

Comparison of Preoperative Assessment of Gastric Volume and pH in Patients Undergoing Elective Surgery with Prior Two Hour Fasting versus Overnight Fasting- A Randomised Clinical Trial

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ABSTRACT

Introduction: Aspiration of gastric content is a known life-threatening, yet preventable complication of anaesthesia. While mostly all elective procedures do follow the preoperative fasting protocols as recommended by American Society of Anaesthesia (ASA), there are many situations where the fasting guideline cannot be followed considering the emergency. In such cases, bedside ultrasound assessment of gastric volume can become an important tool to stratify aspiration related risk.

Aim: To find out the actual trends of gastric volume and pH in patients with two hour fasting with a prokinetic drug versus overnight fasting who are undergoing elective procedures.

Materials and Methods: This single centre, randomised clinical trial was conducted in the Department of Anaesthesia at Dr. Sampurnanand Medical College, Jodhpur, Rajasthan, India, between December 2020 and July 2021, among 50 patients of ASA grade I undergoing elective procedures under general anaesthesia. Participants were divided into two groups. Group A patients were advised overnight fasting while group B participants were advised

two hour fasting for clear liquids followed by intravenous (i.v.) metoclopramide injection. Assessment of gastric volume and other gastric parameters were done using a portable ultrasound machine. The pH of gastric content was measured using pH strips. Gastric content was obtained using Ryle's Tube placed in the patient, postinduction of anaesthesia. Collected data was statistically analysed using Unpaired t-test for all qualitative data.

Results: Significant difference in the anteroposterior diameter (3.46 ± 0.34 in group A versus 2.24 ± 0.30 in group B), cranio-caudal diameter (4.77 ± 0.51 in group A versus 3.71 ± 0.36 in group B), antral curved surface area (9.90 ± 0.77 in group A versus 7.77 ± 1.04 in group B) and gastric volume (127.48 ± 13.09 in group A versus 104.65 ± 15.43 in group B) and pH (2.08 ± 0.28 in group A versus 2.80 ± 0.41 in group B) was observed (p -value=0.0001). However, no significant difference in any gastric parameter, mentioned above, was noted before and after injecting intravenous metoclopramide.

Conclusion: Bedside ultrasound assessment of gastric volume is an important tool for aspiration risk stratification especially in emergency, non-fasting patients.

Keywords: Aspiration pneumonia, Gastric pH, Gastric volume assessment, Metoclopramide, Ultrasound of antrum

INTRODUCTION

It is a well-established fact that aspiration of gastric content causes significant morbidity and at times even mortality [1,2]. However, the severity of the complication depends on the volume and the nature of the aspirate with particulate matter carrying the highest risk [3].

Fasting guidelines provided by the American Society of Anesthesiologists (ASA) ensures that the stomach is emptied before induction of anaesthesia, which is the primary method to prevent gastric aspiration [4]. But, this cannot be applied for emergency procedures. Multiple meta-analysis of Randomised Clinical Trials (RCT) have been included by the ASA to prepare a recommendation for preoperative fasting [5]. These studies compare gastric volumes and pH in patients fasting for 2-4 hours versus more than 4 hours. Meta-analysis of RCT reports lower risk of aspiration when gastric volume is <25 ml and pH is >2.5 [4,6]. This happens when clear liquids are allowed for up till 2-4 hours before anaesthesia.

The study aimed to find the gastric volume and pH in patients with two hours fasting with a prokinetic drug versus overnight fasting who were scheduled to undergo elective procedures.

MATERIALS AND METHODS

This single centre, randomised clinical trial was conducted in the Department of Anaesthesia at Dr. Sampurnanand Medical College,

Jodhpur, Rajasthan, India, between December 2020 and July 2021. Ethical approval was taken from the Institutional Ethical Committee (Reference Number: SNMC/IEC/2020/Plan/256). The study has been registered under CTRI and has been given the following registration number- CTRI/2020/11/029391 on 26/11/2020.

Sample size calculation: Sample size was calculated using the formula :

$$N = 2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / d^2$$

where $(Z_{1-\alpha/2})$ = Standard normal variate for type 1 error taken as 1.96 for 95% Confidence Interval,

$(Z_{1-\beta})$ = Standard normal variate for type 2 error taken as 1.28 for 90% study power,

σ = Pooled standard deviation of gastric volume taken as 8 and

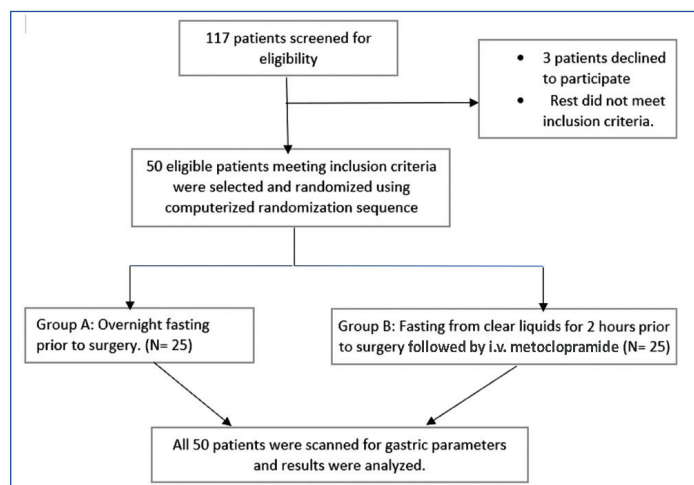
d = minimum expected significant difference in gastric volumes between the two groups taken as 11, based on the study conducted by Van de Putte P et al., [7].

With this calculation the minimal sample size required for the study was 12 subjects in each group. Considering attrition, sample size was enhanced and rounded off to 25 subjects in each group.

Inclusion and exclusion criteria: The ASA grade I patients undergoing elective surgery under general anaesthesia, aged between 18 to 60 years with body mass index <30 kg/m² were

included in the study. Patients who refused to participate or were pregnant or with Gastro-oesophageal reflux disease were excluded from the study.

A total of 100 patients were screened for eligibility. Out of which, 50 eligible patients meet the inclusion criteria and were selected, three patients declined to participate for which three new patients were inducted [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) diagram.

After obtaining the written informed consent for participation from 50 included participants, participants were allocated into two groups based on computer generated randomised table:

Group A (n=25): Patients with overnight fasting prior to surgery .

Group B (n=25): Patients with fasting for clear liquids two hours for and receiving 10 mg metoclopramide intravenously (i.v.) through i.v. cannula of 18-20 G, 2 hours before surgery.

Procedure

The gastric volume was measured using portable Siemens Acuson X300 ultrasound machine. Ultrasound was done by anaesthesia team. However, all the findings were confirmed by residents of Radiology Department. The patient was positioned in the Right Lateral Position (RLP). Abdominal probe of 3-5 MHz frequency was used to visualize the gastric antrum which could be identified as a round to oval structure between the left lobe of liver anteriorly and pancreas posteriorly when the probe is placed in the sagittal plane in the epigastrium. In case the stomach was empty, antrum appeared flat with juxtaposed anterior and posterior walls while peristalsis and or dilated antrum could be noted if stomach was filled.

Antral Cross-sectional Area (CSA): The antral cross-sectional area (CSA) was measured using the equation, $CSA = \pi [D_1 \times D_2] / 4$, where D1 and D2 are two antral dimensions- antero- posterior diameter and cranio-caudal diameter.

Gastric Residual Volume (GRV): The GRV was calculated using the equation- $GRV (mL) = 27.0 + 14.6 \times \text{Right Lateral CSA} - 1.28 \times \text{age}$ (Perlas and colleagues' equation for RLP [7]).

Group A patient underwent ultrasound once prior to surgery in the preoperative area, while group B patients underwent ultrasound twice, once before and then after giving i.v. metoclopramide just prior to surgery (that is, in a gap of 2 hours).

pH measure: The pH was measured using E17 Merck litmus paper pH strips. The gastric aspirate was obtained by gentle suctioning with a 20 mL syringe attached to a Ryle's tube of size 18 F that was inserted after the induction of anaesthesia.

STATISTICAL ANALYSIS

Demographic data included age, gender and Basal Metabolic Index (BMI) distribution. All statistical analysis was performed by using Statistical Package for Social Sciences (SPSS version 22.0, Chicago,

IL, USA). Unpaired t-test was used for comparison of all qualitative data. All data was summarized as Mean±SD for continuous variables, numbers and percentages for categorical variables. A 95% Confidence Interval (CI) was calculated and p-value <0.05 was considered as statistically significant.

RESULTS

All the participants were comparable in terms of demographic parameters as shown in [Table/Fig-2]. There was no significant difference in their baseline parameters. Majority of patients in the groups A and B were between 18-29 years of age (68% and 56% respectively). Majority of the patients in the groups A and B had BMI within the range of 18.5- 25 kg/m² (52% and 68% respectively).

Parameters	Group A	Group B	p-value
Age (Mean±SD) (years)	27.92±9.17	27.96±9.24	0.988
Males/Females	13 (53%)/12 (48%)	15 (60%)/10 (40%)	
BMI (Mean±SD) (kg/m ²)	25.33±3.19	24.27± 2.056	0.35

[Table/Fig-2]: Demographic parameters of both groups.

Significant difference in the anteroposterior diameter, cranio-caudal diameter, antral curved surface area and gastric volume and pH was observed in group A and B as shown in [Table/Fig-3]. However, no significant difference in the any gastric parameter was noted before and after injecting i.v. metoclopramide as shown in [Table/Fig-4].

Parameters	Group A (Mean±SD)	Group B (Mean±SD)	p-value (Unpaired t test)
Anteroposterior diameter (cm)	3.46±0.34	2.24±0.30	<0.0001
Cranio-caudal diameter (cm)	4.77±0.51	3.71±0.36	<0.0001
Antral cross-sectional area (CSA)	9.90±0.77	7.77±1.04	<0.0001
Gastric volume (cm ³)	127.48±13.09	104.65±15.43	<0.0001
pH	2.08±0.28	2.80±0.41	<0.0001

[Table/Fig-3]: Pre-anaesthesia gastric parameters and pH in both groups.

Parameters	Administration of prokinetic drug in group B		p-value (Unpaired t-test)
	Before	After	
Anteroposterior diameter (cm)	2.24±0.30	2.08±0.29	0.072
Cranio-caudal diameter (cm)	3.71±0.36	3.63±0.37	0.441
Antral curved surface area (cm ²)	7.77±1.04	7.6±1.06	0.478
Gastric volume (cm ³)	104.65±15.43	101.6±15.69	0.485

[Table/Fig-4]: Gastric parameters before and after injecting metoclopramide in group B.

DISCUSSION

Abdominal ultrasound was used to assess the gastric content and volume a few times before but difference between preoperative gastric antral diameters have not been compared between overnight fasting and two hours fasting for clear liquids in patients undergoing surgery [7].

This clinical trial was designed to answer if any difference exists in the gastric volume, when a patient has fasted overnight versus those who fasted for two hours and were administered i.v. metoclopramide. The results show a significant decrease in the gastric volume when the patient has fasted for two hours for clear liquids as compared to overnight fasting. However, no difference in the gastric parameters was noted before and after the use of i.v. metoclopramide. The results support the hypothesis, that by reducing the fasting time for clear liquids, gastric volume decreases due to increased gastric motility. Aspiration due to gastric content aspiration during anaesthesia is a preventable complication that accounts for 9% of deaths due to anaesthesia [8].

This study contradicts the findings by Sharma S et al., where no significant correlation was found between hours of fasting and

residual gastric volume (p-value=0.47). In their study, average hours of fasting in elective procedures was 7.75 hours [9].

Earlier, gastric volume of >0.8 mL/kg was considered high-risk for aspiration [8]. However, widely accepted values in current practice is that of >1.5 mL/kg of residual gastric volume which puts a patient at a higher risk for aspiration [8]. The gastric volume assessment with ultrasound helps in clinical decision making and risk stratification especially in emergency situations where the patient has not followed the fasting protocols.

The role of prokinetic drugs to improve gastric emptying has been established in healthy patients. However, its role in gastroparesis is unclear. In the present study, intravenous metoclopramide was used, which acts by binding to D2 receptors and as an antagonist to chemoreceptor trigger zone in the central nervous system and via 5-HT4 receptor agonist activity thereby showing its gastroprokinetic effect and enhancing gastric motility. However, no significant difference was noted in the gastric parameters before and after two hours of injecting metoclopramide intravenously in patients who fasted for two hours with clear liquids.

The present findings contradict the findings of Sayyadi S et al., where CSA significantly decreased in metoclopramide group as compared to control group. This states that metoclopramide can reduce gastric ultrasonographic indices (CSA) which correlates with the gastric volume, in patients with incomplete fasting before induction of general anaesthesia [10].

Gastric emptying can be affected by age, American Society of Anaesthesiologists (ASA) class III, IV, gastro-oesophageal reflux disease, obesity, diabetes mellitus, pregnancy, pain or preoperative medication. Most of the factors in this study were excluded during participant selection. For the rest of the factors such as age and BMI subgroup analysis were performed. However, the numbers in each group were so small to have a clinical or statistical significance.

The noteworthy strength of the current study has been the fact that, gastric volume was measured by a single operator, under the supervision of a radiology fellow which ruled out the inter-rater reliability. No special training in ultrasound was needed by the observer to perform gastric volume measurement. Availability of ultrasound machine to perform the abovesaid measurements was easy. The understanding of the basic mechanics of the machine, probe placement and taking measurements was taught and supervised thereafter by the radiology fellow during the study.

Limitation(s)

Firstly, gastric pH was measure using pH strips, which are known to be less accurate than those determined by point of care Arterial Blood

Gas (ABG) machine or pH meter. Secondly, detailed history including chronic antacid use was not ruled out completely which could have been a reason for lesser secretion of gastric acid and therefore, false high pH. And lastly, the duration of overnight fasting was not the same for all patients due to the variations in the timing of surgery.

CONCLUSION(S)

While standard fasting guidelines are adequate for low risk, healthy patients, they are not conclusive for patient with additional risk factors. For those emergency situations where, fasting protocols were not followed or there are additional factors influencing risk of aspiration in a patient, bedside ultrasound assessment of gastric volume should become a standard of care for risk stratification.

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