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## ORIGINAL CLINICAL RESEARCH

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### Sonographic Evaluation of Gastric Volume before General Anesthesia in Full-Term Diabetic Patients Scheduled for Elective Cesarean Section in Comparison with Diabetic Patients in the First and Second Trimester Scheduled for Gynecological or Surgical Procedures

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#### Abstract

**Background:** This study assessed the risk of aspiration in full-term pregnant women with diabetes compared to that of diabetic women in the first or second trimester through sonographic evaluation of gastric volume.

**Methods:** This cross-sectional study enrolled 274 adult pregnant women diagnosed with diabetes and classified as American Society of Anesthesiologists physical status II or III. The first group included 137 full-term pregnant women scheduled for elective Cesarean section under general anesthesia. The second group included 137 pregnant women in the first or second trimester scheduled for minor gynecological or surgical procedures. The gastric volume and antral cross-sectional area (CSA) were assessed by ultrasonography in both supine and right lateral decubitus positions based on Arzola grade model. The primary outcome measure was gastric volume, while secondary outcomes included the antral CSA and an evaluation of the risk of aspiration.

**Results:** We found no significant differences between the groups in terms of demographic, diabetic data, gastric volume, or the Arzola grades. However, it was found that full-term diabetic pregnant women had a significantly larger antral CSA compared to those who were in the first or second trimester ( $311.32 \pm 18.74$  vs  $279.61 \pm 20.59$  mm<sup>2</sup>,  $p < 0.001$ ). Additionally, a significant positive correlation was discovered between the duration of diabetes mellitus and antral CSA in full-term women ( $p = 0.031$ ).

**Conclusion:** Sonographic assessment of gastric volume in diabetic pregnant women does not indicate that gastric volume is an aspiration risk in any trimester of pregnancy. Meanwhile, long-standing diabetes mellitus may be an aspiration risk in full-term women scheduled for elective cesarean section under general anesthesia.

**Keywords:** Antral cross-sectional area; diabetes mellitus; gastric volume; pregnancy; ultrasound.

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## Introduction

General anesthesia is a suitable choice for Cesarean delivery in diverse circumstances, encompassing emergency Caesarean delivery when there is a shortage of time to provide neuraxial anesthesia or attain the obligatory surgical level via a labor epidural catheter. It can also be considered where the mother refuses or is unable to cooperate with neuraxial anesthesia when there are contraindications to neuraxial anesthesia, and when the neuraxial technique is unsuccessful.<sup>1</sup> The mortality rate resulting from an aspiration incident occurring during labor vary between 5% and 15%. Sedation and general anesthesia impair the physiological systems that protect against aspiration, specifically the tone of the lower esophageal sphincter and the upper airway reflexes. Therefore, pulmonary aspiration is linked to approximately 9% of fatalities related to anesthesia.<sup>2</sup>

Pregnant women who receive general anesthesia face a significant risk of pulmonary aspiration of stomach contents. Irrespective of the length of preoperative fasting, anesthesiologists adopt a careful approach when handling pregnant women over 18 weeks gestation due to the assumption of a full stomach and the

heightened risk of aspiration and associated complications.<sup>3,4</sup>

Patients with diabetes typically experience gastropathy due to autonomic dysfunction, which increases their vulnerability to delayed gastric emptying.<sup>5</sup> Therefore, they are more susceptible to an increased risk of aspiration than those who do not have this medical condition.<sup>6</sup>

To reduce the risk of perioperative aspiration, guidelines for fasting have been created by the American Society of Anesthesiologists<sup>7</sup> and the European Society of Anesthesiology.<sup>8</sup> Nonetheless, the recommendations are principally designed for healthy individuals undergoing elective surgery and may be somewhat unreliable for patients with coexisting conditions affecting gastric emptying.

Gastric volume evaluation can be performed utilizing point-of-care ultrasound. The process is marked by its simplicity, widespread accessibility, non-invasiveness, and ease of execution while demonstrating consistent results with inter- and intra-observer agreement.<sup>9</sup> The stomach antrum holds a dependable position and identifiable anatomical features, making it easy to locate, visualize, and measure.<sup>10</sup>

The correlation between antral cross-sectional area (CSA) measurements and gastric volume is linear. This association has been verified in adults by comparing it to the standard gastric volume estimation through gastroscopy, and in the pediatric population by comparing it to gastric volume estimation via nasogastric tube aspiration.<sup>11, 12</sup> Several techniques can be used to estimate the residual stomach volume before surgery through a quantitative or semi-quantitative approach. The procedures entail utilizing position-specific validated formulas, wherein measurable values of the antral CSA are used to determine stomach volumes.<sup>13, 14</sup> Additionally, mathematical models or measuring scales that depend on the visualization of stomach fluid in different areas can be employed to quantitatively determine the volume of gastric fluid.<sup>9</sup>

There were observed discrepancies in the results obtained through direct and indirect methods of stomach volume evaluation among pregnant women.<sup>15-17</sup> Therefore, the current study was conducted among diabetic pregnant women to compare gastric volume in full-term to that in the first or second trimester and determine the risk of aspiration correlated with each trimester.

## Materials And Methods

### *Ethical considerations*

The investigators obtained approval from the Ethics Committee of the Faculty of Medicine, Cairo University, Egypt. Each participant signed an informed written consent after receiving a comprehensive explanation of the study's aim and methodology. The confidentiality of each participant's information was maintained.

### *Study design and setting*

This cross-sectional study was conducted at the operating room of Cairo University Hospitals, Egypt between April 2023 and September 2023.

### *Eligibility criteria*

The study recruited pregnant women with diabetes, between the ages of 18 and 45 years, who were American Society of Anesthesiologists (ASA) physical status grades II or III. The participants were scheduled for elective Cesarean section or minor surgical or gynecological procedures during the first or second trimesters. The study excluded patients with ASA physical status greater than III, morbid obesity, a history of upper gastrointestinal surgery, hiatus hernia, or gastroesophageal

reflux disease. Furthermore, patients with emergency operations or those suspected of having difficult intubation were also excluded.

The recruited patients were divided into two groups. The first group included full-term diabetic women who were scheduled for elective Cesarean section under general anesthesia. The second group included pregnant diabetic women who were in their first or second trimester and scheduled for minor gynecologic or surgical procedures.

#### *Procedures and interventions*

All participants underwent in-depth history taking and complete physical examinations. The fasting time for solids and liquids and the duration of diabetes were evaluated and recorded. According to the American Diabetes Association and the Toronto Consensus Panel on Diabetic Neuropathy, a score of  $>2$  on the Michigan Neuropathy Screening Instrument indicates peripheral neuropathy. The Michigan Neuropathy Screening Instrument is a validated tool consisting of a self-administered questionnaire and a 5-item physical examination and has been widely used in various longitudinal studies to

determine the presence of peripheral diabetic neuropathy.<sup>18,19</sup>

Diabetic nephropathy was assessed through microalbuminuria and estimated glomerular filtration rate. Fasting, postprandial plasma glucose concentration and glycosylated hemoglobin level were performed preoperatively.

All participants adhered to the prescribed fasting durations outlined in the recommendations, which included 2 hours for clear drinks, 6 hours for a light meal, and 8 hours for a meal high in fried or fatty content. A decision was made to implement a uniform light lunch for all patients as their final meal. Gastric ultrasonography tests were conducted at a particular time, specifically 6 hours after completing the patient's most recent meal.

Before the administration of anesthesia, each patient underwent scanning in both the supine and right lateral decubitus (RLD) postures. The scanning process was conducted by a sole operator with prior experience in the specific technique. The ultrasound imaging procedure used a Philips HD11XE or CX50 ultrasound system (Philips Healthcare, Andover, MA, USA). A curvilinear low-frequency transducer with a

2-5 MHz range was employed for the imaging process.

On a sagittal scanning plane of the epigastrium, the identification of the stomach antrum within the scanning area was achieved by utilizing sonographic landmarks, including the liver, aorta, vena cava, and pancreas, alongside the characteristic visual representation of the gastric antrum on sonography. An inconclusive examination is when the antrum is completely invisible or only visible when the patient assumes a supine position.<sup>20</sup>

The stomach was considered 'empty' if the antrum appeared flat with the anterior and posterior walls close together in both the supine and right lateral decubitus positions. If the antrum appeared distended with thin walls and hypoechoic content, it was considered to contain fluid. If the antrum appeared distended with contents of mixed echogenicity, it was considered to be thick fluid or solid based on qualitative observations.

According to Perlas et al.,<sup>13</sup> the validated calculation of stomach volume was performed for the RLD.

Gastric volume (mL) = 27 + 14.6 CSA (in RLD) (cm<sup>2</sup>) – 1.28\*age (years).

According to the Arzola grading system,<sup>21</sup> the grading system for the antrum

was established based on the observation of clear fluid presence or absence in both the supine and RLD positions. The term "clear fluid" is used to describe the existence of a non-particulate substance that exhibits echogenicity.

Grade 0: Gastric contents in the antrum cannot be observed in either the supine or RLD positions.

In Grade 1, there is the presence of a transparent fluid that may be viewed within the antrum, localized exclusively to the RLD.

Grade 2: in both the supine and RLD positions, clear fluid in the antrum was noted.

### *Study outcomes*

The primary outcome was gastric volume through abdominal ultrasound in diabetic pregnant women scheduled for elective Cesarean section or minor gynecological or surgical interventions. Secondary outcomes included the grade of gastric volume according to the Arzola scoring system, the antral CSA, and the risk of aspiration.

### Sample size

According to Gal et al.<sup>22</sup> 137 participants were estimated to achieve a confidence level of 95% with 80% power and a margin of error of 5%, using Epi Info STATCALC. To account for potential dropouts during follow-up, the sample size was increased to 150.

### Statistical analysis

The SPSS (Statistical Package for the Social Sciences) version 25 was utilized for the coding and entry of the data. The mean, standard deviation, median, minimum, and maximum were used to describe the data for quantitative data. In contrast, frequency (count) and relative frequency (%) were used to summarize the data for categorical data. The unpaired t-test was used for the parametric data, whereas the Mann-Whitney test was used for the non-parametric data. The Chi-square test was carried out for categorical data. Spearman's correlation coefficient was utilized for detection of correlations. P-values that were lower than 0.05 were regarded as being statistically significant.

### Results

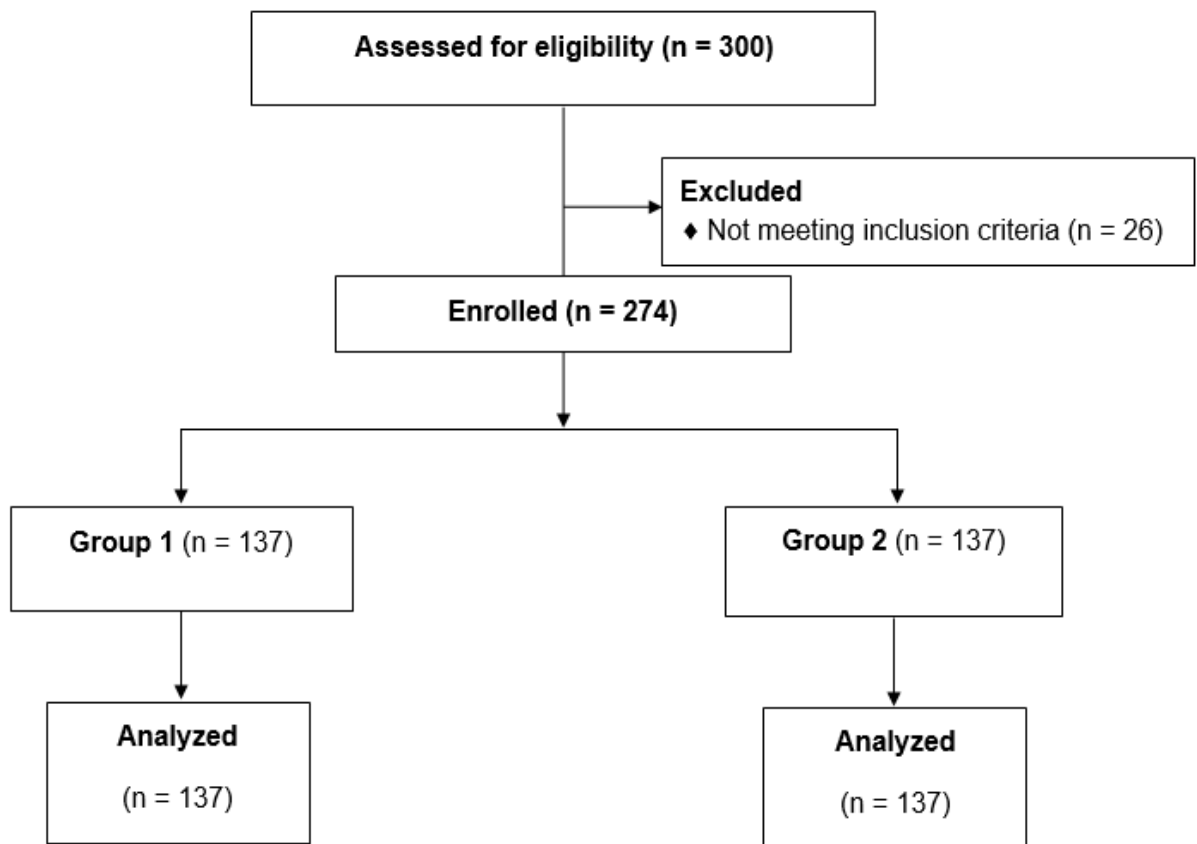
Three hundred patients were recruited, six patients were excluded because

of emergency surgery, 6 patients were excluded due to morbid obesity and 14 patients had gastroesophageal reflux disease. A total of 274 participants were divided into two groups. The first group included 137 full-term pregnant diabetic women scheduled for elective Cesarean section in whom the airway was secured using the rapid sequence induction method. The second group included 137 first- or second-trimester pregnant diabetic women scheduled for minor gynecological or surgical procedures (Figure 1).

Patient characteristics including age, weight, height, and body mass index were comparable between the study groups. Total fasting hours, glycosylated hemoglobin, and disease duration were not statistically different between the two groups (Table 1). In the second group, the most common types of surgeries were urological (33.6%) and orthopedic (29.2%) procedures (Table 2). Table 3 shows that the antral CSA was significantly larger in group 1 than in group 2 ( $311.32 \pm 18.74$  vs.  $279.61 \pm 20.59$  mm<sup>2</sup>,  $p < 0.001$ ). However, gastric volume and Arzola grade were not significantly different between groups ( $p = 0.106$  and  $0.288$ , respectively).

There was a statistically significant correlation between antral CSA and duration of diabetes mellitus in the full term diabetic

pregnant women (Table 4). No other statistically significant correlation was observed (Table 4).



**Figure 1.** Flow chart of the studied patients



**Table 1.** Demographic data

Variable	Group 1 (n=137)	Group 2 (n=137)	P-value
Age, year	31.19±4.66	30.04±6.1	0.079
Weight, kg	81.01±8.96	79.85±8.39	0.272
Height, cm	167.37±7.84	167.95±7.48	0.534
BMI, kg/m <sup>2</sup>	27.94±2.71	28.35±2.56	0.199
Hours of fasting	7.85±1.19	7.64±1.09	0.129
HbA1c, %	7.35±0.863	7.51±0.671	0.088
Disease duration, year	8.49±2.36	8.78±2.21	0.295

Data is presented as mean ± standard deviation.

**Table 2.** Type of surgeries

	Group 1 (n=137)	Group 2 (n=137)
Elective CS, n (%)	137 (100%)	0
Gynecology surgery, n (%)	0	24 (17.5%)
Urology surgery, n (%)	0	46 (33.6%)
Orthopedic surgery, n (%)	0	40 (29.2%)
ENT surgery, n (%)	0	27 (19.7%)

CS: Cesarean section; ENT: ear, nose, and throat.

**Table 3.** Ultrasound measurements and the Arzola assessment grade

	Group 1 (n=137)	Group 2 (n=137)	t	P-value
Cross-sectional area, mm <sup>2</sup>	311.32±18.74	279.61±20.59	13	<0.001*
Gastric volume, mL	17.89±9.64	16.35±1.09	1.62	0.106
Arzola Grade				
0, n (%)	35 (25.5%)	28 (20.5%)	2.49	0.288
1, n (%)	86 (62.8%)	98 (71.5%)		
2, n (%)	16 (11.7%)	11 (8%)		

Data is presented as mean ± standard deviation or number (percentage)

**Table 4.** Correlation between antral cross-sectional area and other parameters

	Group 1		Group 2	
	r	P	r	P
BMI (kg/m <sup>2</sup> )	-0.083	0.337	0.009	0.916
Hours of fasting (h)	-0.079	0.356	-0.058	0.499
DM duration (h)	0.184	0.031*	-0.137	0.109
HbA1c (%)	-0.021	0.804	0.111	0.197
Gastric volume (mL)	-0.002	0.981	-0.022	0.803

BMI: body mass index; DM: diabetes mellitus; HbA1c: glycosylated hemoglobin

## Discussion

This study found that diabetic pregnant women had comparable gastric volumes in each trimester of pregnancy. However, the full-term pregnant women scheduled for elective Cesarean section had a larger CSA than the first- or second-trimester diabetic women scheduled for minor surgery. In addition, long-standing diabetes mellitus was positively correlated with CSA in full-term diabetic women.

During pregnancy, the uterus can exert pressure on the stomach, causing it to move upwards. As a result, the size and position of the antrum may be altered, potentially affecting the relationship between the antral area and gastric contents.<sup>3</sup> In addition, the ability of the lower esophageal sphincter is reduced due to decreased functionality, which is exacerbated by increased levels of progesterone and estrogen. The enlarged uterus increases gastric pressure, while the production of gastrin by the placenta increases gastric acid secretion, resulting in decreased gastric pH in pregnant women.<sup>24</sup>

Ultrasonographic assessment of gastric content and volume is a useful tool for assessing the risk of aspiration in the perioperative period. The gastric antrum is the most consistently identified gastric

landmark on ultrasound (98%-100% of cases).<sup>25</sup> Important vascular landmarks such as the aorta or inferior vena cava and the superior mesenteric artery or vein are used to standardize a scan plane through the antrum.<sup>26</sup> With increasing volume, the antrum becomes round and distended with thin walls, which can be measured with a standard abdominal ultrasound transducer.

Carp et al.<sup>27</sup> were able to differentiate between liquid and solid gastric contents using ultrasound. In the current study, the gastric antrum was visualized in the cross-sectional view and antral CSA was calculated. Our results showed that antral CSA was greater in second and third trimester pregnant women who were allowed to eat during labor than in those who were given a clear-liquid-only diet. In addition, antral CSA decreased with time after oral intake. Sequential measurements of antral CSA have been used to assess gastric emptying time after a standardized oral intake and have shown a strong correlation with scintigraphy.<sup>28</sup> Bedside two-dimensional ultrasonography is a reliable method for both quantitative and qualitative analysis of gastric contents.<sup>28</sup>

In the current study, pregnant women with diabetes had a similar gastric volume to

those in early pregnancy. Full-term diabetic women had a higher mean antral CSA, which is consistent with earlier research in pregnant women.<sup>23, 29</sup> However, previous studies<sup>22, 30-32</sup> have shown discrepancies with our findings, possibly due to differences in the study population and body mass index. The three-point grading system confirms the semiquantitative classification of the antrum as validated by Arzola et al.<sup>32</sup> This approach is comparable to the validation performed in non-pregnant adults. Nevertheless, the threshold of 340 mm<sup>2</sup> established for term pregnant women in semi-recumbent right lateral position is insufficient to accurately differentiate an empty stomach from one at risk of aspiration due to contents.<sup>32</sup> Gal et al.<sup>22</sup> found that the group of women who underwent Caesarean section had a shorter fasting period before the procedure. However, there were no significant differences in their abdominal volumes compared with non-pregnant or early pregnant women.

Furthermore, Rouget et al.<sup>30</sup> evaluated qualitative and quantitative ultrasound measurements of the gastric antrum in term pregnant women before and after elective Cesarean section. The study found a significant decrease in the depth and distance of the antrum from the aorta between

the two measurement periods, indicating a significant shift in the anatomical location of the antrum. Also, they found that the gastric contents of parturients undergoing elective Cesarean section were minimally altered, while the antral CSA experienced a reduction, particularly in the semi-recumbent position. This reduction is attributed to a shift in the position of the stomach within the abdominal cavity. This finding suggests that the established relationship between antral CSA and gastric content volume observed in non-pregnant individuals may not apply to term pregnant women. Rouget et al.<sup>30</sup> concluded that insufficient sample size was the possible cause of the non-significant results regarding the semi-recumbent right lateral position. This was because the sample size was calculated based on the changes observed in the antral area assessed in the same position.

The age and body mass index of the participants in each group were similar in this study. Antral CSA did not show any significant correlations with fasting hours or body mass index. Contrary to our results, Amaral et al.<sup>33</sup> showed a positive correlation between gastric antral CSA and body weight and body mass index. Identification of patients at risk of pulmonary aspiration can be achieved by calculating gastric volume,

which requires measurement of gastric antral CSA. Obese patients had a larger gastric antral CSA and a higher estimated gastric volume than non-obese patients. According to Riveros-Perez et al.,<sup>34</sup> body mass index is a reliable measure of antral CSA and gastric volume in pregnant patients scheduled for Cesarean section. Perioperative fasting guidelines for pregnant women should be adjusted when dealing with individuals classified as obese or severely obese.

Based on prior studies,<sup>22, 29, 31-33</sup>, our study found that both groups had a similar fasting duration, with participants fasting for  $7.85 \pm 1.19$  and  $7.64 \pm 1.09$  hours, respectively. In addition, Sarhan et al (33) reported that non-pregnant, full-term women were less likely to have a high residual gastric volume after an 8-hour fast following consumption of a standardized meal. According to the guidelines of the American Society of Anesthesiologists,<sup>7, 35</sup> individuals should fast for at least 2 hours before consuming clear liquids, 6 hours after consuming a light meal, and 8 hours after consuming a high-calorie or high-fat meal. These recommendations are specifically for patients undergoing elective surgery. The 2011 European Society of Anesthesiology guidelines do not provide specific recommendations for fasting in

people with diabetes.<sup>8</sup> Moreover, they lack credibility when applied to patients with comorbidities that affect gastric emptying or volume, those who may experience difficulties with airway management, or those in emergency situations.<sup>36</sup> There is currently no consensus on the recommended duration of fasting in people with diabetes to reduce the risk of pulmonary aspiration. A gastric residual volume of 1.5 mL/kg or less does not pose a significant aspiration risk in healthy fasting individuals. This volume threshold is considered important because of the presence of gastric fluid, which can cause aspiration.<sup>37</sup> Prediction of surgical time is often accurate. However, it should be noted that the surgical schedule is subject to change. In addition, prolonged periods of fasting can cause an increase in gastric acid secretion, resulting in a decrease in the pH of the gastric contents, usually below 2.5.<sup>38</sup> Recent advances in the medical field suggest an increasing trend towards more flexible procedures.<sup>39</sup>

Numerous studies have reported variable results regarding the effect of glycosylated hemoglobin and blood glucose levels in individuals with type 2 diabetes mellitus.<sup>38, 39</sup> However, our study found no apparent relationship between antral CSA and glycosylated hemoglobin concentrations.

Diabetic patients are often considered to have a full stomach and are at increased risk of pulmonary aspiration due to autonomic gastropathy. Gastroduodenal motor abnormalities resulting in delayed gastric emptying have been observed in diabetic patients as reported by Camilleri et al.<sup>40</sup> The accuracy of determining the nothing per mouth status of patients is a topic of discussion among physicians, especially in high-risk populations. This uncertainty may lead to an increased risk of aspiration. In addition, Demirel and colleagues<sup>6</sup> found that certain patients with type 2 diabetes mellitus experienced a sensation of fullness in the stomach even after following standard fasting protocols. The authors suggest that patients with type 2 diabetes mellitus, especially those with long-standing diabetes of eight years or more and peripheral neuropathy, should undergo preoperative ultrasound evaluation of gastric contents. Haramgatti et al.<sup>23</sup> found that patients diagnosed with chronic diabetes had increased levels of gastric remnant and antral CSA compared to patients without diabetes. These findings may explain the association between wide antral CSA and longstanding diabetes mellitus in our full-term diabetic pregnant women. Therefore, our results strongly suggest that anesthetists should be more cautious when managing

patients with a history of long-standing diabetes. Current guidelines lack specific preoperative recommendations for this group, indicating an urgent need for further prospective studies to fill this gap.

#### *Limitations*

This was a single-center observational study with a small sample size; therefore, it would be difficult to generalize the results. The efficiency of ultrasound is highly dependent on the expertise of the operator. In the current study, ultrasonography was performed by a single observer, which limits the applicability of the findings. In addition, the volume of gastric contents was not directly measured. In the clinical setting of the study, invasive techniques, including the use of a nasogastric tube, and noninvasive techniques, such as magnetic resonance imaging or gastric tomodesitometry, were not practical. Also, it was possible that some gastric emptying occurred during the procedure. Conducting a multi-center study to assess gastric capacity in individuals with diverse demographics and backgrounds would add to the existing knowledge base.

#### *Conclusion*

For diabetic pregnant women, it is recommended to include sonographic evaluation of gastric volume as a routine



practice before surgeries. Although gastric volume is not considered a risk of aspiration during any trimester of pregnancy, long-standing diabetes mellitus can increase the risk of aspiration in full-term women scheduled for elective cesarean section under general anesthesia.

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**Conflict of interest**

The authors declare no competing interests.

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