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Original Research Article

Preoperative evaluation of gastric contents and volume using ultrasound in patients with well- controlled and poorly-controlled diabetes mellitus: An observational, cross–sectional study

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Abstract

Background and Aims: Aspiration of gastric contents during anaesthesia induction is a critical concern, particularly in diabetic patients who are at risk of delayed gastric emptying due to autonomic neuropathy. The degree of glycemic control may influence gastric motility and, consequently, the gastric volume and contents. Point-of-care ultrasonography (USG) has emerged as a non-invasive, reliable tool for assessing gastric contents and predicting aspiration risk preoperatively. This study aimed to evaluate the gastric contents and volume in patients with well-controlled and poorly controlled diabetes mellitus using bedside ultrasonography (USG) to assess the risk of aspiration during the induction of anaesthesia.

Materials and Methods: Sixty adult participants were categorized into two groups: well-controlled diabetes (HbA1c < 8%) and poorly controlled diabetes (HbA1c ≥ 8%), with 30 patients in each group. After overnight fasting of 8 hours, gastric ultrasonography was performed to measure the antral cross-sectional area (CSA) in supine and right lateral decubitus positions and to determine the nature of gastric contents. Patients with gastric contents exceeding safe thresholds or solid content were flagged for potential rapid sequence induction.

Results: Poorly controlled diabetics exhibited significantly larger gastric antral CSA and volumes compared to well-controlled diabetics ($p < 0.0001$). The CSA exceeded the critical threshold of 340 mm² in poorly controlled diabetics, indicating a heightened aspiration risk. In contrast, well-controlled diabetics demonstrated CSA and gastric volumes within safe limits.

Conclusion: Preoperative gastric ultrasonography highlighted a greater aspiration risk in poorly controlled diabetics due to larger gastric volumes and contents. This assessment can guide perioperative anaesthesia management, emphasizing the need for tailored induction strategies in this population.

Keywords: Aspiration, Diabetes mellitus, Gastric content, Ultrasound, Point-of-care.

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1. Introduction

India, with its vast aging population that has been steadily growing over time due to improvements in economic status, lifestyle changes, and enhanced access to healthcare, has witnessed a rise in the prevalence of chronic diseases like diabetes mellitus (DM) and hypertension (HTN).[1]

DM is a metabolic disorder affecting multiple organ systems and resulting in abnormally high blood glucose levels. One significant complication of DM, stemming from autonomic dysfunction, is delayed or insufficient gastric emptying. Such individuals often have increased gastric content volumes even when presumed to have adequately fasted. Prolonged gastric emptying has been reported in approximately 4.8% of type 1 diabetics and 1% of type 2 diabetics.[2]

Aspiration of gastric contents into the lungs during general anaesthesia is a serious perioperative risk, associated with a very high mortality rate.[3] According to the UK National Audit Project 4, aspiration of gastric contents is the most frequent cause of death related to airway management.[4]

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Bedside preoperative point-of-care gastric ultrasound (GUS) has emerged as a valuable screening tool to determine gastric volume (GV) in the fasting state. This is particularly relevant in diabetic patients, who may exhibit increased gastric volumes despite adhering to standard fasting protocols.[5]

To date, the effects of DM control (well-controlled versus poorly controlled) on gastric contents and gastric volumes following fasting have not been comprehensively addressed in the literature. Additionally, there is no consensus on the optimal fasting period to minimize aspiration risk in diabetic patients.[6]

This study aimed to utilize bedside preoperative point-of-care GUS as a screening tool to evaluate gastric contents and gastric volumes in well-controlled and poorly controlled diabetic patients following stipulated fasting times. By assessing whether these volumes fall within recommended safe limits, the study sought to provide insights into aspiration risk during the induction of general anaesthesia.

2. Materials and Methods

This cross-sectional observational study was conducted from December 2020 to October 2022, after obtaining approval from the Scientific Board and the Institutional Ethics Committee (IEC Protocol # YEC2/662). Written informed consent was obtained from all participants. The study included 60 adult patients with type 2 diabetes mellitus, aged 18 years or older, of either gender, and classified as American Society of Anaesthesiologists (ASA) physical status II or III. All patients were scheduled for elective procedures after an 8-hour overnight fast. Patients were excluded if they were pregnant, on medications affecting upper gastrointestinal (GI) motility (e.g., metoclopramide, loperamide, cisapride, antidepressants), had a history of esophageal or upper GI surgeries, were morbidly obese, unable to lie in the right lateral position, or had medical conditions influencing GI motility (e.g., thyroid disorders, chronic kidney disease, connective tissue disorders).

The patients were divided into two groups based on glycemic control using HbA1c levels: Group A comprised individuals with well-controlled diabetes (HbA1c <8%), and Group B included patients with poorly controlled diabetes (HbA1c ≥8%), with 30 participants in each group. Sample size was calculated using G*Power software, with parameters set at a 5% level of significance (α), 85% power (1-β), standard effect size (d) of 0.8, and a 95% confidence interval based on the study by Sharma G et al.[7]

On the morning of surgery, patients were advised to withhold insulin or oral hypoglycemic agents. After 8 hours of fasting, blood glucose levels were measured. No premedications were administered. A detailed medical history was obtained, including coexisting illnesses, medication use, diabetes duration, glycemic management, and symptoms of gastropathy. Physical examinations and required investigations were conducted, and patient characteristics, such as age, weight, height, BMI, and ASA classification, were recorded.

Gastric ultrasound (GUS) was performed in the preoperative holding area using a Sonosite M-Turbo® portable ultrasound machine with a curved array, low-frequency (2–5 MHz) probe. In the supine position, the epigastrium was scanned sagittally, moving from the left to the right subcostal margins, with anatomical landmarks including the aorta, superior mesenteric artery, inferior vena cava, pancreas, stomach, liver, and vertebral bodies. In the right lateral decubitus (RLD) position, the stomach's antrum was visualized beneath the left lobe of the liver and pancreas, with the aorta and superior mesenteric artery serving as key landmarks. Gastric contents were categorized as empty, clear liquids, or solids based on their ultrasound appearance.

Using criteria defined by Perlas et al.,[8] the gastric antrum was graded into three categories: grade 0 (empty antrum), grade 1 (fluid visible exclusively in the RLD position), and grade 2 (fluid visible in both supine and RLD positions).

The antral cross-sectional area (CSA) was calculated using the formula for an ellipse:

$CSA = (AP \times CC \times \pi) / 4$, where AP is the anteroposterior diameter and CC is the craniocaudal diameter. Gastric volume (GV) was estimated using a previously validated formula: GV (ml) = 27.0 + 14.6 × right-lateral CSA - 1.28 × age (years).[9]

Statistical analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Data were entered into a Microsoft Excel® spreadsheet. Descriptive statistics were computed as frequencies and proportions for categorical variables and mean ± standard deviation (SD) for continuous variables. Categorical variables were expressed as percentages, while mean differences between groups were analysed using independent samples t-tests. Associations between categorical variables were evaluated using the chi-square test. A p-value <0.05 was considered statistically significant. Patient characteristics, including age, weight, height, BMI, gastric antrum CSA, and gastric volumes, were reported as mean ± SD, while ultrasound grading of the gastric antrum appearance was presented as frequencies or percentages.

3. Results

Preoperative bedside GUS examination was performed on 60 subjects, 30 in the Group A: HbA1c<8% group-with good control of diabetes) and 30 in the Group B: HbA1c≥8% with poor control of diabetes, to measure the type of stomach contents, gastric CSA, and GV (**Figure 1**).

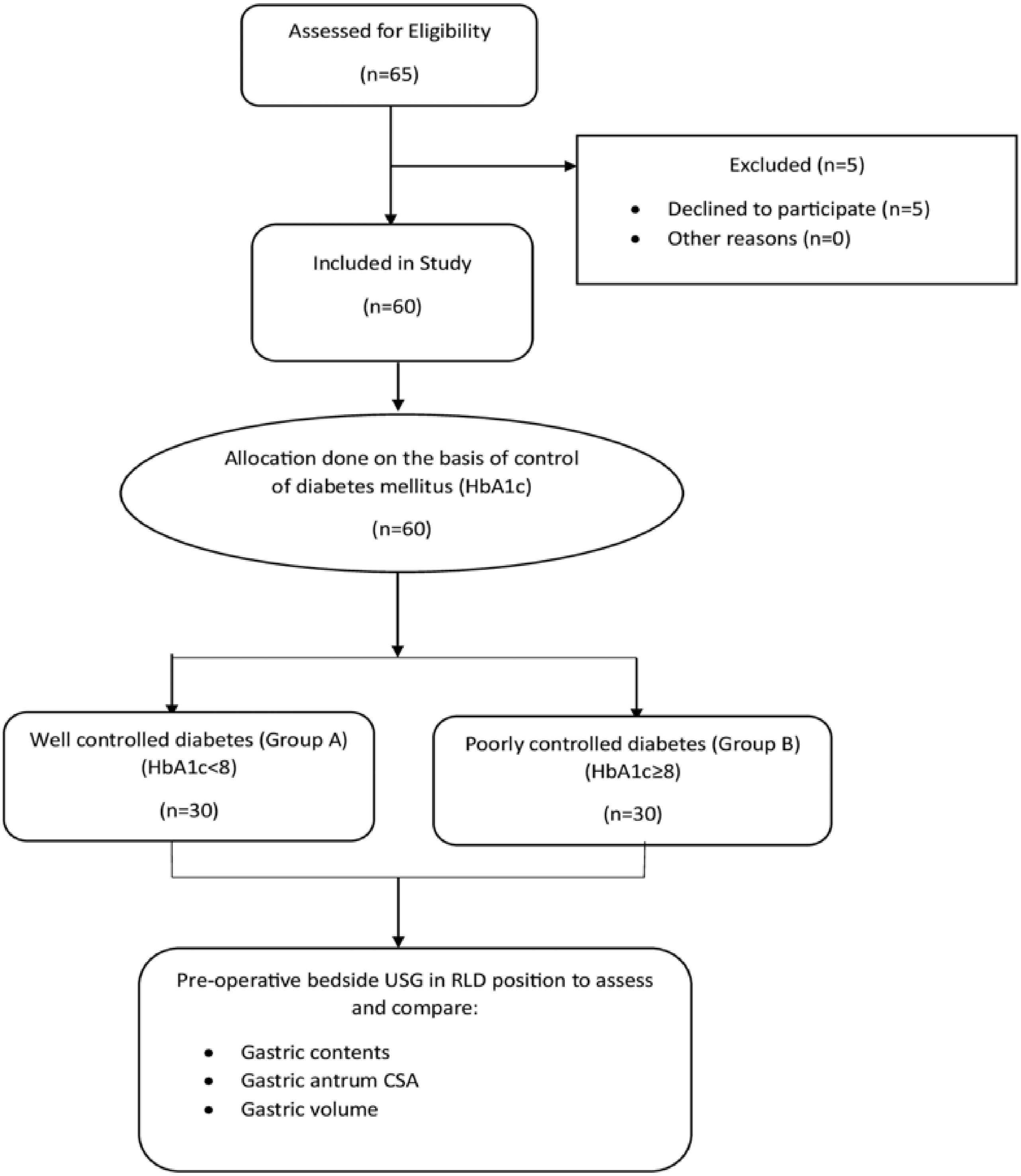

Figure 1: The study's CONSORT flow diagram
***CONSORT:** Consolidated Standards of Reporting Trials, HbA1c: glycosylated haemoglobin, CSA: Cross-sectional area.

The demographic characteristics of the study participants, categorized into Group A (well-controlled diabetes) and Group B (poorly controlled diabetes), are summarized in **Table 1**. The mean age was 53.17±14.85 years in Group A and 54.27±10.61 years in Group B, with no statistically significant difference (p=0.71). Regarding gender distribution, males constituted 73.33% of Group A and 56.67% of Group B, while females comprised 26.67% and 43.33%, respectively, with no significant difference (p=0.48). The mean BMI was 24.99±4.85 kg/m² in Group A and 26.48±3.30 kg/m² in Group B, showing no significant difference (p=0.18).

Table 1: Demographic characteristics

Parameter assessed	**Age (years)**			**Gender**			**BMI(kg/m²)**		
	Mean	**SD**	**p-value** (independent samples t-test)	**Males**	**Females**	**p-value** (chi-square test)	**Mean**	**SD**	**p-value** (independent samples t-test)
Group A	53.17	14.85	0.71	22(73.33%)	8(26.67%)	0.48	24.99	4.85	0.18
Group B	54.27	10.61		17(56.67%)	13(43.33%)		26.48	3.30	

Table 2: Co-existing co-morbidities

Co-morbidities	**Group A (%)**	**Group B (%)**	**Total (%)**
Hypertension	16(53.33)	9(30)	25(41.67)
Ischemic heart disease	1(3.33)	1(3.33)	2(3.33)
Cerebrovascular accident	7(23.33)	11(36.67)	18(30)

Table 3: Duration of diabetes mellitus (DM), glycosylated haemoglobin (HbA1c) levels and dietary status

Parameter assessed	**Duration of DM(years)**			**HbA1c (%)**			**Dietary Status**		
	Mean	**SD**	**p-value (Student's unpaired t-test)**	**Mean n (n %)**	**SD n (n %)**	**p-value (Student's unpaired t-test)**	**Vegetarian n (n %)**	**Non-vegetarian n (n %)**	**p-value (Chi-square test)**
Group A	7.30	3.15	0.13	22(73.33%)	8(26.67%)	0.0001	5(16.67)	25(83.33)	0.13
Group B	10.03	4.16		17(56.67%)	13(43.33%)		15(50)	15(50)	

Table 2 illustrates the co-existing comorbidities in the two groups. Hypertension was present in 53.33% of Group A and 30% of Group B, with an overall prevalence of 41.67%. Ischemic heart disease was seen in 3.33% of patients in both groups, while cerebrovascular accident was observed in 23.33% of Group A and 36.67% of Group B, with no significant differences between the groups.

Table 3 highlights the duration of diabetes mellitus (DM), glycosylated hemoglobin (HbA1c) levels, and dietary status. The mean duration of DM was 7.30±3.15 years in Group A and 10.03±4.16 years in Group B, with no significant difference (p=0.13). However, HbA1c levels showed a statistically significant difference, with mean values of 6.37±0.69% in Group A and 9.91±2.35% in Group B (p=0.0001). Dietary status analysis revealed that 16.67% of Group A and 50% of Group B followed a vegetarian diet, while 83.33% of Group A and 50% of Group B consumed a non-vegetarian diet, with no significant difference (p=0.13).

Table 4: The duration of the operation (in minutes)

The duration of the operation (minutes)	**Mean**	**SD**	**p-value** (unpaired t-test)
Group A	153.50	91.83	
Group B	135.33	85.24	0.41

The duration of the operation, as shown in **Table 4**, averaged 153.50±91.83 minutes in Group A and 135.33±85.24 minutes in Group B, with no statistically significant difference (p=0.41).

Table 5: Gastric CSA in right lateral decubitus position

Gastric CSA Right lateral position(cm²)	**Mean**	**SD**	**p-value (independent samples t-test)**
Group A	3.32	0.49	
			0.0001
Group B	4.40	1.19	

The mean gastric CSA in the right lateral decubitus (RLD) position was significantly larger in Group B (4.40±1.19 cm²) compared to Group A (3.32±0.49 cm²), with a highly significant p-value of 0.0001, indicating a notable difference in gastric CSA between the two groups (**Table 5**, **Figure 2**).

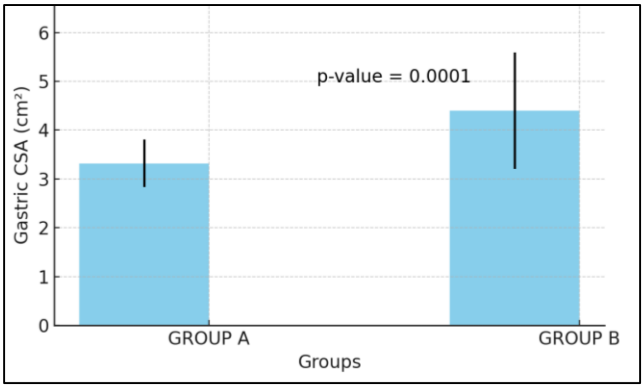

Figure 2: Comparison of gastric CSA in the lateral position between groups

Table 6: Gastric volume (GV) in RLD position

GV in RLD (ml)	Mean	SD	p-value (t test for independent samples)
Group A	13.38	13.70	0.02
Group B	22.58	17.38	

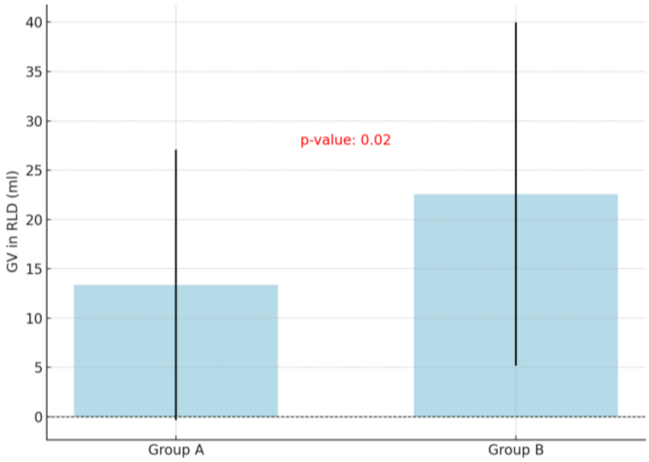

Figure 3: Comparing the gastric volume in RLD (ml) between Groups

The mean gastric volume in the RLD position was also significantly higher in Group B (22.58±17.38 ml) than in Group A (13.38±13.70 ml). This difference was statistically significant, with a p-value of 0.02, highlighting the increased gastric volume in poorly controlled diabetic patients (**Table 6**, **Figure 3**).

Table 7: Gastric content characteristics

Gastric Content (%)	Group A (%)	Group B (%)	p-value (Pearson chi-square)
Liquids	1(3.33)	4(13.33)	0.045
Solids	0	0	

Regarding gastric content, 3.33% of patients in Group A and 13.33% in Group B had liquids present in their stomachs, a statistically significant finding with a p-value of 0.045. Importantly, no solid gastric contents were observed in either group (**Table 7**).

4. Discussion

Diabetes Mellitus (DM) is a heterogeneous metabolic disorder characterized by chronic hyperglycemia resulting from impaired insulin secretion, insulin action, or a combination of both. Currently, the South-East Asia Region (SEAR) accounts for 20% of the global diabetes burden, with projections suggesting a threefold increase from approximately 30 million cases in 2025 to 80 million.[10] India, often referred to as the "diabetes capital of the world," has an estimated 101 million individuals living with diabetes and approximately 136 million with prediabetes.[11,12]

The diagnosis of diabetes relies on hallmark symptoms and elevated glucose levels, with fasting blood glucose ≥126 mg/dl or plasma glucose ≥200 mg/dl two hours after a 75-g oral glucose challenge. Additionally, random plasma glucose ≥200 mg/dl confirms the diagnosis.[13] Glycated hemoglobin (HbA1c) serves as an essential marker for glycemic control over three months, with levels ≥6.5% indicative of poor control. HbA1c of 8% corresponds to an average blood glucose of 183 mg/dl, underscoring its utility in monitoring disease progression.[14,15]

Pulmonary aspiration of gastric contents during anaesthesia remains a potentially fatal complication, with an estimated incidence of 1 in 2600 to 1 in 3200 cases (4.7 to 3.1 per 10,000) in adults.[16] This condition carries a high mortality rate and is a significant contributor to anaesthesia-related deaths. The perioperative risk of aspiration ranges from 1.9% to 19%, influenced by multiple factors.[17] Delayed gastric emptying, a hallmark feature of diabetic gastroparesis, significantly increases the risk. Camilleri et al. highlighted that up to 56% of patients with type 2 diabetes experience delayed gastric emptying.[18,19] This condition persists even after an adequate fasting period, independent of the severity of diabetes, thereby elevating the risk of aspiration during anaesthesia.

Evidence linking diabetes mellitus and aspiration risk is primarily derived from limited, mostly non-blinded studies. These studies utilize surrogate markers such as gastric emptying rates and gastric volume (GV) to infer aspiration risk. Xiao et al. emphasized the uncertainty surrounding this risk in fasting diabetic individuals due to conflicting and inadequate data on fasting gastric content and GV.[20]

Many methods, such as radiation-free imaging tomography, diets with radioactive substances, paracetamol absorption, and estimating of suctioned gastric content, have been described to assess the stomach's content. These methods are not suitable and also difficult to use in the perioperative period. Amongst the methods available to assess the gastric contents preoperatively, the most objective form of evaluating the stomach's contents is GUS. A point of care ultrasound, as an imaging tool, has been defined with an intention to improve the outcome of patient and has focused easily recognizable, goal-oriented findings. This skill can be easily learnt and performed; results are also obtained quickly at the patient's bedside.

Point of care GUS quantifies the gastric contents and provides qualitative information regarding the type of content that is present in the stomach. It is also possible to measure the exact CSA of the stomach's antrum. GUS has high sensitivity at 1, specificity at 0.975, positive predictive value at 0.976, and negative predictive value at 1.[21] Anaesthesia providers can decide whether to reschedule or defer surgery based on bedside pre-operative GUS findings, or they can go ahead with surgery using a different anaesthetic approach (such as rapid-sequence induction or regional anaesthesia).

A 3-point grading system to screen patients in the peri-operative period who are at a probable risk of aspiration has been proposed. Grade 0 indicates gastric antrum which is empty in the supine and RLD positions, limited volume and less risk of aspiration, present in 45-50% of subjects who are scheduled for elective surgeries and fasting. Grade 1 indicates antrum that appears empty in supine, but contains clear fluids in the RLD position, present in 45-50% and correlates with an antral volume of less than 1.5 ml kg^{-1}. Grade 2 denotes fluid in both the supine and RLD postures, is consistent with a volume of ≥1.5 ml kg^{-1}, present in 3-5% of the subjects.[8]

In this study, non-invasive, bedside GUS was used to assess gastric contents and GV in well-controlled and poorly controlled diabetic patients before anaesthesia induction. The goal was to evaluate the necessity of rapid sequence induction by assessing aspiration risk and confirming if it was within the recommended safety limits, defined as less than 1.5 ml/kg clear fluids, absence of solid contents, and an antral CSA of less than 340 mm².[5,7,9,22] Sixty patients were divided into two groups of 30 based on glycemic control using HbA1c levels: group A comprised well-controlled diabetics with HbA1c levels <8%, and group B comprised poorly controlled diabetics with HbA1c levels ≥8%.[23] Elective procedures were planned for all patients after an 8-hour overnight fasting period..

In the current study, the mean HbA1c level in group A was 6.37 ± 0.69%, while in group B, it was 9.91 ± 2.35%, showing a statistically significant difference (p=0.0001) (**Table 3**). The groups were comparable in terms of age, gender, BMI, co-morbidities, dietary preferences, and average surgery duration, which aligns with studies by Garg et al. and Sharma G et al.[5,7] Although the poorly controlled diabetic group had a longer average duration of diabetes (10 ± 4.16 years) than the well-controlled group (7.30 ± 3.15 years), this difference was not statistically significant (p=0.13).[5,7]

Although the weight of the patients in the two groups did not differ statistically, diabetes patients weighed more, even when their blood sugar levels were under control. This observation was consistent with the results of Garg et al's study.[5] However, weight or BMI were not taken into account in the mathematical model that we utilized to calculate GV in the current study.

The HbA1c test is currently the most commonly used tool for monitoring and managing diabetes mellitus over the long term since it offers a reliable measure of chronic glycemia and corresponded with the risk of long-term complications of diabetes. Nonetheless, there is a continuing controversy regarding the HbA1c cut-off point from a diagnostic perspective.[14] The American Diabetes Association (ADA) defined HbA1c ≥6.5% as a diagnostic criteria for DM in 2010.[24] In the present study, the mean HbA1c levels in group A, i.e. well controlled diabetics, was 6.37+/-0.69% and in group B, i.e. poorly controlled diabetics, was 9.91+/-2.35%. A statistically significant difference (p=0.0001) was observed between the groups.

In the RLD position, the mean CSA in group A was 3.32 ± 0.49 cm², while in group B, it was 4.40 ± 1.19 cm², with a statistically significant difference (p=0.001). These findings suggest that poorly controlled diabetics have a larger CSA, which exceeds safety limits and indicates a higher aspiration risk. These results are consistent with the findings of Gültekin Y et al., who demonstrated a substantial linear relationship between CSA and GV up to 200 ml, and Garg et al., who observed higher gastric antral CSA and GV in diabetic patients compared to non-diabetics.[5,25]

The mean GV in the RLD position was 13.38 ± 13.70 ml in group A and 22.58 ± 17.38 ml in group B. This difference was statistically significant (p=0.02) (**Table 6**). Quantitative analysis of GV revealed higher values in poorly controlled diabetics. The commonly used formula by Perlas et al. for calculating GV, which has a strong correlation with visually guided suctioning and GUS grades, was applied in this study.[6] The gastric CSA and GV values observed in this study are comparable to those in studies by Sharma G et al. and Garg et al. [5,7]

In a 538-patient retrospective cohort study, Putte et al. discovered that even in healthy individuals, the standard fasting time does not always ensure sufficient gastric emptying. They found that 32 patients had gastric volumes (GV) exceeding the acceptable range, leading to modifications in the anaesthetic induction plan.[26]

For gastric secretions or clear liquid content, the generally accepted maximum volume limit is 1.5 ml/kg of body weight, which is approximately 100–130 ml in an average adult. When the volume of clear fluids is less than 1.5 ml/kg, even in the presence of antral fluid, this is typically attributed to baseline stomach secretions, posing minimal risk of aspiration-induced pneumonia. However, a volume of ≥1.5 ml/kg is rare during fasting and suggests either recent fluid intake or delayed gastric emptying, both of which elevate the risk of aspiration.[27]

In our study, poorly controlled diabetics (13.33%) had more liquid contents in the stomach than the well-controlled diabetic group (3.33%), the difference of which was statistically significant (p=0.045) This finding aligns with the observations made by Sharma G et al., who, in an observational correlation study involving 100 adult patients undergoing elective surgery, found that 16 patients had clear fluid volumes exceeding 1.5 ml/kg, and six patients had solid gastric contents despite fasting for 10 to 15 hours.[7]

There were some limitations in our study. Firstly, fasting interval for all the patients in the current study was 8 hours. In routine clinical practice, owing to various factors, achieving sufficient control over the fasting interval during the preoperative phase is challenging. Secondly, the classification into well and poorly controlled diabetics is not clearly defined in the literature. We have taken the HbA1C value of 8% as it correlated with the blood sugar levels of 183 mg/dl.[15] Thirdly, we only performed a preoperative scanning of the study patients, which was our primary objective. We could have furthermore followed up on the general anaesthesia induction of the participants and assessed / documented the risk of aspiration of gastric contents, if any. Lastly, application of USG for gastric CSA and gastric volume evaluation varies with the skill of the assessor. Therefore, the findings may be subjective till the learning curve is crossed by the operator. For the diabetic population scheduled for elective procedures, further research is needed to accurately determine fasting volumes and their impact on aspiration risk during anaesthesia induction.

5. Conclusions

The study concluded that gastric contents and gastric volume assessed preoperatively, following an 8-hour overnight fasting period using bedside gastric ultrasound (GUS), were within safe limits for patients with well-controlled diabetes mellitus compared to poorly controlled diabetics. The estimation of gastric volume and gastric contents can guide anaesthesia management for patients requiring general anaesthesia or sedation and may help anticipate the need for rapid sequence induction. This approach can contribute to better planning for airway management and assist in determining the necessity of rapid sequence induction in diabetic patients.

6. Disclosures

Human and animal subjects- Every participant in the current study gave their consent or waived it. Approval from Yenepoya Ethics Committee 2 (YEC2/662) was obtained. The Yenepoya Ethics Committee 2 approved the study with protocol number YEC2/662 titled "Pre-operative evaluation of gastric contents and volume using ultrasound in patients with well controlled and poorly controlled Diabetes Mellitus: a cross-sectional, observational study" after reviewing the documents through a review process. All authors have confirmed that this study did not involve animal subjects or tissue.

7. Details of Payment and Services

All authors have stated that no grant of funds was obtained for the work they submitted.

8. Financial Relationships

Every author has disclosed that they have no financial ties to any groups that might be interested in the work they have contributed, either now or in the last three years.

9. Conflicts of Interest

All authors disclose the following in accordance with the ICMJE universal disclosure form.

10. Other Relationships

No other affiliations or activities that might seem to have influenced the submitted work have been disclosed by any of the authors.

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