Ultrasonographic evaluation of gastric content in fasting volunteers and in tirzepatide users: an observational and cross-sectional study

Date: February 4, 2026

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1. INTRODUCTION

Obesity and type 2 diabetes mellitus constitute a global public health problem. Medications with glucagon-like peptide-1 (GLP-1) receptor agonist activity are a modern therapeutic option for both diseases (1,2,3). Liraglutide, semaglutide, dulaglutide and tirzepatide are representatives of this drug class (1), whose mechanism of action results in delayed gastric emptying, reduced gastric motility and increased gastric volume (4). These effects are implicated both in weight loss (4) and in the occurrence of adverse events such as nausea, vomiting, acute gastroparesis (5) and gastro-esophageal reflux disease (GERD) (4).

Tirzepatide, however, presents a dual agonist action, combining GLP-1 agonism with glucose-dependent insulinotropic polypeptide (GIP) agonism (6). Its use has been approved by the Food and Drug Administration (FDA) and by the European Medicines Agency (2) and is associated with weight loss, glycaemic control and improvements in other metabolic parameters in individuals with obesity, with or without type 2 diabetes mellitus (7,8).

The presence of gastric content during anaesthesia may lead to pulmonary aspiration and the development of chemical pneumonitis, a potentially devastating complication (9), with an incidence of 1 in 3,000 to 4,000 elective procedures (10). To avoid such complications, in healthy patients, fasting of 8 hours for solids and 2 hours for clear liquids is recommended (11). However, when there is a risk factor for delayed gastric emptying, despite adequate fasting, the stomach may still present residual content, and bedside ultrasonography is an effective, non-invasive and rapid method to measure this content and stratify aspiration risk (12).

Some studies corroborate a higher occurrence of a full stomach in patients using semaglutide despite adequate fasting (13,14). However, the association between the use of this class of medications and the occurrence of gastric aspiration remains uncertain.

Due to the scarcity of data associating the use of dual GLP-1 and GIP analogues with increased aspiration risk in individuals who have undergone adequate fasting for anesthesia, there is no evidence-based consensus recommendation for the suspension of these medications (15), nor for routine preoperative gastric ultrasonography. Some institutions and societies empirically recommend preoperative suspension.

Given the severity of broncho aspiration, the biological action of GLP-1 analogues on gastric function and the increasing use of these medications, a better understanding of gastric content in fasting individuals using a dual GLP-1 and GIP analogue is required. Thus, through ultrasonography, we aim to evaluate the gastric content of volunteers who have no risk factors for broncho aspiration, who will not undergo anesthesia, but who have adhered to recommended fasting and are using tirzepatide, a dual GLP-1 and GIP analogue.

Our hypothesis is that most individuals using tirzepatide present a full stomach even after fasting times recommended in the literature. Therefore, safety criteria during anesthesia should be adjusted for this population.

2. OBJECTIVES

2.1 Primary objective

To evaluate the prevalence of a full stomach using gastric ultrasonography in volunteers using tirzepatide who have fasted for at least 8 hours for solids and 2 hours for clear liquids.

2.2 Secondary objectives

To evaluate whether demographic characteristics, duration of medication use, time since the last dose of tirzepatide, dose and dosing regimen, indication for use, and the presence of symptoms such as nausea, vomiting and a sensation of gastric fullness influence gastric emptying when assessed by ultrasonography.

3. Study design

Observational, cross-sectional, non-interventional study.

4. Study population

Thirty volunteers will be included, of whom 15 will be current users of tirzepatide and 15 will not be using the medication.

Potential volunteers may be invited in person, such as colleagues, individuals from the investigators' social environment, or patients already referred to the Interventional Medicine Centre for other examinations or procedures.

Thirty healthy volunteers, 15 using tirzepatide analogues and 15 not using the medication, both groups having fasted for at least 8 hours for solids and 2 hours for clear liquids.

The informed consent process will be conducted by the principal investigator or a trained and delegated member of the research team, in person, before the ultrasound examination. After understanding the study and voluntary agreement to participate, written informed consent will be obtained prior to participation. A copy signed by both parties will be provided to the participant, and a note will be recorded in the medical record indicating the date of consent.

After inclusion, gastric ultrasound will be performed at Hospital Israelita Albert Einstein by an anesthesiologist experienced in gastric ultrasound. Images will be recorded in the PACS system and reviewed by a radiologist.

5. Inclusion and exclusion criteria

5.2 Inclusion criteria

• Adults aged 18 years or older.
• Individuals currently using tirzepatide.
• Individuals fasting for at least 8 hours for solids and 2 hours for clear liquids without residue.

5.3 Exclusion criteria

• Pregnant or postpartum individuals.
• Technical limitation for gastric ultrasound assessment.
• Presence of risk factors for gastroparesis.
• Use of prokinetic medications such as bromopride, metoclopramide or domperidone.

5.4 Sample size calculation

Based on the literature (16), control individuals presented residual gastric fluid areas ranging from 3 to 7 cm^2, with a median of 5.1 cm^2, corresponding to residual volumes of 32.4 mL, 90.8 mL and 63.1 mL after 8 hours of fasting. Assuming a mean increase of at least 20 mL in patients using semaglutide, with 95% confidence and 80% power, the required sample size is 14 patients per group. To compensate for possible losses, the sample was increased by 10%, resulting in 15 volunteers per group.

6. Risks and benefits

6.1 Risks

Abdominal ultrasonography is a non-invasive examination that does not emit radiation. There is no evidence that ultrasound causes harm to health. Participants may experience discomfort related to fasting. There is a risk of data confidentiality breach; however, all precautions will be taken to ensure data confidentiality.

6.2 Benefits

There is no direct benefit to participants. However, they may benefit from the study results if undergoing surgery in the future, as the findings may guide safety measures for individuals using tirzepatide.

7. Methods

7.1 Study outcomes

7.1.1 Primary outcome

Comparison of the prevalence of a full stomach after fasting using gastric ultrasonography in volunteers using tirzepatide versus those not using the medication. The outcome is binary: a full stomach is defined as the presence of solids or clear liquid volume greater than 1.5 mL/kg.

7.1.2 Secondary outcomes

- Demographic characteristics
- Dose and dosing regimen
- Indication for medication use
- Presence of symptoms (nausea, vomiting, gastric fullness, early satiety, abdominal pain)
- Use of other medications

7.2 Randomization

Not applicable.

7.3 Definitions

7.3.1 Ethnicity

Caucasian, Black, Hispanic, Asian, Indigenous or Other (self-declared).

7.3.2 Risk factors for broncho aspiration

• Diabetes mellitus with neuropathy or gastroparesis
• Obesity (BMI ≥ 30 kg/m²)
• Active cancer
• Gastro-esophageal reflux disease
• Opioid use
• History of bariatric surgery
• Neurological disease
• Chronic or acute kidney disease
• Symptomatic hypothyroidism

7.3.3 Technical limitations

• Previous gastric surgery
• Large hiatal hernia

7.3.4 Adequate fasting

Clear liquids: 2 hours
General diet: 8 hours
(*Clear liquids: water, pulp-free juices)

7.3.5 GLP-1 analogue

• Tirzepatide (Mounjaro®, Zepbound®)

7.4 Gastric ultrasound protocol

It consists of scanning the abdomen in the sagittal plane in the 45° dorsal decubitus position, in the supine position, and in the right lateral decubitus position with a curvilinear, low-frequency (2 to 5 mHz) ultrasound probe and locating the gastric antrum by identifying the main reference points – the left lobe of the liver and a main vessel, the aorta or inferior vena cava.(12) Gastric emptying will be assessed quantitatively and qualitatively by evaluating the composition of its contents and measuring the gastric volume, respectively.

The qualitative assessment will evaluate whether the stomach is empty, with clear liquid, or with solids. The stomach is considered empty when the antrum presents with the anterior and posterior walls juxtaposed, denoting a "buffalo eye" or "target" pattern, a characteristic attributed by the identification of a thick, hypoechoic outer ring. (12) In this case, there is no risk of aspiration of gastric contents during the induction of anesthesia and it is classified as low risk. When fluid is identified in the antrum, hypoechoic content is observed in the center and distended walls. The antrum may appear empty in the supine position and contain fluid in the right lateral decubitus position. The fluid volume should be measured in this position, and if it is less than 1.5 ml/kg (average of 100 ml in adults), it is considered normal in fasting individuals, and the risk of broncho aspiration is considered low (12). On the other hand, the visualization of fluid in both the supine and right lateral decubitus positions is suggestive of a large gastric volume. When the fluid measurement is greater than 1.5 ml/kg, the patient presents a high risk for broncho aspiration (18). Thick liquid, milk, or suspensions have a hyperechoic appearance, generally homogeneous. After ingestion of solid foods, the air content mixed with the solid bolus during mastication forms an air-mucosa interface along the anterior wall of the distended antrum. This area of air artifacts is referred to as a "ground-glass" pattern. After a time interval, this air is displaced and the antrum then appears distended with content of typically mixed echogenicity (16)

Whenever clear liquids are visualized, gastric volume is measured by means of the cross-sectional area of the gastric antrum (AA) using the outer wall of the stomach, which has a linear correlation with gastric volume. This is performed in the right lateral decubitus position with two perpendicular diameters of the antrum, from serosa to serosa, the longitudinal or craniocaudal diameter (CC) and the anteroposterior diameter (AP), using the ellipse formula developed by Bolondi (19) where $AA = (CC \times AP \times \pi)$

/4. With the value of π = 3.14. After calculating AA, the total stomach volume ("predicted volume") will be evaluated in each volunteer using a previously tested and validated mathematical model (18), where stomach volume (mL) = 27 + 14.6 AA (cm2) − 1.28 age (in years).

8 Statistical analysis plans

Patients included will be divided into two groups according to the ultrasound result: high risk for broncho aspiration and low risk for broncho aspiration. Differences between the groups regarding continuous numerical variables will be analyzed using the Student's t-test (normal distribution) or the Mann-Whitney U test (variables not normally distributed). Proportions will be compared using the Chi-square test or Fisher's Exact Test, if the assumptions for using the Chi-square test are violated.

We will use the Kolmogorov-Smirnov test to assess the distribution pattern of continuous numerical variables. Continuous variables with a normal distribution will be expressed as mean ± standard deviation or as median and interquartile range when appropriate. Categorical variables will be presented as absolute and relative frequencies.

All significance probabilities (p-values) presented will be two-tailed. P-values will be considered statistically significant when less than 0.05. All analyses will be performed using R 3.4.1 software (R Foundation for Statistical Computing, Vienna, Austria).

9 Safety and ethical considerations

9.1 Adverse Events

Abdominal ultrasound is a non-invasive examination that does not emit radiation. There is no evidence to support that the use of ultrasound may cause any harm to health. The research participant may experience some discomfort related to fasting for 8 hours for solids and 2 hours for liquids. There are risks related to the loss of data confidentiality, and the research team is responsible for taking all precautions to ensure data confidentiality.

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