

The Impact of Preoperative Oral Ingestion of Water on Intraoperative Gastric Fluid Volume for Elective Gastrosocopy: A Randomized Controlled Trial

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Abstract

Background: Preoperative fasting of clear fluids is recommended to reduce the incidence of pulmonary aspiration under anesthesia but non-compliance may cause aspiration or an inconvenient delay in surgery. Safe reduction of fasting time below the current standard of 2 hours has been reported but has not been demonstrated clinically. The aim of this study was to determine if reducing the fast of clear fluids to 1 hour increases residual gastric volume.

Methods: 181 adult patients scheduled for gastroscopy at three sites were randomized to receive 200 ml of water either 80-150 (Standard Fast group) or 40-75 minutes (Short Fast group) before anesthesia. Patients were stratified to current proton pump and antacid therapy. Gastric contents were aspirated under vision by gastroscopy after induction of anesthesia and the volume and pH were compared between groups.

Results: Non-compliance with fasting time resulted in exclusion of 41 patients leaving 140 patients for analysis. The mean fasting times (mean \pm SD) were 102 \pm 20.5 min in the Standard Fast group and 56 \pm 10.8 min in the Short Fast group. The proportions of patients receiving proton pump inhibitors were not different between groups (45.2% and 47.8% respectively, $p=1.0$). The gastric volumes and pH were similar (volume: 0.18 ml/kg \pm 0.25 and 0.19 ml/kg \pm 0.31, $P=0.92$; pH: 2.85 \pm 2.02 and 3.10 \pm 2.48, $P=0.61$). There was no correlation between fasting time and gastric volume ($r=0.03$; $p=0.72$) or pH ($r=0.02$; $p=0.84$) and no difference in the proportion of participants with residual gastric volumes greater than 0.4 ml/kg.

Conclusions: In patients without risk factors for delayed gastric emptying, consumption of 200 ml of water up to 56 minutes before general anesthesia does not significantly affect gastric volume and pH compared with a longer fasting time of 102 minutes.

Keywords: Preoperative fasting, Gastric fluid, Pulmonary aspiration, Endoscopy

Introduction

Preoperative fasting guidelines are widely used by hospitals to minimize the risk of pulmonary aspiration of gastric contents during anesthesia, a rare [1-4] but potentially serious complication [3]. Worse morbidity is associated with solid rather than fluid gastric aspirates, and higher volume and lower pH [5,6]. It is routine in most centers for fasting of solids and all liquids from midnight before the procedure but recognized guidelines recommend a minimum fasting time of two hours for clear fluids and six hours for solids [7,8]. However these recommendations are based on limited scientific evidence.

A two-hour fluid fast may cause some logistical inconvenience for endoscopy. Patient non-compliance with fasting instructions or confusion of fluids with solids may result in postponement of the procedure. In some centers this has led to a routine fast of six hours for both fluids and solids but this may result in dehydration (especially in patients receiving preoperative laxative bowel preparations) thirst and anxiety. There is accumulating evidence that clear fluids may be safely consumed less than 2 hours before anesthesia [9-23]. A recent MRI study on stomachs of healthy volunteers suggests that fasting times as short as 1 hour may be safe [24]. This may avoid problems of patient non-compliance and dehydration. Limitations of these studies include reliance on estimation of gastric fluid volumes from imaging such as ultrasound, MRI or from collection of fluid from nasogastric tubes, which may not be accurate. To our knowledge there are no reports of direct measurement of gastric fluid by aspiration by gastroscopy.

The aims of this randomized controlled trial were to determine if the gastric volume and pH aspirated by endoscopy were different in patients with a 1-hour and 2 hour fast of 200 mL water.

Materials and Methods

Ethics approval was obtained from The Southern Health Human Research Ethics Council (Approval reference number 12011A) and the St John of God Health Care Ethics Committee (Approval reference number 529) for the study to be conducted at three hospital sites: Monash Health (Monash Medical Centre and Dandenong Hospital) and St John of God Health Care Berwick Hospital. The study was registered with the Australian New Zealand Clinical Trials Registry. From April to August 2012, adults scheduled for elective gastroscopy were included in the study after written informed consent. Exclusion criteria included conditions associated with delayed gastric emptying or increased gastric volumes such as pregnancy, insulin-requiring

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diabetes, gastric outlet obstruction, previous gastric surgery or active upper gastrointestinal hemorrhage. Subjects were not excluded who were treated with medications that increased (such as metaclopramide) or decreased gastrointestinal motility (such as opiates).

Subjects were randomized to receive 200 ml water either 80 to 150 minutes (Standard Fast Group) or 40 to 75 minutes (Short Fast Group) before anesthesia for elective gastroscopy. The time interval of 40-75 minutes was chosen for the Short Fast group as this represents the typical time frame for patients to arrive at the hospital before surgical procedures. A volume of 200 ml was chosen as it represents the volume of a standard drinking cup. Therapy with proton pump inhibitors and antacids is common in this study population and may represent a significant confounder. To obtain comparable numbers of patients on PPI's and/or antacid in each group, patients were stratified for proton pump inhibitor (PPI) or antacid therapy and block randomized using a computer-generated schedule. Patients in both groups complied with standard institutional fasting guidelines (solid fast for a minimum of 6 hours and clear fluid fast for a minimum of 2 hours). The gastroenterologist aspirating the gastric fluid and the attending anesthesiologist were blinded to the participant's group allocation. The anesthetic technique was not standardized and left to the discretion of the anesthesiologist as this was not considered to have an effect on the gastric content.

Where the actual fasting time did not fall within the designated fasting time interval of a participant's randomized group, the participant was categorized as a protocol failure and the results were excluded from the final data analysis.

Each patient was given a 200 ml of water at the allocated time as deemed by the group allocation and estimated by the preoperative admitting nurse and the time of consumption was recorded. The gastric contents were aspirated by direct vision via the gastroscope immediately post induction of anesthesia with the patient in the left lateral position. The time of gastric aspiration was recorded. The fasting time was calculated by the difference between time of ingestion and gastric aspiration and rounded up to the closest 5 minutes. Any oral intake (fluid or solid) in the 6 hours prior to hospital admission was recorded.

The primary endpoint was the aspirated gastric volume, which was measured to the nearest milliliter with a syringe. Gastric fluid pH was measured with a pH reader (OakTon pHTestr 20, Eutech Instruments, Vernon Hills, IL, USA), which has an accuracy of ± 0.01 pH, requiring a minimum sample volume of 4 ml.

The secondary endpoint was the incidence of suspected and/or clinically significant regurgitation of gastric contents and/or pulmonary aspiration, as recorded prospectively by the attending anesthesiologist. A gastric volume of 0.4ml/kg was chosen as clinically significant in terms of pulmonary aspiration as described by Raidoo and Roberts et al. [6,25]

Sample Size Calculation and Statistical Analysis

A sample size of 64 patients in each group was required to detect a 10 ml difference between groups with 80% power and an alpha value of 0.05 based on a mean gastric volume of 19.4 ml and standard deviation of 20 ml obtained from previous published data [9]. A sample size of 181 was chosen to account for protocol failures. Student's t-test was used to compare the volume and pH of gastric fluid between groups. Pearson correlation was used to evaluate the association between fasting time and gastric volume and pH. Fisher's Exact test was used to compare

the proportions of subjects with clinically significant residual gastric volumes in each group. Data were coded and stored in Microsoft Excel 2010 and analyzed using Sigma plot 11.0 (Systat Software, San Jose, CA USA). Statistical significance was defined as a value of $P < 0.05$.

Results

Of the 181 patients recruited during the study period, 41 were excluded due to non-compliance with allocated group fasting time leaving 140 patients for analysis. There were no difference in the number of patients excluded between group ($P=1$) and there were no significant differences in age, sex, or body mass index, non-insulin requiring diabetes and those on PPI therapy (Table 1).

Gastric volume and pH

All participants fasted for both solid and fluid for a minimum of 6 hours prior to their hospital admission. The mean fasting times were 102 ± 20.5 minutes in the Standard Fast Group and 56 ± 10.8 minutes in the Short Fast Group. There was no statistically significant difference in the gastric volumes between the Standard and Short Fast groups (0.18 ± 0.25 ml/kg and 0.19 ± 0.31 ml/kg, $P=0.92$, 95% CI: -0.10 to 0.09, Table 2). There was also no difference in pH of gastric aspirate (2.85 ± 2.0 and 3.10 ± 2 , $P=0.61$, 95% CI: -1.22 to 0.72). However 55 samples of gastric fluid were less than 4ml and hence pH was unable to be measured but there was no difference in numbers of patients excluded between groups (26 from the Standard and 29 from the Short Fast Groups, $P=1$). There was no correlation between fasting time and gastric volume ($r=0.03$; $p=0.72$) or pH ($r=0.02$; $p=0.84$). There was no difference in the proportion of participants with residual gastric volumes greater than 0.4ml/kg between groups (Table 2).

Secondary endpoint

There was no recognized occurrence of gastric regurgitation or pulmonary aspiration as recorded by the attending anesthesiologist.

Discussion

This study demonstrated that in patients presenting for elective gastroscopy, without recognized risk factors for delayed gastric emptying, reducing the fasting time of 200 mL of water from 102 minutes to 56 minutes is not associated with an increase in gastric volume, a reduction in pH, or an increase in proportion of patients with a critical gastric aspiration volume at the time of endoscopy. A reduction of fasting time of clear fluids to 1 hour would enable drinking of water by

	Standard Fast Group	Short Fast Group	P
N	73	67	
Age; years (SD)	58.8 (16.2)	51.8 (16.4)	0.01
Male (%)	49	51	1
Mean BMI (SD)	27.4 (5.1)	27.5 (5.5)	0.89
Diabetes (%)	8.2	6.0	1
Patients on PPIs (%)	45.2	47.8	1

BMI: Body Mass Index; PPI: Proton Pump Inhibitor

Table 1: Demographic data of 140 patients.

	Standard Fast Group	Short Fast Group	P
Fasting Time-min (mean \pm SD)	102 ± 20.5	56 ± 10.8	<0.001
Gastric Volume-ml (mean \pm SD)	13.6 ± 17.8	13.6 ± 17.8	0.97
Gastric Volume-ml/kg (mean \pm SD)	0.18 ± 0.3	0.19 ± 0.3	0.92
N with gastric volume >0.4 ml/kg	11	11	0.99
Mean gastric pH (SD)	2.85 ± 2.02	3.10 ± 2.48	0.61

Table 2: Volume and pH of gastric aspirates.

patients right up until admission and may reduce unnecessary delays due to patient non-compliance with fasting instructions. This may be advantageous in patients who are at risk of dehydration from fasting from fluids, for example in elderly patients receiving bowel preparation prior to colonoscopy.

A limitation of the majority of previous studies is that gastric content may have been under or overestimated due to either indirect measurement of gastric fluid with imaging or aspiration via a nasogastric tube. This limitation was overcome in this study, in which the entire aspirated gastric content was visually confirmed with endoscopy.

Unlike previous reports, there was no significant increase in pH with a shorter fasting time fluids [9,20,23]. This may have been due to the reduced difference in duration of only 48 minutes between groups in our patients, compared with 4 hours in the previous studies (who compared 6 hours to 2 hours fasting of clear fluids).

Limitations

Due to the difficulty in predicting the exact time of aspiration of gastric fluid, the mean fasting time of clear fluids achieved in the Standard Fast Group was 18 minutes shorter than the currently accepted fasting time of 2 hours and therefore the comparison between a "Standard" Fast and a Short Fast may not be strictly applicable. In addition there was a small degree of overlap in fasting times between groups, but only at two standard deviations (Standard Fast Group 102 ± 41 min and Short Fast Group 56 ± 21.6 min). This variability in preoperative fasting time was due to the inherent error of relying on estimation of the time before insertion of the gastroscopy. The admitting nurse instructed the patients to ingest the water when they anticipated the time to gastroscopy to be either 1 or 2 hours, depending on which allocated group the patient was in. The only way to avoid this would be to have the endoscopist wait until the exact fasting time had been reached, which is not feasible. The authors believe that this is an acceptable result and does not detract from the significance of the results. Despite blinding of the endoscopist and anesthesiologist to patient group, the researcher responsible for recruitment of patients also performed gastric aspirate measurements, which may represent some degree of measurement bias. In this study only patients without risk factors for delayed gastric emptying were included and therefore the results cannot be extrapolated to patients with reduced gastric emptying. However the results may be extrapolated to adults having other procedures requiring anesthesia without risk factors for delayed gastric emptying. It is currently unclear whether the gastric emptying rate of water is comparable to that of clear fluids with caloric content. This may be useful to investigate as diabetic patients may present with hypoglycemia after fasting from solids for 6 hours who might benefit from caloric fluids to restore norm glycemia before the procedure.

Conclusion

There is no difference in the residual gastric fluid volume or pH after consumption of 200ml of water up to 56 minutes compared with 102 minutes before anesthesia in adults presenting for gastroscopy without known risk factors for delayed gastric emptying.

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