at the recommended time before surgery. These literatures didn't seem to support the protocol of not drinking water for 2–3 hours before surgery. AGARWAL found that in patients who took 150 ml of water orally 2 hours before surgery, gastric residual volume was found, but gastric fluid had a higher pH than in patients who fasted overnight, which is beneficial for reducing the risk of aspiration pneumonia. [16] Maltby found that patients who took juice or coffee orally 2–3 hours before surgery had higher gastric contents than those who did not. [15] This may be because the gastric empty-speed of juice or coffee was slower than that of water. In addition, patients who did not take any drinks before surgery were given ranitidine orally, which may also reduce gastric fluid secretion and gastric volume. Jonatan Hausel found that compared with patients who did not take drinks, although a certain amount of residual gastric volume could be found in the stomach before operation, there was no significant change in gastric volume and PH. Moreover, patients' comfort was significantly improved. [13] Over the past three decades, from the 1990s to the present, numerous studies have shown that it is safe for both adults and children to drink clear fluids two hours before surgery. [39–42] This is consistent with the results of this study. Although the subjects in this study had a certain incidence of risk stomach within 2 hours after taking drinks, there was no significant difference between the experimental group and the control group in the incidence of risk stomach after 3 hours of taking drinks.

In this study, after 8 hours of fasting and abstaining from drinking, the subjects who took liquid less than 400ml also had significantly lower hunger and thirst than the control group, which would greatly improve the satisfaction of the patients. Shortening the time of patients' fasting, and reducing thirst, hunger and anxiety to relieve stress response were also important components of ERAS. [9, 10, 43] ERAS aims to use a series of optimized management measures confirmed by evidence-based medicine to reduce the psychological and physical traumatic stress responses of patients. Thus, complications can be reduced, the length of hospital stay can be shortened, patients can recover quickly and medical costs can be reduced. It is one of the key measures to implement ERAS that patients take oral drinks before operation to shorten the period of fasting and abstinence. Preoperative administration of beverages to shorten the period of fasting and abstinence is one of the most critical measures in implementing ERAS.[9, 10, 43]
With the updating of medical concepts, ERAS also emphasizes the importance of shortening the fasting and abstinence of drinking in patients before surgery, which is beneficial to improve the postoperative prognosis of patients. Li Ren et al. found that shortening the time of fasting and drinking before surgery could reduce the insulin resistance of patients within 5 days after surgery and reduce the protein decomposition of patients before surgery[44]. Francesco Donatelli et al. showed that shortening the fasting and abstaining time of patients before surgery could not only improve perioperative hyperglycemia, but also reduce perioperative C-reactive protein concentration and alleviate perioperative inflammatory reactions.[45] C. BOPP et al. also found that shortening the time of fasting and drinking before surgery could not only reduce the hunger and thirst of patients before surgery, but also reduce stress response of patients.[46] Some studies have also shown that drinking clear liquid before surgery can reduce the adverse reactions of nausea and vomiting after laparoscopic cholecystectomy in adults. [11–13]

This study relied on the application of ultrasound in the perioperative period. At present, the gold standard for evaluating gastric emptying is to observe the gastric emptying time by nuclide imaging after eating 99Tc or 113mIn DTPA-labeled food. However, due to the deficiencies of radiation, time consuming and high cost, it is not practical for routine preoperative evaluation.

Recent studies have found that ultrasound can quickly and accurately assess the gastric volume of different populations,[36] guide anesthesiologists to prepare for anesthesia and manage the airway to minimize the risk of reflux aspiration.[37] Its effectiveness in evaluating gastric emptying is comparable to that of nuclide imaging.[38] Based on the results of ultrasound evaluation, anesthesia management and induction methods were guided to reduce the risk of reflux aspiration in perioperative patients.[47]

Therefore, whenever there is any doubt about gastric residual capacity, routine ultrasound measurement of gastric contents should be a part of our clinical practice, which will become the best strategy to avoid gastric contents reflux aspiration.[38]

**Limitations**

Gastric residue or gastric fluid acidity were two important factors that determine the risk of reflux aspiration and the severity of pneumonia. This study only researched the change of gastric volume, but did not researche the changes of gastric acid concentration.

There were significant differences in pathophysiology between the healthy volunteers and the preoperative patients. The increased stress response before surgery might lead delayed gastric emptying, which might interfere with outcomes.

In this study, GV greater than 1.5ml/kg was defined as a risk stomach, but no cases of GV greater than 1.5ml/kg were found. So this definition still remained to be controversial, which needed to be verified by more randomized clinical trials.
In conclusion, compared with non-beverage subjects, oral carbohydrate more than 2 hours before surgery not only did not increase the incidence of risk stomach, but also reduced preoperative hunger, thirst, and anxiety. It was really a good choice to drink carbohydrate-rich fluid more than 2 hours before surgery.

**Abbreviations**

AP: Antero posterior diameter; CC: craniocaudal diameter; CSA: cross-sectional area of the gastric antrum; GV: gastric volume; VAS: Visual Analog Scale.

**Declarations**

**Acknowledgements**

We thank the participants for agreeing to share their medical data.

**Ethics approval and consent to participate**

The study conformed to the guidelines of the Declaration of Helsinki and was approved by Ethics Committee of Sichuan Orthopaedic Hospital August 20, 2020. All participants gave written informed consent and completed the questionnaires. All methods were performed in accordance with the relevant guidelines and regulations. The trial was registered before patient enrollment.

**Informed consent statement**

All participants gave written informed consent.

**Authors’ contributions**

Gang Zhang designed and conducted the study and drafted and revised the manuscript. Gang Zhang and Xiaoyan Huang conducted the statistical analysis. Gang Zhang, Ji Feng and Lan Zhang revised the manuscript and conducted the study. All authors approved the final version of the paper.

**Funding**

Support was provided solely from General Research Project of Sichuan Provincial Orthopedic Hospital, Chengdu, Sichuan, China (Project Number: 20PT05).

**Availability of data and materials**

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

**Institutional review board statement**
The study conformed to the guidelines of the Declaration of Helsinki and was approved by Medical Ethics Committee of Sichuan Orthopaedic Hospital.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

1Department of Anesthesia, Sichuan Provincial Orthopedic Hospital (Chengdu Sports Hospital and Chengdu Research Institute for Sports Injury), Chengdu, China.

2Department of Operation Room, the Third People's Hospital of Chengdu, Chengdu, China.

References


**Tables**

Tables 1-2 is available in the Supplementary Files section.

**Figures**
Fig. 1 Ultrasound scan of the gastric antrum in the right decubitus position in a subject who was classified as Perls 1.

AP, antero posterior diameter; CC, craniocaudal diameter; S, skin; L, liver; SMA, superior mesenteric artery; AA, abdominal aorta. AP=285mm, CC=163mm.

**Figure 1**

See image above for figure legend.
Figure 2

See image above for figure legend.
Fig. 3 Gastric volume changes at different time points in the two groups. GV, gastric volume.

*: The differences of gastric volume between the two groups were statistically significant (P<0.01)

Figure 3

See image above for figure legend.

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- Table12.pdf