Original Research Paper

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Gastroenterology

AN OBSERVATIONAL STUDY OF ULTRASOUND GUIDED GASTRIC EMPTYING TIME AT FOURTH HOUR AND SIXTH HOUR AFTER A STANDARD LIGHT BREAKFAST IN PATIENTS POSTED FOR ELECTIVE SURGERIES UNDER REGIONAL ANAESTHESIA

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KEYWORDS :

INTRODUCTION

Current guidelines recommend 6 h of fasting for solids before anaesthesia. However, prolonged fasting may lead to discomfort, hunger, thirst, misbehavior, and lipolysis. To prevent this, a more liberal fasting regimen has been empirically implemented for allowing a shorter fasting time of 4 h for a standardized light breakfast.1 However, even when fasting time is elucidated, patients tend to fast for longer periods due to operation delays. As a result, patients are put at an increased risk for the complications listed above.

Preoperative fasting, also known as nil per os (NPO), is defined as no food or fluids by mouth before a procedure.1 Expert opinion suggest that fasting is warranted to help ensure patient safety by reducing the risks of vomiting and pulmonary aspiration during an elective surgery requiring sedation. Pulmonary aspiration is defined as aspirating stomach contents after administration of anesthesia, during the surgical procedure, or the period immediately following the procedure.[1]

'The American Society of Anesthesiologists' current guidelines for an elective surgery requiring sedation are for a minimum NPO status of six hours for solid foods, four hours for non-clear fluids, and two hours for clear fluids (also known as the "6-4-2 regimen"),1,2 These guidelines replace outdated pre-surgical guidelines that recommended NPO status begins[3]

Studies have found that a prolonged fast, such as NPO after midnight, led to increased risks of electrolyte imbalances, insulin resistance, dehydration, and patient discomfort.[2] The shorter preoperative fasting period, recommended by the new ASA guidelines, has demonstrated similar patient safety without increasing risks associated with prolonged fasting however, even when fasting time is elucidated, patients tend to fast for longer periods due to operation delays. As a result, patients are put at an increased risk for the complications listed above.4

Airway related death due to pulmonary aspiration is relatively rare and occurs in about one in 350,0005.Due to the rarity of this serious complication, studies have noted the power to properly assess the risk of aspiration during procedural sedation.6 Currently,NPO guidelines are based upon a few studies, but mostly expert opinion and general consensus because there are not enough published studies to base the guidelines on.

Due to the unknown risk of pulmonary aspiration in patients undergoing procedural sedation, the ASA continues to state that practitioners should follow perioperative guidelines, despite the insufficient evidence. This is to ensure the safety of patients from major airway complications; but fails to take into account the post-operative complications mentioned previously. The NPO guidelines recommended by the ASA are a shorter duration than the NPO duration recorded for many patients. ASA recommends no solids for at least 6 hours, however, many patients are either told to go much longer than this or end up fasting longer due to delayed procedures[4]

Despite studies that contradict the need for prolonged fasting, surgeons still continue to recommend an NPO status greater than the current preoperative fasting guidelines of two hours for clear liquids and six hours for solids. An unnecessary extended fast puts the patient at risk for increased mortality and other complications.[4]

The aim of this study would be to determine if an NPO status greater or less than six hours by assessing ultrasound assisted gastric content.

AIMS AND OBJECTIVES OF THE STUDY

To determine the gastric emptying time after a standardized light breakfast in healthy adults posted for surgical procedure involving regional anaesthesia under ultrasound guided technique.

MATERIALS AND METHODS

SOURCE OF DATA:

The data was collected from patients between 18 to 60 years of age who was undergoing elective surgery for under spinal anaesthesia.

STUDY DESIGN: An observational study.
PERIOD OF STUDY: From 1st November 2019 to 30th April 2021.
STUDY SETTING : Hospital based study

STUDY POPULATION : The data was collected from patients between 18 to 60 years of age who were undergoing elective surgery under spinal anesthesia. The patients were assessed for the inclusion and exclusion criteria during the mentioned period of study, after obtaining a written informed consent from the study population.

SAMPLE SIZE : 85
SAMPLING METHOD: Systematic random sampling method
METHOD OF COLLECTION OF DATA-

Inclusion criteria:
1) Patients posted for elective surgeries under spinal anaesthesia .
2) Patients in the age group of 18 to 60 years of age
3) American society of anesthesiologists physical status I and II

Exclusion criteria
1) Patients not willing to participate in the study.
2) Patients posted for emergency surgeries.
3) Patient with gastrointestinal disturbances.
4) Patients with spinal deformities.
5) Pregnant women and patient unable to turn and lie in lateral position
6) Patients having absolute contraindications for spinal anaesthesia .
7) Local infection
8) Patients diagnosed to have Diabetes mellitus and renal diseases

METHODOLOGY:

This study was conducted in the department of Anaesthesia at KVG

Medical College and Hospital Sullia a tertiary care teaching hospital in Dakshina Kannada District of Karnataka over a period of 18 months from 1st November 2019 to 30th April 2021. Those who fulfill the inclusion criteria and the patients undergoing elective surgery under spinal anaesthesia for any indication during the mentioned period of study will be selected as study population. Data was collected after taking written informed consent from the properly selected patients. First, thorough history as per prepared proforma along with any comorbidities like diabetes and renal disorders are taken along with Patient's age, height, body weight, ASA grading, and number of hours of fasting were noted, then clinical examination will be done and information was collected.

Patients were given a a light breakfast 8 hours prior to surgery then ultrasound examinations of the gastric antrum was performed as described by Van de Putte[7]. Briefly, using a standard convex ultrasound probe (C5-2 wireless transducer, mindray) the gastric antrum was scanned in a sagittal plane between liver and pancreas at first in the supine and then in the right lateral position (RLP) , and two orthogonal diameters (D1 and D2) of gastric antrum including the gastric wall will be determined in each position. The gastric antral area (GAA), which correlates with gastric volume was then calculated (GAA¼p_D1_D2/4). This was repeated three times in each position and then averaged. All ultrasound examinations were planned to conduct by a single expert, who is an experienced examiner

FOLLOW UP PERIOD: NIL

STATISTICAL ANALYSIS: -

Data Entry was done using Microsoft excel 2013 and analysis done using SPSS V 16. Qualitative data was expressed in frequencies and percentages and Quantitative data in mean and standard deviation. Nonparametric statistics i.e. Chisquare test/ Fishers exact test was used to find the significant association between the two qualitative variables. Unpaired t test was used to find the statistical significance between quantitative variables. Bar diagrams and pie chart were used to represent the data. p value of <0.05 was considered statistically significant.

SAMPLE SIZE ESTIMATION

FORMULA USED:

In a study conducted by Christiane E B et al[8] on ultrasound assessment of gastric emptying time after a standardized light breakfast in healthy children reported that gastric antral area in right lateral position was 3.06±0.7.

Sample size for the present study was estimated using the formula

$$n = \frac{Z^2_{1-\alpha/2}\sigma^2}{\epsilon^2\mu^2}$$

$Z^2_{1-\alpha/2}$ at 95% confidence interval= 1.96

σ = Standard deviation = 0.71

ϵ = Margin of error = 0.05

μ = Mean

$$n=\frac{(1.96)^2*(0.71)^2}{(0.05)^2*(3.06)^2}$$

$$=\frac{1.92}{0.023}$$

=83.4

n=85

minimal sample size required = **85**

RESULTS

Age distribution in years

In the present study mean age of the participants was 42.43 ± 11.51 years. 21.2% of the subjects were aged 18-30 years, 18.8% were aged 31-40 years, 27.1% were aged 41-50 years, 32.9% were aged 51-60 years.

Gender distribution

In the present study 49.4% were male and 50.6% were female.

Anthropometric details

In the present study, weight of the subjects ranged between 35-88 kgs and the mean weight among the study subjects was 61.60 ±8.86 kgs.

In the present study, height of the subjects ranged between 1.48-1.78mts, the mean height observed among the study participants was 1.62 ±0.07 mts.

In the present study the BMI ranged between 15.60-36.6 and the mean BMI was 23.46 ±3.88kg/m^2

Pie chart: ASA distribution

In the present study, 70.6% belonged to ASA grade 1 and 29.4% belonged to ASA grade 2.

Comparison between parameters at 4th hour and 6th hour Age

AL (mm)	Control (n=40)		POAG (n=40)		PACG (n=40)		Total	
	No.	%	No.	%	No.	%	No.	%
19-21	0	0	1	2.5	8	20	9	7.5
21.01-23	27	67	8	20	30	75	65	54
23.01-25	13	32	29	72.5	2	5	44	36.7
25.01-27	0	0	2	5	0	0	2	1.7

In the present study a significant difference in all the mean gastric emptying parameters has been observed across 4th hour and 6th hour.

DISCUSSION

Perioperative aspiration of gastric contents is a serious complication of anaesthesia and is associated with high morbidity and mortality.[9,10] It can result in severe pneumonia requiring mechanical ventilator support in up to one-third of patients with a mortality of 5%, representing up to 9% of all anaesthesia-related deaths. The severity of the resulting respiratory compromise is thought to be related to both the volume and nature of the aspirate, with particulate matter carrying the highest risk. Preoperative fasting guidelines help limit the risk in elective patients with minimal co-morbidities. However, fasting intervals are not applicable or reliable in urgent or emergency surgeries or for patients with certain medical conditions.

In anaesthesiology and acute care medicine, there is a growing interest in bedside evaluation of gastric 'fullness' to assess pulmonary aspiration risk. With the advent of portable ultrasound machines, performing point-of-care ultrasound has become relatively easy and feasible. Gastric ultrasound examination is finding a place as a point-of-care tool for aspiration risk assessment. It can identify the nature of the gastric content, i.e., empty, clear fluid and solid and when clear fluid is present, its volume can be quantified.

The aim of this study would be to determine if an NPO status greater or less than six hours by assessing ultrasound assisted gastric content

Objectives:

To determine the gastric emptying time after a standardized light breakfast in healthy adults posted for surgical procedure involving regional anaesthesia under ultrasound guided technique.

Socio demographic characteristics:

In the present study mean age of the participants was 42.43 ± 11.51 years. 21.2% of the subjects were aged 18-30 years, 18.8% were aged 31-40 years, 27.1% were aged 41-50 years, 32.9% were aged 51-60 years.

In the present study 49.4% were male and 50.6% were female.

Anthropometric details:

In the present study, weight of the subjects ranged between 35-88 kgs and the mean weight among the study subjects was 61.60 ±8.86 kgs.

In the present study, height of the subjects ranged between 1.48-1.78mts, the mean height observed among the study participants was 1.62 ±0.07 mts.

In the present study the BMI ranged between 15.60-36.6 and the mean BMI was 23.46 ±3.88kg/m2

ASA grade:

In the present study, 70.6% belonged to ASA grade 1 and 29.4% belonged to ASA grade 2.

Gastric emptying:

A full stomach prior to general anaesthesia has been widely recognized as a cause for concern ever since Mendelson, in 1946, described his dreaded 'Mendelson's syndrome' or acid aspiration syndrome. This can lead to severe aspiration pneumonia with a mortality of up to 5%, representing up to 9% of all anaesthesia-related deaths.

Patients presenting for urgent surgical procedures are usually not fasted and they may have significant gastric content despite long

periods of fasting. Aspiration and the severity of the resulting respiratory compromise is thought to be related to both the volume and nature of the aspirate (content), with particulate matter carrying the highest risk.

In the absence of data, it was considered safer to assume a 'full stomach' in emergency situations leading to either surgical cancellations, re-scheduling in elective cases or modification of interventions to prevent aspiration, such as a rapid sequence induction and tracheal intubation. In elective cases, preoperative fasting guidelines help limit the risk in patients with minimal co-morbidities. Most people believe that fasting a patient for more than 6 h places them in the 'safe' category for aspiration risk stratification.

Many techniques have been described to assess the contents of the stomach like paracetamol absorption, electrical impedance tomography, radio-labelled diet, polyethylene glycol dilution and gastric content aspiration These methods are not suitable in the perioperative period and none of these methods have proved foolproof or easy to use. However, with the advent of the newer portable ultrasound machines, one can accurately diagnose the presence of unsafe stomach contents non-invasively. It can help clinicians individualize aspiration risk at the bedside and guide anaesthetic management more appropriately.

At 4th hour:
An empty stomach may appear flattened, liquid is seen as hypoechoic, liquid and air as a 'starry sky' appearance and solids as frosted glass with blurring of the posterior wall Once learned, we found that the ultrasound is an easy non-invasive tool to use.

For proper risk stratification, scanning in both the supine and right lateral positions in all patients is very important. The antrum may appear empty in the supine position but will appear fuller in the right lateral position. This apparent increase in gastric volume in the right lateral position is probably due to the gastric contents gravitating towards the gastric outlet.

ACSA in supine D1 ranged between 3.52-5.67 and the mean value was 4.27 ± 0.45 ACSA in RLD D2 ranged between 3.55-5.97 and the mean value was 4.56 ± 0.50 Gastric antral area ranged between 10.69-26.83 and the mean value was 15.65 ± 3.43 Gastric volume in ml at 4th hour ranged between 16.05-63.08 and the mean value was 39.37 ±13.03 GASTRIC VOLUME </>1.5Ml/kg ranged between 0.27-1.47 and the mean value was 0.65 ±0.26

At 6th hour:
ACSA in supine D1 ranged between 3.22-5.44 and the mean value was 4.02 ± 0.43 ACSA in RLD D2 ranged between 3.41-5.87 and the mean value was 4.28 ± 0.46 Gastric antral area ranged between 9.34-25.07 and the mean value was 13.68 ± 2.98 Gastric volume in ml at 6th hour ranged between 11.96-61.23 and the mean value was 35.27 ±13.38

GASTRIC VOLUME </>1.5Ml/kg ranged between 0.20-1.36 and the mean value was 0.59 ±0.26

Correlation at 4th hour and 6th hour:
In the present study a significant difference in all the mean gastric emptying parameters has been observed across 4th hour and 6th hour.

In the study conducted by Sharma G et al., they have also found a statistically significant difference in the gastric emptying parameters across 4th hour and 6th hour irrespective of the comorbidities and this finding was in consonance with the present study.

There was still no consensus on the critical volume of risk stomach. It was reported that at least 200ml of GV was required to induce pulmonary aspiration. Bouvet considered GV of 50 ml (or 0.8 ml/kg) as the critical volume for serious aspiration in adults. While in another study, Reide reported that just 10 to 30 ml of GV could lead aspiration in adult patients. Gastric ultrasound was performed on 440 emergency patients prior to induction of anesthesia and a three-point scoring system could also be used as an important indicator to evaluate the risk of aspiration. In supine position, patients with CSA less than 340mm^2 was considered as fasting.

Fukunaga et al also measured CSA in 44 patients after endotracheal intubation and analyzed the relationship between CSA and GV. When CSA reached 340mm^2, GV would exceed 0.8 ml/kg, which could be a criteria to predict a high risk of aspiration.

But a recent clinical trial does not support this conclusion. This study found that GV with a total of 100–130 ml (1.5 ml/kg) was common in healthy fasting subjects and didn't increase the risk of aspiration. In most previous researches, 1.5 ml/kg of GV was a more reliable threshold to assess the risk of aspiration.Conversely, GV larger than 1.5 ml/kg indicated a non-fasting state (or "full stomach"). In emergency patients, there was no correlation between duration of fasting and risk stomach.

For the patients with high risk of aspiration, elective surgery should be delayed or canceled until the stomach meets fasting states evaluated by ultrasound (GV<1.5 ml/kg was considered as low risk of aspiration in most research). For the emergency operation, the optimal drug pre-treatment with antacids including proton pump inhibitors or H_2 blockers was recommended. It has been proved to be effective in reducing the incidence of vomiting when serotonin receptor antagonists and dexamethasone were administrated. For these patients, it can also avoid aspiration when general anesthesia is turned to regional block. Rapid sequence induction (RSI) was also recommended in patients with no 2h liquid and no 6h food fasting or acute vomiting, sub-ileus or ileus, or no protective reflexes or a gastrointestinal disorder.

CONCLUSION
Regurgitation and aspiration is a serious threat to the safety of patients and the risk could be decreased by a long fasting time. While with the development of ERAS, anesthesia doctors have gradually realized the disadvantages (such as hunger, thirst and insulin resistance) lead by the inappropriate fasting time. As a result, fasting protocol recommended by ASA will provide a balance between decreasing the risk of aspiration and keeping a normal physiological function. However, it is carried out not ideally for the concerns that the reduced fasting time could increase risk of aspiration. Current studies have shown that bedside ultrasound can provide reliable information about the volume and nature of gastric contents. With this technology, anesthesiologists can make individual decision to minimize the risk of perioperative aspiration an even a 4hour NPO status after a light breakfast have significantly less gastric volume which can cause aspiration but its morte compare to 6th .I-AIM framework directed by ultrasound also provided a standard procedure to diagnose and treat the patients with high risk of aspiration. It will benefit the implementation of proper fasting protocol. However, a best fasting protocol still remains to be answered by more clinical studies in the future.

SUMMARY
The study entitled "AN OBSERVATIONAL STUDY OF ULTRASOUND GUIDED GASTRIC EMPTYING TIME AT FOURTH HOUR AND SIXTH HOUR AFTER A STANDARD LIGHT BREAKFAST IN PATIENTS POSTED FOR ELECTIVE SURGERIES UNDER REGIONAL ANAESTHESIA" Was a prospective comparative clinical study which was conducted on patients in the study subjects were aged between 18-60 years, belonging to ASA I and II and were undergoing elective surgeries under regional anaesthesia. The study period was from 1st November 2019 to 30th April 2021. Patients not willing to participate in the study. Patients posted for emergency surgeries. Patient with gastro intestinal disturbances, patients with spinal deformities, pregnant women and patient unable to turn and lie in lateral position patients having absolute contraindications for spinal anaesthesia,local infection, patients diagnosed to have Diabetes mellitus and renal diseases are excluded from the study.A written informed consent was obtained from all of these patients. A detailed preanaesthetic examination includes history as per prepared proforma along with any comorbidities like diabetes and renal disorders are taken along with Patient's age, height, body weight, ASA grading, and number of hours of fasting were noted, then clinical examination will be done, and information was collected.
Patients were given a a light breakfast 8 hours prior to surgery then ultrasound examinations of the gastric antrum was performed as described by Van de Putte.[7] The gastric antrum was scanned in a sagittal plane between liver and pancreas at first in the supine and then in the right lateral position (RLP) The gastric antral area (GAA), which correlates with gastric volume was then calculated (GAA¼p_D1_D2/4). This was repeated three times in each position and then averaged. All ultrasound examinations were planned to conduct by a single expert, who is an experienced examiner.

Objective of study was to determine the gastric emptying time after a standardized light breakfast in healthy adults posted for surgical procedure involving regional anaesthesia under ultrasound guided technique.

For the patients with high risk of aspiration, elective surgery should be delayed or canceled until the stomach meets fasting states evaluated by ultrasound (GV<1.5 ml/kg was considered as low risk of aspiration in most research). For the emergency operation, the optimal drug pre-treatment with antacids including proton pump inhibitors or H_2 blockers was recommended. It has been proved to be effective in reducing the incidence of vomiting when serotonin receptor antagonists and dexamethasone were administrated. For these patients, it can also avoid aspiration when general anesthesia is turned to regional block. Rapid sequence induction (RSI) was also recommend in patients with no 2h liquid and no 6h food fasting or acute vomiting, sub-ileus or ileus, or no protective reflexes or a gastrointestinal disorder.Regurgitation and aspiration is a serious threat to the safety of patients and the risk could be decreased by a long fasting time. While with the development of ERAS, anesthesia doctors have gradually realized the disadvantages (such as hunger, thirst and insulin resistance) lead by the inappropriate fasting time. As a result, fasting protocol recommended by ASA will provide a balance between decreasing the risk of aspiration and keeping a normal physiological function. However, it is carried out not ideally for the concerns that the reduced fasting time could increase risk of aspiration. Current studies have shown that bedside ultrasound can provide reliable information about the volume and nature of gastric contents. With this technology, anesthesiologists can make individual decision to minimize the risk of perioperative aspiration an even a 4th hour NPO status after a light breakfast have significantly less gastric volume which can cause aspiration but its morte compare to 6th .I-AIM framework directed by ultrasound also provided a standard procedure to diagnose and treat the patients with high risk of aspiration. It will benefit the implementation of proper fasting protocol. However, a best fasting protocol still remains to be answered by more clinical studies in the future.

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