



## Original Research Article

# Randomised clinical trial to compare ultrasonography guided gastric volume in patients after overnight fasting and after ingestion of clear fluids two hours before surgery

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## ABSTRACT

**Introduction:** Aspiration of the gastric contents in the peri-operative period is a serious complication of surgery and anaesthesia. Pre-operative fasting aims to decrease the volume and increase the pH of gastric contents, hence reducing the risk of aspiration. According to the past literature gastric contents of 25 ml (0.4ml/kg) and with pH  $\leq$  2.5 predisposes the patient to pulmonary aspiration hence pre-operative fasting was recommended. But prolonged fast doesn't guarantee empty stomach. Use of two-dimensional ultrasonography is an accurate non-invasive tool to determine gastric volume. With an aim to reduce the hours of pre-operative fasting without increasing the risk of aspiration pneumonia we compared the gastric volume using ultrasonography and pH of gastric aspirate by pH strip in patients after overnight fasting and after ingestion of 200 ml clear fluids (water) 2 hours prior to surgery.

**Materials and Methods:** The study was conducted in 60 ASA I patients undergoing elective surgery after obtaining Institutional ethical committee clearance & written informed consent from all the patients. Thorough pre anaesthetic evaluation was done, investigations were noted. After having achieved the inclusion and exclusion criteria and having obtained informed consent, patients were randomized based on computer generated randomization table into one of the two groups.

Group A: Patients with Overnight fasting

Group B: Patients receiving 200 ml of clear fluids (water) 2 hours before surgery.

Gastric antral dimensions were noted and gastric volume was calculated.

**Results:** We observed that the age and gender distribution were comparable between the two groups. The mean gastric volume by USG in group A is  $29.7 \pm 8.0$  ml and group B is  $19.2 \pm 4.9$  ml. The reduced gastric volume in group B is statistically significant ( $<0.00001$ ).

The mean pH of gastric aspirate in group A is 1.4 and group B is 2.63. The results reveal that group B has a better results in terms of pH of the gastric contents and is statistically significant ( $p < 0.00001$ ).

**Conclusion:** The mean gastric volume in patients who had consumed 200 ml of clear fluid 2 hours prior (group B) was lesser than patients who fasted overnight (group A).

The mean pH in patients who had consumed 200 ml of clear fluid 2 hours prior (group B) was higher than patients who fasted overnight (group A).

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## 1. Introduction

Aspiration of gastric contents in the peri-operative period is a serious complication. The overall incidence of aspiration pneumonia ranges from 0.1% to 19% in the patients

undergoing surgical procedures.<sup>1–6</sup> Aspiration pneumonia is associated with significant morbidity, including prolonged mechanical ventilation, and carries a risk of mortality as great as 5%. Pulmonary aspiration is the cause of around 9% of all anaesthesia related deaths.<sup>1,7,8</sup> In particular, aspiration of particulate material, volumes more than 25 ml with low pH is associated with high morbidity. The physiological

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protective reflexes that prevent aspiration (tone of lower oesophageal sphincter and upper airway reflexes) are inhibited by sedation and general anaesthesia.<sup>9,10</sup>

Some of the interventions to reduce the risk of aspiration being optimizing the time of anaesthesia and surgery, regional vs general anaesthesia, method of induction, airway management technique and pre-operative fasting.

Preoperative fasting aims at reducing the volume and acidity of the gastric contents hence reduce the risk of aspiration.

In spite of the recommendations as per the recent guidelines<sup>11,12</sup> to allow the intake of clear fluids up to 2 hours before surgery,<sup>13</sup> it is common to advice not to take orally after mid- night for both liquids as well as solids.

According to the previous studies have shown that aspiration risk is more in patients with gastric volume of 25 ml(0.4ml/kg). However Cochrane data base has reviewed several studies and concluded that avoiding the intake of clear fluids will not increase the pH of the gastric contents and also that the gastric volume increases with the increase in the hours of fasting.<sup>14</sup> Prolonged fasting before surgery is uncomfortable to the patient.<sup>14</sup>

The volume of gastric contents can be assessed by various methods like aspiration using a nasogastric tube, absorption of paracetamol, electrical impedance tomography, dilution of polyethylene glycol, diet containing radio-active labelled substances, etc which are all invasive methods to determine gastric volume and gastric emptying time.<sup>15-19</sup>

The sizes of viscera have been assessed using Ultrasonography, so also gastric volume can be assessed using USG. 2 Dimensional USG can be a non-invasive tool to determine the gastric volume.<sup>20</sup>

Therefore with an aim to reduce the pre-operative fasting periods without increasing the risk of pulmonary aspiration we compared the gastric volume using ultrasonography and pH of gastric aspirate by pH strip in patients after overnight fasting and after ingestion of 200 ml clear fluids (water) 2 hours prior to surgery.

## 2. Aims and Objectives

Primary Objective: To compare the gastric volume using ultrasonography in patients after overnight fasting and after intake of clear fluids (water) 200ml 2 hours before surgery.

### 2.1. Secondary objective

To assess pH of gastric aspirate.

## 3. Materials and Methods

Following approval by local institutional ethical committee, a written informed consent was obtained from all patients. Adults aged between 18 and 50 years of ASA physical status 1 posted for elective surgery under general surgery

were included in the study. Patients with Body Mass Index (BMI) >30 kg/m<sup>2</sup>, Gastro Esophageal Reflex Disorders and pregnant women were not included in the study. Patients were randomized based on computer generated randomization table into one of the two groups.

1. Group A: Patients with Overnight fasting.
2. Group B: Patients receiving 200 ml of clear fluids (water) 2 hours before surgery.

Preoperatively the patient's intravenous (IV) line was secured with either 18 G or 20 G branula and IV fluid was started at 5 ml/kg/hr. Patient was positioned in right-lateral position and using ultrasonography probe 3-5 Mhz, the gastric antrum was visualized by placing the probe in saggital plane which was seen as round to ovoid and has been compared with a 'target' or 'bull's eye' pattern Then antral CSA is measured by using two perpendicular diameters and the formula of the area of an ellipse : CSA = (AP×CC×π)/4

AP=Antero-Posterior Diameter (in cm)

CC= Craniocaudal Diameter (in cm)

And Gastric volume was calculated using the formula

GV = 27+14.6×rt-latCSA (in cm<sup>2</sup>)-1.28×age(years)

Then the patient was shifted to the operation theatre and routine monitors including electrocardiograph (ECG), pulse oximeter and non-invasive blood pressure were attached and baseline readings recorded. The patient was preoxygenated for 3 minutes and patients were premedicated with glycopyrolate, midazolam, fentanyl and induced with thiopentone and vecuronium. Then patients' airway was secured with an appropriate sized endotracheal tube. Patients were maintained with oxygen, nitrous oxide and vecuronium. Gastric aspirate was obtained via a 16G or 14G Ryles tube in males and females respectively using a 20ml syringe and the upper abdomen was massaged by an assistant to facilitate the aspiration of the gastric contents. The volume of the gastric aspirate noted and the pH was recorded using the standardized pH strip. The parameters noted include:

Sex, age, weight, type of surgery, duration of surgery, gastric volume by ultrasonography, gastric aspirate volume, duration of fasting and interval between ingestion of water and surgery will be noted.

Using the formula, sample size

$$\text{Sample Size} = \frac{2(Z\alpha/2 + Z_{1-\beta})^2 (SD^2)}{d^2}$$

Level of significance is taken as 5%

Power of the test used is taken as 80%

type I error rate  $\alpha = 0.05$  and

type II error rate  $\beta = 0.2$

Taking the level of significance at 5% ( $\alpha=0.05$ ),

Power of the test as 90% ( $\beta=0.2$ ), and

using two tailed test we get

$Z\alpha=1.96$

$Z_{1-\beta}=0.84$

SD= Standard deviation of mean gastric volume of overnight fasted patients.

$d$  = effect size = 1.65 (6% of the mean gastric volume value of 27.48 in fasted patients)

The clinical significance of the effect size value is that any difference of mean value up to 1.65 between the fasting and 2 hour 200ml clear fluid group this study will be able to detect.

The study result is expecting to find a mean gastric volume value less than  $27.48 \pm 2$

Hence,

$$Z\alpha = 1.96$$

$$Z\beta = 1.28$$

Mean gastric volume for fasted patients = 27.48

$$SD = 1.98 = 2$$

$$d = 1.65$$

$$\text{Sample Size } (n) = \frac{2(1.96 + 0.84)^2 (2^2)}{(1.65)^2}$$

$$n = 22.94$$

For ease of calculations and sake of consistent result, sample size has been taken as 30. There are two groups of 30 each group.

#### 4. Results

The results are mentioned as mean +/- standard deviation (S.D.) Data collected was analysed using Student 't' test. Difference was considered significant if P value was < 0.05

The age, weight and sex ratio of the groups were comparable.

**Table 1:** Mean age distribution according to gender in the two study groups

	Group A		Group B
<b>Male</b>	33±11.1	<b>Male</b>	32.08±11.4
<b>Female</b>	36.16±8.76	<b>Female</b>	27.61±7.7
<b>Overall</b>	35.43±9.57	<b>Overall</b>	29.4±9.45

The mean gastric volume by USG in Group A is  $29.7 \pm 8.0$ ml and Group B is  $19.2 \pm 4.9$  ml. The reduced gastric volume in Group B is statistically significant (<0.00001).

The mean pH of gastric aspirate in Group A is 1.4 and Group B is 2.63. Which shows that Group B has a better outcome in terms of gastric pH and is statistically significant ( $p < 0.00001$ ).

#### 5. Discussion

Fasting is considered a mandatory prerequisite for elective surgery. It is widely believed that the goals of pre-operative fasting are (a) to increase the alkalinity of gastric juice and thus decrease the severity of pneumonitis should occur and (b) to reduce the volume of gastric contents and thereby reducing the likely hood of pulmonary aspiration.

The concept of empty stomach is universally followed to safeguard against vomiting, regurgitation and aspiration during anaesthesia. However stomach can never be completely empty even after a midnight fast since it continues to secrete gastric fluid.

Prolonged fasting is associated with reduced gastric pH and increase in gastric volume, placing the patients at risk category for aspiration. Current guidelines<sup>11,12</sup> recommend clear liquids up to 2 h before surgery, which is a compromise between comfort, cooperation and hydration, on the one hand and security on the other.

Gastric emptying is affected by different factors like obesity, gastrointestinal disorders and systemic diseases. The rate of gastric emptying depends on several variables, including the volume of oral fluids.

Previous investigations in adults demonstrated different emptying rates for different fluids, with caloric load, carbonation, carbohydrate levels and nutrient composition a determining factor.

Various methods have been used to determine the gastric volume. The volume of gastric contents can be assessed by various methods like aspiration using a nasogastric tube, absorption of paracetamol, electrical impedance tomography, dilution of polyethylene glycol, diet containing radio-active labelled substances, etc which are all invasive methods to determine gastric volume and gastric emptying time.<sup>15-19</sup>

Many of these are not applicable in perioperative period. Gamma scintigraphy is a non-invasive method considered a gold standard. It has the drawbacks of cost, use of radiation, and is not a practical examination tool.

Measurement of residual gastric volume by an aspiration using a nasogastric tube usually underestimates the gastric volume. MRI was used by Schmitz et al to study the effects of different quantities of sugared clear fluids on gastric emptying and residual volume in children aged 6-14 years. Gastric fluid volume decreased rapidly with a median half-life of <30 min after drinking 7 ml/kg of standardized clear fluids. Body weight corrected gastric air volume ( $GAV_w$ ) continued to increase until 30 -90 min post syrup in most children, but declined below initial value after 120 min ( $P < 0.008$ ).

Previous MRI studies in adults have shown the following elimination half-life: 38 min for 500 ml of glucose 10%, 100- 130 min for several meals and liquid nutrients, 21 min for water, 31 for non-carbonated carbohydrates, 47 for carbonated carbohydrates and 107 min for carbonated cola.

According to the past literature pH <2.5 and volume of gastric aspirate >25 ml (0.4ml/kg) predisposes patients to pulmonary aspiration.<sup>14</sup>

Although there are numerous studies on the safety of drinking clear liquids up to 2 h before surgery and establishment of preoperative fasting guidelines, many anaesthesiologists and surgeons are still unsure of the

**Table 2:** Showing the values of clinical parameters in the two groups.

Variables	Group A (Mean±SD)	Group B (Mean±SD)	Calculated Unpaired t-test value	p value
Mean pH of gastric aspirate during intra-operative period	1.4±0.50	2.63± 0.61	9.69	<0.00001
Mean gastric volume by gastric aspiration during intra-operative period	26.7±7.5	13.47±4.8	9.70	<0.00001
Mean Gastric volume by USG	29.7±8.0	19.2±4.9	6.07	<0.00001

practice. Therefore, non-invasive assessments at the bedside that could determine the volume of gastric contents in the peri-operative period will be useful in assessing the risk of pulmonary aspiration. Until recently there was a lack of a non-invasive diagnostic method that could promptly assess gastric content and be applied peri-operatively. Ultrasound is the first non-invasive technique that provides both quantitative and qualitatively validated information of gastric contents at bedside.<sup>20</sup> Studies have revealed that gastric antrum is the region which will be easily accessible to ultrasonographic examination. It can be identified in 98-100% of cases.<sup>20,21</sup> Several mathematical models were developed for gastric volume calculation using the gastric antrum image and calculating its cross-sectional area.<sup>20,21</sup>

A Perlas et al.<sup>22</sup> reported accurate linear model based on gastroscopic fluid assessment with a mean difference of 6 ml between the predicted and measured volumes. This study had 108 patients. It is applicable to adult, non pregnant subjects with BMI up to 40 kg/m<sup>2</sup>. It can predict volumes up to 500 ml.

Where GV- gastric volume,

Right.lat CSA- antral cross sectional area

In our study ultrasound was used and gastric volume was determined using the above mentioned formula, 60 patients posted for elective surgery were examined. 30 each belonging to overnight fasting group and 30 patients after 2 hours of intake of 200 ml clear fluids. There was no incidence of vomiting or aspiration in both the groups.

In our study the distribution of sex were comparable in both groups with 33.3% male in group A and 40% male in group B. The patients in both the groups were comparable in age with majority of them between 26-41 years old.

The mean gastric volume by ultrasonography in overnight fasting (group A) was 29.7± 8.0 ml, while patients who had 200 ml of clear fluid 2 hours prior (group B) had mean volume estimated by ultrasonography of 19.2± 4.9 ml which was statistically significant (p<0.00001). The mean pH as assessed by pH strip in group A was 1.4± 0.5 and that of group B was 2.63± 0.61. The difference in pH between the groups were statistically significant (p<0.00001).

Malcolm scar and J Roger Maltby<sup>23</sup> studied the effect of oral fluids on residual gastric volume and acidity before

elective surgery in 211 healthy patients. Patients were allowed to have 150 ml of tea or coffee or apple juice or water until 3 hours before surgery. Retrospectively the patients were assigned to one of the four groups depending on the duration of last intake of fluid to induction of anaesthesia (<3 hours, 3-4.9 hours, 5-8 hours, and nothing after midnight). The gastric volume and pH were 2521ml and 1.61.0 in <3 hour of fluid intake, 2420ml and 1.91.1 in 3-4.9hr, 3124 and 2.2 1.7 in 5-8 hr group, 2622ml and 1.70.7 in overnight fasting group. The difference between the groups was statistically insignificant.

Effects of fasting interval on gastric volume and pH was studied by Riaz Hussain<sup>24</sup> in 65 patients aged 15-50 years undergoing elective surgery under general anaesthesia. It was an observational study. The gastric volume in patients who fasted up to 8 hours had 27.8573.058 ml, 8.5 to 12 hours had 27.42.98 ml, more than 12 hours had 27.47015.55 ml. The pH were 3.9290.997, 2.9140.355, and 2.848 0.284 respectively in patients who had fasted up to 8 hours, 8.5-12 hours and more than 12 hours. Both the gastric volume (p=0.998) and pH(p=0.408) changes between the groups were insignificant. This study concluded that prolonged fasting had no added benefits but added to patients' discomfort.

Flora Margarida et al<sup>25</sup> used ultrasound for gastric volume evaluation after consuming different volumes of isotonic saline solution in 80 healthy volunteers. The volunteers were scanned 3 times. Gastric volume was estimated by scan after overnight fast, overnight fast followed by 200 ml saline or 500 ml saline after 2 hours of ingestion of liquid. The scans were graded as grade 0- antrum is empty in both supine and Right Lateral Decubitus (RLD) position, grade 1- Presence of liquid in RLD only, grade 2- Presence of liquid in both RLD and supine. Grade 2 suggested increased gastric volume. 81.25%, 68.75%, 71.25% were found grade 0 on scans in group fasting overnight, 200ml saline, 500ml saline respectively. 5%, 13.75% and 18.75% of volunteers were found to be grade 2 in fasting, 200 ml saline and 500 ml saline group. However, this was not statistically significant (p = 0.07).

The results of our study reflect better outcome with both pH and gastric volume in patients who had 200 ml clear fluids 2 hours prior surgery. This result supports the present

NPO guidelines for clear fluids as 2 hour which helps in reducing the preoperative discomfort of long fasting hours and dehydration of patients

Our study has some limitations,

1. As with all ultrasound techniques, which is dependent on the equipment quality and also the operator, the antrum is not identifiable in all patients and several steps need to be performed systematically to obtain reliable results.
2. The present study was conducted on healthy volunteers and, thus, the results may not be extrapolated to patients with chronic diseases or taken medications that alter the digestive system motility. For such patients, the fasting recommendations should be tailored.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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