

Original Article

Gastric ultrasound in the third trimester of pregnancy: a randomised controlled trial to develop a predictive model of volume assessment[‡]

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Summary

Bedside gastric ultrasonography can be performed reliably by anaesthetists to assess gastric content in the peri-operative period. We aimed to study the relationship between gastric cross-sectional area, assessed by ultrasound, and volumes of clear fluids ingested by pregnant women. We recruited 60 non-labouring third-trimester pregnant women in a randomised controlled and assessor-blinded study. A standardised scanning protocol of the gastric antrum was performed in the 45° semirecumbent and 45° semirecumbent-right lateral positions. Subjects were randomly allocated to drink one out of six predetermined volumes of apple juice (0 ml, 50 ml, 100 ml, 200 ml, 300 ml, 400 ml). Qualitative and quantitative assessments at a baseline period after an 8-h fast, and immediately after the drink, were used to establish the correlation between antral cross-sectional area and volume ingested. A predictive model to estimate gastric volume was developed. Antral cross-sectional area in the semirecumbent right lateral position significantly correlated with the ingested volume (Spearman rank correlation = 0.7; $p < 0.0001$). A cut-off value of 9.6 cm² discriminated ingested volumes $\geq 1.5 \text{ ml.kg}^{-1}$ with a sensitivity of 80%, a specificity of 66.7%, and an area under the curve of 0.82. A linear predictive model was developed for gastric volume based only on antral cross-sectional area (Volume (ml) = $-327.1 + 215.2 \times \log(\text{cross-sectional area (cm}^2\text{)})$). We conclude that in pregnant women in the third trimester of gestation, the antral cross-sectional area correlates well with volumes ingested, and this cut-off value in the semirecumbent right lateral position discriminates high gastric volumes.

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Introduction

Bedside gastric ultrasound is a valuable point-of-care ultrasonographic application for the assessment of content and volume [1], which may alter peri-operative clinical management [2]. Its feasibility and utility have been shown in diverse patient groups, including adult patients having elective [2] or urgent surgery [3], children [4], the morbidly obese [5, 6] and pregnant women [7–9].

A qualitative assessment allows the reliable discrimination between an empty stomach and one containing solid/thick fluid contents or clear fluids [7, 10]. In addition, when clear fluid contents are present, a quantitative assessment can be performed to estimate gastric volume based on the cross-sectional area of the gastric antrum. Such assessment differentiates small volumes $\leq 1.5 \text{ ml.kg}^{-1}$, consistent with baseline gastric secretions, from higher volumes that may increase aspiration risk [11–15].

A mathematical model to estimate gastric volume was validated initially in non-pregnant adults body mass index (BMI) $\leq 40 \text{ kg.m}^{-2}$ [16], and then separately for obese subjects with a BMI $> 35 \text{ kg.m}^{-2}$ [6]. Antral cross-sectional area measured in pregnant women before elective caesarean section [9] followed a very similar distribution to those obtained in fasted surgical adult patients [14]. However, the gravid uterus introduces variations in the ultrasound examination, as the stomach tends to be displaced cephalad and to the right when compared with non-pregnant subjects, which could conceivably affect volume estimation [17, 18]. Hence, further studies are warranted.

Our aim was to evaluate the relationship between gastric antral cross-sectional area assessed by ultrasound and the volume of clear fluids ingested, in order to develop a predictive model to estimate gastric volume in women in the third trimester of pregnancy.

Methods

After approval by the Research Ethics Board of Mount Sinai Hospital, Toronto, Canada, we conducted this randomised controlled and assessor-blinded study on women in the third trimester of pregnancy. Written informed consent was obtained from the study subjects. We followed the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) [19].

Subjects were recruited at the Obstetric Antenatal High Risk Unit at Mount Sinai Hospital on the day before the study assessments. We recruited ASA physical status 2–3 women who were ≥ 32 weeks gestational age with a singleton pregnancy; ≥ 18 years old; height ≥ 150 cm; weight between 50 kg and 120 kg; and able to understand the rationale of the study assessments. We did not recruit women in labour and those with abnormal anatomy of the upper gastro-intestinal tract or previous surgical procedures on the oesophagus, stomach or upper abdomen.

We recruited only when a study investigator was available to perform the ultrasound examinations. Ultrasound examinations were performed by either one of two anaesthetists (CA, JC) with ≥ 4 -year experience in gastric ultrasound assessment in the pregnant and non-pregnant population for clinical practice and research.

A standardised scanning technique was used with a portable ultrasound system and a 5–2 MHz curved-array transducer (M-Turbo[®] ultrasound system, Sono-Site Canada, Inc., Markham, ON, Canada). Following an overnight fast of at least 8 h, a baseline qualitative and quantitative gastric ultrasound assessment was performed (baseline fasted assessment). The gastric antrum was imaged in a sagittal plane in the epigastrium, between the left lobe of the liver and the pancreas, at the level of the aorta. Subjects were examined in the 45° semirecumbent position, followed by the 45° semirecumbent right lateral position. Further details of the ultrasound technique and sonographic assessment of gastric contents have been described elsewhere [20].

The qualitative assessment determined the nature of the gastric contents (empty, fluid or solid content). If only clear fluid was observed, patients were classified into three grades [14]. A grade-0 antrum was defined as the absence of fluid contents in both semirecumbent and semirecumbent right lateral position, suggesting a ‘completely empty’ state. If fluid content was observed only in the semirecumbent right lateral, but not in the semirecumbent position, it was classified as a grade-1 antrum, which has been shown to correlate with a low volume state compatible with baseline gastric secretions both in fasted adults [14] and fasted non-labouring pregnant women at term [9]. In contrast, if fluid was observed in both semirecumbent and semirecumbent

right lateral positions, the antrum was classified as grade 2, which suggests higher-than-baseline volume that is seen uncommonly in fasted patients. The quantitative component of the examination consisted of an assessment of the gastric volume by measuring the cross-sectional area of the gastric antrum between peristaltic contractions, using the built-in free-tracing calliper of the ultrasound unit [21]. One gastric ultrasound examination and measurement was obtained in the semirecumbent position primarily to classify the antral grade, whereas three measurements from three consecutive images in the semirecumbent right lateral position were averaged for gastric volume estimation [16, 21].

The subjects were then randomly allocated into one of six groups who drank either 50 ml, 100 ml, 200 ml, 300 ml or 400 ml apple juice, plus a control group who did not drink. Random allocation was performed in blocks of six subjects with one subject per group, using a computer-generated list of random numbers. Group allocation was concealed from the ultrasound examiner using sealed opaque envelopes that were prepared and kept by an independent research assistant. An after-drink gastric ultrasound assessment was carried out within 10 min, taking three consecutive measurements in the semirecumbent right lateral position.

The primary objective of the study was to evaluate the relationship between antral cross-sectional area and the fluid volume ingested, including the influence of patient characteristics. Secondary objectives included the determination of the cut-off value of antral cross-sectional area to detect ingested volumes $\geq 1.5 \text{ ml.kg}^{-1}$; the relationship or agreement between a previous mathematical model developed in non-pregnant adults [16] to predict gastric volumes based on cross-sectional area: $\text{Volume (ml)} = 27.0 + (14.6 \times \text{cross-sectional area (cm}^2) - (1.28 \times \text{age (years))}$; and to develop a new predictive model applicable to pregnant women.

Our sample size calculation was based on a validation study by Perlas et al. that determined a correlation coefficient of 0.86 (null hypothesis) between the antral cross-sectional area and volume ingested in a group of healthy volunteers [16]. We hypothesised a correlation coefficient of at least 0.7 (alternative

hypothesis) when comparing cross-sectional area and volume ingested in a group of fasted non-labouring pregnant women in the third trimester. Using the Fisher z-transformation of the correlations, a two-sided test, 80% power and an α error of 0.05, a sample size of 54 patients was deemed adequate. We decided to collect a sample of 60 subjects to compensate for possible protocol violations.

For the primary objective, we performed pairwise correlations between antral cross-sectional area, patient characteristics, anthropometric data and volumes ingested. Additionally, Spearman rank correlation coefficient was estimated to determine the relationship between volumes ingested and antral cross-sectional area in the semirecumbent lateral position. Antral cross-sectional area in the semirecumbent and semirecumbent right lateral positions were compared using Student's t-test or the Wilcoxon rank sum test as appropriate, and antral grades were compared using Chi-square or Fisher's exact tests. For the secondary objective, the area under the receiver operating characteristic (ROC) curve was used to evaluate the predictive power of antral cross-sectional area in differentiating grade-0 and grade-1 assessments in the baseline fasted state, and in predicting ingested volumes $\geq 1.5 \text{ ml.kg}^{-1}$ in the after-drink assessment, considering each subject's current weight and using a logistic regression model. The cut-off values of antral cross-sectional area to detect ingested volumes $\geq 1.5 \text{ ml.kg}^{-1}$ with correspondent sensitivities and specificities were provided based on ROC analysis. We also estimated the cut-off value using the Youden method, which maximises statistically the sum of the sensitivity and specificity [22].

We carried out multiple linear regression, both to examine the performance of the prior predictive model developed in non-pregnant adults [16], and to develop a new predictive model to estimate ingested volume in this specific study population. This final model was derived with a backward variables-selection procedure, with inclusion criterion of $p < 0.05$. The variables associated with the outcome identified in the univariate analysis, and their interaction terms, were included in the full model. A Bland–Altman analysis was conducted to examine the agreement between the predicted volume based on the prior model [16] and the

new model for pregnant patients, and to relate the magnitudes of these differences to a clinical context.

The data management and the statistical analyses were performed using SAS 9.3 (SAS Institute, Inc., Cary, NC, USA), R 10.2 (<http://www.r-project.org/>) and STATA/IC for Mac, Release 13.1 (StataCorp, College Station, TX, USA).

Results

Subjects were enrolled from January 2014 until March 2016. One hundred and thirty-three women were assessed for eligibility, and 60 women included in the study (Fig. 1). Baseline characteristics are presented in Table 1.

During the fasted baseline assessment, antral grades were evenly distributed with 27 (45%) women having grade-0 and 33 (55%) having grade-1 ($p = 0.12$) assessments. No women had a grade-2 antrum or solid contents. The median (IQR [range]) antral cross-sectional area measured in the semirecumbent position (3.8 (3.1–4.6 [2.1–7.2]) cm^2) was smaller than in the semirecumbent right lateral position (5.2 (4.0–6.9 [2.4–10.2]) cm^2); $p < 0.0001$). Nevertheless, ROC analysis showed that the cross-sectional area in the semirecumbent right lateral position demonstrated a superior discriminatory performance than that measured while semirecumbent to distinguish an antral grade 0 from grade 1, with area under the curve (AUC) (95%CI) of 0.88 (0.80–0.97) in the semirecumbent right lateral position vs. 0.56 (0.41–0.70) in the semirecumbent position.

During the after-drink assessment, the duration of the ultrasound scanning was 5 (3.6–6.4 [1.9–11.8]) min, and was completed within 10.3 min in 95% of the women. The distribution of antral cross-sectional area vs. ingested volume is presented in Fig. 2. Among antral cross-sectional area and other patient characteristics, only cross-sectional area in the semirecumbent right lateral position was significantly associated with the ingested volume (Spearman rank correlation = 0.7; $p < 0.0001$). Receiver operating characteristic analysis to evaluate the discriminatory performance of antral cross-sectional area measurements in the semirecumbent right lateral position to detect an ingested volume $\geq 1.5 \text{ ml.kg}^{-1}$ rendered an AUC (95%CI) of 0.82 (0.72–0.93). Using logistic regression, a cut-off value of

9.6 cm^2 corresponds to the 95th percentile of baseline fasted measurements. This cut-off value displayed a sensitivity (95%CI) of 80% (66–94%) and a specificity (95%CI) of 66.7% (50–84). Using the Youden method, a cut-off value of 11.5 cm^2 showed a sensitivity (95% CI) of 66.7% (50–84%) and a specificity (95%CI) of 86.7% (75–99%).

Based on linear regression analysis, the relationship between the observed ingested volumes and the volumes predicted by the model from Perlas et al. [16] showed an estimated intercept (95%CI) of 96.6 ml (73.1–120.1 ml) and a slope (95%CI) of 0.33 (0.19–0.48), which are significantly different from 0 and 1, respectively, suggesting a suboptimal fit with our data. After graphically evaluating the relationship between the cross-sectional area in a log-transform scale and the ingested volumes through a scatter plot and residual plot, we found an improved linear relationship. Therefore, we developed a new predictive model for our study population, in which it accounts for 44% of the variability (multiple $R^2 = 0.44$; $p < 0.0001$) (Table 2).

$$\text{Volume (ml)} = -327.1 + 215.2 \times \log(\text{cross-sectional area})(\text{cm}^2)$$

A Bland–Altman analysis was performed to explore the agreement between the volume predicted by the new mathematical model and the ingested volumes. The mean difference (systematic error) was 3.8 ml, and the 95% limits of agreement were –212.3 ml and 219.8 ml (Fig. 3).

In order to further compare our new predictive model for pregnant women and the model validated in non-pregnant adults by Perlas et al. [16], we explored the agreement between the predicted volumes obtained from both models through the Bland–Altman analysis in our study population. The mean difference (bias) of volumes predicted was 25 ml (95% limits of agreement = –37 ml and 87 ml).

Discussion

We have presented the first mathematical model to predict gastric volumes for late pregnancy. Our study has demonstrated a significant correlation of 0.7 between ingested volumes and antral cross-sectional

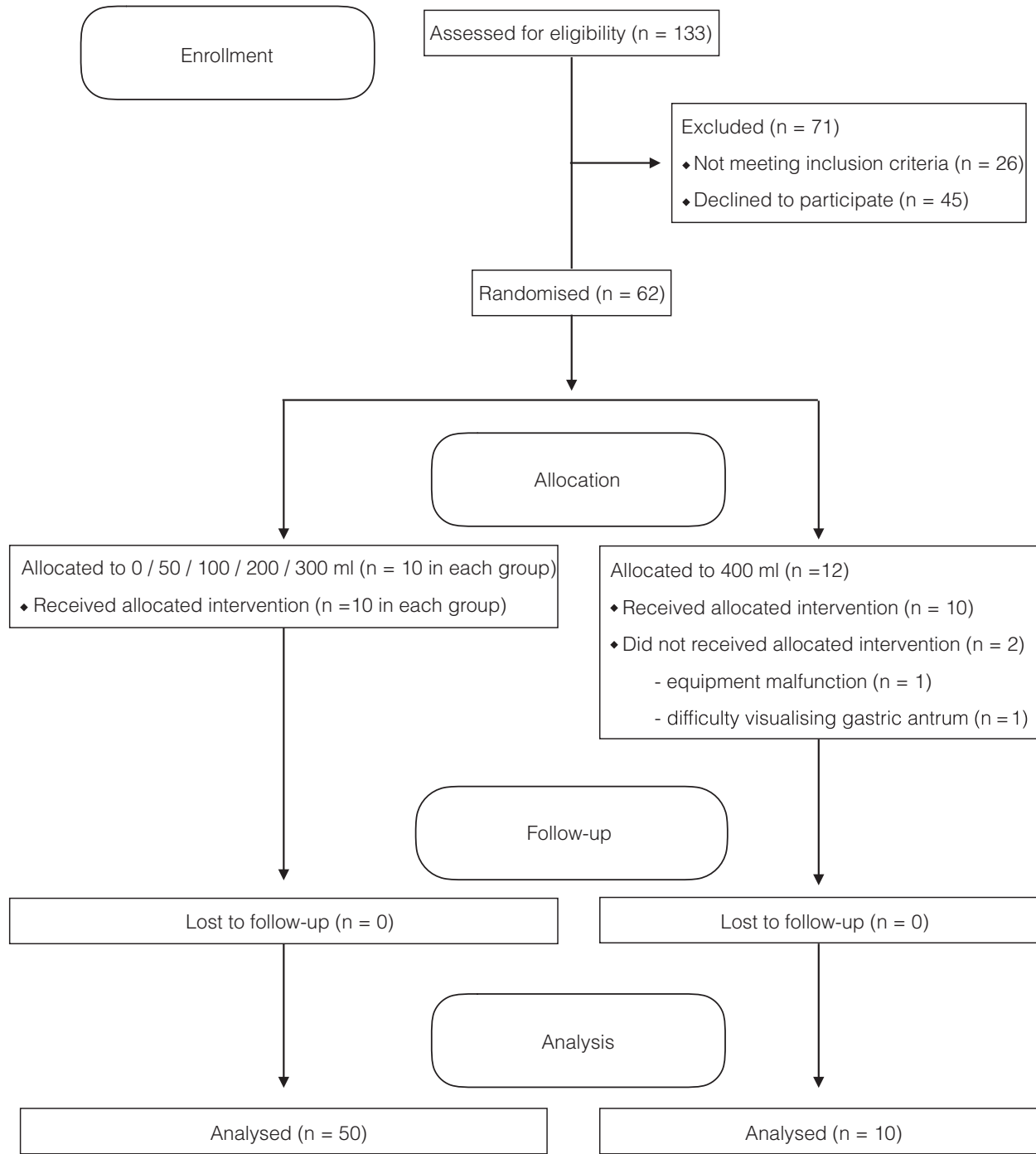


Figure 1 CONSORT study flow diagram.

area measured in the 45° semirecumbent right lateral position in third-trimester pregnant women. We suggest that a threshold value of 9.6 cm² for antral cross-sectional area measured in the 45° semirecumbent right lateral position discriminates high gastric volumes ≥ 1.5 ml.kg⁻¹.

Multiple studies, using various methodologies, have reported a linear correlation between antral cross-sectional area and gastric volume, with correlation coefficients ranging from 0.6 to 0.91 [1, 3, 16, 23–25]. Using a similar approach of controlled fluid ingestion to our current study, but with only two

Table 1 Physical characteristics of 60 women included in the study. Values are median (IQR [range]) or number (proportion).

Age; years	33 (30-36 [18-43])
Height; cm	163 (162-168 [152-175])
Weight; kg	74 (68-90 [54-118])
BMI; kg.m ⁻²	27.4 (25.1-32.6 [22-47])
Gestational age; weeks	34 (33.3-35.9 [31-40])
Nulliparous	45 (27%)

BMI, body mass index.

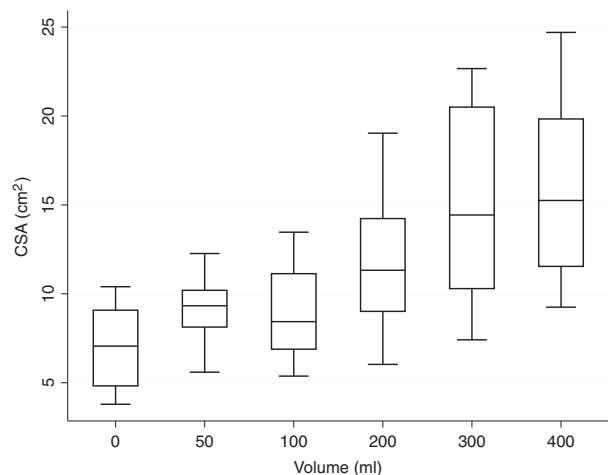


Figure 2 Boxplot of gastric antral cross-sectional area after drinking various fluid volumes. Horizontal line is median, box is 25th and 75th quartiles, whiskers are range.

Table 2 Linear predictive model to estimate gastric volume in semirecumbent right lateral position.

Variable	Estimate	Standard error	p value
Intercept	-327.1	77.3	< 0.0001
Cross-sectional area, cm ²	215.2	32.5	< 0.0001

Volume (ml) = -327.1 + 215.2 × log (cross-sectional area) (cm²). Multiple R² = 0.44.

volumes of 250 ml and 500 ml, Perlas et al. showed a correlation coefficient of 0.86 [1]. Our study results yielded a coefficient of 0.7, which is consistent with the current evidence.

The two previously published models used to estimate gastric volume in adults, based on antral cross-sectional area, analysed covariates [3, 16]. Perlas et al.,

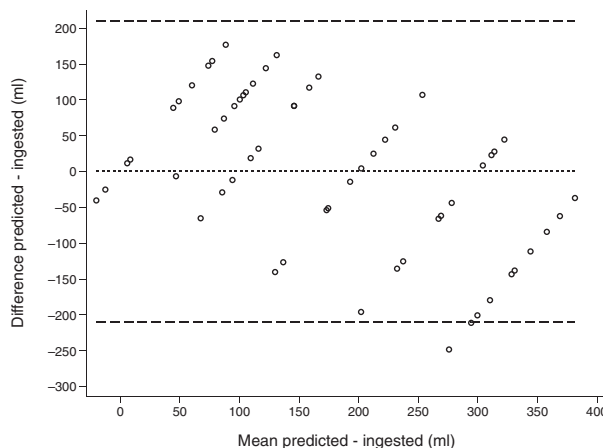


Figure 3 Bland–Altman analysis based on the new model for pregnant women demonstrating the agreement between the predicted volume and the ingested volume. Dotted line is the mean difference; dashed lines are 95% limits of agreement.

using suctioned volume during gastroscopy in the recumbent-right lateral position as a gold standard reference, found only age to be a significant covariate, yielding a R² = 0.731 for the proposed model [16]. An alternative mathematical model was developed by Bouvet et al., using the volume suctioned through a multi-orifice large nasogastric tube as the reference standard measure, in a mixed group of elective and emergency patients in the semirecumbent position [3]. In Bouvet et al.'s model, the antral cross-sectional area was log-transformed, and other variables besides age were also included as covariates, yielding a R² = 0.57.

Our currently proposed model includes no statistically significant covariates other than the log-transformed antral cross-sectional area, with R² = 0.44. Importantly, as the quality of the reference standard to construct the model is less accurate (gastroscopic suction > nasogastric suction > volume ingested), the variability explained by the model will be compromised (lower R²). Furthermore, it is expected that separate data sets originating from different patient populations will render different mathematical models [26]. Nevertheless, our subjects differ from previous studies. Although previous models were constructed based on a non-pregnant population of mixed sexes and age range from 18 to 85 [16], or 18 to 95 [3] years of age, our study population consisted exclusively of pregnant women in the third trimester with

an age range from 18 to 43 years. Interestingly, evidence from critically ill patients also failed to show any significant association between gastric volume and patient variables, in which the reference standard was multiple-detector computerised-tomography scan [27].

Moreover, this proposed new predictive model closely resembles the previous predictive model developed by Perlas et al. in adult non-pregnant subjects, which was validated with gastroscopic examination as the gold standard for gastric volume assessment [16]. Although we found a statistically sub-optimal fit with our data when using the model from non-pregnant adults, the mean difference in the values of the estimated volumes is an overestimation of only 25 ml based on Bland–Altman analysis. Importantly, our study did not include the gold standard of gastroscopic examination, but this is not indicated in this patient group.

Although a strict threshold of gastric volume, above which aspiration risk increases still remains controversial, clinical research suggests that gastric volumes of $\leq 1.5 \text{ ml.kg}^{-1}$ (around 100–120 ml in an average adult) are normal in fasted individuals (11–15). However, this threshold has not been directly validated in pregnant women; only indirect evidence comes from similar ranges of cross-sectional area values among fasted adults and term pregnant women [9]. Based on our study results, we recommend an antral cross-sectional area cut-off value of 9.6 cm^2 in the semirecumbent right lateral position to discriminate a low from a high gastric volume $\geq 1.5 \text{ ml.kg}^{-1}$ in cases where fasting status is unclear or unknown. It may be argued that a single cut-off value is an oversimplification, and disregards the influence of other variables on the area–volume relationship [3, 4, 16]. Nevertheless, this recommended cut-off value is consistent with evidence from our previous report of an antral cross-sectional area of 9.6 cm^2 as the 95th percentile for fasting women before elective caesarean section (9). Based on the particular clinical circumstances, one might choose different cut-off values favouring sensitivity or specificity to guide the decision making. The cut-off value obtained using the Youden method (11.5 cm^2) offers a statistical approach, which maximises the sum of the sensitivity and specificity. However, we recommend a clinical approach targeting the

highest sensitivity while compromising specificity, which errs on the side of safety.

Our results disagree with a recent study by Zieleskiewicz et al. that proposed a cut-off value of 7.19 cm^2 in the semirecumbent right lateral position for ingested volumes $> 1.5 \text{ ml.kg}^{-1}$, with a similar AUC of 0.86 [28]. However, Zieleskiewicz et al. carried out their study on labouring women who had epidural analgesia, and the lack of randomisation and controlled fluid volumes may explain their different results. The feasibility, reproducibility and intra-observer variability in gastric ultrasound in pregnant women have been confirmed across various studies, suggesting its clinical potential for patient care [17, 28, 29].

Our study has several limitations. Firstly, we used an ingested volume of fluid, rather than suction during gastroscopic examination, as the clinical reference standard to compare with the ultrasound measurement; we also combined antral grade 0 and grade 1 in the analysis. We took a number of steps to limit potential bias. We performed the baseline gastric assessment after 8 h of fasting to ensure that the stomach only contained gastric secretions, we used a large range of fluid volumes from 0 to 400 ml for the test drink, and we performed the second gastric assessment immediately after the drink to minimise any error due to emptying of fluid content from the stomach. Secondly, the after-drink assessment was performed only in the semirecumbent right lateral position, and not in the semirecumbent position, which was utilised exclusively to classify antral grades in the baseline fasted assessment. Importantly, measurements in the semirecumbent right lateral position have been acknowledged by several authors to be more reliable for volume estimation [1, 3, 30], especially with low gastric volume. We confirmed this point through ROC analysis, demonstrating superior discriminatory performance in the semirecumbent right lateral rather than the semirecumbent position to differentiate antral grade 0 from grade 1. However, Jay et al. reported better performance in the semirecumbent position in labouring women, although this was not compared with the semirecumbent right lateral [29]. Interestingly, Rouget et al. in a study of women before and after elective caesarean section showed that the cross-sectional area only changed when measuring in the semirecumbent position, but not in the semirecumbent right lateral position [17]. If one

assumes that there was no actual change in gastric contents [17, 18], this might also support the concept that estimation of gastric volume is less reliable in the semi-recumbent position compared with the semirecumbent right lateral position. Nevertheless, we agree with Jay et al. that in clinical practice, the semirecumbent right lateral may be contraindicated due to obstetric emergencies or time constraints, and only the semirecumbent position will allow quick assessment of the stomach [29]. Thirdly, although the presently proposed mathematical model has negligible bias, it displays wide limits of agreement, which may represent a drawback for bedside management, especially at low volume states.

In conclusion, our results confirm the conclusions of previous studies that antral cross-sectional area in the 45° semirecumbent right lateral position correlates with gastric volumes in pregnancy. We present the first mathematical model to predict gastric volumes specifically developed for pregnant women in the third trimester. We also suggest that a threshold value of 9.6 cm² measured in the 45° semirecumbent right lateral position may discriminate baseline from higher gastric volumes, supporting clinical decision making.

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