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Original Article

Comparison of Gastric Volume and pH after Drinking Clear Fluids One and Two Hours before General anesthesia : Rondomized Controlled Trial

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Abstract

Introduction: Gastric residual volume (GRV, >150 ml/kg) can increase the risk of aspiration during general anesthesia (GA). This study aimed to compare GRV and gastric pH in patients admitted for GA who had taken 150 ml of clear fluids 1 and 2 hour (h) prior to surgery.

Methods: This study was conducted among 81 American Society of Anesthesiologists I and II patients aged 18-65 years who underwent elective surgeries under GA. After randomization, the patients were divided into two groups to receive either 150 ml of non-caloric clear fluids 1 or 2 h prior to induction. Gastric volume using sonographic measurement of antral cross-sectional area (CSA), gastric pH, postoperative nausea and vomiting (PONV), and patient satisfaction (Numerical Rating Scale) were assessed. Data was analyzed with an independent t-test, and a Mann-Whitney U test with significance at $P<0.05$.

Results: Antral CSA was comparable between groups. GRV (ml) was significantly higher in the 1 h group than in the 2 h group. The mean GRV indexed to body weight (ml/kg) was 0.840 (0.381) in the 1h group and 0.634 (0.389) in the 2h group. Gastric pH, PONV, and patient satisfaction in 1h group was comparable with 2h group.

Conclusion: The GRV assessed by ultrasonography in patients after 1h of fasting to 150 ml of clear fluids is more than that of 2h fasting, though it did not increase the risk of aspiration as the volume was less than 1.5ml/kg. This demonstrates the safety of clear fluids till 1h prior to general anesthesia.

Introduction

Preoperative fasting in patients undergoing procedures under anesthesia has been an age-old safety practice to reduce the volume of gastric contents and thereby reduce the risk of perioperative aspiration leading to respiratory failure. [1,2] In addition to patient discomfort, the prolonged fasting period increases the risk of dehydration, electrolyte disturbances, hypoglycemia, and an undesired catabolic state. [3] Establishing the safety of a liberal fasting protocol initially with low-volume clear liquids is needed before a change of practice.

The recent worldwide adoption of enhanced recovery after surgery (ERAS) protocols includes goals of minimizing malnourished and catabolic states by decreasing insulin resistance perioperatively. [4] The European preoperative guidelines in pediatric patients recommend clear fluids till 1h prior to induction, and it is safe, and this has been endorsed by several national societies.[5,6] A more liberal fasting protocol for all adult patients other than those with high risk for aspiration will have multilevel benefits.

In an attempt to reduce the starvation hours preoperatively, we aimed to study the safety of drinking 150 ml of clear fluids 1h before surgery as compared to drinking same amount of clear fluids 2h prior to surgery in adult patients who are not high risk for aspiration. If the safety of 1h fasting for clear fluids is established, it can lead to a change in practice regarding preoperative fasting and can enhance patient satisfaction and comfort.

Methods

This was a randomized clinical trial done in a tertiary care medical college from February 2020 to June 2021, after being approved by the Institutional Ethics Committee. Written informed consent was obtained, and the study was conducted on 81 adults of American Society of Anesthesiologists (ASA) class I & II, aged 18-65 years of either sex, scheduled for elective surgery under general anesthesia. This trial followed the principles of Good Clinical Practice and the ethical principles set out in the Declaration of Helsinki 1964 (Revised 2013) and was registered under Clinical Trial Registry India.

Patient and Public Involvement: No patients or public were involved in the design, conduct, reporting, or dissemination plans of this study. The study protocol

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was developed based on clinical expertise and existing literature, with ethical approval ensuring patient safety and informed consent.[8]

To minimize confounding, patients with medical or surgical conditions that may prolong gastric emptying time (diabetes mellitus, end-stage organ dysfunction, critical illness, gastric or esophageal surgery, hiatus hernia) were excluded. Patients with Body Mass Index (BMI) > 30 kg/m^2, current or recent pregnancy (within 3 months), gastroesophageal reflux disease, and patients who were non-adherent to the prescribed fasting guidelines were also excluded. Surgical procedures were limited to elective, non-abdominal surgeries to reduce variability in gastric motility. Sample size was calculated to detect a 30 ml difference in gastric residual volume (GRV) between groups, assuming a standard deviation of 50 ml [8,9,10] with $\alpha = 0.05$ and 80% power, yielding 35 patients per group. We enrolled 40 per group to account for potential protocol violations. A 30 ml difference in GRV was chosen as clinically significant based on prior studies indicating that volumes exceeding 25–30 ml may increase aspiration risk in traditional anesthesiology practice. [11] This threshold was selected to ensure detection of a meaningful difference while maintaining clinical relevance. Preoperative medications (Pantoprazole 40 mg, Ondansetron 4 mg) were standardized.

Primary outcome measures were the gastric residual volume and gastric pH after 1h of clear non-caloric fluids compared with those after 2h. Secondary outcome measures were self-reported patient satisfaction and postoperative nausea and vomiting. Randomization balanced baseline characteristics, and analysis of covariance (ANCOVA) was used to adjust for BMI and age in GRV comparisons [7].

On the day before surgery, after obtaining written informed consent, patients were randomly assigned to two groups, A and B, based on computer-generated sets of random numbers (www.random.org). Allocation concealment was achieved using sequentially numbered, opaque, sealed envelopes containing the computer-generated randomization codes. The envelopes were opened by the ward nurse administering the clear fluids, who was not involved in outcome assessment, ensuring that the primary investigator assessing gastric residual volume remained blinded to group allocation.

Patients were pre-medicated with oral Pantoprazole 40mg and Ondansetron 4mg on the night before and on the day of surgery. Neither solid food nor non-clear fluids were allowed for 6h before anesthesia. To ensure similar fasting time for solids and correct fluid fasting time and volume, the study participants were scheduled first or second on the operating theater list and allowed clear fluids according to protocol.

Group A was given 150 ml of non-caloric clear fluids 2h before, and group B was given 150 ml of non-caloric clear fluids 1h before general anesthesia by the ward nurse who was not part of the study. The fasting time to solids and clear fluids was noted. A single investigator, trained in gastric ultrasonography, performed all measurements to eliminate inter-rater variability. Three measurements of antral CSA were averaged to minimize intra-rater error. The primary investigator was trained for the assessment of gastric residual volume (GRV) with ultrasonography and was blinded to the allocation.

Before induction of anesthesia, the GRV was assessed by the primary investigator in all cases. A curved array transducer 2-5 MHz frequency (SonoSite Micromaxx, Fujifilm Sonosite Inc., Bothwell, WA, USA) was used for scanning. The epigastrium was scanned in a sagittal plane, sweeping the transducer from the left to the right subcostal margins. Scanning was first done in the supine position, followed by the right lateral position. The gastric antrum was identified just below the left lobe of the liver and pancreas, with the aorta/superior mesenteric artery acting as landmarks.

A still image of the antrum was then taken between peristaltic contractions in the right lateral decubitus position. Antral cross-sectional area (CSA) was measured from serosa to serosa, including the full thickness of the gastric wall in the sagittal plane. The CSA of the antrum in the right lateral decubitus position was determined by marking the anteroposterior diameter (AP) and converting it to an elliptical measurement. The CSA was measured three times and its numerical average recorded. Based on antral CSA, total gastric fluid volume was calculated using the formula described by Perlas et al.[8,9]

Volume (ml) = 27.0 + 14.6 x right lateral CSA - 1.28 x age.

Anesthetic techniques, including fluids, opioids, and antiemetics, were standardized in both groups. Induction involved intravenous Propofol (2–3 mg/kg), Fentanyl (2 μg/kg), and Vecuronium (0.08–0.1 mg/kg). Airway management was achieved via endotracheal intubation using a cuffed tube, with placement confirmed by capnography and auscultation. Maintenance was with Sevoflurane (1–2%) in an oxygen-air mixture. After intubation, a 16-G Ryle's tube was inserted and its position confirmed by auscultation of the stomach. Gastric content was aspirated through a 10 ml syringe with the patient supine or in a lateral position to get a sample for assessing the gastric pH using pH indicator paper.

The reversal used was Neostigmine (0.05 mg/kg) with Glycopyrrolate (0.01 mg/kg). Extubation was done after full recovery. PONV was assessed at 6 hours postoperatively using the simplified PONV impact scale, as this timeframe captures early postoperative nausea and vomiting, which is most relevant to preoperative fasting effects.[10] Patient satisfaction was sought using a structured questionnaire and assessed using a numerical rating scale (1-5) with 5 showing maximum satisfaction.

Traditional teaching in anesthesiology is that a gastric residual volume of more than 25ml predisposes to pulmonary aspiration during GA.[11] Now the practice is changing to "sip till send" in the preoperative period.[12] It is ideal to assess the safety of drinking clear fluids before a change in practice. A 30 ml difference in GRV was chosen as clinically significant based on prior studies indicating that volumes exceeding 25–30 ml may increase aspiration risk in traditional anesthesiology practice.[11] This threshold

was selected to ensure detection of a meaningful difference while maintaining clinical relevance. The sample size was calculated using the formula for comparing two means

$n = 2 \times (Z\alpha/2 + Z\beta)^2 \times \sigma^2 / \delta^2$,where $Z\alpha/2 = 1.96$ ($\alpha = 0.05$), $Z\beta = 0.84$ (80% power), $\sigma = 50$ ml, and $\delta = 30$ml.

to detect a 30 ml difference in gastric residual volume (GRV) between groups, assuming a standard deviation of 50 ml based on a study by Perlas et al.[8] with $\alpha = 0.05$ and 80% power, yielding 35 patients per group. We enrolled 40 per group to account for potential protocol violations.

All analyses were conducted on a per-protocol population, including only participants who adhered to the fasting protocol. One patient was excluded due to non-conformance (Figure 1) as the surgery was rescheduled. Missing data were minimal and handled by excluding incomplete cases from specific analyses and one participant was excluded. All the data collected were coded and entered in a Microsoft Excel sheet, which was re-checked and analyzed using Statistical Package for the Social Sciences (SPSS) statistical software version 28 (International Business Machines Corporation, New York, USA). The Shapiro-Wilk test was used to assess the normality of the data. All categorical variables were summarized using frequency and percentage and analyzed using the Chi-square test. Continuous variables were summarized, and the mean and standard deviation as data followed the normality assumption. An independent sample t-test was used to compare GRV (ml), GRV (ml/kg), NPO to solids, BMI, and antral CSA of groups A and B. The Mann Whitney U test was used to compare patient satisfaction and gastric pH. $P < 0.05$ was considered statistically significant.

Results

A total of 82 patients were randomized. One patient was excluded from analysis due to non-conformance to the study protocol[13] (Figure 1). The distribution according to age, gender, BMI,and ASA physical status was comparable in both groups. In group A subjects who had normal BMI were 53.7% compared to 45% in group B. Group A had 46.3% overweight individuals, and group B had 55% overweight individuals**.** (Table 1)

The mean value of NPO to solids in hours in group B was 13.02 (1.98) and in group A 13.46 (1.87) ($P = 0.26$). The calculated Gastric Residual volume (GRV) and Gastric Residual volume indexed to body weight are presented in Table 2. Mean antral CSA was 4.61 (1.49) cm^2 in Group A (2h fasting) and 5.16 (1.42) cm^2 in Group B (1h fasting) ($P = 0.059$). The mean value of GRV (mL) in group B is 53.73 (24.49), and in group A is 38.79 (22.09). The distribution of GRV (ml/kg) values in relation to the recorded intervals of fluid fasting is depicted in Figure 2. There was a significant difference between 1h and 2h of pre-anesthetic clear fluid fasting in GRV, with a mean difference of 15.76 ml ($P = 0.005$). (Figure 3) The range of GRV was 84.51ml in group A and 97.78ml in group B. The gastric fluid volume indexed to body weight and gastric pH did not show any significant difference between the two groups. The mean value of GRV (ml/Kg) in group B was 0.83 (0.38), and in group A was 0.63 (0.39).

Quality of induction of anesthesia and recovery, and postoperative nausea and vomiting were not significantly different between groups A and B. Patient satisfaction according to the numerical rating scale was similar between the two groups. None of the patients had perioperative regurgitation or aspiration. There was no respiratory

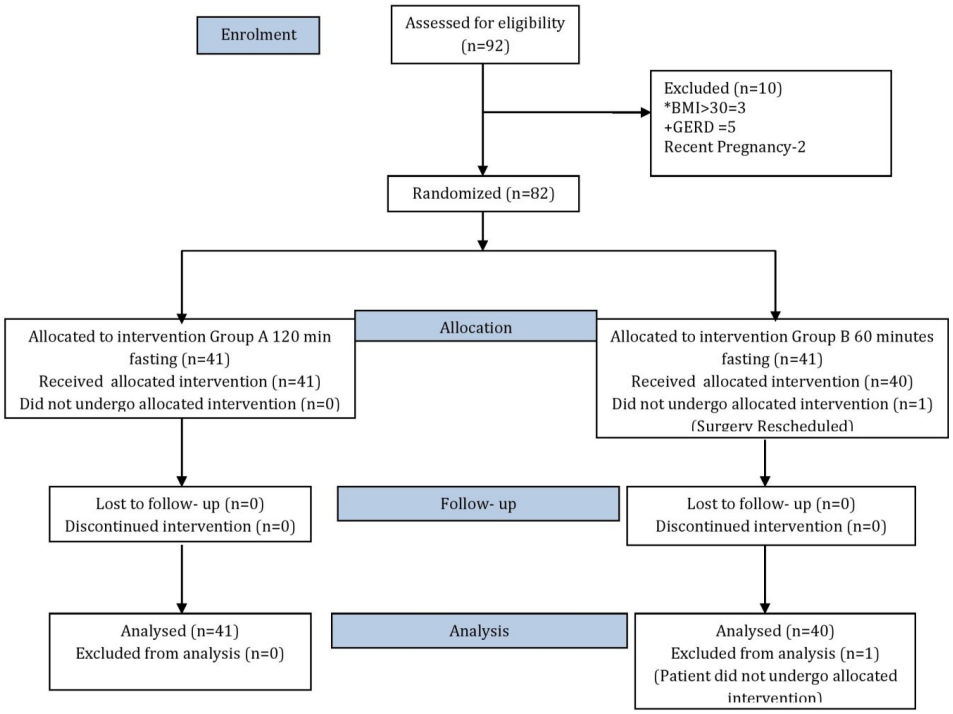

Figure1. Consort Flow diagram (Group A: 2h fasting to clear fluids; Group B: 1h fasting to clear fluids)
*BMI- Body Mass Index; †GERD- Gastro Oesophageal Reflux Disease

Table 1. Patient Demographic data in Group A- 2h and Group B- 1h of clear fluid fasting

	Group A (n=41)	Group B (n=40)	*P* value
Age	43.68 (12.42)	38(12.0)	0.81
Female	29 (70.7%)	32 (80%)	0.33
ǂASA I	31(75.6%)	34 (85%)	0.28
ǂASA II	10 (24.4%)	6 (15%)	0.20
Weight	63.15(9.6)	64.13(7.1)	0.30
Height	160.29 (6.42)	159.4(5.84)	0.27
ǂBMI	24.51(3.01)	25.21(2.49)	0.25
ǂBMI(18.5-24.9) ǂBMI (25-29.9)	22 (53.7%) 19 (46%)	18 (45%) 22 (55%)	0.38
Baseline Antral ǂǂCSA (cm^2)	4.61(1.49)	5.16 (1.42)	0.06
General surgery	9 (21.9%)	12 (30%)	0.40
Laparoscopic surgery	15 (36.5%)	9 (22.5%)	0.16
Gynaecologic surgery	5 (12.1%)	8 (20%)	0.33
Orthopaedic surgeries	5(12.1%)	8 (20%)	0.33
Otorhinolaryngeal surgery	4(9.7%)	2 (5%)	0.41
Urologic surgery	3(7.31%)	1 (2.5%)	0.31

Data presented as Mean (SD), or numbers with percentage.
*SD Standard Deviation, ǂASA- American society of Anaesthesiologists, ǂBMI- Body Mass index, ǂǂCSA- Cross sectional Area

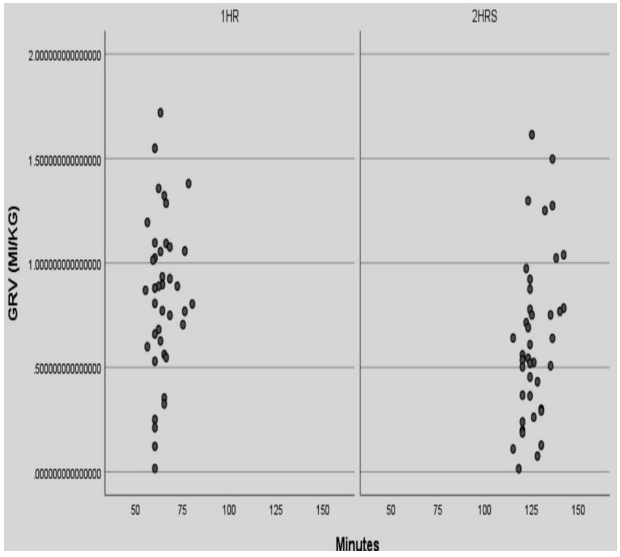

Figure 2. The distribution of Gastric residual volume (GRV) indexed to body weight in relation to recorded intervals of fluid fasting

distress or desaturation during recovery.

Discussion

In our study, 150 ml of clear fluids 1h before induction significantly increased the gastric residual volume when compared to fluids 2h after assessment. The gastric pH, postoperative nausea and vomiting, and patient satisfaction were comparable between the groups.

Current guidelines recommend a preoperative fasting interval of 6 h for light meals and 2h for clear fluids in adults.[1,2] The rationale for the present study to reduce the fasting time is twofold. First, a 2h fasting time translates to a much longer fasting time in practice, and second, this results in considerable patient dissatisfaction and

Table 2. Gastric Residual volume, Gastric pH, PONV and Patient Satisfaction score in Group A-2h and Group B- 1h of clear fluid fasting

	Group A	Group B	95%, ǂC I		*P* Value
			Lower	Upper	
*GRV (ml)	38.79(22.09)	53.73(24.49)	4.53	25.09	0.005
*GRV indexed to body weight (ml/kg)	0.63(0.39)	0.83(0.38)	0.03	0.37	0.02
Gastric pH	3.05(0.22)	3.20(0.40)	0.40	2.03	0.09
ǂPONV	1.5(0.75)	1.70(0.96)	0.10	3.15	0.30
Patient satisfaction (Median)	4 (4-5)	4(4-5)	-	-	0.30

Data presented as Mean (*SD) and Median (IQR 25-75)
*GRV- Gastric Residual Volume, ǂPONV- Post Operative Nausea and Vomiting
ǂC I - Confidence Interval

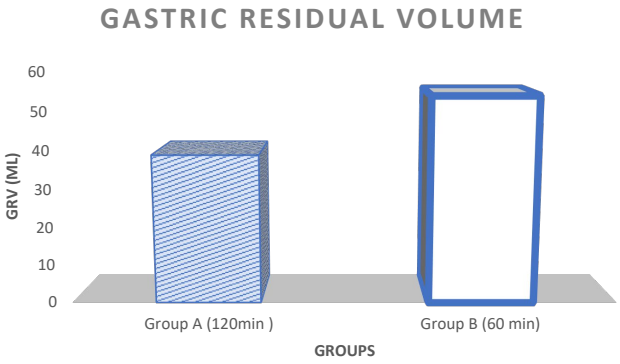

Figure 3. Comparison of Gastric Residual volume (GRV) between Group A- 120 minutes and Group B- 60 minutes of fasting to clear fluids

discomfort. [14,15] Traditionally, values of pH < 2.5 and gastric residual volume > 25ml were supposed to predispose a patient to pulmonary aspiration, hence a strict overnight fasting regimen was instituted.[16] Van de Putt et al. classified patients as empty stomach (no contents or liquid content < 1.5ml/kg) or full stomach (liquid content > 1.5ml/kg or presence of solid contents) on gastric ultrasound.[17] Several other studies show that prolonged withholding of oral fluids does not improve gastric pH or volume, and permitting a patient to drink clear fluids preoperatively may even result in significantly lower gastric fluid volumes.[18,19]

The present study was designed with the aim of assessing the gastric residual volume and pH after intake of 150 ml non caloric clear fluids 1h (group B) and 2h (group A) prior to GA with measurement done using ultrasonography and pH strips. Multiple studies have shown that ultrasonographic assessment of GRV satisfactorily estimates the gastric content. [17] In our study, the mean antral cross-sectional area (CSA) in the 1h group B was 5.16 (1.42) cm^2 which was comparable with the 2h group A 4.61(1.49) cm^2 ($P = 0.059$). The gastric residual volume Group A 38.79 (22.09) vs. Group B 53.73 (24.49) and gastric residual volume indexed to body weight Group A 0.63 (0.39) and Group B 0.83 (0.38) showed a significant difference between the groups. This can be of concern as gastric volume is a major factor in the risk of aspiration. But studies show that healthy fasting patients with residual gastric volumes up to 1.5 ml/kg in adults and 1.25ml/kg in pediatrics are not at an increased risk of aspiration.[20–22] The

GRV in our study was higher in the 1h group than in the 2 h group, but the risk of aspiration was minimal in both groups since the GRV was less than 1.5 ml/kg.

Gastric pH in the 1h group was comparable with the 2 h group, 3.20 (0.40) *vs.* 3.05 (0.22), $P = 0.09$). Schmidt et al. also compared gastric pH after 1h versus 2h of pre-anesthetic clear fluid fasting in children aged 1–16 years of ASA physical status I or II undergoing elective procedures.[23] The study showed no significant difference in mean gastric pH between the 1h group 1.43 (1.30-1.56) *vs.* the 2h group 1.44 (1.29-1.68).

Thirty-eight randomized controlled comparisons (made within 22 trials) in healthy adults showed no significant difference in the gastric pH between groups permitted to shorten the preoperative fluid fasting and those who continued the standard fast.[24]

In our study, neither group had any perioperative nausea or vomiting. This finding is similar to that in the study by Smith and colleagues, which suggested that allowing patients to drink up to 2h preoperatively may make postoperative vomiting less likely.[24] This contrasts with traditional views that suggest a long fast is necessary to prevent postoperative nausea and vomiting. Studies show that a preoperative drink can reduce the incidence of postoperative nausea and vomiting and also reduce the length of hospital stay. This implies that instead of minimizing postoperative vomiting, an extended fast can lead to an increase in postoperative emesis. [25–27] We have given fluids till 1h preoperatively compared to a longer fasting period in these studies, but the incidence of nausea and vomiting was comparable. The preoperative patient satisfaction using the numerical rating scale was also similar between the 2h and 1h fasted groups.

The gastric pH and gastric residual volume are only surrogate parameters for the risk of pulmonary aspiration. By itself, it is not an adequate outcome measure for pulmonary aspiration. Also, a safe and smooth anesthesia technique to prevent regurgitation by coughing, pressing, bucking movements, or hiccups is more important in minimizing the risk of aspiration. The intraoperative hemodynamic stability and fluid management can affect gastric motility. But since the gastric residual volumes were less than 1.5 ml/kg in the study group drinking 150ml of clear fluids 1h before surgery, we argue that the risk of pulmonary aspiration was not increased. Because, in current clinical practice, the recommended fasting period is often exceeded, a reduction in fasting to 1h for clear fluids will improve overall perioperative experience.

The main limitation of this study was that blinding of patients was not feasible. Therefore, we cannot completely exclude bias by the investigator assessing the gastric cross-sectional area. A single assessor has done all the ultrasonography measurements, and an average of three readings in the same patient has been done to decrease the subjective errors. The number of clear fluids given was a constant, irrespective of the weight of the patient, while GRV was assessed indexed to weight. But the two groups had patients with comparable body weight and BMI.

This was a single center study done excluding the patients with high risk for aspiration. Assessing PONV only at 6 hours may miss later episodes, but early assessment aligns with the study's focus on fasting-related outcomes. The concern about intra operative gastric regurgitation and pulmonary aspiration results in patients being kept NPO for considerable lengths of time in our routine practice. As a single-center study, our findings may have limited generalizability due to variations in patient populations, surgical practices, and ultrasound expertise across institutions. Multi-center studies are needed to confirm these results in diverse settings. This study can act as a starting point for further multi-center studies to investigate shorter fluid fasting times than currently recommended by the American Society of Anesthesiologists and the Indian Society of Anesthesiologists, and future research should also analyze whether such a shortened fasting time can optimize preoperative care in all groups of surgical patients.

In this randomized controlled trial, the gastric residual volume assessed by ultrasonography in patients with 1h or 2h fasting to 150ml of non-caloric clear fluids showed an increase in volume in the 1h group. This gastric residual volume was less than 1.5ml/kg and so does not increase the risk of pulmonary aspiration during general anesthesia. There was no difference in gastric pH between the two groups. The patient satisfaction and incidence of nausea and vomiting were comparable.

Conclusion

The gastric residual volume assessed by ultrasonography in patients after 1h of fasting and 150 ml of clear fluids is greater than that after 2h of fasting, though it did not increase the risk of aspiration, as the volume was less than 1.5ml/kg. This demonstrates the safety of clear fluids till 1h before general anesthesia.

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Authors' Contribution

Conceptualization: Linby Chacko, Sara Vergis, Albin Joseph
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Project administration: Sara Vergis
Resources:
Software: Gini M George, Albin Joseph
Supervision: Gini M George, Albin Joseph
Validation: Princy Mol Biju, Albin Joseph
Visualization: Linby Chacko, Gini M George, Sara Vergis
Writing–original draft: Linby Chacko
Writing–review & editing: Linby Chacko, Princy Mol Biju, Sara Vergis

Competing Interests

All authors declare that there is no conflict of interest to disclose

Data Availability Statement

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be

shared after approval as per the authors' institution policy.

Ethical Approval

There are no ethical concerns related to this study. The study was conducted in accordance with ethical guidelines and was approved by the institutional ethics committee (MOSC/IEC/393/2019). Written informed consent was obtained from the patient.
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Institutional Ethics Committee approved - MOSC/IEC/393/2019
Member Secretary – Dr Sandhya Kurup
Name of Institution – MOSC Medical College, Kolenchery, Kerala, India - 682311

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