Original Article

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Anaesthesia Section

Gastric Volume in Diabetic Patients after Overnight Fasting vs Clear Liquid Ingestion Two Hours before Surgery using Ultrasonography: A Randomised Clinical Trial

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ABSTRACT

Introduction: Perioperative gastric aspiration poses risks such as aspiration pneumonia, prolonged hospital stays, and increased mortality. Fasting guidelines may not adequately address the needs of diabetic patients due to the delayed gastric emptying often observed in this population.

Aim: To assess residual gastric volume in diabetic patients who fasted overnight versus those who ingested water preoperatively using ultrasound.

Materials and Methods: A randomised clinical trial enrolled 50 diabetic patients undergoing elective surgery. Patients were randomised into two groups: fasting overnight or receiving water preoperatively. Gastric ultrasound was used to measure antral dimensions and calculate gastric volume. The parameters studied included residual gastric volume in diabetic patients in the Right Lateral Decubitus (RLD) position, antral Cross-Sectional Area (CSA) in the semi-sitting position among diabetic patients, and antral CSA in the RLD position among diabetic patients. Statistical analysis involved descriptive statistics for continuous variables and Chi-square tests for categorical variables, with significance set at p-value <0.05.

Results: The study enrolled 50 diabetic patients, with 25 in group A and 25 in group B. The mean age of patients in group A was 49.3±11.7 years, while in group B, it was 58.6±9.8 years. In the RLD position, the mean Craniocaudal (CC) diameter showed no significant difference between the two groups. However, the mean Anteroposterior (AP) diameter was higher in group B compared to group A, showing a statistically significant difference (p-value=0.012). Similarly, the mean CSA was significantly higher in group B compared to group A. Regarding gastric volume in the RLD position, the mean volume showed no significant difference between the two groups (p-value=0.342). In the semi-sitting position, the mean CC diameter and AP diameter between the two groups, although not statistically significant, were slightly higher in group B. The mean CSA in group A and group B showed a statistically significant difference.

Conclusion: Preoperative intake of clear fluids two hours before surgery showed no significant increase in gastric volume in diabetic patients compared to overnight fasting, as evidenced by ultrasound measurements.

Keywords: Diabetes mellitus, Gastrointestinal emptying, Liquid diet

INTRODUCTION

Gastric aspiration, which involves the inhalation of stomach contents into the respiratory tract, poses significant risks during the perioperative period. These risks include hypoxia, bronchospasm, pneumonitis, pneumonia, acute respiratory distress syndrome, and mortality. Aspiration pneumonia in surgical patients significantly increases the risk of intensive care admission by a factor of 4.0 and extends hospital stays by an average of nine days. Additionally, it is associated with a substantial 7.6-fold increase in the risk of in-hospital mortality [1].

The presence of gastric contents before anaesthesia induction is a significant risk factor for perioperative pulmonary aspiration [2-4]. While preoperative fasting aims to reduce this risk, existing guidelines often lack specificity, especially for patients at increased risk due to conditions such as diabetes mellitus, Gastroesophageal Reflux Disease (GERD), morbid obesity, pregnancy, or recent opioid use [5-7]. Diabetic patients frequently experience autonomic dysfunction, which can lead to gastropathy characterised by conditions such as gastroparesis, resulting in delayed gastric emptying. This condition increases their susceptibility to aspiration, posing a higher risk compared to the general population [8].

Interventions to prevent aspiration include optimising anaesthesia and surgery timing, choosing regional versus general anaesthesia, utilising specific induction techniques, managing the airway, and adhering to preoperative fasting protocols.

Traditional fasting protocols have historically advised refraining from oral intake after midnight, although recent guidelines suggest allowing clear fluids upto two hours before surgery. However, evidence indicates that prolonged fasting can result in increased gastric volume and discomfort for patients [9].

Gastric Ultrasound (USG) has emerged as a valuable tool for qualitatively and quantitatively assessing residual gastric volume, assisting in determining the best timing for elective procedures, planning anaesthesia, and managing the airway [10,11]. It provides a convenient and reliable method for assessing gastric volume. This modality is known for its simplicity, accessibility, non invasiveness, and ease of use, with consistent reliability across different observers [12].

Despite the presence of preoperative fasting guidelines, significant knowledge gaps remain regarding their applicability and efficacy, particularly among diabetic patients. Current guidelines lack specificity in recommending fasting durations tailored to individuals

with conditions like delayed gastric emptying, which is common in diabetic patients, leading to uncertainty in perioperative management. Furthermore, the potential role of gastric ultrasound in assessing residual gastric volume and guiding perioperative decisions is largely unexplored in diabetic populations following various fasting protocols.

This study aimed to address these gaps by investigating residual gastric volume in diabetic patients after overnight fasting and water intake two hours before surgery. By examining the effectiveness of current fasting protocols and the role of gastric ultrasound in perioperative care, this research aims to refine evidence-based practices tailored to diabetic patients, ultimately improving patient safety and outcomes.

Objectives

Primary objective:

- To compare the residual gastric volume in diabetic patients in the RLD position.

Secondary objectives:

- To compare the antral CSA in the semi-sitting position among diabetic patients.
- To compare the antral CSA in the RLD position among diabetic patients.

MATERIALS AND METHODS

This prospective double-blinded Randomised Controlled Trial (RCT) was conducted in a tertiary care setting at Chettinad Hospital between August 2023 and January 2024. The study received approval from the Institutional Human Ethics Committee (Ref No: IHEC-I/1984/23) and was registered with the Clinical Trials Registry of India (CTRI) (CTRI2023/07/055882). For each subject, written informed consent was obtained. The study included 50 diabetic patients aged between 30 and 70 years, with a definitive diagnosis of Type 2 Diabetes Mellitus (T2DM) for more than five years, undergoing elective surgeries.

Inclusion criteria: Patients meeting the inclusion criteria, including both sexes, with American Society of Anaesthesiologists (ASA) Classes II and III, and scheduled for elective surgeries, were eligible for participation.

Exclusion criteria: included pregnancy, cardiac or renal dysfunction, hypothyroidism, obesity (BMI >35 kg/m^2), digestive system diseases including gastro-esophageal reflux peptic ulcer, digestive system tumours, cholelithiasis, or a history of upper gastrointestinal surgery, use of anti-emetic drugs or medications affecting gastrointestinal motility, pre-operative gastrointestinal decompression or nutrition, un-willingness to participate, and ASA Class IV status were excluded from the study.

A total sample size of 50 patients was calculated based on a previous study conducted by Patil MC and Prajwal V with 25 patients in each group [9]. The sample size was calculated for the two independent study groups for continuous variables for a cross-sectional comparative study.

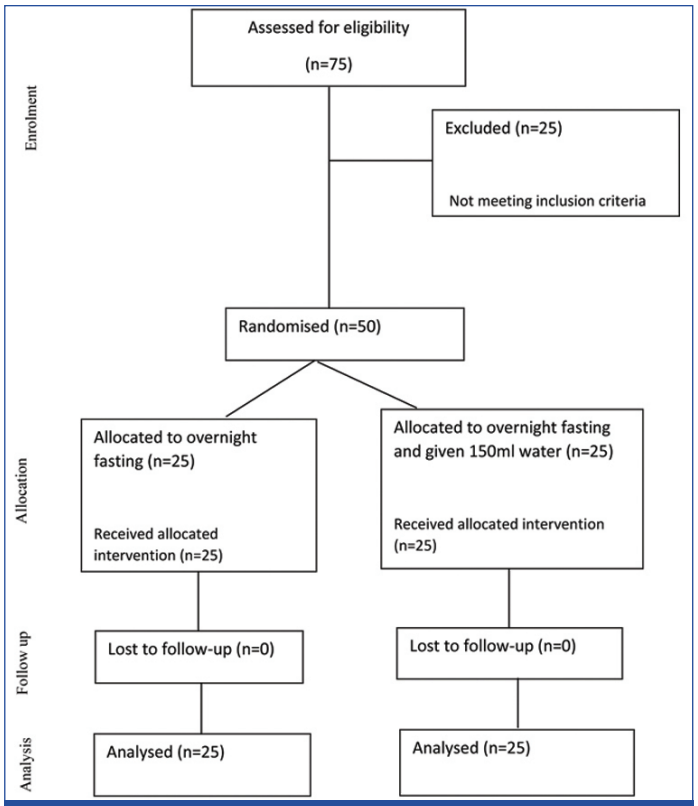
Study Procedure

In a previous study, the mean and standard deviation for gastric volume by USG were 29.7±8.0 in patients in the overnight fasting group and 19.2±4.9 in patients receiving 200 mL of clear fluids two hours before surgery based on the study conducted by Patil MC and Prajwal V [9]. The present study aimed to compare the measure of gastric volume between the two groups of diabetic patients: those who fasted overnight and those who ingested water two hours preoperatively for elective surgeries.

Alpha error was taken as 0.01, beta- 0.01;

- k=n2/n1=1
- n1=(σ12+σ2 2/K) (z1-α/2+z1-β) 2/Δ2
- Δ=|μ2-μ1|=absolute difference between two means
- σ1, σ2=variance of mean #1 and #2
- n1=sample size for group #1
- n2=sample size for group #2
- α=probability of type I error=2.58 at 99% CI
- β=probability of type II error
- z=critical Z value for a given α or β
- k=ratio of sample size for group #2 to group #1
- n1=20 samples in overnight fasting group ~ 25
- n2=20 samples in 2 hrs before elective surgeries group ~ 25
- Hence, the total sample size will be 50.

Patients eligible for intervention were split into two groups at random using a computer-generated randomisation table [Table/Fig-1]. The participants were divided into two groups using a randomised procedure that combined computer-generated numbers with the sealed envelope method.



[Table/Fig-1]: CONSORT diagram.

Random Number Generation:

Each potential study participant is assigned a unique identifier through computer-generated random numbers. These identifiers serve to ensure unbiased allocation throughout the study.

Preparation of Sealed Envelopes:

Subsequently, sealed envelopes are meticulously prepared, each containing the assigned study group for a participant. The envelopes, opaque and securely sealed, safeguard confidentiality and prevent any potential bias during allocation.

Allocation of Study groups:

- A sealed envelope containing a slip of paper with the allocated research group was unsealed once the subject was moved into the operating room.
- To ensure impartiality and blinding, this task was completed by an anaesthesiologist who was not participating in the research.

- The opened envelope determined the group to which the participant belonged-either group 1 (diabetic patients who fasted for 8 hours overnight) or group 2 (diabetic patients who fasted overnight and received 150 mL of water 2 hours preoperatively).

Group 1 consisted of diabetic patients who fasted for eight hours overnight, while group 2 included diabetic patients who fasted overnight and received 150 mL of water two hours preoperatively. Both patients and performers were blinded to group assignment.

Preoperatively, patients underwent physical and systemic examinations, and relevant investigations were conducted. Intravenous (i.v.) lines were secured, and on the day of surgery, patients were shifted to the preoperative room for focused gastric ultrasound performed before the induction of anaesthesia by a clinician blinded to the study group. The study employed a low-frequency (2-5 MHz) curved array ultrasonic transducer on subjects while they were semi-sitting and in the RLD posture. Utilising anatomical landmarks, the gastric antrum was identified in the epigastrium, and measurements of its AP and CC dimensions were taken in each orientation.

Using the formula for area, CSA=(AP×CC×ϖ)/4, two perpendicular diameters, AP and CC, were used to compute the CSA.

Using the previously established formulas and taking into account the patient's position, the gastric volume was computed as follows with the equation proposed by Perlas A et al., for the right lateral position [13]:

Gastric residual volume (mL)=27.0+{14.6×right-lateral CSA (cm^2)}-(1.28×age)

We employed the following categorisation by Perlas A et al., Van de Putte P, and Perlas A to determine the aspiration risk [13,14]:

(a) Patients with an empty antrum or those with a stomach residual volume of less than 1.5 mL/kg are considered to be at low risk of aspiration.

(b) Patients with solid contents or those with a stomach residual volume more than 1.5 mL/kg are at high-risk of aspiration.

Various parameters including age, sex, height, weight, BMI, and ASA grade were recorded. Quantitative assessments of CC and AP diameters, CSA were noted in both RLD and semi-sitting positions, whereas gastric volume was noted in the RLD position only.

STATISTICAL ANALYSIS

Data entry was performed in Microsoft Excel 2013, ensuring accuracy and double-checked for errors. Subsequently, the data was exported to Statistical Package for Social Sciences (SPSS) version 21.0 for analysis, where descriptive statistics for continuous variables and Chi-square tests for categorical variables were employed, with significance set at $p<0.05$. In addition to Chi-square tests for categorical variables, t-tests were utilised for analysing continuous variables where applicable. Results were presented through tables and bar charts.

RESULTS

Out of the 50 diabetic patients enrolled, 25 were randomised to group A and 25 to group B. In group A, patients fasted for eight hours overnight, while in group B, patients fasted overnight and received 150 mL of water two hours preoperatively. [Table/Fig-2] shows the measurement of CC and AP Diameters for calculating gastric antrum CSA in a USG.

In [Table/Fig-3], the demographic variables between group A and B were compared. The mean age of patients in group A was 49.3±11.7 years, while in group B, it was 58.6±9.8 years.

[Table/Fig-4] illustrates the comparison of gastric parameters between the two groups in the RLD position. The mean CC diameter showed no significant difference between the groups. However, the mean AP diameter and CSA were higher in group B compared to group A, with statistically significant p-values of 0.012 and 0.044, respectively. Nonetheless, there was no significant difference in gastric volume between the two groups, with a p-value of 0.342.

[Table/Fig-2]: Measurement of Craniocaudal (CC) and Anteroposterior (AP) Diameters for Calculating Gastric Antrum Cross-Sectional Area (CSA) in a USG.
AA: Craniocaudal diameter; BB: Anteroposterior diameter

Demographic variables		Group A	Group B	Total	p-value
Age Group (Years)	30-40	5 (20)	1 (4)	6 (12)	0.108
	40-50	9 (36)	5 (20)	14 (28)	
	50-60	6 (24)	9 (36)	15 (30)	
	>60	5 (20)	10 (40)	15 (30)	
Sex[a]	Female	16 (64)	14 (56)	30 (60)	0.564
	Male	9 (36)	11 (44)	20 (40)	
ASA grade	II	15 (60)	15 (60)	30 (60)	-
	III	10 (40)	10 (40)	20 (40)	
Body mass index[b]		28±3.6	26.7±3.7		0.102

[Table/Fig-3]: Distribution of demographic variables in both groups.
[a]Chi-square test; Used for categorical variables; (e.g., Age group, Sex, ASA Grade)
[b]Independent t-test: Used for continuous variables (e.g., BMI). Statistical

Ultrasonography (USG) parameters	Group A	Group B	T value	p-value
Craniocaudal diameter (cm)	3.2±0.5	3.3±0.4	-0.16	0.437
Anteroposterior diameter (cm)	2.5±0.4	2.8±0.5	-2.346	**0.012**
Cross-sectional area (cm^2)	6.4±1.8	7.4±2.2	-1.745	**0.044**
Gastric volume	56.9±18.6	59.5±25	-0.41	0.342

[Table/Fig-4]: Comparison of USG parameters in RLD between the groups.
$p<0.05$ statistically significant

In the semi-sitting position, the mean CC diameter and the mean AP diameter were found to be insignificantly higher in group B compared to group A (p-value=0.053 and p-value=0.075, respectively). The mean CSA showed a statistically significant difference between the groups (p-value=0.030) as shown in [Table/Fig-5].

USG parameters	Group A	Group B	T value	p-value
Craniocaudal diameter (cm)	2.9±0.4	3.1±0.6	-1.463	0.075
Anteroposterior diameter (cm)	2.3±0.5	2.5±0.6	-1.647	0.053
Cross-sectional area (cm^2)	5.2±1.6	6.3±2.3	-1.93	**0.030**

[Table/Fig-5]: Comparison of USG parameters in semi sitting between the groups.
Independent sample t-tests, where $p<0.05$ is considered statistically significant

DISCUSSION

The mean age of patients in group A was 49.3±11.7 years, while in group B, it was 58.6±9.8 years. Patil MC and Prajwal V demonstrated relatively younger participants overall, while the present study exhibited a wider age gap between group A and group B, with a higher mean age for group B [9]. Additionally, Haramgatti A et al., and Paidimuddala Y et al., reported mean ages consistent with this study, although with a slight female preponderance [15,16]. These variations highlight the importance of considering age distributions

in interpreting study results and may reflect differences in patient populations and inclusion criteria across studies.

The diverse allocation of participants across studies, ranging from diabetic versus non-diabetic groups to hydration status differentiation, reflects the multifaceted nature of preoperative research objectives [9,15-20]. While the present study uniquely focused on preoperative hydration status in diabetic patients, this approach shows the importance of considering specific patient cohorts in optimising perioperative care protocols.

The comparison of gastric volumes across studies reveals significant variations in findings. In the present study, preoperative clear fluids intake two hours before surgery led to increased gastric volume in diabetic patients compared to overnight fasting, as observed through ultrasound measurements, though the difference was not statistically significant. This finding contrasts with Joshi Y and Dhamija S study, where the 2-hour fasting group with clear apple juice exhibited significantly lower gastric volume, supporting guidelines advocating for shorter fasting durations [17].

Additionally, Patil MC and Prajwal V reported a statistically significant reduction in gastric volume in patients receiving clear fluids before surgery compared to overnight fasting, while Haramgatti A et al., demonstrated higher gastric volumes in diabetic individuals compared to non-diabetics, consistent with findings by Garg H et al., and Khan SA et al., [9,15,18,19]. Furthermore, Bisinotto FMB et al., found varying proportions of increased gastric volume in healthy volunteers across different volumes of isotonic saline solution, highlighting the complexity of gastric volume dynamics [20]. However, the present study focused on diabetic patients and their pre-hydration status, contributing to the broader understanding of gastric volume regulation in clinical practice.

Comparing the findings of this study with those of Haramgatti A et al., and Garg H et al., notable differences and similarities emerge across various parameters [15,18]. In the semi-sitting position, Haramgatti A et al., reported higher CC and AP diameters in diabetic participants compared to non-diabetic participants, whereas CSA was significantly higher in the diabetic group [15]. The present study reported higher CC, AP diameters, and CSA in patients receiving preoperative fluid intake two hours before surgery, with CSA showing a significant difference between groups.

In the RLD position, Haramgatti A et al., reported higher CC, AP diameters, and CSA in diabetic individuals compared to non-diabetics, consistent with Garg H et al., aligning with the trend observed in the present study [15,18]. However, this study did not find a statistically significant difference in CC between the two groups in the RLD position, unlike the significant differences reported by Haramgatti A et al., and Garg H et al., [15,18]. These variations highlight the importance of considering patient positioning and diabetic status in interpreting antral dimensions and emphasize the need for further research to elucidate the underlying factors contributing to these differences.

Thus, the current study provides valuable insights into the demographics, group allocation, gastric volume, and antral dimensions among diabetic patients undergoing pre-operative hydration. The differences and similarities observed in comparison with existing literature highlight the complexity of patient management and show the need for tailored approaches in clinical practice. Clinicians should consider individual patient characteristics and study findings when devising management strategies for diabetic patients undergoing preoperative hydration.

Limitation(s)

Limitations include a single-center setting, which may restrict diversity in patient demographics. Additionally, the study lacks long-term follow-up to assess post-operative outcomes or complications related to gastric aspiration.

CONCLUSION(S)

Pre-operative clear fluids intake two hours before surgery showed no significant increase in gastric volume in diabetic patients compared to overnight fasting, as evidenced by ultrasound measurements. This emphasises the importance of considering pre-operative hydration status in peri-operative management strategies for diabetic patients. Additionally, the observed differences in antral dimensions between the two groups suggest potential implications for gastric physiology and peri-operative outcomes, warranting further investigation and tailored approaches in clinical practice.

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