Validation of a Mathematical Model for Ultrasound Assessment of Gastric Volume by Gastroscopic Examination

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INTRODUCTION: Pulmonary aspiration of gastric contents is a serious perioperative complication. Previous models of ultrasound gastric volume assessment are preliminary and have not been validated by an external "gold standard." In the present study we propose a more accurate model based on prospective data obtained from 108 patients undergoing bedside gastric sonography and upper gastrointestinal endoscopy (UGE).

METHODS: Patients undergoing elective UGE were randomized to ingest one of 6 predetermined volumes of apple juice after an 8-hour fasting period. A cross-sectional area of the antrum in the right lateral decubitus position (Right lat CSA) was measured by a blinded sonographer following a standardized scanning protocol. Gastric fluid was subsequently suctioned under gastroscopic vision during UGE performed by a blinded gastroenterologist and measured to the nearest milliliter.

RESULTS: Data from 108 patients suggest that a previously reported model tends to overestimate gastric volume particularly at low volume states. A new best fit mathematical model to predict gastric fluid volume based on measurements of Right lat CSA is presented. This new model built on a more accurate gold standard can be used to estimate gastric volumes from 0 to 500 mL, in nonpregnant adults with body mass index < 40 kg/m^2.

CONCLUSIONS: We report a new prediction model to assess gastric fluid volume using standard 2-dimentional bedside ultrasound that has several advantages over previously reported models. (Anesth Analg 2013;116:357–63)

Pulmonary aspiration of gastric contents is a serious perioperative complication leading to significant morbidity and mortality.[1–3] Sedation and general anesthesia depress both the tone of the lower esophageal sphincter and upper airway protective reflexes, increasing the risk of pulmonary aspiration in subjects with significant gastric content.[4]

Bedside ultrasound can be used clinically to differentiate an empty stomach from one with fluid or solid gastric content.[5–9] An empty stomach carries a negligible aspiration risk, and the sonographic diagnosis of an empty stomach is a qualitative one; no volume assessment is required.[10] Solid stomach content is associated with a high aspiration risk and poor patient outcome. The diagnosis of solid content is based on sonographic appearance alone (a qualitative examination).[10] When the stomach contains clear fluid, however, an estimation of the volume is of great clinical interest. One needs to clarify whether the clear fluid seen is a small volume of gastric secretions, clinically inconsequential, or a significant volume of clear fluid that could pose an aspiration risk. Although there is no strict "volume threshold" over which aspiration risk increases, gastric fluid volumes of up to 1.5 mL/kg (about 100 mL for the average adult) are common in fasted individuals and are believed to be safe.[11–15] Therefore, a method to estimate the volume of clear fluid in the stomach could help differentiate small negligible amounts from larger volumes that could place patients at risk of regurgitation and pulmonary aspiration. Two preliminary mathematical models have been reported to estimate gastric fluid volume based on sonographic assessment of the gastric antrum.[5,6] However, important limitations in the design of both studies limit their widespread clinical applicability. The initial model reported by our group, although mathematically robust, was based on data obtained from fasted healthy volunteers randomized to ingest known volumes of water, and may have failed to account for baseline gastric secretions present at baseline before ingestion.[5] Similarly, a subsequent model proposed by Bouvet et al. was built on data obtained by "blind" suctioning through a nasogastric tube under general anesthesia, and it is conceivable that the suctioned volumes may not have been the full gastric content.[6] Therefore, both models were built on relatively imprecise volume controls. The main objective of the present study was to prospectively examine the performance of our previously published model by correlating the volumes predicted by our model (based on gastric antral

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cross-sectional area) with the "observed volumes" suctioned under gastroscopic vision, arguably the most precise method of gastric volume assessment.

A secondary objective of this study was to explore the correlation of an existing qualitative grading system (grades 0, 1, 2) with gastric fluid volume.[7] This simple 3-point grading system classifies the gastric antrum as follows: A Grade 0 antrum appears completely empty in both supine and right lateral decubitus positions. A grade 1 antrum appears empty in the supine position but fluid is visible in the right lateral decubitus, suggesting a small volume of gastric content. Grade 2 antrum contains fluid that is visible in both patient positions, suggesting a higher volume state.[7]

METHODS

After receiving University Health Network Research Ethics Board approval, patients undergoing elective upper gastrointestinal endoscopy (UGE) in the Department of Gastroenterology at the Toronto Western Hospital were invited to participate in this study. Inclusion criteria were: age of 18–85 years old; weight of 45–110 kg, height more than 145 cm, ability to understand the study procedures and provide informed consent. Exclusion criteria were: recent upper gastrointestinal bleed (within 1 month), previous lower esophageal or gastric surgery, and known abnormal upper gastrointestinal anatomy including hiatus hernia and gastric tumors. After written documentation of informed consent, and after a minimum fasting period of 8 hours for both fluids and solids, patients were prepared as per standard institutional practice.

A baseline qualitative gastric ultrasound assessment was performed in both supine and right lateral positions to ensure an empty stomach at baseline.[5,7]

Patients were subsequently randomized to ingest one of 6 predetermined volumes of apple juice (0 mL, 50 mL, 100 mL, 200 mL, 300 mL or 400 mL), according to a computer-generated list of random numbers. Three minutes after the ingestion, patients underwent a second sonographic assessment following a previously described scanning protocol.[5] The gastric antrum was identified in a sagittal to right parasagittal plane between the left lobe of the liver and the pancreas, at the level of the aorta, or inferior vena cava (Figures 1A and 1B). The probe was tilted as needed to ensure a proper transverse view of the antrum, avoiding oblique images that may have resulted in an overestimation of the cross-sectional area of the antrum (Right lat CSA) and ultimately gastric volume. Three consecutive still images were obtained, labeled and stored. All images were obtained with the antrum at rest and not during peristaltic contractions. One single certified sonographer experienced in abdominal ultrasound and blinded to the volume ingested, performed all sonographic examinations.

A curvilinear array, low frequency (2 to 5 MHz) transducer and a Philips HD11XE system (Philips Healthcare, Markham, Ontario, Canada) or General Electric Logiq E unit (GE Healthcare Beijing, China) with image compounding technologies were used. The sonographer classified each patient's antrum as grade 0, 1 or 2.[7] After the examination, Right lat CSA was calculated based on the antero-posterior and craniocaudal antral diameters as previously described.[16] The two antral diameters were measured from serosa to serosa as is current standard practice. Therefore, an antrum that is totally empty is expected to have a Right lat CSA that is more than 0, corresponding to the thickness of the gastric wall (usually in the order of 2–5 cm^2).[5–7] Three measurements from three consecutive images were obtained, and the mean of the three measurements used as the Right lat CSA value. A "predicted volume" was calculated based on the Right lat CSA and our previously described mathematical model.[5]

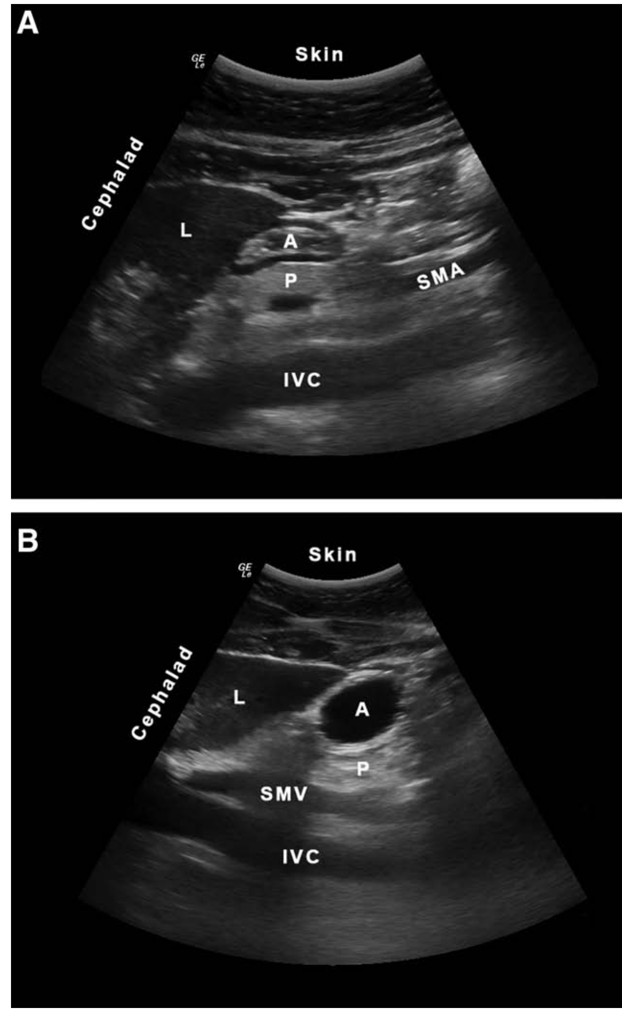

Figure 1. (A) Sagittal scan of the antrum with an empty stomach. The antrum can be found between the left lobe of the liver anteriorly and the pancreas posteriorly, at the level of either the aorta or the inferior vena cava. The superior mesenteric artery can be seen in this patient crossing the head of the pancreas. These regional landmarks help locate the gastric antrum which is small when empty. A = gastric antrum, L = liver, P = pancreas, SMA = superior mesenteric artery, IVC = inferior vena cava. (B) Sagittal scan of the gastric antrum after clear fluid intake. The inferior vena cava and superior mesenteric vein appear similar to the aorta and superior mesenteric artery on a single frozen two-dimesional image. Diagnosis can only be ascertained in this plane with a "live" scan. A = antrum, L = liver, P = pancreas, SMV = superior mesenteric vein, IVC = inferior vena cava.

Once the ultrasound scan was completed, patients underwent UGE under light IV sedation as per current standard practice. This consisted of IV midazolam 1 mg increments (up to a maximum of 2 mg) and IV fentanyl 50 ug increments (up to a maximum of 100 ug). The UGE was performed by an attending gastroenterologist per current standard institutional practice using an Olympus fiberoptic endoscope. Gastroenterologists were blinded to the volume ingested by the subjects and unaware of the ultrasonographic findings. All gastric fluid was thoroughly suctioned through an endoscope side port, measured to the nearest mL and recorded. This volume was called the "observed volume."

Sample Size Calculation and Statistical Analysis

The mathematical model being tested is expressed as

$$\text{Log (Right} - \text{latCSA)} = 1.31878 + 0.00354 * \text{predicted volume} + 0.00594 * \text{weight} \quad (1)$$

To validate this model, a linear regression model was fitted, having as outcome the logarithm of the observed volume and as unique predictor the predicted volume.[17] The fitted regression model can be expressed as

$$\text{observed volume} = a + b * \text{predicted volume} \quad (2)$$

If a = 0 and b = 1, the original model will be proven adequate to describe the new data. If, on the other hand, there is a significant deviation from those values, an update of the original prediction model would be recommended. For the sample size calculation we tested the null hypothesis that H0: b = 1, against the alternative H1: b = 0.75 using estimates of the standard deviations of the observed volume and right lateral CSA from previous studies.[5,7] We estimated that 110 patients are needed for a power of 80% to detect the alternative hypothesis H1: b = 0.75, using a two-sided test with alpha level = 0.05. For the calculation we use PASS software version 08.05, for Windows XP. In addition a Bland-Altman analysis was used to determine the limits of agreement between the predicted volume and the observed volume. If a new model needed to be fitted, the R^2, Akaiki Information Criterion and Root Mean Squared Error model fit criteria would be used. All patient demographics reported were checked in their ability to improve the accuracy of the model.

RESULTS

One hundred ten patients were enrolled in the study. One patient was withdrawn from the study due to a long delay between ultrasound assessment and gastroscopic examination (more than 25 minutes) due to logistical issues. One further patient was withdrawn from the study because a significant amount of air in the stomach impaired proper evaluation of the antrum. The remaining 108 patients (39 males, 69 females) completed all study assessments according to protocol and were included in the final analysis. Patient demographics are summarized in Table 1. The regression model using the observed volume as outcome and the predicted volume as predictor, shows a large deviation from the ideal parameters of intercept equal to 0 (-14.3, SE 17.1, P= 0.41) and a beta coefficient equal to 1 (0.78 ± 0.06, P = 0.0006). In other words, observed volume = 0.78 predicted volume – 14. Pearson's correlation coefficient for this model (r^2) is 0.656.

Table 1. Demographics

	Mean ± SD	Minimum	Maximum
Age (years)	51 ± 14	19	82
Height (cm)	166 ± 10	148	188
Weight (kg)	69.9 ± 18.9	45	110
Body mass index (kg/cm^2)	25.4 ± 5	17.5	38.9
Ultrasound-to-gastroscopy time (min)	9 ± 4	1	21

A Bland–Altman analysis was performed (Figure 2). This type of analysis plots the difference between the estimated volume based on the model being tested and the observed volume (suctioned during gastroscopy) for each subject, against the mean difference of the two values and allows us to place the differences in a clinical context. The 95% limits of agreement calculated by this method represent differences likely to arise between the two measurements with a 95% probability. This analysis suggests that the existing mathematical model tends to overestimate gastric volume with a mean "bias" or systematic error of 70 mL (Figure 2). Additionally, the upper limit of a 95% agreement band is over 230 mL. This difference is clinically relevant, especially at low volume states, and suggests that the existing model may not be accurate enough for clinical use. We therefore decided to fit a new model based on the new dataset considered to be a more accurate "gold standard."

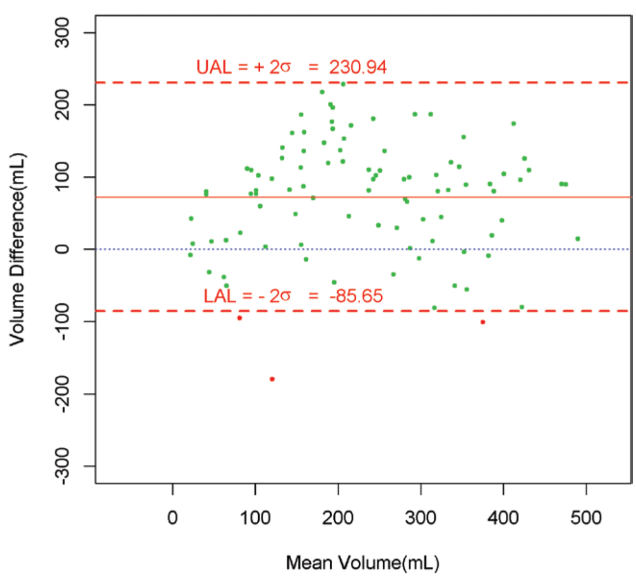

Figure 2. Bland-Altman analysis of the current mathematical model. The graph explores the agreement between the volume predicted by the current mathematical model (equation 1) and the "observed" volume suctioned under gastroscopic vision. The y axis represents the difference between the two values (predicted volume minus observed volume) and the x axis represents the mean between the two values (predicted volume minus observed volume divided by 2). The blue dotted line represents perfect agreement. The red solid line is the mean difference or "bias" of the model. UAL and LAL are the upper and lower limits of a 95% agreement band (mean +/- 2 standard deviations) respectively. This analysis suggests that the agreement band is too wide and that a new model should be fitted.

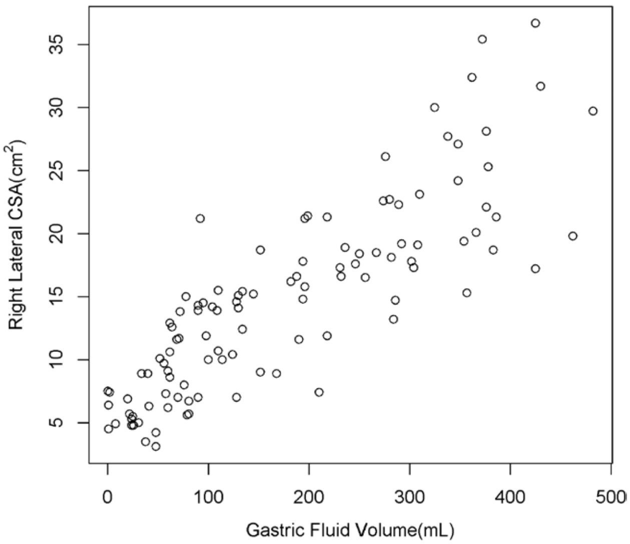

Figure 3. Scatter plot representing the new raw data of suctioned gastric volume as a function of Right lateral antral cross-sectional area.

Fitting a New Model

The raw values of observed volume are presented on Figure 3. Based on these data, we fitted a number of linear regression models of the observed (suctioned) volume (the dependent variable) predicted by the measured Right lat CSA (independent variable), weight, height, body mass index (BMI), age and gender. We also investigated whether the fit of the models was improved if Right lat CSA was log-transformed. Using R^2, Akaiki Information Criterion and Root Mean Squared Error model fit criteria, we selected the model containing as predictors Right lat CSA and age as the best fit as follows:

$$\text{Volume} = 27.0 + 14.6 * \text{Right} - \text{latCSA} - 1.28 * \text{age} \quad (3)$$

This model shows a significant correlation to the new dataset as assessed by Pearson's correlation coefficient ($r^2 = 0.731$, Tables 2 and 3). The remaining demographic variables (weight, height and gender) were not found to be independent predictors of gastric volume. The residual plots for both independent predictors (Right lat CSA and age) are shown in Figure 4. These plots suggest that the linear regression assumption is valid, and that no polynomial transformation is required. Of note, this model is only applicable when the result is a positive value. Thus, when the stomach is empty, small values of Right lat CSA will yield a negative volume value, which only indicates an empty state. In addition, the best fit regression model proposed was validated with the use of a procedure involving partitioning of the data into two sets, one for "training" and one for validating the model, each set comprising 50% of the original data. The Average Squared Error (ASE, equal to the squared difference between the true and estimated volume values averaged over all data points) was calculated. A smaller ASE indicates a better fit. Two possible models were assessed: one with the age as a covariate, and one without the age. This validation procedure showed that the model with age covariate had a smaller ASE value for the validation set (6849.9) than the model without age (7179.1), and therefore was preferred. A Bland-Altman analysis was performed using the "validating" dataset (50% of the data set aside for validating the model). The results are shown in Figure 5. This analysis suggests that the new model predicts gastric volume more accurately, or with a higher level of agreement than the previous model. The new "bias" or systematic error is only 6 mL, and the upper and lower limits of agreement of a 95% agreement band are considerably smaller.

Table 2. New Mathematical Model Parameter Estimates

Variable	Parameter estimate	Standard error	P value
Intercept	27.0	26.7	<.3131
Right lat CSA	14.6	0.9	<.0001
Age	-1.28	0.46	0.006

Rsq = 0.731
CSA = cross-sectional area

Table 3. Predicted Gastric Volume (mL) Based on Measured Gastric Antral Cross-Sectional Area (CSA) (cm²), Stratified by Patient Age

Right lat CSA (cm²)	Age (years)						
	20	30	40	50	60	70	80
3	45	32	20	7	0	0	0
5	74	62	49	36	23	10	0
7	103	91	78	65	52	40	27
9	133	120	107	94	82	69	56
11	162	149	136	123	111	98	85
13	191	178	165	153	140	127	114
15	220	207	194	182	169	156	143
17	249	236	224	211	198	185	173
19	278	266	253	240	227	214	202
21	307	295	282	269	256	244	231
23	337	324	311	298	285	273	260
25	366	353	340	327	315	302	289
27	395	382	369	357	344	331	318
29	424	411	398	386	373	360	347

Shaded cells represent low volume states usually considered within the range of baseline gastric secretions for an average adult.

In addition, we also evaluated a previously described 3-point grading system of the gastric antrum and its correlation with gastric fluid volume.[7] The gastric antrum is classified as grade 0 when it appears empty in both supine and right lateral decubitus positions. The antrum is classified as grade 1 when clear fluid content is visible only in the right lateral decubitus position suggesting a small fluid volume. Finally, a grade 2 antrum is that in which clear fluid is apparent in both supine and right lateral decubitus positions, suggesting a larger gastric fluid volume. To this end we performed a graphical exploratory analysis by plotting estimates for the densities of the gastric fluid volume for the patients classified as having Grade 1 and Grade 2 antrum (Figures 6 and 7). No subjects in this study were classified as grade 0. Figure 7 illustrates that a Grade 1 antrum is associated with lower gastric volumes than a grade 2 antrum. In the sample studied, only 23% of subjects with a grade 1 antrum had a gastric volume larger than 100 mL, and none of them had a volume larger than 250 mL. In contrast, 75% of subjects with a grade 2 antrum had a volume higher than 100 mL, and more than 50% had volumes

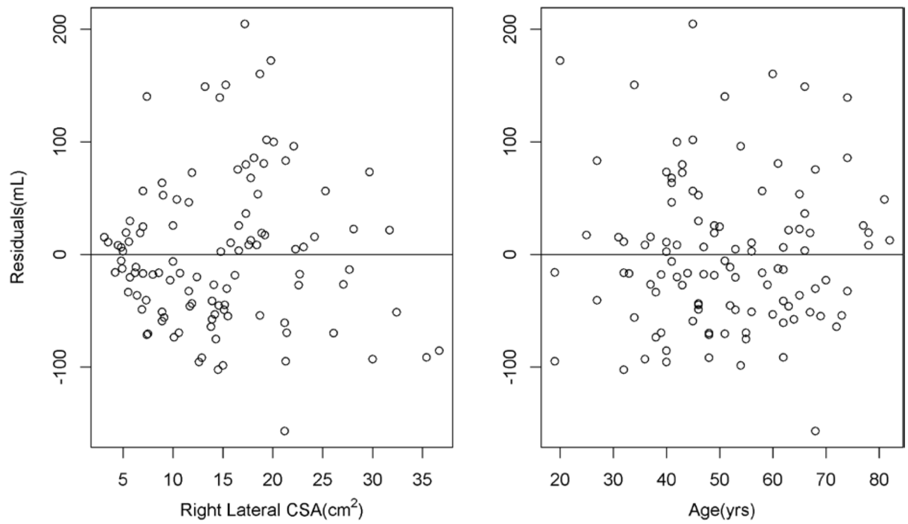

Figure 4. Residual plots for the two independent predictors in the newly fit mathematical model.

larger than 250 mL. In other words, based on binomial proportions with continuity corrections, our data suggest that the absolute risk difference for having more than 100 mL is 52 percentage points (23% for grade 1 to 75% for grade 2). The absolute risk increase is 52%, 95% CI 31–73%, Wald test P< 0.0001).[18] This conventional volume threshold of 100 mL is clinically relevant since it is the upper limit of what is considered normal baseline gastric secretions posing no significant aspiration risk in fasted surgical patients.[11–15] This suggests that this 3-point grading system based on qualitative sonography alone can serve as a screening tool to differentiate between low and high volume states.

DISCUSSION

The present experimental study of 108 patients tested the performance of our previously reported mathematical model by comparing the predicted volume based on antral sonography to the observed volume measured by suctioning all gastric contents under gastroscopic examination,

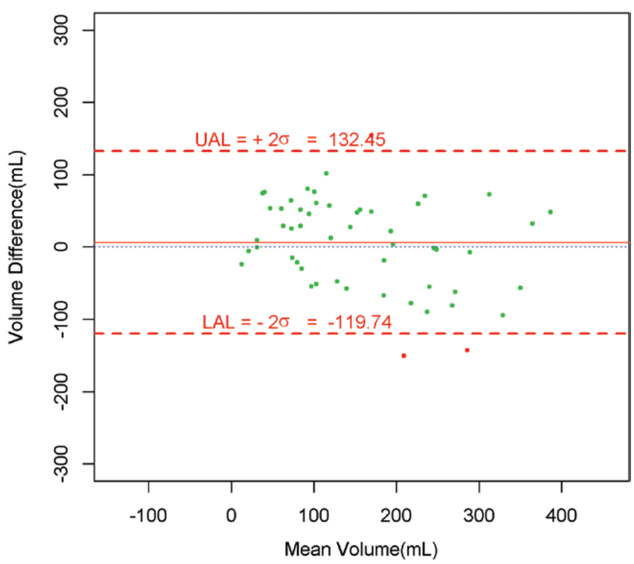

Figure 5. Bland-Altman analysis of the new mathematical model. The graph explores the agreement between the volume predicted by the new mathematical model (equation 3) and the "observed" volume suctioned under gastroscopic vision. The y axis represents the difference between the two values (predicted volume minus observed volume) and the x axis represents the mean between the two values (predicted volume minus observed volume divided by 2). The blue dotted line represents perfect agreement. The red solid line is the mean difference or "bias" of the model. UAL and LAL are the upper and lower limits of a 95% agreement band (mean +/- 2 standard deviations) respectively. This analysis suggests that the new mathematical model predicts gastric volume more accurately than the previous model (compare to Figure 2).

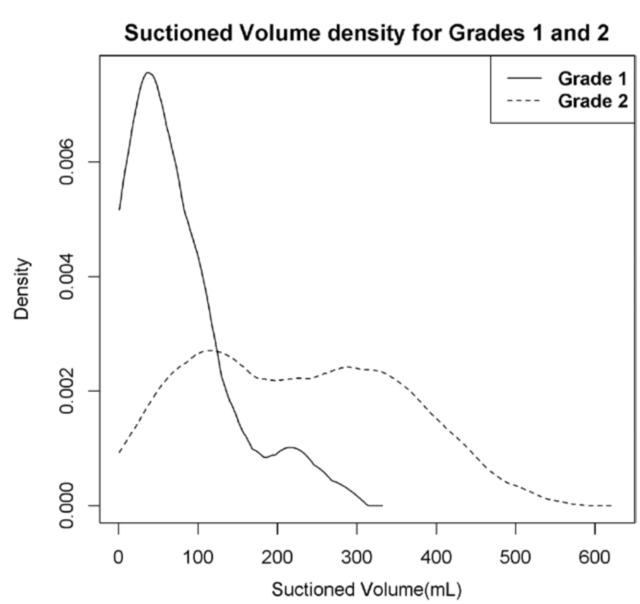

Figure 6. Histogram of frequencies (density) of gastric fluid volume for subjects with grade 1 and 2 antrums. Antral grades are defined by qualitative gastric sonography. Grade 0 antrum appears completely empty in both supine and right lateral decubitus positions. Grade 1 antrum appears empty in the supine position, but some gastric fluid is visible in the right latral decubitus, suggesting a low volume state. Grade 2 antrum has clear fluid visible in both supine and right lateral positions, suggesting a higher volume state.

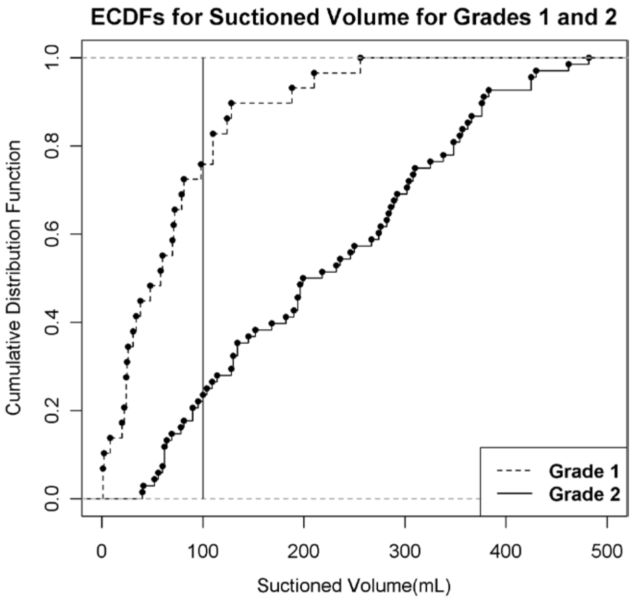

Figure 7. Empirical cumulative distributions of gastric fluid volumes (ECDF) for patients with Grade 1 and Grade 2 antrums. This figure illustrates that antral grade correlates with gastric volume. For example, the likelihood of having 100 mL of gastric volume (vertical line) is 75% for patients with a Grade 2 antrum, but only 23% for patients with a Grade 1 antrum.

arguably the gold standard for gastric volume assessment. Based on our results, we conclude that the previously proposed model tends to overestimate gastric volume to a degree that is clinically significant (mean of 72 mL, but 95% CI up to 200 mL). Therefore we propose a revised mathematical model that better describes the distribution of the new dataset, considered to be more accurate. We believe this new revised model has several advantages over both existing models. First, it is built on data obtained with a more rigorous method of gastric fluid measurement (suctioning under gastroscopic examination). Second, it is statistically robust with a high correlation coefficient (Rsq 0.731). Third, the new revised model is applicable to a wider range of volumes (up to 500 mL) than previous models (up to 250 mL in the model by Bouvet et al and up to 300 mL in the model by Perlas et al). Finally, unlike the model proposed by Bouvet et al, our revised model is only influenced by patient age and is independent of all other patient demographic variables within the demographic range studied (148 to 188 cm tall, 45–110 kg, BMI 17 to 39 kg/m^2). This makes the model simpler to apply in clinical practice. Table 3 results from solving the Best fit model equation in 2 cm^2 intervals for values of Right-lat CSA for every decade of life. The shaded cells in the table represent low volume states that are well accepted in the literature to carry negligible aspiration risk.

The effect of age on predicted volume is intriguing and somewhat unexpected. For any given gastric fluid volume, there is a trend for older patients to have a higher Right lat antral CSA than their younger counterparts (Table 3). Or, in other words, a given Right lat antral CSA corresponds to a lower gastric fluid volume in older versus younger patients. For example, a CSA of 10 cm^2 corresponds to a 147 mL of gastric fluid in a 20 year old patient but only 71 mL of gastric fluid in an 80 year old patient. This could possibly be explained by a more compliant gastric wall in older versus younger patients.

The present study is not without limitations. First, although the method to measure gastric volume is likely more precise than those used in previous studies, no method is infallible. Despite our best efforts to minimize the transition times between study interventions, there was a mean lag of 9 minutes between ultrasound examination and gastric suctioning, during which time some gastric emptying may have occurred. To minimize this possibility, patients were placed in the left lateral decubitus position during this time interval, and a clear fluid with high caloric content (apple juice) was used which is emptied more slowly than noncaloric clear fluids such as water. Second, the model proposed herein is applicable to a wide range of adult individuals but not to all subjects. In particular, it is not applicable to children or adolescents, pregnant women, adults with a BMI over 40 kg/m^2, or with underlying anatomical abnormalities of the upper gastrointestinal tract.

Finally, this prediction model is only applicable when a similar scanning protocol to that used in this study is followed. The gastric antrum needs to be identified in cross-section in a right parasagittal plane with the subject placed in the right lateral decubitus. We have previously demonstrated that for any given fluid volume, antral CSA is larger in the right lateral versus the supine position due to a gravitational fluid shift towards the antrum, and a model based on Right lat CSA is more sensitive than its supine counterpart to detect volume changes particularly in low volume states.[5] This may explain some of the differences between our model and that proposed by Bouvet et al. based on supine assessments.

All measurements need to be taken with the antrum at rest, between peristaltic contractions. Measuring the antrum during a peristaltic contraction would yield a lower Right lat CSA value and would underestimate gastric volume. Finally, for this model, antral CSA is measured from serosa to serosa (including the full thickness of the gastric wall).

The use of sedative medications immediately before UGE on patients who have ingested up to 400 mL of apple juice is potentially controversial. The following precautions were taken to minimize aspiration risk: doses were titrated to achieve anxiolysis only, while maintaining the subjects awake; sedatives were administered immediately before the procedure; patients were placed in the left lateral decubitus position for the gastroscopic examination, and the stomach was thoroughly suctioned as soon as the gastroscope entered the gastric cavity. The study protocol was developed in collaboration with the participating gastroeneterologists and approved by the institutional research ethics board. No cases of aspiration occurred during the study.

Many questions remain to be answered in the future regarding the clinical applicability of this diagnostic tool. Questions regarding the cost effectiveness of this type of assessment, the reliability of measurements, as well as the level of skill and training required to achieve competence are outside the scope of this study and need to be addressed by future studies.

CONCLUSION

Using direct suctioning of gastric fluid under gastroscopic examination on 108 patients, we report a new prediction model (Volume = 27.0 + 14.6 *Right-lat CSA – 1.28*age) to assess gastric volume noninvasively at the bedside based on sonographic measurements of Right lat CSA. This model can predict volumes from 0 to 500 mL and is applicable to nonpregnant adult patients with BMI < 40 kg/m^2. In addition, our data also suggest that a simple 3-point grading system based on qualitative antral assessment, as previously described, could help differentiate low volume from higher volume states. Further research is needed to evaluate the impact of both qualitative and quantitative gastric ultrasound assessment on bedside aspiration risk assessment and patient management

DISCLOSURES:

Name: Anahi Perlas, MD, FRCPC
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript
Attestation: Anahi Perlas has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files
Conflicts of Interest: The author has no conflicts of interest to declare.
Name: Nicholas Mitsakakis, M.Sc, PhD
Contribution: This author helped analyze the data and write the manuscript
Attestation: Nicholas Mitsakakis has seen the original study data, reviewed the analysis of the data, and approved the final manuscript
Conflicts of Interest: The author has no conflicts of interest to declare.
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Attestation: Vincent Chan reviewed the analysis of the data and approved the final manuscript
Conflicts of Interest: Vincent Chan reported a conflict of interest with Philips, reported a conflict of interest with SonoSite, and reported a conflict of interest with General Electric Equipment and support for educational activities (workshops and conferences)
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