Anaesthesia Section

A Randomised Clinical Study

using Gastric Ultrasonography:

Evaluation of Gastric Contents and

Volume after Ingestion of Apple Juice

versus Pure Complex Carbohydrate

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ABSTRACT

Introduction: Gastric ultrasound is a non-invasive tool for assessing gastric content and volume. Aspiration of gastric contents is a serious perioperative complication that contributes to mortality and morbidity following general anaesthesia. The Enhanced Recovery After Surgery (ERAS) protocol and Indian Society of Anaesthesiology (ISA) fasting guidelines recommend consuming a carbohydrate drink two hours before surgery in adults. However, evidence supporting this recommendation, particularly regarding volume, is still limited and variable.

Aim: To examine Gastric Residual Volume (GRV) using Ultrasonography (USG) six hours after a light breakfast and compare it with GRV two hours after consuming clear liquids.

Materials and Methods: A randomised clinical study was conducted involving 100 patients who were assigned randomly to two groups: Group-C (Oral Carbohydrate, CHO) and Group-A (Apple juice), with 50 patients in each group; each patient underwent gastric USG twice: once within the first six hours after a light breakfast and again two hours after consuming 400 mL of clear liquid. USG was performed with the patient in a supine position and a Right Lateral Decubitus (RLD) position, and GRV was estimated by measuring the Antral Cross-sectional

Area (ACSA) using a mathematical model. The final reading was taken from the RLD position, and qualitative analysis of the antrum was conducted using the Perlas grading system. A GRV of <1.5 mL/kg is considered low risk for aspiration. Statistical tests such as Chi-square, paired t-test, and one-way Analysis of Variance (ANOVA) were applied.

Results: A total of 100 patients were analysed in the present study. The mean age was 41.04 years and 39.94 years in Group-A and Group-C, respectively. There was no significant difference in GRV between six hours after a light breakfast and two hours after clear liquid intake in either group (p>0.05). The mean GRV was 7.75 (7.23) mL and 8.01 (7.58) mL six hours after a light breakfast, and 7.71 (8.92) mL and 8.49 (9.47) mL two hours after clear liquid intake in Group-A and Group-C, respectively, among non-CKD patients. GRV was higher in CKD patients and those with an increased Body Mass Index (BMI).

Conclusion: The GRV remains within safe limits after consuming 400 mL of clear liquid two hours before surgery. This finding supports the recommended volume of preoperative clear liquid intake in the ERAS protocol and ISA fasting guidelines. However, careful consideration is necessary for patients with CKD and an increased BMI.

Keywords: Antral cross-sectional area, Enhanced recovery after surgery, Fasting, Residual volume

INTRODUCTION

The concept of pre-loading with oral Carbohydrate (CHO) two hours before surgery has recently been introduced in the ERAS protocol. Giving oral CHO as a preload has been shown to improve the patient well-being, prevent dehydration before surgery, and enable the patient to be in a metabolically fed state prior to surgery. This can have a beneficial effect in reducing insulin resistance and catabolism, thereby improving the quality of recovery [1]. Proponents of the ERAS protocol for elective surgeries have stated that preloading with carbohydrates two hours prior to surgery is safe and does not increase the risk of aspiration, but the evidence for this is still limited [2]. A recent study based on USG showed that fasting for more than 6-8 hours does not guarantee an empty stomach [3]. Aspiration of stomach contents into the lungs is a serious perioperative complication, accounting for nearly 9% of anaesthesiarelated deaths [4]. The American Society of Anaesthesiologists (ASA) and the Indian Society of Anaesthesiologists (ISA) recommend a minimum fasting duration of two hours for clear fluids, six hours for a light meal, and eight hours for a fatty meal in healthy adults who do not have conditions that delay gastric emptying or increase gastric volume [2,5].

Gastric USG guidance has gained widespread acceptance due to its practicality, affordability, and effectiveness as an imaging technique. Recent research utilising bedside gastric ultrasound has provided insights into the composition (liquid, solid, or empty) and volume of stomach contents [6-8]. The novelty of this study lies in the comparison between CHO drink and apple juice, which have different caloric content, and are independent factors affecting gastric emptying. Additionally, the first ultrasound scan was conducted after six hours of fasting, which differs from previous studies that conducted scans overnight [9].

With this background knowledge, an observational study was conducted to examine gastric contents and volume using USG after at least six hours of fasting, and to compare it with gastric volume two hours after ingesting clear liquids (apple juice and pure complex carbohydrate). This study aimed to determine if oral intake of clear liquids two hours before surgery would be safe in terms of the risk of aspiration. The secondary objective was to evaluate the effects of factors such as age, anxiety, BMI, and the presence of comorbidities like Chronic Kidney Disease (CKD) on gastric emptying, content, and volume using gastric USG.

MATERIALS AND METHODS

The randomised clinical trial was conducted on 100 patients over a period of one year, from January 2019 to January 2020, at Karnataka Institute of Medical Sciences, Hubli, Karnataka, India. The study received approval from the Institutional Ethical Committee (312/2018-19), and written informed consent was obtained from all participants.

Inclusion criteria: Patients between the ages of 19 years and 65 years, classified as ASA grade I and II, of any gender, scheduled for elective surgeries were included in the study.

Exclusion criteria: Obese individuals (BMI >30 kg/m²), pregnant women, patients with abnormal upper gastrointestinal anatomy (previous oesophageal or gastric surgery/hiatus hernia), those with active gastric or duodenal ulcers, upper gastrointestinal bleeding, and diabetes mellitus were excluded from the study. CKD was diagnosed based on patient history and a Glomerular Filtration Rate (GFR) less than 60 mL/hr.

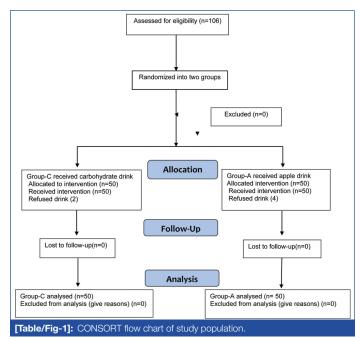
Sample size calculation: Based on previous literature [9], the mean Residual Gastric Volume (RGV) eight hours after Nil Per Oral (NPO) was 13.56 mL (13.25 mL), and two hours after ingesting oral CHO, it was 16.32 mL (11.78 mL), with a mean standard deviation of 5.77 mL. Assuming a correlation coefficient (r) of 0.9 between the two measurements and aiming to reject the null hypothesis that the difference between the two is zero with a power of 0.9 and a Type-I error probability of 0.05, a minimum of 46 subjects in each group was required. Therefore, the total sample size was calculated to be 92, rounded upto 100.

Procedure

The patients were randomly assigned to two groups using computergenerated numbers. The patient and anesthesiologist were aware of the patient's group allocation, but the radiologist remained blinded.

The two groups were as follows:

- Group 1 (CHO group, Group-C),
- Group 2 (apple juice group, Group-A) [Table/Fig-1].



Group-C: Carbohydrate drink (300 mL) containing the following contents (50 gm providing 200 kcal, with a total carbohydrate content of 50 gm and 6 gm of sugar)+100 mL water.

Group-A: Apple juice (300 mL)+100 mL water.

Patients were instructed to fast for six hours. Each patient underwent abdominal ultrasound twice for quantitative and qualitative analysis of gastric contents. The first ultrasound was performed and data were recorded after six hours of fasting following a light breakfast. Immediately after the ultrasound evaluation, the patients drank 400 mL of either apple juice or oral CHO solution, based on their group allocation. The drink was supervised by a research student anaesthesiologist. A second ultrasound was conducted two hours after consuming the solution. Prior to the ultrasound, each patient's anxiety level was assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) questionnaire, which utilises a five-point Likert Scale (1-never; 2-low; 3-moderate; 4-strong; 5-extreme). A cut-off value of >13 was considered significant for preoperative anxiety [10].

The ultrasound assessment of gastric contents was performed by a qualified radiologist using a Philips IU 22 or Philips HD 15 portable ultrasound machine [11]. A convex probe (2-7.5MHz) was used, and patients were initially examined in the supine position, followed by the RLD position. A sagittal plane scan of the epigastrium was conducted, with the transducer moving from the left to the right subcostal margins. The gastric antrum was identified just below the left lobe of the liver and pancreas, with the aorta/superior mesenteric artery acting as important landmarks [Table/Fig-2].





Based on qualitative analysis of the antrum, patients were classified as follows:

Grade-0: Empty antrum in both supine and RLD positions, indicating an empty stomach.

Grade-1: Presence of liquid observed only in RLD position, suggesting a small amount of fluid in the stomach.

Grade-2: Presence of liquid content in both supine and RLD positions, indicating increased gastric volume [8].

For quantitative analysis, the ACSA was measured using the technique originally described by Bolondi L et al., [11] and subsequently by Perlas A et al., utilising the outer wall of the stomach [12]. ACSA was measured in RLD using two perpendicular diameters: Antero-Posterior (AP) and Craniocaudal (CC).

ACSA={(CC×AP)× π]/4.

Using a π -value of 3.14.

After calculating ACSA, the estimated total volume of the stomach (referred to as "expected volume") was determined for each subject using a mathematical model [12]. The stomach volume (in mL) was calculated as follows: Stomach volume=27+14.6×ACSA (in cm²)-1.28×age (in years).

By calculating the expected volume, the relationship between volume and weight (vol/wt) of the patients was obtained. In adults, if the volume is <100 mL or <1.5 mL/kg, it is generally assumed that the patient is at a low risk of aspiration [7].

STATISTICAL ANALYSIS

The data were analysed using the SPSS for Windows statistical package (version 20, IBM, USA). Chi-square test, t-test, Mann-Whitney test, and paired t-test were used for data analysis. A p-value of less than 0.05 was considered significant.

RESULTS

A total of 106 patients were initially enrolled in the study, but 6 patients dropped out. The demographic profile and anxiety scores were comparable between the two groups, as shown in [Table/Fig-3].

Patients characteristics	Group-A (N=50)	Group-C (N=50)	p-value	
Age (years)	41.04 (9.96)	39.94 (11.33)	0.607	
Gender ratio (M:F)	31:19	26:24	0.313	
BMI (kg/m ²)	24 (3.08)	24.23 (3.61)	0.735	
ASA status				
I	39 (78%)	40 (80%)	0.882	
Ш	11 (22%)	10 (20%)	0.002	
APAIS score	10.48 (4.32)	9.94 (4.13)	0.462	
[Table/Fig-3]: Demographic profile of both groups. Chi-square test p-value <0.05 considered significant				

[Table/Fig-4] compares the ACSA and GRV between the two groups. In the apple group, statistical analysis indicated a significant difference in ACSA (2.23 cm²±0.93 versus 2.40 cm²±1.33) and GRV (9.35 mL±9.08 versus 11.71 mL±15.23) between the two time points (after six hours of fasting and two hours after liquid intake). Similarly, in the CHO group, statistical analysis indicated a significant difference in ACSA (2.20 cm²±0.89 versus 2.40 cm²±1.38) and GRV (9.41 mL±9.11 versus 12.22 mL±15.77) between the two time points.

	6-hours NPO Mean (SD)	2-hours after intake Mean (SD)	p-value	
	Group	o-A (N=50)		
ACSA in cm ²	2.23 (0.93)	2.40 (1.33)	0.037#	
GRV in ml	9.35 (9.08)	11.71 (15.23)	0.047#	
Group-C (N=50)				
ACSA in cm ² 2.20 (0.89) 2.40 (1.38) 0.021*				
GRV in mL	9.41 (9.11)	12.22 (15.77)	0.025#	
p-value	0.975	0.870		
[Table/Fig-4]: ACSA and GRV comparison after NPO for 6-hours and 2-hours after intake. Paired samples t-test, p-value <0.05 considered significant				

In non-CKD patients, the mean GRV in Group-A after six hours of fasting was 7.7±7.23 mL, and after 2 hours of fluid intake, it was 7.71±8.92 mL, which was not significant (p-value=0.924). In Group-C, the mean GRV after six hours of fasting was 8.01±7.58 mL, and after 2 hours of fluid intake, it was 8.49±9.47 mL, which was also not significant (p-value=0.3). However, there was a significant increase in GRV in CKD patients, as shown in [Table/Fig-5].

СКD	6-hours NPO Mean (SD)	2-hours after intake Mean (SD)	p-value
	Group-A (Apple juic	e) (N=50)	
CKD present (n=5)	23.73 (12.13)	47.68 (13.09)	0.002#
CKD absent (n=45)	7.75 (7.23)	7.71 (8.92)	0.924#
p-value [@]	<0.0001	<0.0001	
Group-C (CHO) (N=50)			
CKD present (n=4)	25.47 (11.0)	55.04 (7.59)	<0.001#
CKD absent (n=46)	8.01 (7.58)	8.49 (9.47)	0.307#
p-value [@]	<0.0001	<0.0001	
[Table/Fig-5]: GRV between two groups.			

*paired sample t-test, "t-test used to calculate p-value; p-value <0.05 considered significant

There was an increase in Perlas grading after clear liquid intake. In Group-A, 4% of patients moved from Grade-0 to Grade-1 after two hours of fluid intake, and in Group-C, 12% of patients moved from Grade-0 to Grade-1 after two hours of fluid intake [Table/Fig-6].

	6-hours NPO	2-hours after intake	p-value	
	Group-A (Apple juice) (N=50)			
Grade-0	34 (68%)	32 (64%)		
Grade-1	16 (32%)	18 (36%)	0.673#	
Grade 2	0	0		
Group-C (CHO) (N=50)				
Grade-0	40 (80%)	34 (68%)	0.171 [#]	
Grade-1	10 (20%)	16 (32%)		
Grade 2	0	0		
[Table/Fig-6]: Distribution of subjects based on Perlas grading. Chi-square test-p-value, 0.05 was significant				

[Table/Fig-7] shows the association of age with gastric volume, indicating a decrease in gastric volume as age increases.

The association of anxiety and GRV is shown in [Table/Fig-8], demonstrating a significant difference in the change in GRV after fluid intake between patients who are more anxious and less anxious.

 $[\mbox{Table/Fig-9,10}]$ show the association of BMI with gastric volume, indicating an increase in GRV as BMI increases.

Age category	6-hours NPO	2-hours after intake	p-value
Group-A (Apple juice) (N=50)			
18-30 years (n=10)	12.47 (6.79)	13.49 (9.24)	0.332#
31-40 years (n=14)	11.24 (7.28)	12.39 (9.34)	0.202#
41-50 years (n=20)	9.04 (11.06)	12.23 (20.91)	0.214#
51-63 years (n=6)	0.79 (1.94)	5.41 (13.26)	0.363#
p-value [@]	0.062	0.762	
	Group-C (CH	O) (N=50)	
18-30 years (n=14)	12.49 (11.14)	15.31 (18.17)	0.188#
31-40 years (n=17)	12.21 (7.69)	13.52 (13.94)	0.477#
41-50 years (n=10)	6.48 (5.38)	10.95 (14.49)	0.246#
51-63 years (n=9)	2.57 (7.73)	6.35 (17.33)	0.275#
p-value [@]	0.020	0.593	
[Table/Fig-7]: Association of APAIS scores with age.			

^eone-way ANOVA, [#]paired sample t-test used to calculate p-value p-value <0.05 considered significant

APAIS score category	6-hours NPO	2-hours after intake	p-value	
	Group-A (Apple juice)			
13 and less	6.34 (6.77)	6.98 (9.30)	0.507#	
More than 13	15.20 (10.27)	20.87 (20.07)	0.053#	
p-value [@]	<0.001	0.001		
Group-C (CHO)				
13 and less	8.14 (7.50)	9.08 (10.97)	0.265#	
More than 13	12.11 (11.67)	18.87 (21.86)	0.052#	
p-value [@]	0.039	0.039		

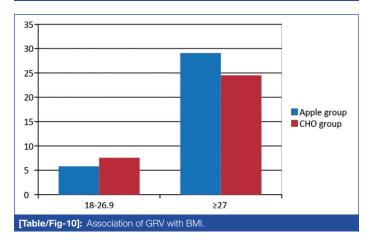
[Table/Fig-8]: Association of APAIS score with GRV. Total N=50 patients in each group; @-t-test, *paired sample t-test used to calculate p-value

-value <0.05 considered significant

BMI	6-hours NPO	2-hours after intake	p-value
Group-C (CHO)			
18-22.9 (n=14)	6.37 (4.67)	5.15 (5.34)	0.179#
23-26.9 (n=24)	7.60 (8.70)	9.97 (15.81)	0.1771#
27 and above (n=12)	16.57 (10.55)	24.52 (17.84)	0.034#
p-value [@]	0.005	0.025	

Group-A (Apple juice)				
18-22.9 (n=17)	7.76 (7.62)	9.05 (13.22)	0.476#	
23-26.9 (n=20)	4.37 (4.44)	2.66 (3.70)	0.009#	
27 and above (n=13)	19.10 (8.93)	29.10 (14.80)	0.003#	
p-value [@] <0.0001 <0.0001				
[Table/Fig-9]: Association of GRV with BMI. *Paired samples t-test, *One-way ANOVA was used to calculate p-values				

p-value <0.05 is considered significant



DISCUSSION

Aspiration of gastric contents is a dreaded perioperative complication that contributes to mortality and morbidity after general anaesthesia. Mendelson CL described aspiration in obstetrics patients 70 years ago in one of the most widely cited articles in medical literature. This study helped in the empirical formation of the 'nothing Per Orally' (NPO) strategy, which recommends fasting for longer than 8-12 hours and has become a standard practice in the name of safety [13]. Studies have shown that prolonged fasting is associated with reduced gastric pH and an increase in gastric volume, placing patients at a higher risk of aspiration [9,14-16]. Current guidelines recommended by the International Society of Anaesthesia (ISA) state that clear liquids can be allowed up to two hours prior to the administration of sedation or anaesthesia. The recommended volume of clear liquid may be restricted to <450 mL, although evidence for this is weak [2].

Clear liquid is defined as any fluid that can be easily digested and cleared from the stomach within two hours [2]. In this study, two clear liquids with different caloric contents were chosen, namely apple juice and a clear complex carbohydrate drink. The carbohydrate drink is an ERAS drink, as recommended in the ERAS protocol. The advantage of this drink is that it allows the patient to be in a metabolically fed state before surgery, which has beneficial effects on reducing insulin resistance and catabolism [1]. A volume of 400 mL of clear liquid was chosen, following the ERAS protocol [17].

Various methods can be used to estimate GRV, such as radiolabeled diets, polyethylene glycol, paracetamol absorption, electrical impedance tomography aspiration by an enteral tube positioned in the stomach, scintigraphy, USG, and Magnetic Resonance Imaging (MRI) [3,9].

Gastric USG is a non-invasive, bedside assessment of GRV. In this study, USG was performed by an expert radiologist. Gastric ultrasound can be done with the patient in a supine and RLD position [18]. The RLD position was chosen as a larger proportion of the stomach's content flows towards the more dependent distal antrum in this position, increasing the test's sensitivity [7]. The gastric antrum, the most distal portion of the organ, was chosen for GRV calculation as it is consistently and superficially located in the epigastric region and is amenable to ultrasound examination [7]. Several mathematical formulas have been used to estimate GRV using ultrasound, with the Perla and Bouvet models being reliable and applicable [6]. Given that the current study was conducted in the RLD position, the Perlas mathematical method was deemed appropriate for calculating stomach volume in this position.

The demographic profile of the current study was comparable to other similar studies and did not show any statistical significance regarding age, gender, height, weight, and BMI (p-value >0.05) [3]. When patients were subdivided into CKD and non-CKD groups, non-CKD patients showed no difference in GRV after fasting for six hours compared to two hours after intake of clear liquids. Additionally, no patient in the present study had a critical residual volume (The critical volume of aspiration is defined as a volume of clear fluid in excess of 1.5 mL/kg) [7]. A study conducted by Gomes PC et al., in 20 healthy volunteers found no difference in stomach volumes after eight hours of fasting and those obtained at 120 and 180 minutes following intake of either 200 or 400 mL of CHO (carbohydrate) or CHO+GLN (glutamine) [9]. Similarly, Bisinotto FM et al., reported no variations in the findings of quantitative evaluation, antral area, stomach volume, and volume/weight ratio at all three measurement intervals in 80 volunteers who underwent gastric ultrasound after an eight-hour fast [8]. Comparable results were noted by Patil MC et al., in a study of 60 ASA I patients scheduled for elective surgery and fasted overnight. The study concluded that allowing 200 mL of clear liquids two hours prior to surgery resulted in lesser residual gastric volume [18].

Patients suffering from CKD have significantly delayed gastric emptying due to uraemia, which can lead to significant gastric volume despite fasting. This puts them at a higher risk of aspiration during anaesthesia [3]. In the study, there were nine CKD patients, all of whom showed a significant increase in gastric volume, although the volume was not significant enough to indicate aspiration.

The two study drinks had different caloric contents: apple juice with 148 kcal and oral CHO (carbohydrate) with 200 kcal. According to Okabe T et al., the caloric content of a drink, rather than its composition, determines gastric emptying. They compared equal volumes of non-human milk and pulp-free orange juice diluted with either gum syrup or water to match the calorie count and found no significant difference in gastric emptying time after consuming an equal number of calories. They also discovered that ingestion beverages that do not exceed 220 kcal were adequately cleared in less than two hours [19]. This finding aligns well with the present study, as the caloric content of our drinks was less than 220 kcal.

In the study conducted by Bisinotto FM et al., eighty volunteers underwent gastric ultrasound three times after an eight-hour fast. They observed an increase in Perlas grading after fluid intake, which is comparable to our study [8].

While other researchers have reported that gastric emptying slows down and GRV increases as patients age [20], the present study found that as age increases, GRV decreases in both groups, with a statistically significant difference in the apple juice group. This discrepancy may be due to the use of the Perlas formula for calculating GRV, which includes age as a negative factor, and the unequal subdivision of age groups, which may act as a confounding factor.

According to a study by Hong JY and Oh JI on the effect of preoperative anxiety on gastric fluid acidity and volume, there were no differences in preoperative gastric pH and volume between highly anxious and low-anxious patients [21]. However, in the present study, as the APAIS score for anxiety increased, there was an increase in GRV. Factors such as CKD and BMI may have acted as confounding factors in this relationship.

An increase in GRV was observed in patients with higher BMI, which is consistent with the findings of Sharma G et al., In their study of 100 patients scheduled for elective surgery, gastric ultrasound showed that as a patient's BMI increases, GRV also increases [3].

Limitation(s)

The fasting status of the patients in this study was based solely on their medical history.

CONCLUSION(S)

Gastric ultrasound is a simple and non-invasive method used to assess the content and volume of the stomach. It proves to be an effective tool for evaluating the risk of aspiration, especially during anaesthesia. The intake of 400 mL of clear liquid two hours before undergoing anaesthesia is considered safe, but careful consideration is needed for individuals with CKD or elevated BMI. However, to ensure a more accurate assessment in CKD patients, a larger sample size is essential.

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AUTHOR DECLARATION:

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- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Mar 21, 2023
- Manual Googling: Jun 08, 2023
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