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Diagnostic Accuracy of Point-of-Care Gastric Ultrasound

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BACKGROUND: Pulmonary aspiration of gastric contents is associated with significant perioperative morbidity and mortality. Previous studies have investigated the validity, reliability, and possible clinical impact of gastric ultrasound for the assessment of gastric content at the bedside. In the present study, we examined the accuracy (evaluated as sensitivity, specificity, and likelihood ratios) of point-of-care gastric ultrasound to detect a "full stomach" in a simulated scenario of clinical equipoise.

METHODS: After a minimum fasting period of 8 hours, 40 healthy volunteers were randomized in a 1:1 ratio to either remain fasted or ingest a standardized quantity of clear fluid or solid. Each subject was randomized twice on 2 independent study sessions at least 24 hours apart. A gastric ultrasound examination was performed by a blinded sonographer following a standardized scanning protocol. Using a combination of qualitative and quantitative findings, the result was summarized in a dichotomous manner as positive (any solid or >1.5 mL/kg of clear fluid) or negative (no solid and ≤1.5 mL/kg of clear fluid) for full stomach.

RESULTS: Data from 80 study sessions were analyzed. In this simulated clinical scenario with a pretest probability of 50%, point-of-care gastric ultrasound had a sensitivity of 1.0 (95% confidence interval [CI], 0.925–1.0), a specificity of 0.975 (95% CI, 0.95–1.0), a positive likelihood ratio of 40.0 (95% CI, 10.33–∞), a negative likelihood ratio of 0 (95% CI, 0–0.072), a positive predictive value of 0.976 (95% CI, 0.878–1.0), and a negative predictive value of 1.0 (95% CI, 0.92–1.0).

CONCLUSIONS: Our results suggest that bedside gastric ultrasound is highly sensitive and specific to detect or rule out a full stomach in clinical scenarios in which the presence of gastric content is uncertain. (Anesth Analg 2019;128:89–95)

KEY POINTS

- **Question:** How accurate is point-of-care ultrasound to detect a full stomach?
- **Finding:** In a simulated clinical scenario with a pretest probability of 50%, gastric ultrasound was highly sensitive and specific for the condition of full stomach.
- **Meanings:** Our results suggest that bedside gastric ultrasound can help decrease the diagnostic uncertainty when clinical information is lacking or contradictory.

Pulmonary aspiration of gastric contents is associated with significant perioperative morbidity and mortality.[1–3] The incidence of aspiration is highly variable, from 1% based on a statewide audit of all surgical procedures in Maryland, to 1:4000 in the setting of elective low-risk surgery.[4–7] Aspiration is the leading cause of death from anesthesia airway events,[5] and major morbidity (including pneumonia, acute respiratory distress syndrome, multiple organ dysfunction, and brain damage) is common among survivors.[6] Several factors influence the degree of morbidity that results from an episode of aspiration. The 3 most established factors are the aspiration of solid particulate matter, a volume of aspirate >0.8 mL/kg, and a low pH (<2.5) of the aspirated contents. A common root cause of severe cases of aspiration that result in death is the failure to recognize a full stomach preoperatively.[5]

Point-of-care (POC) gastric ultrasound can inform aspiration risk assessment by providing bedside information on both the type of gastric content (nothing, clear fluid, thick fluid, or solid particulate matter) and the volume.[8–10] This type of bedside examination may be particularly useful in clinical settings where gastric content is questionable or uncertain. A standardized scanning protocol has been described.[8,10] The examination can differentiate an empty stomach from one that contains clear fluid, thick fluid, or solid particulate content based on qualitative findings.[8,9] While the presence of thick fluid (homogeneous hyperechoic content) or solid particulate content (either heterogeneous content of mixed echogenicity or a "frosted glass patter") are by themselves indicative of a full stomach, clear gastric fluid (homogeneous hypoechoic content up to a volume of about 1.5 mL/kg) is normal in healthy fasting individuals with

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low aspiration risk.[11] Therefore, when clear fluid is present, estimating its volume may be useful to identify a high-volume that is not compatible with the fasting state. We previously developed and validated a mathematical model for this purpose based on a 2-dimensional cross-sectional area (CSA) of the gastric antrum measured with the patient in the right lateral decubitus (RLD) (right lateral CSA).[10,12] This volume model is reliable[13] and valid for nonpregnant adults.[10,12] A clinical decision tool based on both qualitative and quantitative ultrasound findings[14,15] can change anesthetic management in >60% of subjects who present for elective surgery without following fasting instructions.[16]

However, the accuracy of gastric ultrasound to positively identify or rule out a full stomach has not been systematically evaluated. The aim of the present study is to evaluate the accuracy (evaluated as sensitivity, specificity, and likelihood ratios) of gastric ultrasound in a simulated clinical scenario with a pretest probability of 50%. We hypothesized that POC gastric ultrasound has a sensitivity of at least 95% in a sample with a conventional prevalence of full stomach of 50%.

METHODS

This study was approved by the University Health Network Research Ethics Board (UHN REB No. 14–7883), and written informed consent was obtained from all subjects participating in the trial. The trial was registered before subject enrollment at clinicaltrials.gov (NCT02588495; principal investigator: A.P.; date of registration: October 25, 2015). With a prospective, randomized, observer-blinded design, subjects were enrolled from October 2015 to September 2016. It was conducted and reported using the guidelines of the STAndards for Reporting Diagnostic accuracy (STARD) initiative.[17]

Healthy volunteers from the Toronto area were invited to participate. Inclusion criteria were as follows: 18–85 years of age, American Society of Anesthesiologists physical status I–II, height >145 cm, and ability to understand the study protocol. Exclusion criteria were as follows: pregnancy, previous gastric or lower esophageal surgery, known abnormalities of the upper gastrointestinal tract (such as hiatal hernias and gastric tumors), diabetes, renal or hepatic impairment, and neurological disorders.

After providing written informed consent, study subjects fasted for at least 8 hours for both solids and liquids. After confirmation of an "empty stomach" from a baseline ultrasound examination, subjects were randomized in a 1:1 ratio using a computer-generated list of random numbers to one of 2 groups. Eighty randomization numbers were generated, and individual subjects were randomized on 2 separate occasions. There was a minimum of 24 hours between the 2 randomization events for the same individual to allow sufficient time for complete emptying of gastric content between sessions. Each session was considered an independent event, and therefore, the same individual could be randomized to the same group twice. Each session generated a separate dataset for a total of 80 study sessions. Study groups were defined as follows: subjects in group 1 (n = 40) remained fasted; and subjects in group 2 (n = 40) ingested either clear fluids (250 mL of apple juice, n = 19) or a solid meal (1 muffin and a cup of coffee with cream, n = 21). Group allocation was concealed in sealed opaque envelopes.

Three minutes after ingestion, the index gastric ultrasound examination was performed by a staff anesthesiologist with a previous experience of >100 gastric examinations and who was blinded to group allocation. A standardized scanning protocol in both the supine and RLD positions was used.[8,10] A Philips Sparq ultrasound system with image-compounding technology and a low-frequency (2–5 MHz) curvilinear array transducer (Philips HealthCare, Andover, MA) was used with abdominal settings. A transverse view of the antrum was identified between the liver anteriorly and the pancreas and aorta posteriorly in a sagittal scanning plane in the epigastrium. Care was taken to avoid oblique views from transducer over-rotation that could overestimate antral size. A 6-second video clip and 3 still images of the antrum were stored and labeled. Still images were taken between peristaltic contractions with the antrum at rest to avoid underestimation of antral size.

The type of content was categorized based on qualitative sonographic findings into 3 categories: (1) "nothing" (antrum collapsed with no visible content); (2) "clear fluid" (homogenous, hypoechoic, or anechoic content); or (3) "solid" (hyperechoic or mixed echogenicity). When the stomach is completely empty, the antrum appears small

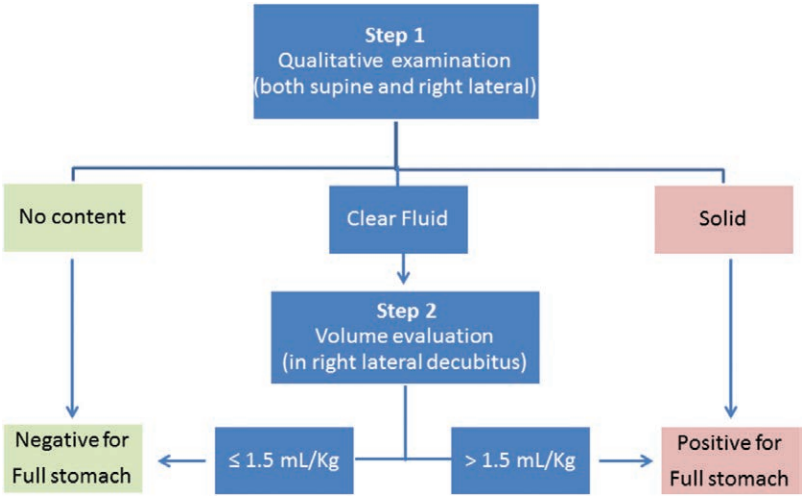

Figure 1. Interpretation of gastric ultrasound findings.

and flat or round with anterior and posterior walls juxtaposed.[8–11] After ingestion of solid food, the antrum appears distended, and the content is either hyperechoic or of mixed echogenicity,[8,9] while clear fluid (such as apple juice) appears hypoechoic or anechoic.[8,9] If clear fluid was present, a right lateral CSA of the gastric antrum was measured at the level of the aorta to estimate gastric fluid volume using a previously validated model[10]:

$$\text{Volume} = 27.0 + 14.6 \times \text{Right lateral CSA} - 1.28 \times \text{age}$$

Finally, using a combination of qualitative and quantitative findings, the result of the test was summarized in a dichotomous manner as negative or positive for full stomach. A "positive" test for full stomach was defined as either solid particulate content or >1.5 mL/kg of clear fluid (Figure 1).[14–16] A "negative" test for full stomach was defined as no content at all visible in either the supine or RLD, or <1.5 mL/kg of clear fluid, consistent with baseline gastric secretions (Figure 1). A test was considered inconclusive (neither positive nor negative) if the gastric antrum could not be imaged in both supine and RLD positions or the findings were atypical and the examiner could not comment with certainty.

Statistical Analysis

SAS version 9.4 (SAS Institute, Cary, NC) was used for the estimation of diagnostic measures, including sensitivity, specificity, positive predictive value, negative predictive value, and the likelihood ratio of positive and negative tests. We present sensitivity and specificity values as percentages and positive and negative likelihood rations as ratios. The analysis was performed for the entire dataset and separately for each randomization. To account for possible intrasubject correlation, we used a bootstrapping approach for the estimation of the confidence interval (CI) for each diagnostic test parameter. As data show 100% sensitivity and high specificity, the general sampling with replacement will not provide usual distribution from the bootstrapped samples by sampling with replacement. We adopted the bootstrap approach described by Marill et al[18] and obtained the 95% CIs of each diagnostic test parameter estimate based on 10,000 bootstrapped samples. Bootstrapping was performed using R (version 3.4.3; R Foundation for Statistical Computing, Vienna, Austria).[19]

We based our sample size estimate on a hypothesis of >95% sensitivity to detect a full stomach in a study population with a conventional preestablished prevalence of 50%. This prevalence of 50% was intended to reflect a scenario of true clinical equipoise or conflicting clinical information. Using the formula by Buderer,[20,21] we estimated that a minimum of 40 subjects (20 per group) would be required to rule out the null hypothesis with a type 1 error <0.05 and an absolute precision of 0.1. To increase the strength of the result and to allow for variability in the sonographic appearance of fluid and solid content,[9,11] we planned to perform twice the number of study sessions for a total of 80 datasets.

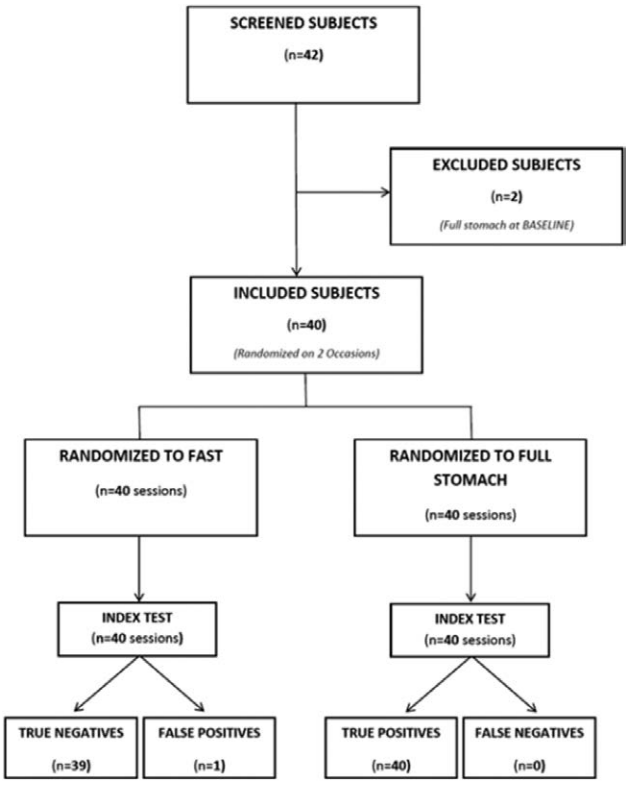

Figure 2. Subject flow.

RESULTS

Forty-two healthy subjects were screened for participation. Two subjects were excluded after finding a full stomach at baseline (Figure 2). One excluded subject had clear fluid content in excess of 1.5 mL/kg despite fasting for 11 hours. The second subject had solid content 10 hours after a large meal with high lipid content. The remaining 40 subjects (19 males and 21 females, American Society of Anesthesiologists I–II, 37 ± 10 years, 69 ± 11 kg of body weight, 168 ± 9 cm tall, and a body mass index of 24 ± 3 kg/m^2) participated in the study on 2 separate occasions, a minimum of 24 hours apart. A total of 80 independent study sessions were performed, and 80 full data sets were included in the final analysis.

The gastric antrum was identified in every subject in both positions, and there were no "inconclusive" examinations. No adverse events were documented. The distribution of positive and negative test results for full stomach is summarized in Figure 2 and Table 1. There were 40 true-positive results, 0 false negatives (sensitivity, 1.0; CI, 0.925–1.0), 39 true-negative, and 1 false-positive results (specificity, 0.975; CI, 0.95–1.0). The likelihood ratio of a positive test is estimated at 40.0 (95% CI, 10.33–∞), indicating that a positive gastric ultrasound result significantly increases the probability of a full stomach, and the negative likelihood ratio is 0, which is consistent with the high sensitivity of the test (Tables 1–2, Figure 3).

Regarding the relative accuracy of gastric ultrasound to positively identify the type of content (fluid or solid) in a full stomach, all subjects with solid content (n = 21) had a "true-positive" test. While 18 of them were correctly identified as containing both solid particles and fluid, the remaining 3 subjects in this subgroup (14.3%) were not recognized as having solid particles, but rather were diagnosed as positive on the basis of a high volume of fluid content (>1.5 mL/kg). Similarly, all subjects who ingested a glass of apple juice (n = 19) were correctly identified as true positives. Eighteen

Table 1. Contingency Table for Gastric Ultrasound Diagnosis of Full Stomach

		Condition Full Stomach (as Determined by Randomization)		
		Condition Positive, Full Stomach	Condition Negative, Empty Stomach	Total
Gastric Ultrasound Test Outcome	Test Positive, Full Stomach	40	1	41
	Test Negative, Empty Stomach	0	39	39
	Total	40	40	80

Contingency table comparing results of the index test (gastric ultrasound) with the results of the reference standard (known history).

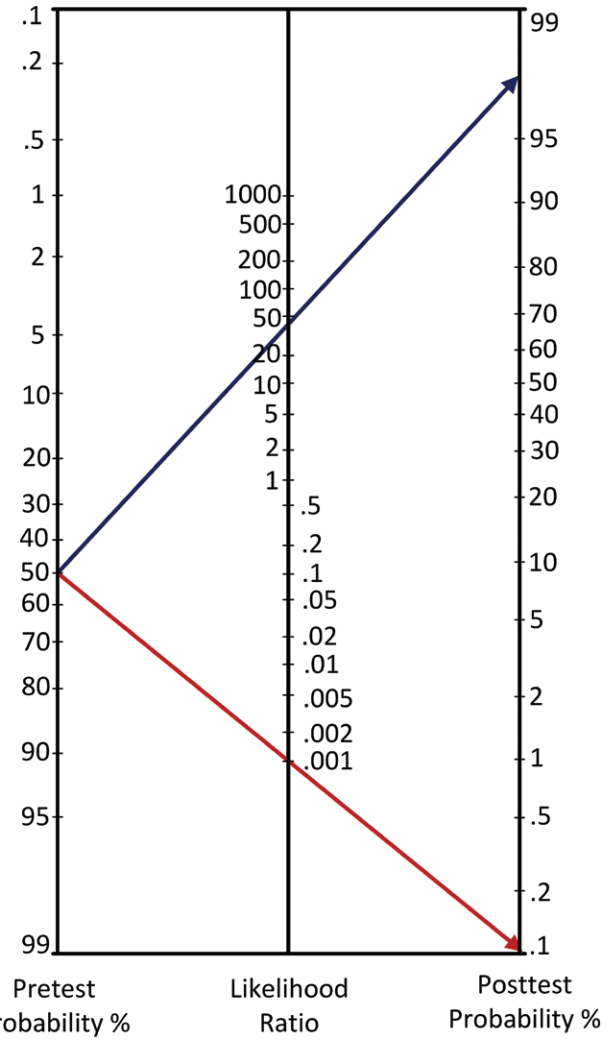

Figure 3. Likelihood ratio nomogram for the impact of gastric ultrasound test results on posttest probability of a full stomach. Adapted from Fagan.[29]

of the 19 were evaluated as having a high volume of clear fluid, while the remaining 1 subject (5.3%) was thought to contain both solid and fluid because some small particles were seen suspended on a background of clear fluid.

DISCUSSION

This study investigated the accuracy of a standardized gastric ultrasound test to detect or rule out a full stomach in a simulated clinical scenario with a pretest probability of 50%. The results suggest that the test is highly sensitive and specific when the subject has ingested either a glass of clear fluid (250 mL of apple juice) or a cup of coffee and a muffin. The choice of 2 different types of content was purposeful because the sonographic appearance varies significantly between clear fluid and solids, and also to include both components of gastric POC ultrasound (PoCUS). These 2 components of the examination are as follows: (1) qualitative to differentiate the nature of the content; and (2) a volume assessment to determine whether the amount of fluid observed is consistent with baseline fasting secretions.

The exclusion of 2 subjects who presented a full stomach despite prolonged fasting deserves comment because it illustrates the fact that there is significant individual variability in gastric emptying. While recommended fasting intervals limit gastric content in the vast majority of preoperative subjects, emptying may be incomplete after large meals with high fatty content.

To date, preoperative assessment of gastric content has relied primarily on a patient's history of fasting, which may be unknown or unreliable, especially in urgent or emergency situations or in the setting of serious comorbidities that prolong gastric emptying.[22] Anesthesiologists and emergency physicians are often faced with difficult decisions regarding anesthetic and airway management for patients in whom gastric content is uncertain. Given the serious consequences of aspiration, a prudent approach is often recommended when the risk is unclear. Common strategies involve delaying a surgical procedure if it is elective or protecting a patient's airway with endotracheal intubation, often with a rapid sequence induction of anesthesia if the procedure is urgent or emergent. These are safe strategies, but when used based on a generic assumption of risk, they may lead to unnecessary surgical delays or cancellations or unnecessary airway interventions. On the other hand, an underappreciation of risk may lead to failure to protect the airway and pulmonary aspiration.

PoCUS is an evolving imaging paradigm that is increasingly relevant for emergency physicians, anesthesiologists, and intensivists.[23,24] It implies: (1) a focused, limited, ultrasound examination of an organ; (2) that it is performed at the patient's bedside (or at the "POC"); (3) that it is usually performed by the same clinicians providing care; (4) to answer a well-defined clinical question; (5) to guide patient management; (6) the intention of improving patient outcome.[25]

Several recent editorials in major anesthesiology journals have called for greater adoption and teaching of gastric PoCUS in anesthesia practice.[26–28] Benhamou[26] suggested that this skill should be part of the basic armamentarium of anesthesiologists in daily practice. Mahmood et al[27] reported a comprehensive PoCUS curriculum for anesthesiologists that includes gastric ultrasound along other more established applications such as lung and cardiac assessment. Finally, Lucas and Elton[28] suggested that the 3 most useful ultrasound applications in obstetric anesthesia are

Table 2. Measures of Diagnostic Accuracy (n = 80)	
	Estimate (95% CI)
Sensitivity	1.0 (0.925–1.0)
Specificity	0.975 (0.95–1.0)
PPV	0.976 (0.878–1.0)
NPV	1.0 (0.92–1.0)
Likelihood ratio test (+)	40.0 (10.33–∞)
Likelihood ratio test (−)	0 (0–0.072)

Abbreviations: CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value.

ultrasound of the spine before neuraxial anesthesia, ultrasound for airway assessment, and gastric ultrasound.

The mathematical model to assess gastric volume used in this study has been validated against a gold standard of endoscopically guided suctioning[10] and has low intrarater and interrater variability.[13] In addition, a prospective study suggested that gastric ultrasound examination can change aspiration risk stratification and patient management in a large proportion of patients (>60%) who present for elective surgery without following fasting instructions.[16] However, its diagnostic accuracy to differentiate a full from an empty stomach had not yet been systematically evaluated.

Any dichotomous diagnostic test is arguably most useful in situations of clinical equipoise, that is, when there is true uncertainty regarding the condition of interest, in other words, when the pretest probability is around 50%. Using the classic nomogram by Fagan,[29] our results suggest that with a pretest probability of 50%, a positive test result increases the probability of a full stomach to 97% (given the positive likelihood ratio of 40) (Figure 3). For the same subject, a negative test result decreases the probability of a full stomach to <0.1% (given the negative likelihood ratio of 0). On the other hand, and similar to other diagnostic tests, gastric ultrasound is much less likely to be clinically useful when the pretest probability is either very high or very low. For instance, a healthy patient following standard fasting intervals has a very low pretest probability of a full stomach of around 3% at the most.[11,30] In this setting, a positive test result would only change that probability to 55% (Figure 3).

The specificity of the test is high but not 100%. One subject out of 40 had a false-positive result. Indeed, in our experience, the presence of air in the antrum at baseline may cause an air artifact along the anterior wall. Although this amount of baseline air is usually small, it may on occasion resemble a pattern of solid content ("frosted glass artifact") and can lead to a false-positive test.[8–10,15,31] This suggests that the test is not recommended as a routine intervention in subjects who are clearly at low risk of a full stomach based on clinical evaluation.

Some of the strengths of this study include its prospective randomized design, the standardization of the scanning technique, the use of previously validated methods and conceptual framework, the inclusion of a wide range of nonpregnant adult subjects of either gender, the use of a simulated pretest probability of 50%, and the blinding of the sonographer.

There are limitations that need to be considered. First, the results reflect the performance of the test under ideal circumstances and in a very well-controlled experiment, on subjects with normal body habitus. Therefore, the test may perform differently in clinical practice with a heterogeneous patient population who has ingested various types and quantities of food at different time intervals.

Second, the accuracy metrics reported here are applicable to quantities of food and fluid that are at least similar or greater than those in the study. The sensitivity of the test will likely be lower if a very small amount of food or fluid were ingested. We would expect the sensitivity and specificity of the test to be inversely proportional to the volume of gastric content. Even though the minimum threshold of volume that increases aspiration risk is not universally accepted, previous studies have shown that up to 100–120 mL (or ≤1.5 mL/kg) of baseline gastric fluid is normal in healthy fasted subjects with low aspiration risk.[32–36] Therefore, 250 mL of clear fluid is a reasonable volume to study, low enough to be close to the upper limit of normal but high enough to be clinically relevant and detectable by the test, which has a mean error of about ±30 mL.[10] Similarly, 1 cup of coffee and a muffin is a clinically plausible and relevant example of solid content to study. We decided to include an option with solid content as the sonographic findings are qualitatively different from those of clear fluid and the pulmonary aspiration of solid particulate content is associated with worse patient outcome. It is therefore not possible to ascertain from this study what the accuracy of the test would be for a smaller amount of solid or fluid, but it is reasonable to assume that it could be lower.

Third, the use of individual subjects more than once, but assumed to be independent, is a limitation of the study. This limitation was partially mitigated by establishing a minimum time interval of 24 hours between sessions, to allow for complete emptying of gastric contents between study sessions. In addition, to take into account possible intersubject correlation, we used a bootstrap method to calculate the 95% CIs based on 10,000 bootstrapped samples.

Fourth, gastric ultrasound as used in this study applies to adult subjects with normal anatomy of the gastrointestinal tract. The assumptions and conceptual framework used here were previously built on subjects with normal gastric anatomy and specifically exclude those with previous upper gastrointestinal tract abnormalities such as large tumors, large hiatal or diaphragmatic hernias, and previous gastric surgeries.[8–13]

Finally, the results of this study are only valid when a similar scanning protocol and conceptual framework are used. Measuring antral area in the RLD is of particular importance as this was the position used in model development[10] and the size of the antrum will be larger in the RLD than in any other patient position for a given volume.[8,9,11,37,38] Measuring the antrum at rest (between peristaltic contractions) and including the full thickness of the gastric wall are also important technical aspects.[8,10]

Gastric ultrasound has many advantages: it is noninvasive, posing minimal-to-no discomfort to the patients, it is performed at the bedside, it takes only minutes to perform,[39] it is easily learned,[31] it is applicable to a wide range of subjects,[10,12,40] it is highly reliable,[13] and as this study suggests, it is highly accurate. So, the question has been posed as to whether it should be performed routinely on every patient before anesthesia or sedation.[26] We advocate that like other POC applications, gastric ultrasound is best used when the

clinician is uncertain about gastric content, in other words when the pretest probability of a full stomach is close to 50%. Some clinical examples could be: (1) conflicting information regarding a last meal; (2) severe comorbidities such as diabetes, end-stage renal disease, or neurological disease; and (3) urgent or emergency situations in which delayed gastric emptying could result in a full stomach despite prolonged fasting.[20] Testing all healthy fasted subjects presenting for elective procedures will have a low yield, and it may result in the occasional false positive, leading to unnecessary interventions or delays. Similarly, testing subjects who clearly have a high aspiration risk based on clinical information seems unnecessary, and could potentially lead to unsafe management in the event of a false-negative test.

In conclusion, our results suggest that bedside gastric ultrasound is highly sensitive and specific to positively identify or rule out a full stomach. This study adds to a growing body of literature that supports the role of gastric PoCUS to inform aspiration risk assessment at the bedside and guide anesthetic management to prevent pulmonary aspiration of gastric contents.

DISCLOSURES

Name: Richelle Kruisselbrink, MD, FRCPC.
Contribution: This author helped recruit the study subjects and prepare the first draft of the manuscript.
Conflicts of Interest: R. Kruisselbrink was the physician sonographer.
Name: Angineh Gharapetian, MD, FRCPC.
Contribution: This author helped design the study, obtain research ethics board approval, and prepare the study protocol and manuscript.
Conflicts of Interest: None.
Name: Luis E. Chaparro, MD.
Contribution: This author helped recruit the study subjects, collect the data, and prepare the manuscript.
Conflicts of Interest: None.
Name: Noam Ami, MSc, CCRP.
Contribution: This author helped screen the study subjects, collect the data, and prepare the study logistics and manuscript.
Conflicts of Interest: N. Ami was the study coordinator.
Name: Dustin Richler, MD.
Contribution: This author helped collect the data, and prepare the data summary and manuscript.
Conflicts of Interest: None.
Name: Vincent W. S. Chan, MD, FRCPC, FRCA.
Contribution: This author helped design the study, and prepare the protocol development and manuscript.
Conflicts of Interest: V. W. S. Chan has received honoraria from SonoSite, Braun, and Aspen Pharma. He is also a member of the medical advisory board for Smiths Medical.
Name: Anahi Perlas, MD, FRCPC.
Contribution: This author helped design the study, develop the protocol, obtain research ethics board approval, and prepare and submit the manuscript.
Conflicts of Interest: A. Perlas has received research support from Fisher and Paykel. She is an associate editor of *Regional Anesthesia and Pain Medicine*, and she is the principal investigator of this study.
This manuscript was handled by: Maxime Cannesson, MD, PhD.

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