Title: Residual Gastric Volume Measured by Ultrasound in Diabetic Surgical Population Versus Non-diabetic Surgical Population.

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BACKGROUND: Traditionally, diabetics have been considered patients with a high risk of aspiration due to having delayed gastric emptying; However, the evidence concerning residual gastric volume (GV) in fasting diabetic patients is inconsistent. This study aimed to compare the fasting GV of diabetic patients with or without dysautonomia with control patients scheduled for elective surgery using gastric ultrasound.

METHODS: Prospective, observational, single-blinded study. All adult patients, both those with DM and those without, who were scheduled for elective surgery under general or regional anesthesia, underwent assessment for eligibility to participate in the study. Written informed consent was obtained from all participants before enrollment. The inclusion criteria were as follows: body mass index (BMI) <40 $kg.m^{-2}$; age ≥18 years; ASA physical status I to III; individuals undergoing elective surgery who had the ability to understand the study rationale and provide informed consent. Exclusion criteria included pregnancy, recent upper gastrointestinal bleeding (<1 month), abnormal anatomy of the upper gastrointestinal tract (such as hiatal hernias and gastric tumors), prior surgical procedures on the esophagus, stomach, or upper abdomen, gastroesophageal reflux disease, nondiabetic autonomic-neurological diseases, chronic kidney diseases, and previous use of prokinetics or opioids. Participants satisfying the inclusion criteria were consecutively enrolled as permitted by surgical programming and availability of research team members and were distributed in 2 groups (DM patients and controls) in a 1:1 ratio. According to the standard institutional practice, all patients underwent an 8-hour fasting period without solids and a 2-hour period without clear liquids before their scheduled elective surgery. Patients were permitted to take their regular morning medications with a sip of water 1 hour before the surgery. DM patients underwent an evaluation for the duration of DM, medication history, glycemic control assessed by glycosylated hemoglobin (HbA1c) levels, and symptoms of gastropathy (such as bloating/ abdominal distension, early satiety/postprandial fullness, nausea/vomiting, or abdominal pain/ discomfort). Additionally, other DM-related complications including diabetic nephropathy, diabetic retinopathy, diabetic vascular disease, and the presence of cardiovascular autonomic neuropathy (CAN; as an indicator of gastric dysautonomia)17 were documented for analysis. Patient demographics, ASA physical status, and treatments were also collected. During preoperative evaluation, assessment of
dysautonomia was conducted using 2 tests from the battery of standardized tests described by Ewing et al. al. The first test, performed with the patient at rest and in a supine position (requires having abstained from coffee or not having experienced a hypoglycemic episode the night before), involved monitoring heart rate variability by electrocardiography (ECG) while the patient breathed in and out at 6 breaths per minute. A difference in heart rate of >15 beats per minute (bpm) was considered normal, while a difference of <10 bpm

was considered abnormal. For the second test, the patient exhaled forcibly into a manometer mouthpiece to reach 40 mm Hg for 15 seconds while ECG monitoring was conducted. This maneuver was repeated 3 times with 1-minute intervals between each repetition. The Valsalva ratio, defined as the ratio of the longest R-R interval after the maneuver to the
shortest R-R interval during the maneuver, was calculated. The mean of the 3 Valsalva ratios was taken as the final value. Values of less than 1.10 were considered abnormal. In our study, a patient was classified as having dysautonomia if either of the 2 tests yielded positive results. Patients were categorized into 3 groups based on their DM history and the presence of dysautonomia: non-DM patients, DM patients with dysautonomia (DM-DYS), and DM patients without dysautonomia (DM-NDYS).

Ultrasound Assessments

On the day of surgery, gastric ultrasound scans were performed in the preoperative room before anesthesia induction by a skilled operator, who was blinded to the patient's study group. A GE LOGIQ e R7 series ultrasound machine with abdominal presets was used to acquire a cross-sectional view of the antrum in the sagittal plane at the level of the liver and aorta using a C1-5 curvilinear probe (3–5 MHz) positioned in the epigastrium. Scans were performed in 2 positions: supine with the upper body elevated at 45° and RLD, after the protocol outlined by Perlas et al. Qualitative data regarding the nature of gastric content (empty, clear fluid, thick fluid/solid) were collected based on sonographic findings. Additionally, the sonographic appearance of the gastric antrum was categorized using the 3-point grading scale established by Perlas et al. Grade 0 denoted the absence of any content appearance (a flat antrum with juxtaposed anterior and posterior walls) in both the semi-upright and RLD positions. Grade 1 indicated the presence of fluid appearance solely in the RLD position, while Grade 2 signified the presence of any content appearance in both the RLD and supine positions. For volume assessment, the antral CSA was measured at the level of the aorta, with the antrum in a resting state (between peristaltic contractions), and 3 consecutive measurements were taken in the RLD position. These measurements were averaged to estimate GV, aiming to minimize measurement errors. During this process, the CSA was measured using the free-tracing tool of the equipment, encompassing the entire thickness of the gastric wall. The estimated GV was calculated using the mathematical model proposed by Perlas et al, based on the CSA of the gastric antrum in the RLD position. The calculation is as follows: volume (mL) = 27.0 + 14.6 × CSARLD (cm2) − 1.28 × age (years).

OUTCOMES

Our primary outcome was to assess the prevalence of full stomach using the Perlas gastric content grading scale in diabetic patients with or without dysautonomia, as well as in healthy controls. Secondary outcomes included measuring the CSA and GV in RLD, as well as determining the prevalence of solid gastric residue.

STATISTICAL ANALYSIS

The primary end point was the percentage of patients in each group with a Perlas grade 2 antrum. Based on an estimated prevalence of full stomach in fasting patients scheduled for elective surgery of approximately 5%, and a prevalence of gastroparesis in DM patients of around 15%, 141 patients per group would be required, assuming an alpha risk of 0.05 with a power of 80%. To account for an anticipated attrition rate exceeding 5%, we aimed to include a total of 296 patients (148 per group). Continuous data were presented as mean plus standard deviation (SD) for normally distributed data, and median plus interquartile

range (IQR) for nonnormally distributed data, after assessment of normality using the Shapiro-Wilk or Kolmogorov-Smirnoff test. Categorical variables were summarized as counts and percentages and were compared with a $\chi 2$ test or Fisher exact test when appropriate. Group comparisons between patients with or without gastroparesis were performed using Student *t* test or the Mann-Whitney test as appropriate. Subgroup analyses were performed using 1-way analysis of variance (ANOVA), with post hoc Tukey-Kramer´s method for pairwise subgroup comparison in the event of a positive ANOVA result. Alternatively, the Kruskal-Wallis test was used when ANOVA assumptions were not met, with the Dunn test for subgroup comparison in cases of a positive Kruskal- Wallis test result.