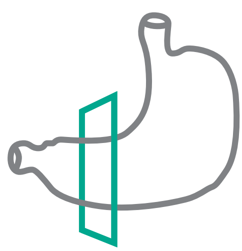
POINT-OF-CARE GASTRIC ULTRASOUND: AN ASPIRATION RISK ASSESSMENT TOOL

Peter Van de Putte



Point-of-care gastric ultrasound: an aspiration risk assessment tool.

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POINT-OF-CARE GASTRIC ULTRASOUND: AN ASPIRATION RISK ASSESSMENT TOOL

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CHAPTER 1: General introduction

Peter Van de Putte

1.1. Introduction

In 1848, twelve months after the first general anaesthesia at the Massachusetts General Hospital in Boston, James Simpson, a Professor of Midwifery at the University of Edinburgh, published in the Lancet a case of anaesthetic-related death that recognized the involvement of pulmonary aspiration of gastric contents as the cause of death.[1,2] The patient was a 15-y-old girl whose toenail was removed under general anaesthesia with chloroform. A seizure during the anaesthetic was treated with the ingestion of a mixture of brandy and water. This was repeated when her situation clinically improved but she went into cardiac arrest soon afterwards. The autopsy report stated she "died from congestion of the lungs, from the effects of chloroform". Simpson however concluded that the patient deceased because of the methods used during the resuscitation of the patient, namely the administration of brandy and water that "were poured with the best of motives in the girl's mouth but they were of course allowed to rest in and fill up the pharynx as in her state of anaesthesia, she was not in a condition to swallow them".

In 1946, a century later, Curtis Mendelson described in what became a landmark paper, 66 cases of pneumonia in 44016 parturients with two fatalities.[3] He was not the first to show pathological changes caused by aspiration- there were earlier case series and animal research [4-13] but he established the aetiology of pulmonary aspiration of gastric acid and solids through extensive clinical observations and animal research.[14]

Definition: the general definition of the word "aspiration" is "to draw in or out by means of suction". From a medical point of view, the term "aspiration" often refers to the inflow of material from the nasopharynx or upper gastrointestinal tract through the larynx into the lungs.[15] The nature of the aspirated material is not reflected in the term and can vary from saliva, secretions, blood and bacteria to liquids, food and gastric contents.[16] The syndrome we now know as aspiration pneumonitis, Mendelson's syndrome, is a chemical acute lung injury caused by the inhalation of noxious sterile gastric contents. This is distinct from aspiration pneumonia which is an infection caused by the inhalation of oropharyngeal

secretions, colonized by pathogenic bacteria.[17] When aspiration pneumonitis occurs, the chemical burn of trachea, bronchial tree and lung parenchyma cause an intense parenchymal inflammation. Patients can present with bronchial wheezing, coughing, fever, tachycardia and dyspnoea or more dramatic symptoms such as cyanosis and pulmonary oedema that can rapidly progress to acute respiratory distress syndrome and death.[15,18] The severity of the lung injury after aspiration varies based on the amount, content and acidity of what has been aspirated.[15]

Incidence: perioperative aspiration of gastric contents is a rare event in healthy, elective surgical patients. The incidence has been investigated in numerous large historical studies and reported rates vary around 1:4.000-5.000. However, higher frequencies have been reported in high-risk groups such as emergency surgery patients and patients with increased ASA (American Society of Anesthesiologists) grading.[19-22] Warner et al. reported that the aspiration risk for elective surgical ASA 1 patients increased from 1:10.000 to 7:10.000 in ASA 4 patients. In emergency patients the risk rose from 3:10.000 to 29:10.000.[20] Table 1.1 summarizes the literature on the frequency of perioperative aspiration but interpreting and comparing this information remains difficult since data such as aspiration prevention measures, the type and urgent character of the surgery are not systematically reported.[3,19,20,23-40] However, aspiration pneumonitis, when it occurs, is a serious clinical entity and one of the important causes of anaesthesia-related death.[34,40,41] The NAP4 study (Report and findings of the 4th National Audit project of the Royal College of Anaesthetists) reported in 2011 that pulmonary aspiration was the single most common cause of death in reported airway management incidents, accounting for 50% of all anaesthesia-related deaths.[40] This outweighs the frequency of the much feared can't intubate, can't ventilate scenario.[42] The incidence of anaesthesia-associated fatal aspiration varies historically from 1/45.000 to 1/240.000 (Table 1.1) The NAP4 study described an incidence of 1 in 350.000.[40] Aspiration is often seen as only relevant during induction but this is contrary to the evidence that it also happens in a significant number of cases during maintenance (n=13/23,NAP4) or after the removal of the endotracheal tube (36%).[20,40]

Table 1.1: Reported incidence and mortality of anaesthesia-related pulmonary aspiration. Adapted with permission from Lionel Bouvet, MD, PhD. Détermination et optimisation du contenu gastrique en anesthésie. https://tel.archives-ouvertes.fr/tel-01158738, 2015.

Author	Period	Context of GA	Patients (n)	Aspiration (n)	Ratio /10000	Death (n)	Ratio /10000
Mendelson[3]	1932-45	Obstetrics	44016	66	15	2	0.45
Blitt[23]	1970	All types	900	6	66.7	-	-
Krantz[24]	1962-72	Obstetrics (no INT)	37282	5	1.3	-	-
Krantz	1962-72	C section intubation	3076	7	22.8	-	-
Tiret[25]	1978-82	All types	198103	27	1.4	4	0.2
Cohen[26]	1975-83	All types	112000	72	6.4	-	-
Olsson[19]	1975-83	C-sections	2643	4	15	-	-
Olsson	1975-83	All types	185358	87	4.7	4	0.2
La Rosa[27]	1980-90	C-sections	10017	8	7	-	-
Warner[20]	1985-91	All types	215488	67	3.1	4	0.2
Mellin-Olsen[28]	1989-93	All types	85594	25	2.9	0	0
Kubota[29]	1962-92	All types	85708	0	0	0	0
Verghese[30]	1992-93	All types	39824	1	0.2	0	0
Soreide[31]	1996	Gynaecol-Obstetrics	30000	11	3.6	4	1.3
Borland[32]	1988-93	Paediatric	50880	52	10.2	0	0
Neela-kanta[33]	1991-94 1996-00	All types	199429	23	1.2	1	0.05
Sakai[34]	2001-04	All types	99441	14	1.4	1	0.1
Landreau[35]	2002-07	All types	117033	40	3.4	5	0.4
Bernardini[36]	1997-98	All types	30082	7	2.3	0	0
Bohman[37]	2000-16	Upper GI endoscopy	60770	28	4.6	-	-
Walker[38]	2010-11	Paediatric	118371	24	2	0	0
Tan[39]	2000-13	Paediatric	102425	22	2.1	0	0
Cook[40]	2008-09	All types	114904	34	2.9	8	0.7

Table 1.2: Predisposing factors that increase aspiration risk

Lower oesophageal sphincter incompetence
sliding hiatus hernia
gastroesophageal reflux disease (GERD), dyspepsia
oesophageal disease (achalasia)
presence of nasogastric tube
medication (atropine, diazepam, morphine)
Increased intra-abdominal pressure
Pregnancy
morbid obesity
intestinal obstruction
laparoscopy, (upper) abdominal surgery
lithotomy (head down) position during surgery
Increased gastric volume (“full” stomach)
disobedience to the institutional fasting guidelines
urgent surgery
decreased gastric emptying:
-neuropathology (Parkinson’s, multiple sclerosis)
-endocrinal pathology (diabetes, hypothyroidism)
-opioid medication
-chronic renal disease
-pain, anxiety
-women in active labour
-raised intra-cranial pressure
-surgical pathology (intestinal obstruction, previous GI - surgery, vagotomy)
-substance abuse (cannabis, alcohol)
-recent trauma
Absent upper airway reflexes
sedation or anaesthesia

Conditions: for aspiration to occur, three conditions must be fulfilled: [43,44]

a) there must be reflux of the stomach contents through the incompetent lower oesophageal sphincter (LOS). The LOS that is formed where the low border of the oesophagus makes an acute angle with the gastric fundus, has a resting pressure of 15-25 mmHg above the gastric pressure which creates a physiological barrier to gastro-oesophageal reflux.[42,44,45] When the intra-gastric or intra-abdominal pressure exceeds the pressure of the LOS, stomach contents flow back via the oesophagus.

b) there must be an incompetence or absence of the protective pharyngo-laryngeal reflexes (laryngospasm, gagging and coughing, spasmodic panting and forced expiration) that allow stomach contents that are pooled in the pharynx to pass the vocal cords and to reach the tracheobronchial tree.[44,45]

c) the stomach must contain a "critical volume" of stomach contents.

The protective tone of the lower oesophageal sphincter and upper airway reflexes are depressed or impeded by sedation and anaesthesia. Therefore, the presence and amount of gastric contents are the only of the abovementioned conditions that can be influenced. The amount of contents is determined by three factors: the volume of gastric juice produced by the stomach itself, the amount and type of ingested liquids/ solids and the rate of gastric emptying.

Predisposing factors: there is a long list of factors that increase the risk of perioperative aspiration.[45] (see Table 1.2) One factor is missing from the table: in 50% of the cases of aspiration in the NAP4 study, a trainee anaesthetist was involved but this has not been confirmed in other studies.[40]

Aspiration prevention strategies: because of the potentially devastating effects of perioperative aspiration of gastric contents, prevention and proactive management are crucial and remain a cornerstone of anaesthetic practice.[42] Although not universally accepted, strategies and guidelines are recommended to decrease the risk of aspiration or to minimise its consequences.[40,47] These are summarized in Table 1.3.

Table 1.3: Aspiration prevention strategies

The use of fasting guidelines (starvation)
Experienced anaesthesia assistance available to all times
Premedication with prokinetic agents (e.g. metoclopramide) and antacids
The use of regional anaesthesia to avoid general anaesthesia
The pre -or perioperative insertion of a nasogastric tube to drain the stomach
The use of second generation supraglottic airway devices
Tracheal intubation (routine or rapid sequence induction)
-all emergency cases
-consider seriously in the following:
delayed GE
increased intra-abdominal pressure
Extubate high-risk cases awake after return of airway reflexes and on their side
Extubate all others on their side

The most important preventive strategy are the preoperative fasting guidelines that restrict fluid and food intake prior to anaesthesia and were developed by anaesthesiology societies.[48,49] For example, current guidelines by the European Society of Anaesthesiology recommend that drinking clear fluids should be encouraged up to 2 hours before elective surgery, solid food should be prohibited for 6 hours before elective surgery.[48] The American Society of Anaesthesiologists recommend a minimum of 2 hours of fasting for clear fluids, 6 hours following a light meal (toast and clear fluids) and 8 hours following a full meal with high calorie or fat content.[49] However, these guidelines apply to healthy patients only for elective surgery and are not reliable for patients with coexisting diseases that affect gastric emptying or volume, patients in whom airway management might be difficult or in emergency situations. The NAP4 study provided evidence that aspiration often happens as a consequence of incomplete or failed assessment of the aspiration risk or failure to modify the anaesthetic technique.[40,42] Failure of risk assessment was a persistent theme in the NAP4 study. Only 10% of the primary anaesthesia-related aspiration cases were thought to have any risk factors for aspiration at the time of surgery but 93% of the patients that aspirated had an identifiable risk retrospectively.[40,42]

It is clear that aspiration risk is a continuous spectrum - it goes from very low over intermediate to very high.[42] Anaesthesiologists have to work with this spectrum, assess aspiration risk and make anaesthetic technique management decisions based on a standardized protocol that is mostly based on a general assumption of hours of fasting. It might therefore very useful to have a tool that provides objective information on the type (qualitative) and amount (quantitative) of stomach contents.

Point-of-Care Ultrasonography (PoCUS) is defined as ultrasonography brought to the patient at the bedside and performed in real time by the provider. Rather than recording images and interpreting them later, ultrasound findings are directly correlated with the patient's condition. Additionally, PoCUS is easily repeatable and it may involve a series of focused ultrasound scans if needed.[50] Certain characteristics are shared by all PoCUS applications:[51]

-the exam needs to be done for a clearly defined condition in which ultrasound has been shown to improve patient care or in which it is the primary diagnostic modality.

-the exam should be focused ("limited" or "goal-directed") and designed to answer a specific question that guides care. This concept of a focused exam is important because clinicians from different specialties can be very adept at investigating a particular organ in their field of expertise as compared to radiologists who have a more comprehensive and complete way of working.

-the exam should be characterized by one or two easily recognizable findings. This results in "simple questions, straightforward examinations and useful answers".

-the exam should be easy to learn.

-the exam should be performed quickly.

-the exam should directly influence clinical decision making.

-the exam should be done at the bedside.

This clinical diagnostic paradigm is particularly useful in acute care settings as anaesthesia, intensive care and emergency medicine.[51]

Point-of-Care gastric Ultrasonography (gastric PoCUS) is an emerging tool that provides bedside information on gastric content and volume.[52-54] Similar to other more established PoCUS applications (such as cardiac or lung assessment) this diagnostic modality aims to answer a well-defined clinical question namely "*what is the aspiration risk in this particular patient?*" in a short period of time intended to guide patient management with the ultimate goal of improving patient outcome.[51]

1.2. Objectives

The objectives of this PhD thesis are specified per chapter below:

Chapter 1: to offer a general introduction on the aspiration of gastric contents.

Chapter 2: to summarize the state of knowledge in a systematic review on the use of bedside gastric ultrasound in 2013 at the start of this PhD project to evaluate gastric content and volume as they relate to aspiration risk assessment from the perspective of the clinical anaesthesiologist. The following questions will be addressed: 1) Can ultrasound determine the nature of gastric content (empty, clear fluid or thick fluid/solid)? and/or 2) Can ultrasound estimate the volume of gastric fluid?

Chapter 3: to suggest a framework, based on the I-AIM mode (Indication; Acquisition; Interpretation; Medical management), for the logical stepwise clinical implementation of point-of-care GUS which can also serve as an educational tool during theoretical and hands-on sessions. In addition, we present a sample report template for standardized written communication of findings.

Chapter 4: to investigate the feasibility of implementation of gastric ultrasound in severely obese patients (BMI ≥35 kg/m^2) who have fasted overnight prior to elective surgery in a prospective cohort study. The primary outcome measure is the proportion of subjects in which gastric ultrasound provides a complete image of the gastric antrum. Secondary outcome measures include the proportion of subjects in which it is possible to use a 3-point grading system, the measurement of the antral cross-sectional area and the estimation of total gastric volume, antral wall thickness, the depth of the antrum and the time required for image acquisition.

Chapter 5: to perform a retrospective analysis of a departmental database containing clinical and gastric sonographic information of fasted patients presenting for elective surgery. Primary outcome is the incidence of full stomach.

Chapter 6: to perform a retrospective analysis of a departmental database containing clinical and sonographic information on elective surgical patients who had been non-compliant with fasting instructions. Primary outcome is the incidence of changes in aspiration risk stratification and anaesthetic management from a standard history-based clinical assessment to one including gastric sonography. Secondary outcomes include a) types of changes (timing of the surgical procedure or change in anaesthetic technique) b) the incidence of aspiration.

Chapter 7: to describe and to discuss cut-off values of antral cross-sectional area, gastric volumes and volume per body weight that allow us to distinguish a “full” from an “empty” stomach when clear fluid is present.

Chapter 8: to compare the distribution of gastric fluid volumes with gastric ultrasound in term fasted non-labouring parturients and their non-pregnant female counterparts in a prospective cohort study. The primary outcome is the distribution of total gastric fluid volumes in fasted term pregnant and non-pregnant females. Secondary outcomes are: a) to establish the upper limits of the antral cross-sectional area and gastric fluid volumes (95th percentile) in this patient population b) to describe the distribution of antral grades in the pregnant population.

Chapter 9: to describe the clinical application of gastric PoCUS in daily practice with two case reports.

Chapter 10: to summarize the state of knowledge in a narrative review on the use of gastric point-of-care ultrasound at the end of completing the PhD thesis in 2018.

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CHAPTER 2: Ultrasound assessment of gastric content and volume. A systematic review of the literature.

Peter Van de Putte

Anahí Perlas

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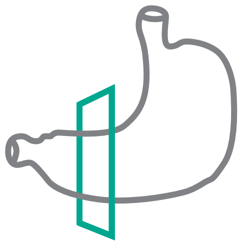

2.1. Summary

Pulmonary aspiration of gastric content is a serious anaesthetic complication that can lead to significant morbidity and mortality. Aspiration risk assessment is usually based on fasting times. However, fasting guidelines do not apply to urgent or emergent situations and to patients with certain co-morbidities. Gastric content and volume assessment is a new point-of-care ultrasound application that can help determine aspiration risk. This systematic review summarizes the current literature on bedside ultrasound assessment of gastric content and volume relevant to anaesthesia practice. Seventeen articles were identified using predetermined criteria. Studies were classified into those describing the sonographic characteristics of different types of gastric content (empty, clear fluid, solid), and those describing methods for quantitative assessment of gastric volume. A possible algorithm for the clinical application of this new tool is proposed and areas that require further research are highlighted.

Keywords: antrum, gastric content, ultrasound, pulmonary aspiration.

2.2. Introduction

Perioperative aspiration of gastric contents is a rare but serious complication of anaesthesia. The overall incidence in a mixed surgical population ranges between <0.1% and 19% depending on patient and surgical factors and it hasn't changed in the last few decades.[1-5] Aspiration pneumonia is associated with significant morbidity such as prolonged mechanical ventilation[6] and mortality as high as 5%. Pulmonary aspiration is involved in up to 9% of all anaesthesia related deaths.[7 8] One of the main risk factors for aspiration is the presence of gastric content. The critical volume threshold of gastric fluid that by itself increases aspiration risk is controversial but healthy fasted patients frequently have residual gastric volumes of up to 1.5 mL/kg without significant aspiration risk.[9-13] Sedation and general anaesthesia depress or impede the physiological mechanisms that protect against aspiration (the tone of the lower oesophageal sphincter and upper airway reflexes).[14 15] Since restriction of fluid and food intake prior to general anaesthesia is vital for patient safety, anaesthesiology societies have developed guidelines for preoperative fasting.[16,17] For example, current guidelines by the American Society of Anesthesiologists recommend a minimum of 2 hours of fasting for clear fluids, 6 hours following a light meal (toast and clear fluids) and 8 hours following a full meal with high calorie or fat content.[17] However, these guidelines apply only to healthy patients for elective surgery and are not fully reliable for patients with coexisting diseases that affect gastric emptying or volume, patients in whom airway management might be difficult or in emergency situations.[17] This systematic review summarizes the current state of knowledge on the use of bedside ultrasound to evaluate gastric content and volume as they relate to aspiration risk assessment from the perspective of the clinical anaesthesiologist.

2.3. Methods

The recommendations and checklist of the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) were followed to conduct and report this review.[18]

The National Library of Medicine's PubMed, OVID Medline and EMBASE databases were searched since their date of inception to February 2013 using the following Medical Subject Headings: *gastric ultrasonography OR gastric ultrasound* OR *gastric sonography AND stomach OR antrum* were used. The search was restricted to English language articles and human subjects. Two independent reviewers read all citations. Prospective or retrospective experimental studies of portable 2D ultrasonography on human subjects, case series or observational studies were selected for inclusion if they addressed one or two of the following questions: 1) Can ultrasound determine the nature of gastric content (empty, clear fluid or thick fluid/solid)? and/or 2) Can ultrasound estimate the volume of gastric fluid? Commentaries, abstracts, letters to the editor, case reports, editorials and meeting proceedings were excluded. Discrepancies were settled by discussion and consensus. Selected articles underwent full text review and references were screened for further articles not identified by the searches.

The following data were extracted from each included study: publication year, country of origin, study design, number of subjects and demographics, gastric sections studied (antrum, body, fundus), scanning position and plane. For quantitative studies, details of mathematical models were extracted (reference standard, correlation coefficient).

2.4. Results

Three hundred and ninety-four citations were identified (Figure 2.1). Based on title and abstract, 356 were excluded as not meeting inclusion criteria, and 5 were duplicates. Thirty-three articles were retrieved for full text review. Of these, 22 publications were excluded (13 studied gastric emptying, 3 studied gastric motility and 6 were on other gastroenterology applications not directly related to aspiration risk assessment). Six additional articles were identified from reference lists. Seventeen articles were included in this review. Eight articles dealt with qualitative assessment (Table 2.1), 7 articles dealt with quantitative assessment (Table 2.2) and 2 additional studies were included in both categories. Of the included studies, 41 % (n=7) were published before 2000, 18 % (n=3) between 2000 and 2009 and the

remaining 41 % (n=7) in or after 2010. The majority of the studies originated in North-America (47 %, n= 8) and Europe (41 %, n=7), whereas 12 % (n =2) were from Japan. A total of 533 subjects were included in the qualitative studies and 542 subjects in the quantitative studies. Study populations consisted of healthy volunteers (n=267), pregnant patients (n=73), newborns (n=32), other paediatric patients (n=16), elective adult surgical subjects (n=467), upper gastric endoscopy (n=140) or intensive care patients (n=80). The antrum was evaluated in 82% of the studies, the fundus in 23% and the gastric body in 35%. Two studies did not specify which section of the stomach was evaluated.

2.4.1. Qualitative gastric sonography: Can ultrasound determine the nature of gastric content (empty, clear fluid or thick fluid/solid)?

Ten articles describe the utility of ultrasound to determine the nature of the gastric content (Table 2.1).

Scanning technique: The stomach has been imaged with the patient in the supine, sitting, semi-sitting or right lateral decubitus position (RLD). The best position depends on the section of the stomach to be imaged and affects sonographic findings. Several studies suggest that the distal parts of the stomach (antrum and body) are better evaluated in a semi-sitting or RLD position.[19 - 26] Due to a gravitational shift, a greater proportion of gastric content will move towards the more dependent areas of the stomach in these two positions. This may be especially important to evaluate gastric content in low volume states in which gastric fluid may only be visible in a sitting or RLD position.[20 24 25] Scanning technique was similar among different reports whether they studied healthy volunteers or patients. The only exception is a report on critically ill patients in which it may not be feasible to scan in a patient position other than supine.[27]

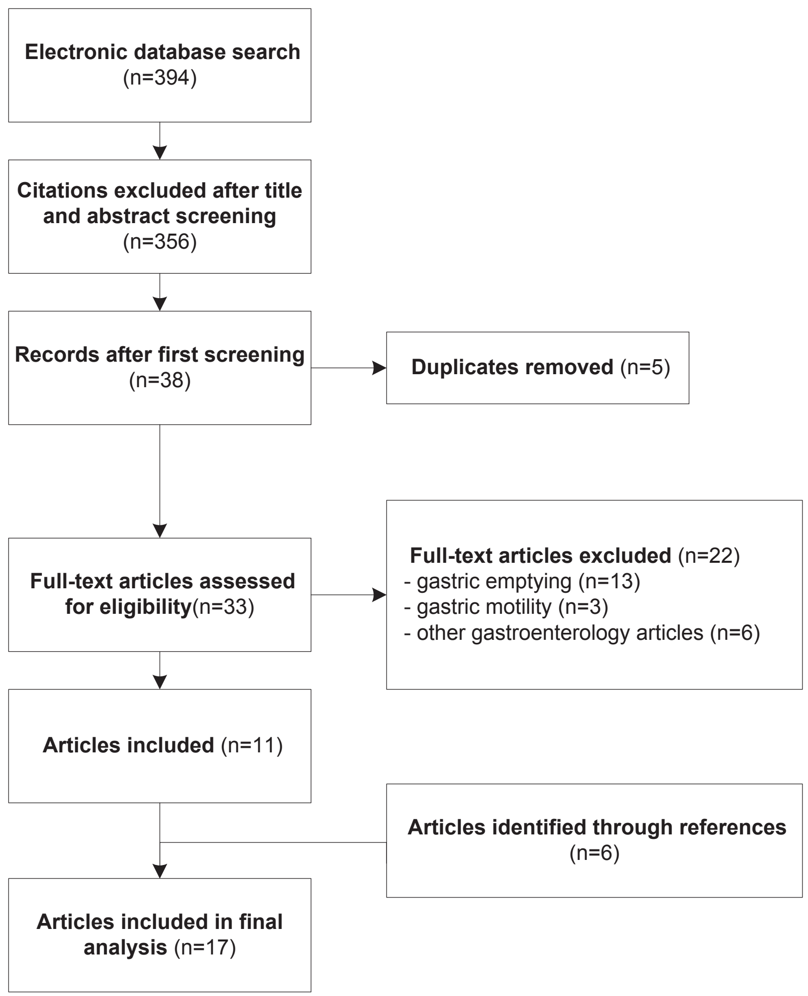

Figure 2.1: Results.

Table.1: Qualitative studies

Author	Year	Country	Design	Study population	N	Age (y)	BMI	Patient position	Gastric section	Scanning plane	Empty	Fluid	Solid
Sijbrandij[19]	1991	Netherlands	Pictorial essay	NA	NA	NA	NA	RLD	A/F/B	Oblique left upper quadrant	No	Yes	No
Carp[20]	1992	USA	OBS	Females (OB and non-OB)	93	NR	NR	SIT/RLD	A/B	Oblique left upper quadrant	No	Yes	Yes
Jayaram[22]	1997	USA	OBS	Females (OB and non-OB)	94	20-40 °	20-40 °	SIT	A/B	Oblique left upper quadrant	No	Yes	Yes
Jacoby[23]	2003	USA	INT Blind	Volunteers	20	NR	NR	SUP/RLD	NR	Axial	No	Yes	Yes
Perlas[24]	2009	Canada	OBS	Volunteers	18	NR	NR	SUP/RLD	A/B/F	Parasagittal	Yes	Yes	Yes
Bouvet[29]	2009	France	INT Blind	Volunteers	22	27-51 °	21-24 °	Semi SIT	A	NR	Yes	Yes	Yes
Sporea[28]	2010	Romania	Technical Report	NA	NA	NA	NA	NA	A/B/F	Axial/ Sagittal	Yes	Yes	No
Koenig[27]	2011	USA	OBS	ICU patients for urgent Intubation	80	20-91 °	NR	SUP	B/F	Axial/ Mid axillary line	Yes	Yes	Yes
Perlas[25]	2011	Canada	OBS	Adult surgical	200	51±16 *	28±5 *	SUP/RLD	A	Sagittal	Yes	Yes	No
Cubillos[26]	2012	Canada	Pictorial essay	Volunteers	6	34±7 *	27±2 *	RLD	A	Axial/ Sagittal	Yes	Yes	Yes

a) Legend: A=antrum B=body F=fundus INT=interventional NA=not available NR=not reported OB= obstetric OBS=observational RLD=right lateral decubitus SIT=sitting SUP=supine

b) Age and BMI are mean ± SD (*) or range (°)

Table 2.2: Sonographic presentation of antrum and contents

	Empty	Clear fluid	Milk or suspensions	Solid
Antral shape	Flat, collapsed OR round (Bull's eye)	Round, distended	Round, distended	Round, distended
Antral wall	Thick Prominent muscularis propriae	Thin	Thin	Thin
Content	None (grade 0) OR Small amount of hypoechoic content (grade 1)	Hypoechoic	Hyperechoic	Hyperechoic Heterogeneous ± mixed with air
Peristalsis	None	Present (usually fast waves)	Present	Present (usually slow waves)

A curved array low frequency transducer (2-5 MHz) with standard abdominal settings is most useful in adults. It provides the necessary penetration to identify the relevant anatomic landmarks.[19] A linear high frequency transducer can be used in leaner or paediatric patients or to obtain detailed images of the gastric wall. The gastric wall is 4-6 mm thick and has a characteristic appearance of 5 distinct sonographic layers that are best visualized with a high frequency transducer (e.g. 5-12 MHz) in the fasting state.[19 25 26 28] These layers help differentiate the stomach from other hollow viscus. Starting at the inner surface of the stomach, the first thin hyperechoic layer corresponds to the mucosal-air interface. A second hypoechoic layer is the muscularis mucosa. A third hyperechoic layer corresponds to the submucosa. A fourth hypoechoic layer is most prominent and corresponds to the muscularis propria whereas a fifth thin hyperechoic layer is the serosa.[19 25 26 28]

Table 2.3: Quantitative studies

Author	Year	Country	Design	Study population	N	Age (y)	BMI	Patient position	Gastric section	Scanning plane	2D measure	Reference standard	Model	CC (r)
Fujigaki[21]	1993	Japan	OBS	Adults	39	46±3*	NR	SIT	Distal	Sagittal	ACSA	NG suction	No	NR
Ricci[37]	1993	Italy	INT Blind	Volunteers	15	24-47°	NR	SUP/SIT	A	Transverse to the organ	ACSA	NG suction	No	NR
Hveem[34]	1994	Norway	INT	Adults	35	16-90°	NR	Semi SIT	A	Sagittal	ACSA	Gastroscopy	No	0.91
Tomomasa[35]	1996	Japan	INT	Newborns	32	≤1 m°	NR	RLD	A	Sagittal	ACSA	NG suction	No	0.83
Perlas[24]	2009	Canada	INT	Volunteers	90	21-42°	21-26°	SUP/RLD	A	Parasagittal	ACSA	Ingested Volume	Yes	0.82
Bouvet[29]	2009	France	INT Blind	Volunteers	22	27-51°	21-24°	Semi SIT	A	NR	ACSA	Ingested volume	No	NR
Bouvet[30]	2011	France	OBS	Adult surgical	183	49±18*	23±3*	Semi SIT	A	Sagittal	ACSA	NG suction	Yes	0.72
Schmitz[36]	2012	Switzerland	INT	Paediatric volunteers	16	6-13°	NR	SUP/RLD Semi SIT	A	Sagittal	ACSA	MRI	Yes	0.79
Perlas[31]	2013	Canada	INT blind	Patients for UGE	110	51±14*	25±5*	RLD	A	Sagittal	ACSA	Gastroscopy	Yes	0.86

a) Legend: A=antrum ACSA=antral cross-sectional area CC=correlation coefficient INT=interventional NG=nasogastric NR=not reported OBS=observational RLD=right lateral decubitus SIT=sitting SUP=supine UGE=upper gastric endoscopy

b) Age and BMI are mean±SD (*) or range (°)

Gastric antrum: Several studies suggest that the antrum is the gastric region that is most amenable to sonographic examination.[19 21 24-26 28] It is the gastric portion most consistently identified (98 to 100% of cases).[24 29 30] It is found superficially between the left lobe of the liver anteriorly and the pancreas posteriorly in a sagittal or para-sagittal scanning plane in the epigastrium.[23-26 28 29 31] Important vascular landmarks including both the aorta or inferior vena cava (IVC) and either the superior mesenteric artery or vein have been used to standardize a scanning plane through the antrum.[23-26 29] Not only is the antrum highly amenable to ultrasound imaging, its evaluation accurately reflects the content of the entire organ.

Gastric body: The body of the stomach may be imaged by sliding the transducer towards the left subcostal margin using an oblique scanning plane.[19 20 22 24 27 28] In this plane, the anterior wall is consistently identified, extending from the lesser to the greater curvature.[24] However, the presence of air in the body frequently obscures the posterior wall, and it may be more difficult to image a full cross-section of the gastric body.

Gastric fundus: The fundus is located in the left upper quadrant of the abdomen, inferior to the diaphragm, anterior to the left kidney and posterior to the spleen. It is the most challenging section of the stomach to image due to its deep location and the lack of a wide acoustic window due to the rib cage. Two different approaches have been described. A left lateral, intercostal, transsplenic approach has been reported with limited success.[24 28] Alternatively, a longitudinal scan in the mid-axillary line has been used.[27] Air is commonly found in both the fundus and the body, even in "empty" stomachs, which hinders visualization of these two sections.[19 24]

Sonographic evaluation of gastric content: An early study of gastric ultrasound in the anaesthesia literature differentiated between liquid and solid gastric contents.[20] In this patient series the stomach could only be identified in 60% of patients and could not be located when empty. However, more recent studies using contemporary technology report consistent success in identifying the stomach, especially the gastric antrum, even in the empty state.[24 25 28-30] In the empty stomach the antrum appears flat with juxtaposed anterior and posterior walls (figure 2.2). In

a sagittal plane, it is round to ovoid and has been compared to a "target" or "bull's eye" pattern (Table 2.2).[24 26] In an axial scanning plane, the empty antrum has a "gloved finger" appearance.[28]

Baseline gastric secretions, water, apple juice, black coffee and tea appear hypoechoic or anechoic.[24 26 28 29] With increasing volume, the antrum becomes round and distended, with thin walls (figure 2.3). Air or gas bubbles appear as multiple mobile punctuate echoes, giving the appearance of a "starry night".[24] Milk, thick fluids or suspensions have increased echogenicity.[26] Following a solid meal, a "frosted-glass" pattern has been described caused by substantial amount of air mixed with the food bolus during the chewing and swallowing processes (figure 2.4).

The air/solid mixture creates multiple ring-down artefacts on the anterior gastric wall, which typically "blur" the posterior wall of the antrum.[24 26] After some time the air is displaced and the solid content can be better appreciated with a mixed echogenicity (Table 2.2).[24 26] Following oral intake of any type, peristaltic gastric contractions occur. They are noted easily on ultrasound and can be lumen occlusive or non-occlusive.[32]

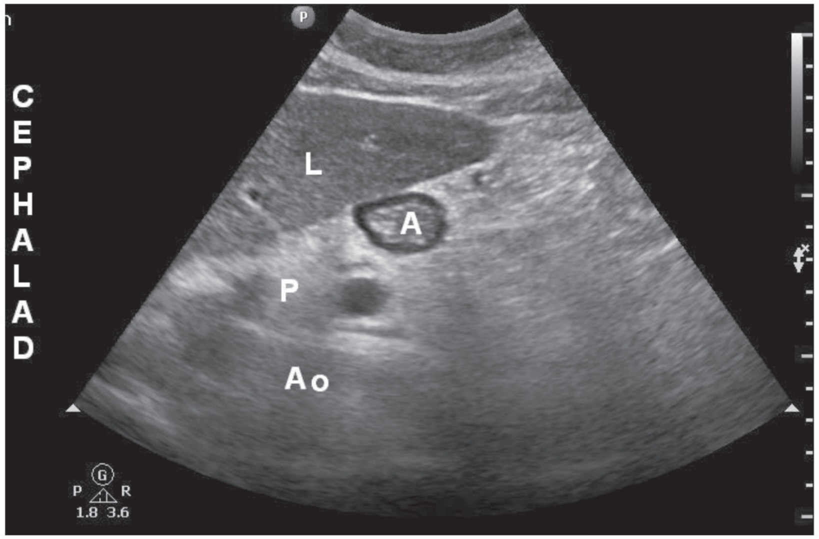

Figure 2.2: Sonographic image of the gastric antrum of an empty stomach. Note the antrum appears small, with no visible content. The muscularis propia is seen distinctly as a thick hypoechoic layer of the gastric wall. A= antrum; L=liver; P=pancreas; Ao=aorta.

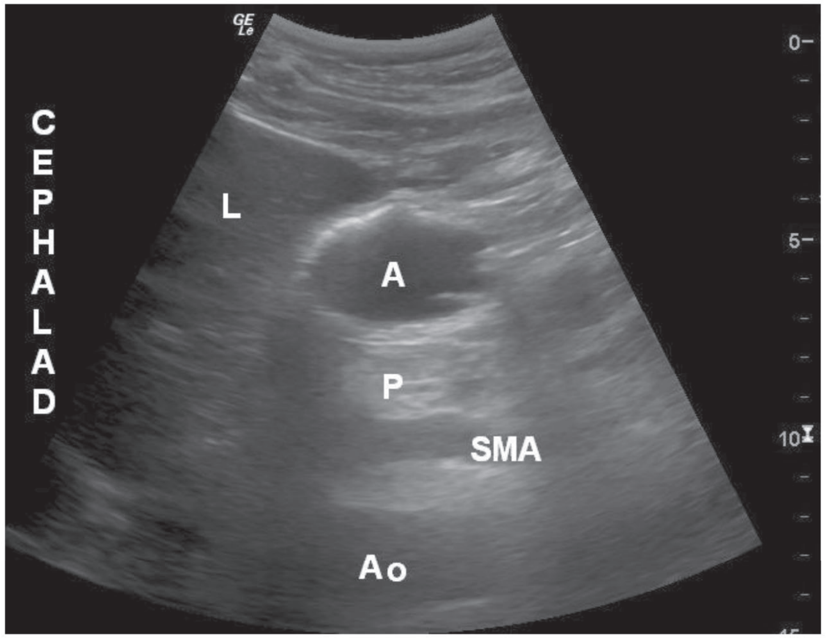

Figure 2.3: Sonographic image of the gastric antrum containing clear fluid. Note the antrum appears distended with hypoechoic/anechoic content. A=antrum; L=liver; P= pancreas; Ao= aorta; SMA= superior mesenteric artery.

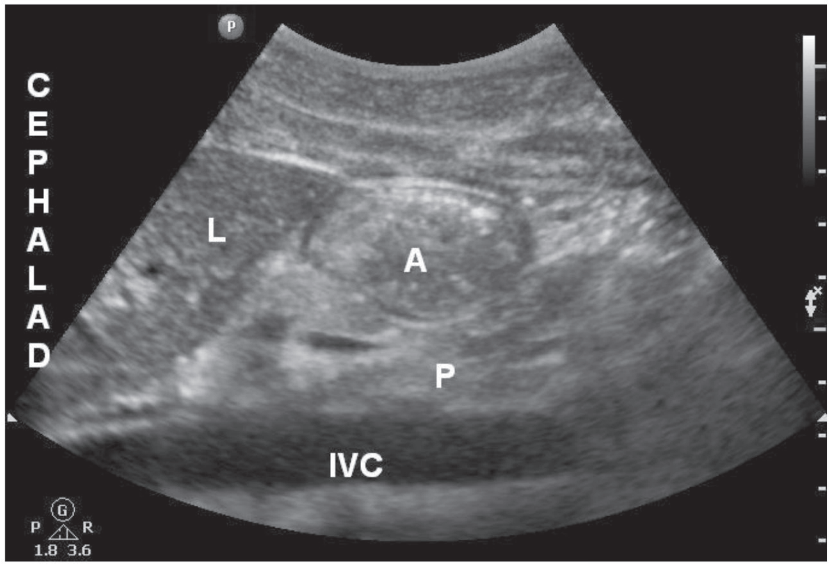

Figure 2.4: Sonographic image of the gastric antrum with solid content. A= antrum; L=liver; P=pancreas; IVC= inferior vena cava.

2.4.2. Quantitative gastric sonography: Can ultrasound estimate the volume of gastric fluid?

Nine articles report a numerical correlation between an ultrasound-determined antral cross-sectional area (CSA) and the total volume of gastric fluid (Table 2.3). Antral CSA can be measured by using two perpendicular diameters and the formula of the area of an ellipse:

CSA = $(AP \times CC \times \pi)/4$ (AP= antero-posterior diameter and CC= cranio-caudal diameter) (figure 2.5A).[33]

Alternatively, a "free tracing" tool for area measurement has been used in some reports (figure 2.5B).[21 34] Regardless of the method used, all measurements need to be taken with the antrum at rest (between contractions) to avoid underestimating volume.[24 29-31 35] In most recent studies antral CSA was measured including the full thickness of the gastric wall, from serosa to serosa.[24 29-31 34 36] Previously, the inner surface of the mucosa[37] or the muscularis propriae were used.[35]

Most authors report a linear correlation between antral CSA and gastric fluid volume with Pearson correlation coefficients ranging between 0.6 and 0.91.[21 30 31 34-36] Three studies directly compare the strength of this correlation in different patient positions.[24 35 36] All three studies conclude that antral CSA measured in the RLD correlates most strongly with gastric volume (GV). This is conceivably explained by a greater proportion of gastric content moving preferentially from the fundus and body towards the more dependent antrum in the RLD. So, for any given gastric volume, the antrum appears larger in the RLD versus other patient positions.

Four studies report mathematical models that allow prediction of total gastric volume.[24 25 30 36] In a preliminary study, Perlas and others described a logarithmic predictive model based on 70 adult non-pregnant subjects randomized to ingest 6 different pre-determined volumes of water.[24] This preliminary model was as follows:

GV (ml) = -372.54+ 282.49 x log (Right lat CSA) - 1.68 x Weight

However, in a follow up validation study using blinded gastroscopic suction as a reference standard in 108 adult subjects, this preliminary model was found to overestimate gastric volume especially at low volume states. This may be due to the original study's inability to account for baseline gastric secretions. A new more accurate linear model was reported based on gastroscopic fluid assessment:

GV (mL) = 27.0 + 14.6 x Right-lat CSA – 1.28 x age [31]

This newer model is mathematically robust (r= 0.86), yet simple to apply clinically with age as the only demographic co-variant (Table 2.4). It is accurate with a mean difference of 6 mL between the predicted and measured volumes. It is applicable to adult, non-pregnant subjects with BMI up to 40 kg/m^2 and can predict volumes of up to 500 mL.

In a prospective observational study of 183 surgical patients, Bouvet and others presented an alternative model based on measurements of antral CSA in the semi-sitting position, using blind nasogastric aspiration as a reference standard, as follows:

GV (mL) = -215 + 57 log CSA (mm^2) – 0.78 Age (years) – 0.16 Height (cm) – 0.25 weight (kg) – 0.80 ASA + 16 mL (in case of emergency) + 10 mL (in case of preoperative ingestion of 100 mL Antacid Prophylaxis).[30]

With a correlation coefficient of 0.72, this model is applicable to the adult non-pregnant population and can predict volumes of up to 250 mL.

One final model has been reported by Schmitz and others who studied 16 children at various intervals following ingestion of 7 mL/kg of raspberry syrup using magnetic resonance imaging as the reference standard.[36] The reported model is as follows:

GV (ml/kg) = 0.009 × antral CSA_{RLD} (mm^2) - 1.36

This model has a correlation coefficient of 0.79. However, the limits of agreement between the predicted and measured volumes according to a Bland-Altman analysis were too wide for accurate clinical prediction (±2.8 ml/kg). This is possibly due to the small number of subjects studied (n= 16) and total readings used for model development (n=23). Furthermore, most readings were performed in empty (n=6) or near empty (n=14) conditions. The authors of this model indicated it is not accurate enough for clinical application.

In summary, two mathematical models are available to predict gastric volume based on antral CSA in adults (Table 2.5).[30 31] They are currently thought to be accurate and clinically applicable. Regardless of which of these two models one decides to use, a number of steps need to be followed to ensure accurate results. First, the scanning technique needs to follow a similar scanning plane and patient position as described in the original source publication (i.e. a sagittal plane in the semi-sitting position for Bouvet 2011 or RLD for Perlas 2013) Second, measurements need to be taken with the antrum at rest, between peristaltic contractions. Third, CSA is measured from serosa to serosa, including the full thickness of the gastric wall. Finally, each model is only applicable within the demographic range in which it was built (adult, non-pregnant subjects) and within the ranges of volumes studied in the source publication (Table 2.5).

A semi-quantitative 3-point grading system has been reported as a simple screening tool to differentiate low from high volume states.[25] This 3-point grading system is based solely on qualitative evaluation of the clear-fluid-containing gastric antrum that is scanned in both the supine and RLD position. A Grade 0 antrum appears empty in both positions, and suggests no gastric content is present. A Grade 1 antrum appears empty in the supine position but clear fluid is visible in the RLD, consistent with a small volume of gastric fluid. A subsequent validation study suggests that subjects with a grade 1 antrum have less than 100 mL of gastric fluid in 75% of cases.[31] A Grade 2 antrum is that in which clear fluid is evident in both patient positions consistent with a higher volume state. Subjects with a grade 2 antrum have over 100 mL of gastric fluid in 75% of cases.

Table 2.4: Predicted gastric volume (mL) based on measured gastric antral cross sectional area (cm2), stratified by patient age. Shaded cells represent low volume states usually considered within the range of baseline gastric secretions for an average adult. (Reprinted with permission from Wolters Kluwer Health) [28]

Right lat CSA (cm^2)	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

Table 2.5: Current models for gastric volume assessment based on antral cross-sectional area (CSA). Legend: CSA=cross-sectional area GV=gastric volume NA=not available

	Bouvet 2011 [26]	**Perlas 2013** [28]
Formula	GV (mL) = -215 + 57 log CSA (mm^2) –0.78 Age(years)– 0.16 Height (cm)–0.25 Weight (kg) – 0.80 ASA + 16 mL (emergency)+ 10 mL (if antacid prophylaxis 100 mL)	GV (mL) = 27.0 + 14.6 x Right-lateral CSA (cm^2) – 1.28 x age (years)
Scanning plane	sagittal	sagittal
Scanning position	semi-sitting	right lateral decubitus
Antral CSA measurement	serosa to serosa	serosa to serosa
Demographics	non-pregnant adults	non-pregnant adults
Age (y)	18 - 95	18 - 85
BMI (kg/cm^2)	14 - 31	19 - 40
Max predicted volume (mL)	250	500
Correlation coefficient (r)	0.72	0.86
Reference standard	nasogastric suction	gastroscopy

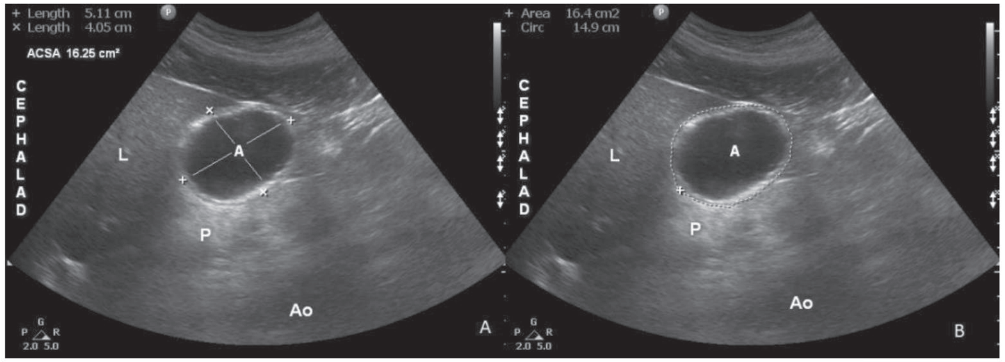

Figure 2.5: Two alternate methods to measure antral CSA. A illustrates a method based on two perpendicular diameters (cranio-caudal and antero-posterior). B illustrates a free-tracing method following the outer border of the antrum at the level of the gastric serosa.

2.5. Discussion

Until recently, there were no readily available tools to assess gastric content in the acute setting. Paracetamol absorption, electrical impedance tomography, radiolabeled diet, polyethylene glycol dilution and gastric content aspiration are invasive methods to study gastric volume or gastric emptying and are not applicable in the perioperative period.[38-42]

Gastric ultrasonography has been used by gastroenterologists for over 2 decades to assess gastric motility and emptying [43-46] or to diagnose gastric wall lesions such as cancer.[47-49] Sequential ultrasound measurements of antral CSA at fixed time intervals following a standardized solid-liquid meal have been reported.[33] This approach has been used by gastroenterologists to study gastric emptying time and motility [37 50 51] and has been shown to correlate closely to scintigraphy, a more invasive gold standard using radioactive material.[52]

However, it was only recently that bedside ultrasound has been used to evaluate gastric content and volume to assess peri-operative aspiration risk and guide anaesthetic management.

As a new diagnostic tool, gastric sonography needs to be characterized in terms of its *validity* (does it assess what it intends to assess, and how accurately), *reliability* (how reproducible are the results) and *interpretability* (i.e. what are the clinical implications of specific findings). Most studies to date deal with validity considerations and suggest that bedside ultrasound accurately determines gastric volume.[30 31 34] Even though several descriptions of the type of content (i.e. empty, clear fluid, solid) have been published [19 24 26 27] the sensitivity and specificity of a qualitative exam (how well can we differentiate between different types of content) remain to be studied in a systematic manner.

One single study on 15 subjects scanned by two independent sonographers suggests that antral assessment is highly reproducible.[37] The range of differences between the two observers was 1-13 mL when empty and 2-85 mL after a standardized meal. More rigorous studies following current recommended guidelines for assessing reliability need to be done.[53]

As data on the validity (i.e. accuracy) and reliability (i.e. reproducibility) of gastric sonography becomes increasingly available, the next important question is how to best incorporate this new diagnostic tool into daily clinical practice to assess aspiration risk and tailor anaesthetic management in appropriate cases.[54 55] We envision this tool to be useful in many clinical situations in which aspiration risk is unclear or undetermined. Three common clinical scenarios are as follows: First, patients who have not followed fasting guidelines, either because of a communication gap or due to the urgent nature of the clinical situation. Second, patients with delayed gastric emptying due to significant comorbidities in whom recommended fasting intervals may not reliably ensure an empty stomach (e.g. diabetic gastroparesis, advanced liver or renal dysfunction, critically ill patients). Finally, patients with unreliable or unclear history (e.g., language barrier, cognitive dysfunction, altered sensorium). In the absence of data, it is safer to assume a "full stomach", leading to either surgical cancellations or re-scheduling in elective cases or in interventions to prevent aspiration, such as a rapid sequence induction and endotracheal intubation. However, gastric ultrasound can help clinicians individualize aspiration risk at the bedside and more appropriately guide anaesthetic management (figure 2.6). An empty stomach implies a low aspiration risk and can be determined solely on qualitative assessment. Solid, particulate or thick fluid content, carrying a high aspiration risk, can also be detected based on sonographic appearance as previously discussed.[56-58]

In the presence of clear fluid, a sonographic volume assessment can determine if the volume present is consistent with baseline gastric secretions and negligible risk (up to 1.5 mL/kg) or if it is a higher volume posing a significant aspiration risk requiring intervention.[9-13 59-61]

Several areas require further investigation including defining the minimum training requirements to ensure accurate assessments. In addition, most of the current published data pertains to adult individuals. Volume assessment models in particular have only been validated for adult non-pregnant patients and further work is required in the paediatric and obstetric patient populations. In addition, 3D and 4D ultrasonography are newer imaging modalities that may have a future role in ultrasound gastric assessment.[62]

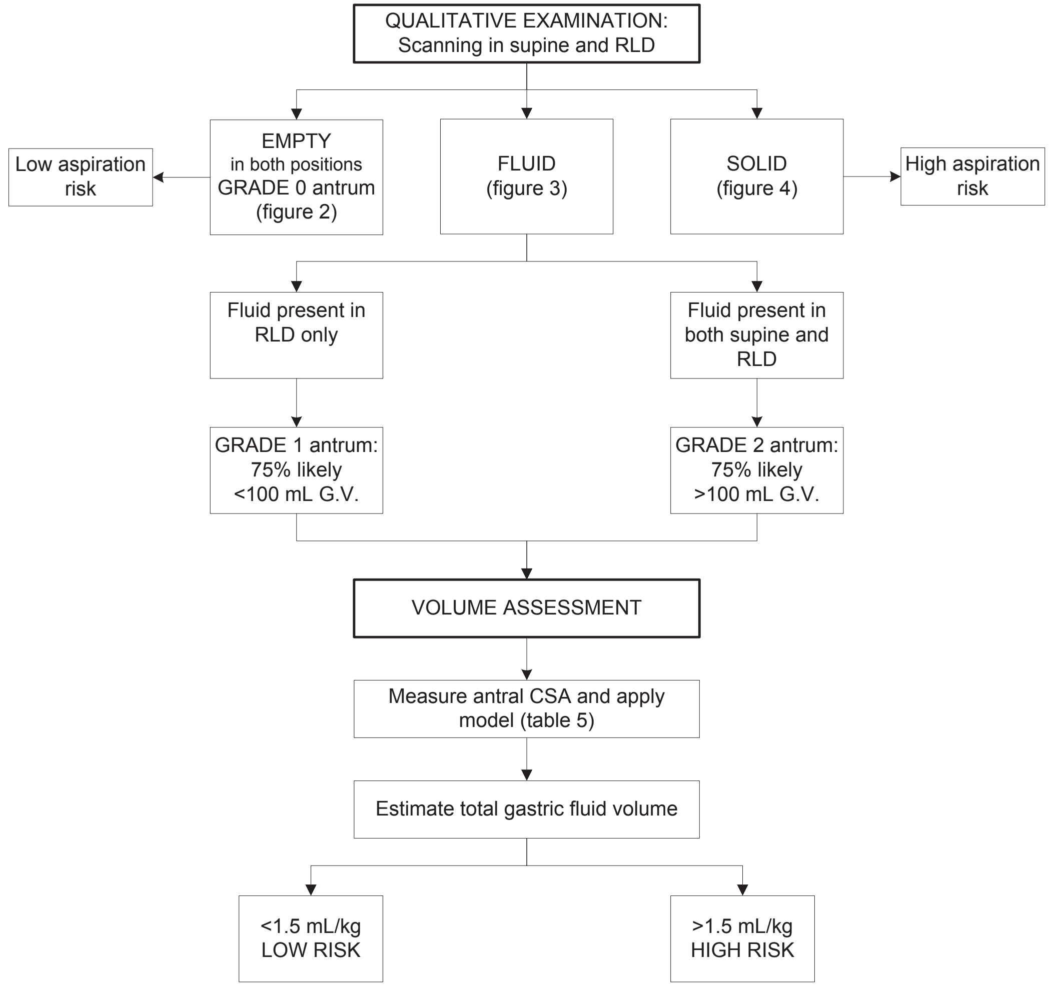

Figure 2.6: Suggested clinical algorithm for gastric ultrasound and aspiration risk assessment.

Legend: CSA= cross-sectional area G.V.= gastric volume RLD= right lateral decubitus

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CHAPTER 3: I-AIM framework for point-of-care gastric ultrasound.

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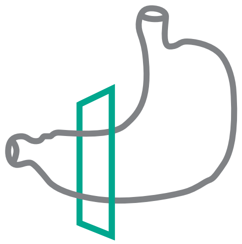

3.1. Abstract

Gastric ultrasound is an emerging non-invasive bedside tool to examine stomach contents as a determinant of pulmonary aspiration risk. The purpose of this article is to suggest an educational and clinical practice model for the implementation of point-of-care gastric ultrasound. We propose a framework, based on the I-AIM model and also present a standardized report template.

Keywords

Pulmonary aspiration, gastric ultrasound, point-of-care ultrasound, framework.

3.2. Introduction

Gastric ultrasound (GUS) is an emerging point-of-care diagnostic tool to examine stomach contents and determine pulmonary aspiration risk at the bedside.[1-7] This type of assessment is useful to guide airway and/or anaesthetic management in the acute care setting when NPO status is questionable or unknown. A point-of-care ultrasound application has a well-defined purpose aimed at improving patient outcome and is therefore focused and goal oriented; the findings need to be easily recognizable and the exam easily learned and quickly performed at the patient's bedside.[8]

GUS complies with these characteristics. It is a limited exam to assess gastric content type (empty, clear fluid, thick fluid/solid)[1,3,4] and volume[2,5], with the ultimate goal of preventing pulmonary aspiration, therefore being focused and goal-oriented. It can be performed by clinical anaesthesiologists with a minimum of 33 scans required by trainees to obtain an accuracy of 90%, which suggests it is easy to learn.[9] In addition, the findings are accurate and reliable.[2,5,10]

The ultrasound diagnosis of empty and solid content states is usually self-evident and represents extremes of aspiration risk (low and high respectively).[1,3,4] In addition, when the stomach contains clear fluid, its volume can be determined based on a cross-sectional area of the gastric antrum (CSA) which further defines aspiration risk.[2,5,7]

However, ultrasound is often cited as the most operator-dependent of all imaging modalities.[11] Protocol-guided ultrasonography ensures examination consistency, fast and correct image acquisition, decreased examination times and accurate diagnosis and annotation.[11] Several protocols and guidelines for point-of-care ultrasonography have been described in the intensive and emergency care settings. Examples of such protocols are the focused assessment of transthoracic echocardiography (FATE)[12], the focused echocardiography in emergency life support (FEEL)[13], and focused lung ultrasound (BLUE).[14] Focused assessment with sonography for trauma (FAST) is a well-established backbone of emergency trauma management.[15] The recently proposed I-AIM framework (Indication; Acquisition;

Interpretation; Medical management) describes a logical stepwise approach to point-of-care ultrasound exams and offers a procedure-specific standardized approach to implementation for improving use and performance.[16,17]

The purpose of this article is to suggest a framework, based on the I-AIM model, for the clinical implementation of point-of-care GUS which can also serve as an educational tool during theoretical and hands-on sessions. In addition we present a sample report template for standardized written communication of findings.

3.2.1. (I) Indication (table 3.1)

Being a new tool, most current indications for GUS are mechanism-based rather than evidence-based. The main indication is pre-anaesthetic aspiration risk assessment in patients in whom prandial status is questionable. This includes urgent or emergency surgical procedures, major comorbidities that may delay gastric emptying (e.g. diabetic gastroparesis, advanced liver or renal dysfunction, critically illness) or questionable adherence to fasting instructions (e.g. cognitive dysfunction, altered sensorium).[7] Preliminary but growing evidence suggest that GUS changes aspiration risk stratification and helps guide anaesthetic and airway management.[6,18]

GUS findings have been validated in patients with normal gastric anatomy. Qualitative information on stomach contents in patients with structural abnormalities (e.g. previous lower esophageal or gastric surgery, hiatal hernia, gastric cancer) can still be useful. However, volume assessment may not be accurate.

3.2.2. (A) Acquisition

Image acquisition relates to patient, probe, picture and protocol considerations.[16]

PATIENT

The most useful patient position is the right lateral decubitus (RLD) since a greater proportion of stomach contents will move towards the more dependent antrum following gravity, thus increasing the sensitivity of the test to detect small volumes.[1] In critically ill patients however, it might not be possible to scan in a position other than supine.[19] The upper abdomen is exposed and gel is used as an acoustic medium.

PROBE

In adult patients, a curved array low-frequency probe (2-5MHz) is required and abdominal settings are selected. In lean or paediatric patients, a linear high-frequency probe (10-12 MHz) can be used. The epigastrium is scanned in a sagittal or parasagittal plane and the transducer is swept widely from the left to the right subcostal margin to image the stomach.

PICTURE

The stomach can be found superficially as a hollow viscus between the left lobe of the liver anteriorly and the pancreas posteriorly.[1,3-5] Important regional vascular landmarks are the aorta, the inferior vena cava and the superior mesenteric artery and vein (figure 3.1 and 3.2).[1,3,4] The gastric wall is about 4 mm thick in the healthy adult and has 5 characteristic sonographic layers that are well described elsewhere.[4] These can be appreciated with a linear high frequency probe, especially in the empty state.[3,4] With a curved low frequency probe, the 5 layers are rarely distinguishable except for the prominent muscularis propriae (a thick hypoechoic layer) that is consistently observed (figure 3.1 and 3.2). The transducer is moved gently (rocking, sliding, rotation and heel-to-toe movement) to identify the antrum at the level of the aorta and to optimize acoustic reflections while avoiding oblique views. The antrum is usually located superficially at a depth of 2-3 cm. In severely obese patients, it can be found approximately at a depth of 7 cm.[20] Depth, gain, tissue harmonics and focal zone are adjusted to center the antrum and to reduce image artifacts. Color Doppler or Color Power Doppler can be used to confirm vessel identity if necessary. The images can be captured as still frames or videos. Storing images may be useful for comparison with previous exams, and for quality assurance, educational and medico-legal purposes.

If a volume estimate is desired (in case of clear fluid content), then the following steps are followed:

a) The antrum is identified in cross-section at the level of the abdominal aorta in the RLD

b) A still image is obtained with the antrum at rest (between peristaltic contractions)

c) Antral CSA is measured using the free-tracing tool of the ultrasound equipment and including the full thickness of the gastric wall (from serosa to serosa).[1,2,5]

d) The total gastric volume is estimated using the following model:

Volume (mL) =27.0 + 14.6 x Right-lat CSA – 1.28 x age.[6]

This model has been validated for non-pregnant adult patients with BMI up to 40 kg/m^2, and accurately predicts gastric volumes from 0 to 500 mL (appendix 1).[5]

PROTOCOL

It is recommended that the findings of the bedside examination be recorded in a written report. There is no current consensus on what constitutes a good ultrasound report/protocol.[21] However, it should contain a logical clear structure, document accurately all relevant information (e.g. patient identification data and relevant medical history) as well as all salient qualitative and quantitative findings that will help answer the clinical question.[22] It should offer, if appropriate, management suggestions supported by precise findings. We hereby present a sample report form with limited open text-field that can be used as a template (appendix 1).

3.2.3. (I) Interpretation

After identifying the relevant structures the qualitative appearance of the antrum is used to establish the nature of the gastric content (empty, clear fluid, thick fluid/ solid). When the stomach is empty after a long period of fasting, the antrum appears collapsed with juxtaposed anterior and posterior walls and a round to ovoid shape that has been compared with a "bull's eye" or "target" pattern (figure 3.1).[1,4] An empty stomach carries a low aspiration risk.

At the other end of the aspiration risk spectrum, thick fluid content such as milk or particulate fruit juice appears relatively homogenous and of high echogenicity (figure 3.3). Immediately following a solid meal a distended antrum with a 'frosted-glass' pattern is common (figure 3.4).[1,4] At this point, the air mixed with the solid food during the chewing process forms a mucosal-air interface along the anterior wall of

the antrum that casts an artifact of multiple "ring-down" artifacts, blurring the gastric content and the posterior wall of the antrum. After a variable period of time, the air is displaced, and the antrum appears distended with heterogeneous content of mixed echogenicity (figure 3.5).[1,4] Particulate fluid of solid gastric content is considered to pose a serious risk of aspiration often correlated with poor patient outcome .

On the other hand, baseline gastric secretions and clear fluids (e.g. water, tea, black coffee) appear anechoic or hypoechoic (figure 3.2).[1,4] Increasing fluid volume renders the antrum round and distended with thin wall. Air bubbles can appear as fluctuating small echoes ("starry night" appearance).[1] When the stomach contains clear fluid a volume assessment is indicated. A volume of <1.5 mL/kg is normal in fasted patients, in keeping with baseline gastric secretions and low aspiration risk. Conversely, volumes >1.5 mL/kg are not common in fasted individuals, therefore suggesting incomplete gastric emptying and possibly higher aspiration risk. Although a strict threshold of gastric volume over which aspiration risk increases is still controversial, clinical data strongly suggest that gastric fluid volumes of up to 1.5 mL/kg (approximately 100 ml for the average adult) are normal in fasted individuals and safe.[23-25]

It is also possible to use a semi-quantitative three-point grading system to differentiate low- from high-volume states.[3,5] It is based solely on qualitative evaluation of a clear fluid containing antrum that is scanned in both supine and RLD positions. The antrum is classified as grade 0 if it appears empty in both positions. This suggests minimal or no fluid content is present. Close to 50% of fasted adults present a Grade 0 antrum. The antrum is defined as grade 1 when fluid is apparent in the RLD only, correlating with low gastric volume. Approximately 50% of fasted individuals present a grade 1 antrum.[3,26] Finally, in a grade 2 antrum, clear fluid is apparent in both supine and RLD positions. A grade 2 antrum correlates with higher than baseline gastric volume and is uncommon in fasted subjects .[4,20]

3.2.4. (M) Medical decision making

GUS is a clear example of point-of-care ultrasonography. The overriding aim of this exam is to guide safe airway and anaesthetic management and prevent pulmonary aspiration in cases of clinical equipoise, when aspiration risk is unclear and the management options carry potential risks for the patient.

Both qualitative and quantitative findings contribute to risk stratification. The clinician will distinguish a low risk situation (empty stomach, or low volume consistent with baseline secretions) versus a high risk situation (clear fluid in excess of baseline secretions, thick fluid or solid content) (figure 3.6). Once aspiration risk is classified as low or baseline vs. high, the medical intervention to follow will depend on the clinical scenario. For example, if an elective surgical procedure is planned (e.g. diagnostic knee arthroscopy), the presence of solid food in the stomach will likely result in deferral of the surgical timing. If however, the patient being evaluated is presenting for urgent or emergency treatment (e.g. emergency open reduction and internal fixation of an open ankle fracture), postponing the surgical procedure would carry a high risk of infection and surgery should proceed despite the aspiration risk. In this case, the anaesthetic technique should be tailored to minimize aspiration risk (e.g. a spinal anaesthetic with an awake patient or a rapid sequence induction of anaesthesia with endotracheal intubation).

3.3. Conclusion

Gastric ultrasound is an emerging tool to examine stomach contents and to determine pulmonary aspiration risk at the bedside. This article proposes a framework based on the I-AIM model for the clinical implementation of point-of-care gastric ultrasound. It also presents a standardized sample report template.

Table 3.1: I-AIM framework for gastric ultrasound

(I) INDICATION

Pre-anesthetic aspiration risk assessment in the setting of questionable per os intake: ▪ Elective procedures but NPO guidelines not followed ▪ Urgent/emergency procedures ▪ NPO status unknown

(A) ACQUISITION

Patient		▪ Position: supine and RLD ▪ Adjust ambient light ▪ Expose the upper abdomen **Probe** ▪ Adults: low frequency curved probe ▪ Pediatrics: consider high frequency linear probe ▪ Acoustic medium: gel ▪ Sagittal scanning plane in the epigastrium
Picture	Scan	▪ sweep widely from left to right subcostal margin to systematically identify the stomach as a hollow viscus located superficially between the left lobe of the liver and the pancreas with a prominent muscularis layer within its wall ▪ rock and slide to positively identify the antrum at the level of the aorta ▪ rotate to obtain a true cross section of the antrum avoiding oblique views ▪ heel to toe movement to optimize acoustic reflections
	Knobology	▪ primary: adjust depth and gain ▪ secondary: adjust tissue harmonics and focal zone ▪ tertiary: color or power Doppler to confirm vessel identity if required
	Capture	▪ still frame or video as required ▪ if clear fluid content, measure antral CSA in RLD as a mean of 3 readings, between peristaltic contractions and estimate gastric volume as follows: (Volume(mL)=27.0 + 14.6 x Right-lat CSA – 1.28 x age)
Protocol	Complete written report (appendix 1)	

(I) INTERPRETATION

Pattern recognition: gastric content nature ▪ Empty stomach, grade 0 antrum: minimal clear fluid/air content, flat antrum or "bull's eye" pattern in both supine and RLD ▪ Clear fluid (distended antrum with hypoechoic content) -Grade 1 antrum (fluid visible in RLD only, suggesting low gastric volume) -Grade 2 antrum (fluid visible in both supine and RLD, suggesting high gastric volume) ▪ Thick fluid or solid (distended antrum with hyperechoic/heterogeneous content)
Volume estimation Differentiates clinically insignificant volume consistent with baseline gastric secretions (<1,5 mL/kg of clear fluid) from greater than baseline volumes (>1,5mL/kg)

(M) MEDICAL DECISION MAKING

Clinical context	▪ History and physical exam ▪ Elective versus urgent versus emergency procedure ▪ Time interval since last meal ▪ Type and amount of meal ▪ Other aspiration risk factors (diabetes, GERD, stroke, active labor, Neuromuscular disease)
Image analysis	▪ Adequate ▪ Technically difficult ▪ Inadequate
Physician interpretation and decision making Classify findings into one of 3 categories: ▪ Empty stomach or baseline gastric secretions suggesting LOW aspiration risk ▪ Clear fluid content (>1,5mL/kg) suggesting higher than baseline gastric volume and HIGH aspiration risk ▪ Thick fluid or solid content suggesting HIGH aspiration risk Medical decision making ▪ Decide on anesthetic/surgical timing: proceed, delay, cancel ▪ Decide on anesthetic technique: general versus regional anesthesia ▪ Decide on the need for aspiration precautions (e.g., need for intubation, rapid sequence induction, NG tube placement)	

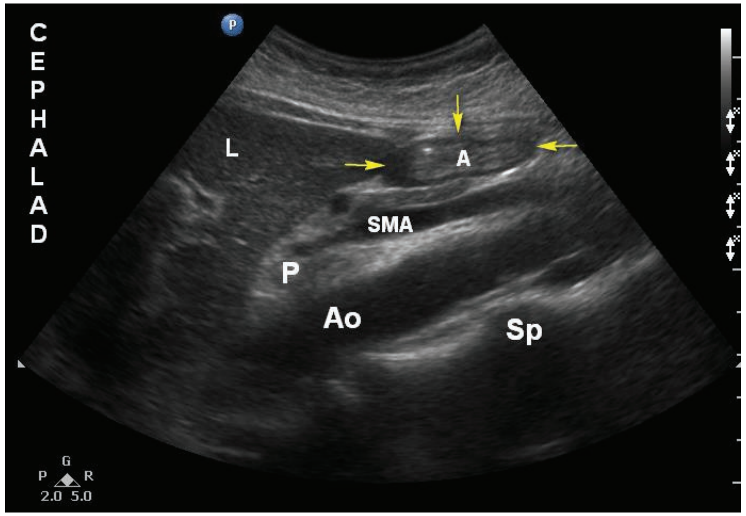

Figure 3.1: Sonographic image of the gastric antrum of an empty stomach. The antrum appears small with no visible content.

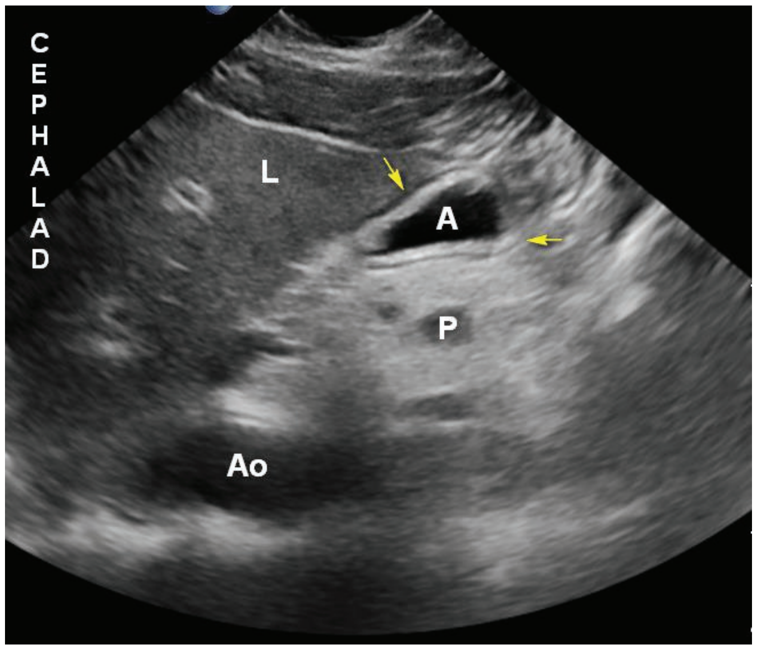

Figure 3.2: Sonographic image of the gastric antrum containing fluid. The antrum appears distended with hypoechoic content. A: antrum; Ao: aorta; L: liver; P: pancreas; SMA: superior mesenteric artery; Sp: spine; Yellow arrows: muscularis propria.

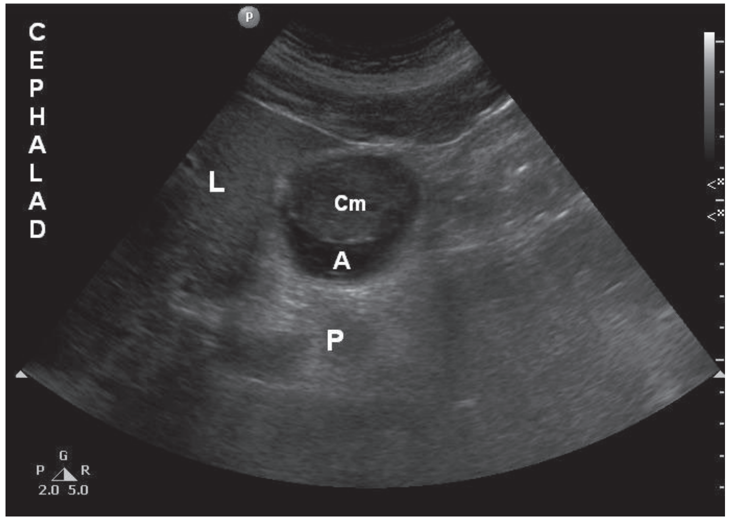

Figure 3.3: Sonographic image of the gastric antrum containing milk. Cm: curdled milk; L: liver; P: pancreas.

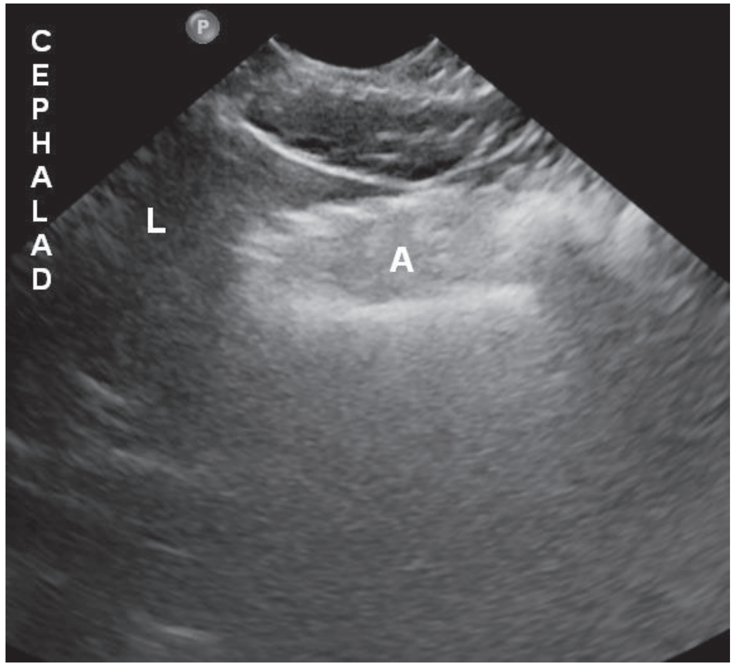

Figure 3.4: Sonographic image of the antrum with solid food, frosted glass appearance. A: antrum.

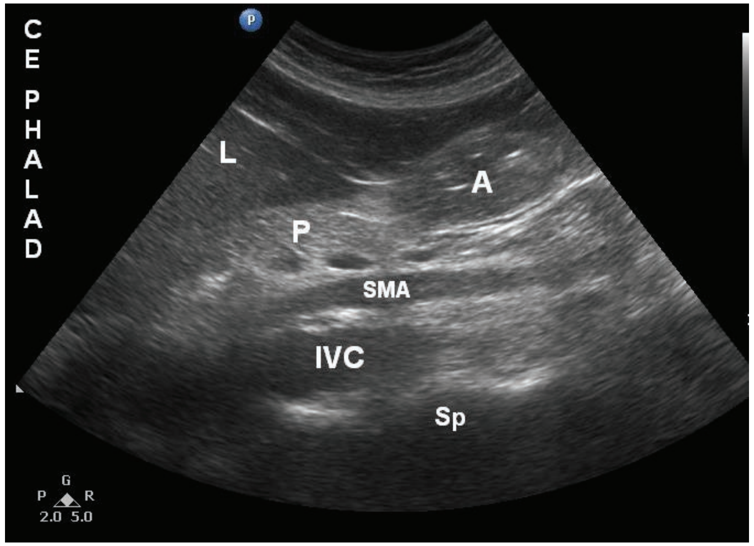

Figure 3.5: Sonographic image of the antrum with solid food, mixed echogenicity. A: antrum IVC: inferior vena cava; L: liver; P: pancreas; SMA: superior mesenteric artery; Sp: spine

Appendix 1:

GASTRIC ULTRASOUND REPORT FORM

patient sticker

EXAM INFORMATION	
Date (dd/mm/yy):	Time:
Sonographer:	Referring physician:
☐ Initial exam	☐ Repeat exam

PATIENT INFORMATION	
Last name:	First name:
Date of birth (dd/mm/yy):	☐ M ☐ F
Weight (kg):	Height (cm):
Proposed procedure:	Proposed anesthesia:
Procedure classification: ☐ Elective ☐ Urgent ☐ Emergency	
Type of intake per os: ☐ Unknown	
Time interval since last intake (h): ☐ Unknown	
Aspiration risk factors: ☐ GERD ☐ Labour ☐ Diabetes ☐ Stroke ☐ NMD	

TECHNICAL ASPECTS	
Probe type: ☐ Curved ☐ Linear	Patient position: ☐ Supine ☐ RLD

RESULTS		
Antrum identified? ☐ Yes ☐ No		
Regional landmarks: ☐ Liver ☐ Aorta ☐ Pancreas ☐ IVC		
Gastric content type: ☐ Empty		
☐ Empty		
☐ Clear fluid	Antral area in RLD: cm^2	Estimated volume: mL
☐ Thick fluid/solid		

COMMENTS

SUMMARY AND INTERPRETATION	
☐ Inconclusive / technically difficult	
☐ Empty stomach	☐ ***grade 0***
☐ Clear fluid: mL	☐ ***grade 1***: consistent with baseline gastric secretions
	☐ ***grade 2***: likely in excess of baseline gastric secretions
☐ Thick fluid/solid	

ADDENDUM: Predicted GV (mL) based on measured gastric antral CSA (cm^2), stratified by patient age.

	Age (y)						
Right Lat CSA (cm^2)	**20**	**30**	**40**	**50**	**60**	**70**	**80**
2	31	18	5	0	0	0	0
4	60	47	34	21	9	0	0
6	89	76	63	51	38	25	12
8	118	105	93	80	67	54	41
10	147	135	122	109	96	83	71
12	177	164	151	138	125	113	100
14	206	193	180	167	155	142	129
16	235	222	209	200	184	171	158
18	264	251	239	226	213	200	187
20	293	281	268	255	242	229	217
22	323	310	297	284	271	259	246
24	352	339	326	313	301	288	275
26	381	368	355	343	330	317	304
28	410	397	385	372	359	346	333
30	439	427	414	401	388	375	363
32	469	456	443	430	417	405	392

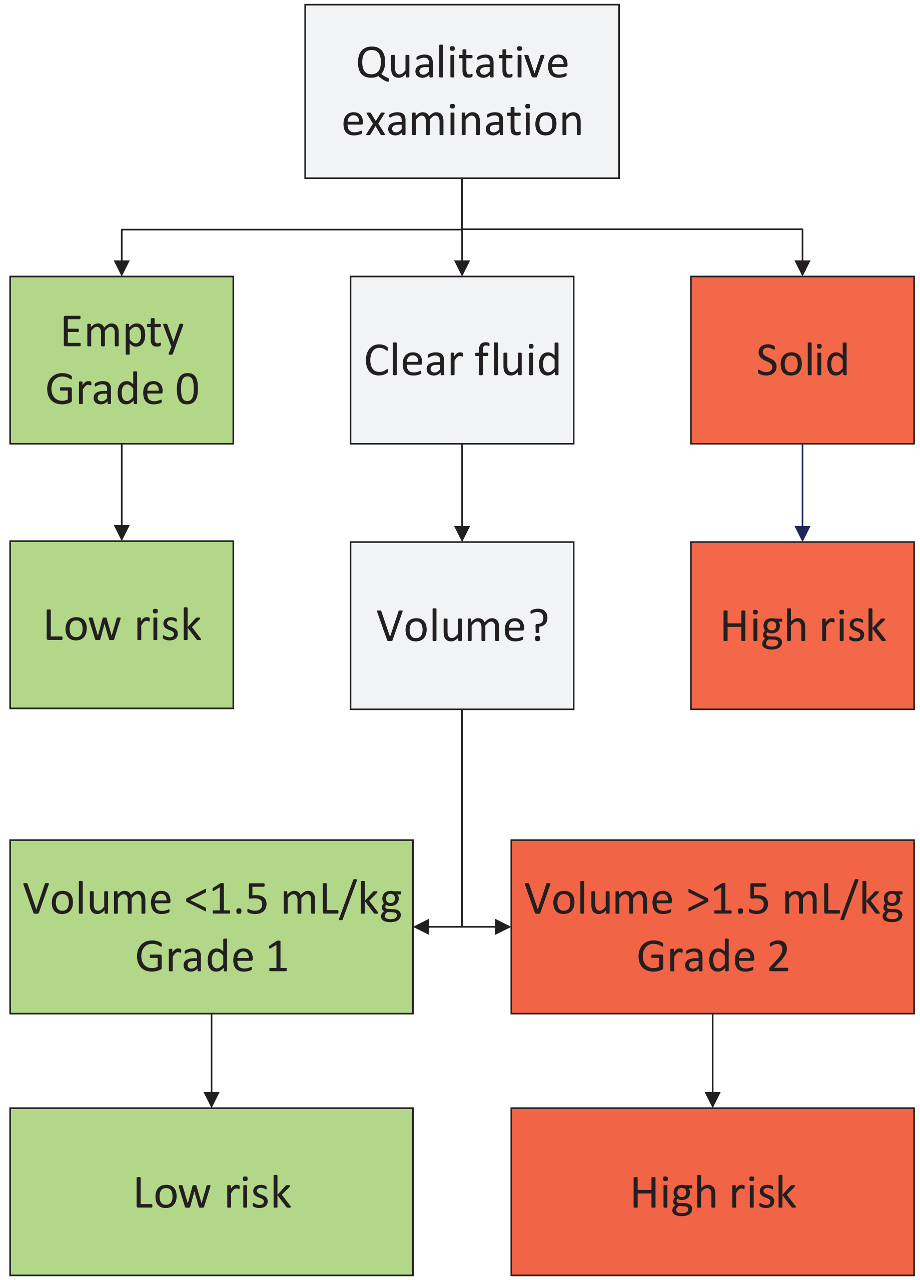

Figure 3.6: Clinical algorithm for gastric ultrasound and aspiration risk assessment.

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CHAPTER 4: Gastric sonography in the severely obese surgical patient. A feasibility study.

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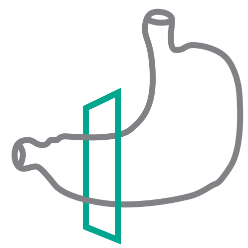
Anahí Perlas

Anesthesia and Analgesia 2014 Nov;119(5):1105-1110.



4.1. Abstract

BACKGROUND: Gastric ultrasonography allows qualitative and quantitative assessment of gastric contents and volume in non-obese subjects. The aim of this study is to determine the feasibility of gastric ultrasound in severely obese patients (BMI≥35 kg/m^2). We defined feasibility as the ability to identify a full cross-section of the gastric antrum in at least 80% of subjects when imaged in the right lateral decubitus position.

METHODS: This is a prospective cohort study on fasted surgical patients with BMI> 35 kg/m^2. The primary outcome measure was the feasibility of gastric sonography. Secondary outcomes included the distribution of antral grade following an existing 3-point grading system. In addition, the antral cross-sectional area (CSA) and gastric volumes in this cohort were compared to historical data from a previously published study in non-obese individuals. Time to image capture, antral wall thickness and depth of the antrum are also reported.

RESULTS: Sixty patients (BMI range 35.1-68.7) were studied. The antrum was identified in 95% of subjects in the right lateral decubitus (95% CI [0.86-0.99]) and 90% of subjects in the supine position. Definition of antral grade (0-2) was possible in 88.3% (95% CI [0.77-0.95]) of cases. As expected, antral grade correlated with antral CSA and gastric volumes ($p<0.0001$). When compared to historical data, our results suggest that severely obese patients have a larger baseline cross-sectional area and gastric volume than non-obese patients ($p<0.001$), but a similar gastric volume per unit of weight ($p=0.141$).

CONCLUSIONS: Gastric ultrasound assessment is feasible in fasted severely obese subjects. Our data also suggest that obese individuals present larger antral size and gastric volume than their non-obese counterparts.

4.2. Introduction

Gastric ultrasonography (GUS) is as a non-invasive tool to examine stomach contents at the bedside as a determinant of pulmonary aspiration risk.[1-8] It provides qualitative information about stomach contents (empty, clear fluid, thick fluid/solid).[1,2,4,5] In addition, the volume of gastric fluid can be estimated based on a measurement of the cross-sectional area (CSA) of the antrum[3,6] and a recently proposed 3-point grading system is an easy "screening tool" to discriminate between low and high gastric volumes.[4,6] However, previous research has focused on individuals with normal or close-to-normal body habitus and the feasibility of GUS in patients with severe obesity (BMI ≥35 kg/m^2) has yet to be established.

The main goal of this prospective cohort study is to establish the feasibility of gastric ultrasound assessment in severely obese patients (BMI ≥35 kg/m^2) who have fasted overnight prior to elective surgery.[9] We defined feasibility (our primary outcome) as the ability to identify a full cross-section of the gastric antrum in at least 80% of subjects in the right lateral decubitus position (RLD). Secondary outcome measures include the proportion of subjects in which it was possible to use a 3 point grading system (antral grades 0-2) and the image capturing time. In addition, we compared antral cross-sectional area and estimated gastric volume to historical data from a previously published study in non-obese subjects.[4]

4.3. Methods

After approval by the Institutional Ethics Board and obtaining written informed consent, 60 patients were invited to participate. Inclusion criteria were 18 years of age and older, ASA physical status I-III, BMI ≥35 kg/m^2 and elective surgery. Exclusion criteria were: pregnancy and pre-existing abnormal anatomy of the upper intestinal tract (previous lower oesophageal or gastric surgery, hiatal hernia, gastric cancer). The presence of gastroesophageal reflux was not an exclusion criterion. As per standard institutional practice, all patients fasted for both fluids and solid food 8 hours before surgery. A complete medical history and demographic data were obtained.

A previously described standardized scanning protocol was followed.[1] A curved low frequency (2-5 MHz) probe and a Philips HD11XE ultrasound system (Philips Healthcare, Andover, MA) were used. All patients were first scanned in the supine followed by the right lateral decubitus position. A sagittal scanning plane in the epigastrium was used to locate the antrum, using the left lobe of the liver anteriorly and the pancreas posteriorly as anatomical landmarks. The aorta or inferior vena cava served as additional reference points.[1,2,4-6,10,11] All scans were performed prior to induction of general anesthesia by a single clinical anaesthesiologist with 8 years' experience using sonography for other clinical applications and two years' experience in gastric sonography (greater than 200 previous gastric scans).

The visibility of the antrum was evaluated in a binary manner (visible or not) in both supine and RLD positions. If the antrum was visible, it was judged to be empty if it appeared flat with juxtaposed anterior and posterior walls. If the antrum was distended, with thin walls and hypoechoic content, it was judged to contain fluid. It was judged to contain solid food or thick fluid if it appeared distended with a content of mixed echogenicity.[1] The antrum was classified as grade 0 when empty in both supine and RLD positions, suggesting an empty stomach (figure 4.1 A-B). A grade 1 antrum was defined as the presence of fluid only apparent in the RLD, suggesting a low fluid volume (figure 4.2 A-B). In a grade 2 antrum fluid is apparent in both supine and the RLD positions, suggesting a higher fluid volume (figure 4.3 A-B).[4,6] In addition, three still images of the antrum were obtained in each patient position with the antrum at rest between peristaltic contractions. The image acquisition time was documented. The antral CSA was measured for every subject with a visible antrum in the RLD using the free tracing tool of the ultrasound equipment and including the whole thickness of the antral wall. Total gastric volume was estimated only for subjects with a BMI < 40 kg/m^2 using a previously reported mathematical model (Volume (mL) = 27.0 + 14.6 x Right-lat CSA – 1.28 x age [6]) This model has been validated for BMI <40 kg/m^2 only (R^2= 0.731). The thickness of the antral wall and the depth of the anterior wall of the antrum were also measured. Antral CSA and baseline gastric volume were compared with data from an earlier study by one of the

authors in non-obese surgical subjects.[4] From this original study (n=200), only patients with a BMI < 35 were included as a comparative control cohort (n=179).

Statistical analysis: To demonstrate a minimum feasibility of 80%, assuming a conventional "true" feasibility of 92% in the general population (based on our clinical experience), we used the z test for binominal proportions to estimate a sample size of n=55 (nominal power = 0.8, alpha = 0.05). Sixty subjects were recruited to account for possible patient exclusions or missing data. The assumption of normal distribution was checked with the Shapiro-Wilk test. Categorical data (such as gender, grade classification, history of gastroesophageal reflux, diabetes and obstructive sleep apnea) are expressed as incidence or ratios and analyzed with Fisher's exact test. Continuous variables (such as age, CSA, volume) are expressed as mean plus minus standard deviation (SD). Means were compared using one-way analysis of variance (ANOVA) test. Weight and BMI were compared using the Kruskal-Wallis non-parametric test. Differences were considered significant if $p < 0.05$.

The distribution of the data on antral size and gastric volume for the purpose of comparison with the historical cohort was visually inspected with Q-Q plots and tested with the Kolmogorov- Smirnov test. Statistical analysis was performed using SAS 9.1 for Windows (SAS Institute Inc., Cary, NC, USA).

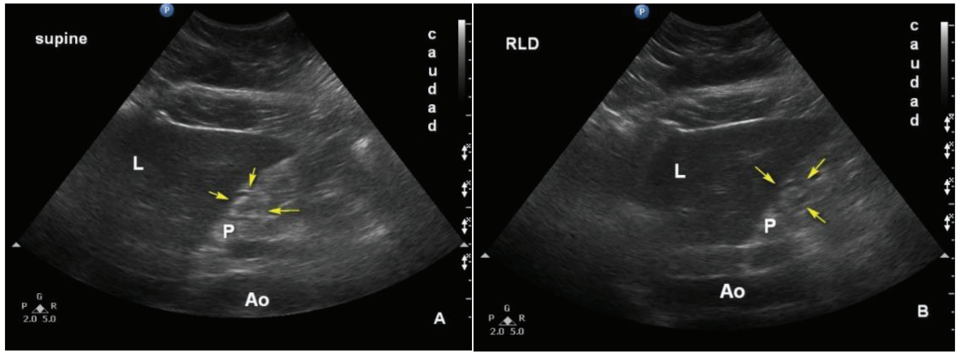


Figure 4.1: A: grade 0 antrum, supine position. B: grade 1 antrum: right lateral decubitus. Ao: aorta L: liver P: pancreas Yellow arrows: antrum RLD: right lateral decubitus

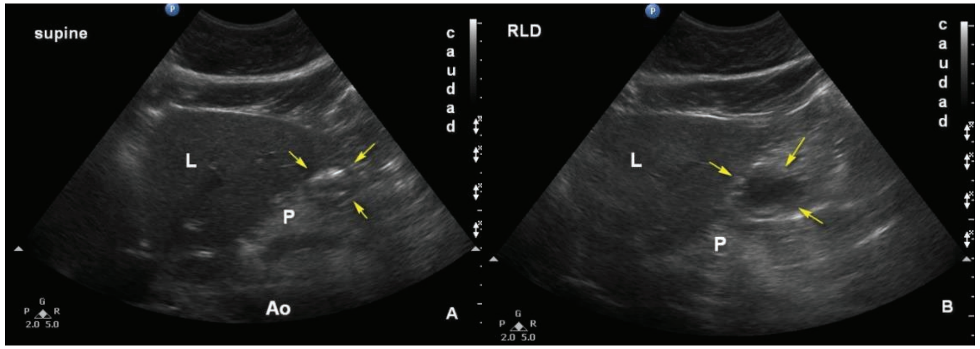


Figure 4.2: A: grade 1 antrum, supine position. B: grade 1 antrum, right lateral decubitus. Ao: aorta L: liver P: pancreas Yellow arrows: antrum L: liver P: pancreas Yellow arrows: antrum RLD: right lateral decubitus

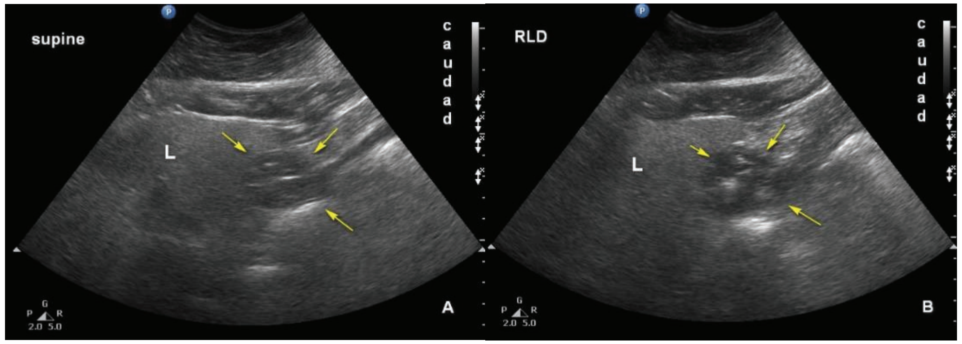


Figure 4.3: A: grade 2 antrum, supine position. B: grade 2 antrum, right lateral decubitus. L: liver Yellow arrows: antrum RLD: right lateral decubitus

4.4. Results

Sixty patients with BMI from 35.1 to 68.7 kg/m^2 were enrolled in this study. Demographic data are summarized in table 4.1. Pre-operative co-morbidities included diabetes (30%), gastro-esophageal reflux (21.7%) and obstructive sleep apnea (11.7%). The surgical procedures were orthopedics (35%), bariatric surgery (31.7%), other abdominal (8.3%), gynecological (8.3%) and urological (5%) interventions, endoscopic procedures (6.7%) and other surgery (5%). Following the

World Health Organization International Classification, 32 patients (53.3%) were class II (BMI>35-39.9 kg/m^2), 22 patients (36.7%) were class III (BMI>40-49.9 kg/m^2) and 6 patients (10%) were super-obese (> 50 kg/m^2) (table 4.2)*.

Gastric ultrasound was feasible in 95% of subjects in the RLD (95% CI [0.86-0.99]) and in 90% of subjects in the supine position (table 4.2). The antrum could not be imaged in either position in one subject (1.7%). The antrum was graded in 53 patients (88.3%) (95% CI [0.77-0.95]). Twenty-one subjects (39.6%) presented a grade 0 antrum, 29 subjects (54.7%) presented a grade 1 antrum and 3 patients (5.7%) presented a grade 2 antrum (table 4.3). No patients had thick fluid or solid gastric contents. The thickness of the gastric wall was 4.8 ± 1.3 mm (n=59). The depth of the antrum was 7.1 ± 1.4 cm in the supine position (n=55) and 7.2 ± 1.6 cm in the RLD (n=57). The median image acquisition time was 3.5 minutes. Image acquisition took less than 5 minutes in 76% (n=45) of patients (95% CI [0.63-0.86]).

As expected, increasing antral grade was associated with greater CSA and higher predicted gastric volume (24 ± 16 mL, 69 ± 19 mL and 165 ± 35 mL for grades 0, 1 and 2 respectively). There was no correlation between antral grade and age, gender, weight, BMI, or incidence of diabetes, gastroesophageal reflux and obstructive sleep apnea (table 4.1).

Compared to the historical control cohort of non-obese subjects[4], this current cohort of severely obese individuals presented larger antral CSA and larger baseline gastric volumes ($p<0.001$). However gastric volume per unit of weight was similar in both cohorts ($p=0.141$) and all values were within previously reported ranges in the general population (table 4.4). The data did not follow a normal distribution as visualized by the Q-Q plot (figure 4.4) and were analyzed with the Kolmogorov-Smirnov test.

*http://apps.who.int/bmi/index.jsp?introPage=intro_3.html (accessed October 31, 2013)

Table 4.1: Demographics. BMI= body mass index; GERD=gastroesophageal reflux disease; OSA=obstructive sleep apnea syndrome.

	Antral grade					
	Grade 0	Grade 1	Grade 2	Unable to grade	All subjects	P value
	(n = 21)	(n = 29)	(n = 3)	(n = 7)	(n = 60)	
Male/female	4/17	8/21	0/3	¾	15/45	0.57
Age (y)	49.2 ± 16.9	46.8 ± 12.2	46.7 ± 8.4	50.1 ± 18.9	48.0 ± 14.3	0.83
BMI (kg/m^2) (25th-75th %)	40.4 ± 4.8 (36.1 -41.8)	41.5 ± 7.8 (37.5-40.6)	39.7 ± 0.9 (38.7-40.6)	43 ± 4.7 (40-46.1)	41.2 ± 6.3 (36.8-42)	0.94
Weight (kg)	111.6 ± 15.2	115.1 ± 23.8	105.0 ± 6.6	117.8 ± 21.2	113.6 ± 19.9	0.66
Diabetes *n* (%)	5 (23.8%)	9 (31.0%)	1 (33.3%)	3 (43%)	18 (30.0%)	0.77
GERD *n* (%)	5 (23.8%)	5 (8.3%)	1 (33.3%)	2 (28.5%)	13 (21.7%)	0.67
OSA *n* (%)	2 (9.5%)	3 (10.3%)	2 (66.6%)	0	7 (11.7%)	0.21

Table 4.2: Results per obesity class. BMI: body mass index RLD: right lateral decubitus

				All patients
	BMI 35-39.9 (n=32)	BMI 40-49.9 (n=22)	BMI ≥50 (n=6)	BMI 35-68.7 (n=60)
Antrum detected in supine position *n* (%)	31 (96.8%)	18 (81.8%)	5 (83.3%)	54 (90%)
Antrum detected in RLD *n* (%)	31 (96.8%)	20 (90.9%)	6 (100%)	57 (95%)

Table 4.3: Results: antral size and gastric volume**.** CSA: cross-sectional area

	Grade 0	Grade 1	Grade 2	P value
Antral CSA right lateral (cm^2)	4.8 ± 1.3 (n=21)	7.0 ± 1.4 (n=29)	12.1 ± 2.5 (n=3)	<0.0001
Predicted gastric volume (mL)	24 ± 16 (n=10)	69 ± 19 (n=20)	165 ± 35 (n=2)	<0.0001
Predicted gastric volume (mL/kg)	0.3 ± 0.1 (n=10)	0.6 ± 0.2 (n=20)	1.6 ± 0.2 (n=2)	<0.0001

Table 4.4: Results: antral size and gastric volume in obese vs non-obese patients

CSA: cross-sectional area

	Obese patients	Non-obese patients	Kruskal-Wallis P value	Kolmogorov-Smirnov P value
Median antral CSA right lateral (cm^2)	6.2 (n=57)	4.5 (n=179)	<0.0001	<0.0001
Median predicted gastric volume (mL)	61.7 (n=33)	32.3 (n=179)	<0.0001	<0.0001
Median predicted gastric volume (mL/kg)	0.57 (n=33)	0.39 (n=179)	0.053	0.141

4.5. Discussion

This prospective study suggests that gastric sonography for the perioperative evaluation of gastric contents is feasible in the severely obese patient. Previous studies of bedside GUS in both the anesthesia and intensive care literature have focused on subjects with a normal to mildly obese body habitus (BMI 17- 42.5 kg/m^2).[1-6,11-15] The feasibility of GUS has not been systematically documented in the severely obese to date. Only one previous small study on 10 obese pregnant patients (pre-pregnancy BMI of 42 ± 9 kg/m^2) reported successful scanning in that sample.[15] In addition, two mathematical models have been described to calculate total gastric volume based on antral CSA in subjects with BMI< 31 kg/m^2 and BMI < 40 kg/m^2 respectively.[3,6] This current study was performed in Belgium where the prevalence of severe obesity is lower than in North America. To complete the study within a reasonable time frame, we decided to choose a BMI≥35 kg/m^2 as a cutoff for the inclusion criteria, which also coincides with the lower limit of Class II obesity following the WHO classification.

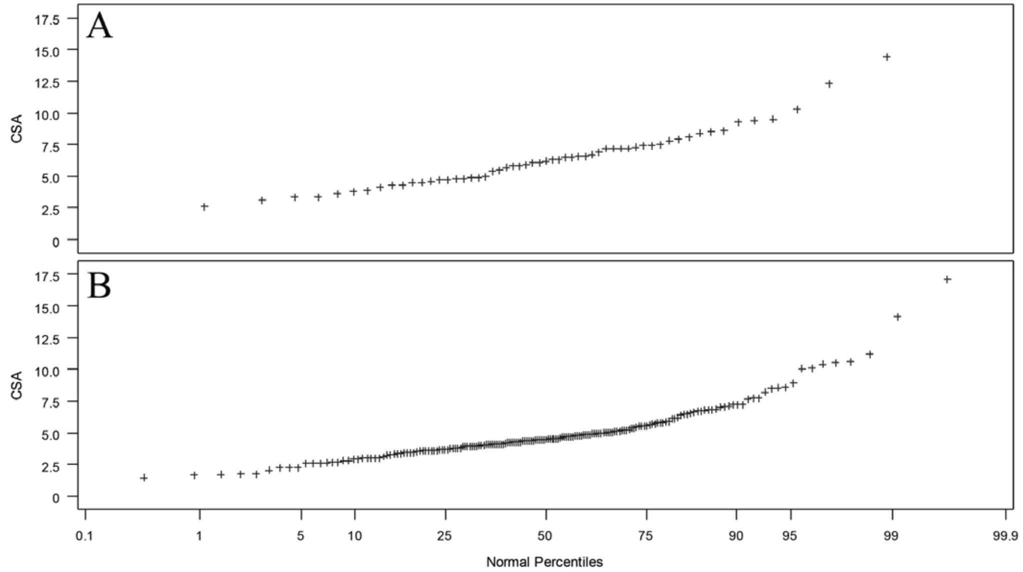


Figure 4.4: Q-Q plot antral CSA obese vs non-obese patients. A: obese patient cohort, B: non-obese patient cohort. CSA: cross-sectional area.

The incidence of obstructive sleep apnea (OSA) in our study population (11.7%) is lower than quoted in recent studies of severely obese males (up to 55%).[16] However, patients scheduled for bariatric surgery are not routinely tested for OSA at our institution. For the purpose of this study, OSA was noted if there was a previously known diagnosis. The true incidence of OSA may therefore be higher than reported.

Following a standardized scanning protocol,[1] the gastric antrum was successfully imaged in 95% of subjects in the RLD and 90% of subjects in the supine position. These findings are comparable with those from previous studies in non-obese patients. Bouvet et al. imaged the antrum in 98% of subjects in the semi-sitting position whereas Perlas et al. reported a 100% success rate in the RLD position.[2-4] This latter position is particularly useful because a larger proportion of gastric contents move preferentially towards the more dependent areas of the stomach, i.e. the antrum in the RLD.[1] In our sample of severely obese individuals, antral scanning was sub-optimal in 7 patients (11.7%). Of these, the antrum was not visible in the

RLD in 2 patients after locating it without difficulty in the supine position. In one of these two cases, the surgeon reported a thick fat omentum and a lean small stomach intraoperatively. In our patient sample, the antrum was relatively deep (anterior wall at 7.2 ± 1.6 cm from the skin) which may make imaging more challenging. We did not find any solid or thick fluid content in our patient sample. This is expected in a fasted population (mean fasting time 12 ± 3 hours). Several reports suggest that one can determine if the gastric content is nil, clear fluid or thick fluid/solid based on qualitative characteristics of the substance in the gastric lumen.[1,5] However, the minimum volume that gastric sonography would detect with a high degree of sensitivity is still unknown and it is possible that a very small amount of fluid or solid may be undetectable. It has been previously shown that scanning in either the right lateral or the semi-sitting position helps increase the sensitivity of this test to detect small volumes compared to the supine position, since a greater proportion of gastric content moves preferentially to the more dependent antrum.[1,17,18]

A 3-point grading system (grades 0-1-2) based on qualitative antral sonography has been shown to correlate with gastric fluid volume in non-obese individuals.[3,6] A grade 0 antrum corresponds to an empty stomach. It has been previously shown that a grade 1 antrum corresponds with a gastric volume of less than 100 mL 75% of the time and is commonly seen in fasted subjects.[3,6] Conversely, a Grade 2 antrum corresponded with volumes over 100 mL 75% of the time in non-obese subjects and is uncommon in fasted subjects.[3,6] The distribution of antral grade in this cohort of fasted severely obese individuals (39.6 % grade 0, 54.7 % grade 1 and 5.7 % grade 2) was comparable to that of a previous cohort of non-obese individuals (43 % grade 0, 53.5 % grade 1 and 3.5 % grade 2).[4] Our current cohort presented significantly larger antrums at baseline with significantly larger baseline gastric volumes (table 4.4). However, the volume per unit of weight was no different between the two cohorts and the volume levels were within previously reported ranges in the general population.[19-23]

In a previous study on pregnant patients, Wong et al. reported a slightly larger fasting CSA in obese (5.2 ± 2.1 cm^2) vs. non-obese patients (4 ± 2.5 cm^2).[24,25] The mean antral CSAs per grade in our current study are also modestly higher than the values reported in a previous study of non-obese patients (4.8 ± 1.3 cm^2 vs. 3.6 ± 1 cm^2 for grade 0, 7.0 ± 1.4 cm^2 versus 5.6 ± 1.4 cm^2 for grade 1 and 12.1 ± 2.5 cm^2 vs. 11.6 ± 3.2 cm^2 for grade 2 respectively).[4] However, these modest differences are unlikely to be clinically significant and may be explained by other factors including minor technical differences between studies and investigators. The thickness of the gastric wall in our patient cohort was 4.8 ± 1.3 mm, which is consistent with that of non-obese subjects (3-5mm).[26-28] Similarly, a previous endoscopic ultrasound study reported no correlation between gastric wall thickness and BMI.[29]

As expected, increasing antral grade was associated with increasing antral CSA and gastric volume ($p<0.0001$) (table 4.3). The reported volumes were estimated on the subset of patients with a BMI <40 kg/m^2 using a validated mathematical model.[6] These observations are in line with previous studies in non-obese subjects.[19-23] Although the minimum threshold of gastric volume that increases aspiration risk is controversial, it has been well established that healthy fasted individuals with low aspiration risk commonly present gastric volumes of up to about 1.5mL/kg (or 100 mL in the average weight adult). Using aspiration of gastric fluid through a nasogastric tube immediately after induction, five studies reported upper limits of residual gastric fluid between 75 -130 mL (total n=802).[19-23] On a separate study, the upper limit of normal baseline gastric volume in fasted patients was 103 mL by nasogastric aspiration and 163 mL by a marker dilution method (n=252).[30] Another study using magnetic resonance imaging to study gastric emptying in 20 volunteers reported an upper gastric volume of 95 mL at baseline.[31]

Limitations of this study include a single operator. A recent cohort study describing learning curves in patients with BMI of 25 ± 3 kg/m^2concluded that a mean of 33 exams are required to achieve 95% success rate with qualitative assessment of gastric content.[32] Even though the operator in our study had substantial experience with gastric ultrasound it is still unknown how many exams are required to obtain similar levels of competence for gastric volume calculation or for qualitative assessment in severely obese patients. In addition, this is a descriptive observational study of a single patient cohort and the results have to be evaluated in the context in which the study was made.

Further research is warranted to fully determine the best way to apply gastric sonography to severely obese subjects. In particular, a mathematical model that allows gastric volume assessment in patients with a BMI ≥40 kg/m^2 has yet to be described. The application of 3-dimensional ultrasound could be another promising method to measure gastric volume accurately but data remain preliminary.[33]

4.6. Conclusion

This prospective cohort study of 60 patients suggests that gastric ultrasound assessment is feasible in fasted severely obese patients (95% CI [0.86-0.99]). Our data also suggest that absolute antral size and baseline gastric volume are larger in severely obese individuals.

Acknowledgements

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CHAPTER 5: When fasted is not empty. A retrospective study in fasted surgical patients.

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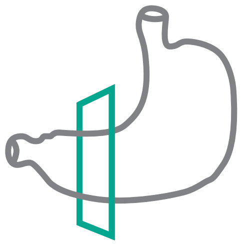

5.1. Abstract

BACKGROUND: Perioperative aspiration leads to significant morbidity and mortality. Point-of-care gastric ultrasound is an emerging tool to assess gastric content at the bedside.

METHODS: We performed a retrospective cohort study of baseline gastric content on fasted elective surgical patients. Primary outcome was the incidence of full stomach (solid content or > 1.5 mL/kg of clear fluid). Secondary outcomes included gastric volume distribution (entire cohort, each antral grade), the association between gastric fullness, fasting intervals and comorbidities, anaesthetic management changes and incidence of aspiration.

RESULTS: We identified 538 patients. Thirty-two patients (6.2%) presented a full stomach. Nine of these (1.7%) had solid content and 23 (4.5%) had clear fluid >1.5 mL/kg. An empty stomach was documented in 480 (89.8%) patients. The exam was inconclusive in the remaining 20 subjects (5.0%). As expected, increasing antral grade correlated with larger antral CSA and higher gastric volume ($p<0.001$). Of the 32 patients with a full stomach, only 6 had a documented risk factor for prolonged gastric emptying. The anaesthetic management was changed in all 9 patients with solid content. No aspiration was reported.

CONCLUSIONS: This retrospective cohort study suggests that a small proportion of elective surgical patients may present a full stomach despite recommended fasting. Further research is needed to establish the clinical implications of these findings in the elective setting. At the present time, the clinical role of gastric ultrasound continues to be for the evaluation of gastric contents to guide management when the risk of aspiration is uncertain or unknown.

Keywords: fasted; gastric contents; gastric ultrasound

5.2. Introduction

Seventy years after Mendelson’s work, pulmonary aspiration remains a serious perioperative complication.[1] The National Audit by the Royal College of Anaesthesists of the United Kingdom reported that pulmonary aspiration was the single most common cause of death from airway management incidents, accounting for 50% of all cases.[2] Most of these cases of aspiration (72%) were in urgent or emergency settings. The presence of gastric content at the time of anaesthetic induction increases the risk of pulmonary aspiration.[3,4]

Preoperative fasting guidelines aim to reduce the volume and acidity of stomach contents, thus limiting both the risk of aspiration and its related morbidity and mortality .[5] These guidelines apply to healthy patients for elective surgery but may not be reliable in patients with comorbidities that affect gastric emptying as well as in urgent or emergent situations.[5,6] However, even in healthy individuals, standard fasting periods may not be sufficient to ensure an empty stomach in all patients and aspiration may complicate apparently low risk cases.[2] It has been suggested that at least in the emergency setting, a significant number of aspiration episodes occur due to failure to appreciate the true risk and to establish appropriate airway management.[2,7]

Gastric ultrasound is an emerging point-of-care tool that evaluates gastric content at the bedside both qualitatively and quantitatively.[8-13] We performed this retrospective cohort study to evaluate the incidence of full stomach in a population of fasted patients presenting for elective surgery, using bedside gastric ultrasound.

5.3. Methods:

After approval by the Institutional Ethics Board of Algemeen Ziekenhuis Monica, Deurne, Belgium, (OG 106,EC/271), we performed a retrospective cohort study. Inclusion criteria were: age greater than 16 years, ASA physical status I-III, scheduled for elective surgery under general anaesthesia, having followed institutional fasting guidelines (a minimum of 2 hours for clear fluids, 6 hours for a light meal, 8 hours for a meal that included fried or fatty food). Exclusion criteria were abnormal anatomy or previous surgery of the oesophagus or stomach, hiatus hernia and current pregnancy.

The primary outcome was the incidence of full stomach defined as the presence of solid food or gastric fluid volume greater than 1.5 mL/kg. Secondary outcomes included the distribution of gastric volume values in the entire cohort and in each antral grade subgroup and the association between gastric fullness, fasting intervals and common comorbidities. Anaesthetic management and incidence of aspiration were also evaluated. Data were obtained from an internal departmental database which was queried from January 2015 to January 2016 for the following information: a) demographic variables (age, height, weight, BMI), b) comorbidities commonly associated with delayed gastric emptying (diabetes, gastro-oesophageal reflux disease (GERD), neurologic disorders), c) type of surgery, d) fasting interval for fluids and solids, e) gastric ultrasound examination results, f) anaesthetic management and g) aspiration events.

All ultrasound examinations were performed in the immediate preoperative period by either a staff anaesthesiologist with 5 years' experience in gastric ultrasound (GUS) or a resident under direct staff supervision. A previously described standardized scanning protocol was followed.[8] A curvilinear low-frequency (2-5 MHz) transducer and a Philips HD11XE (Philips Healthcare, Andover, MA), a GE Healthcare Logic E (General Electrics) or a SonoSite X-porte (Fujifilm SonoSite) ultrasound system were used. All patients were first scanned in the supine position, followed by the right lateral decubitus (RLD) position. The gastric antrum was identified on a sagittal scanning plane in the epigastrium. The liver anteriorly and the pancreas posteriorly were used as anatomical reference points.[8-11]

The examination was considered conclusive if the antrum was identified in both supine and RLD positions. Once the antrum was identified, the stomach was deemed "empty" or "full" based on a combination of qualitative and quantitative findings. The stomach was considered empty if no content was visible in either position or if ≤ 1.5 mL/kg of clear fluid was present. The stomach was deemed to be full if solid content was observed or >1.5 mL/kg of clear fluid was present. The volume of clear fluid was measured using a cross-sectional area (CSA) of the gastric antrum in the RLD and the following mathematical model: *Volume (mL)= 27.0 + (14.6 x Right-lat CSA) – (1.28 x age).*[13,14]

This model was validated for non-pregnant adult individuals with BMI up to 40 kg/m^2 and reliably predicts gastric volumes from 0 to 500 mL.[13,14] In addition the antrum was classified according to a 3-point grading system (Perlas grade 0-2) based on the presence or absence of clear fluid in the supine and RLD positions.[10,13] Grade 0 refers to the absence of appreciable gastric content in the antrum in both supine and RLD positions. Grade 1 refers to clear fluid that is appreciable in the antrum only in the RLD. Grade 2 refers to clear fluid that is documented in both the supine and RLD positions.

Statistical analysis:

Descriptive statistics were used for continuous data. The assumption of normal distribution of continuous variables was checked with the Shapiro-Wilk test. If variables were normally distributed, central tendency was expressed as mean ± standard deviation (SD). Means were compared using t-test or 1-way analysis of variance test as appropriate. Non-normally distributed continuous variables were analysed using nonparametric statistics (Mann-Whitney *U* test/Wilcoxon signed-rank test; Kruskal-Wallis equality-of-populations rank test among grades). Categorical data are expressed as count and percentages or ratios and analysed with the Fisher exact test. Differences were considered significant if $p < 0.05$. Statistical analysis was performed using SAS 9.4 for Windows (SAS Institute Inc., Cary, NC).

5.4. Results:

Five hundred and thirty eight patients were identified (Figure 5.1). Demographic data were normally distributed and are summarized in Table 5.1. Patients presented for a variety of surgical procedures (orthopaedics 62.4%, abdominal surgery 11.2%, general surgery 10%, maxillofacial surgery 6.9%, gynaecology 2.8%, urology 2%, endoscopy 1.7% and other 3%). Mean fasting times were 10.8 h for fluids and 13.9 h for solids. The ultrasound examination was inconclusive in 26 subjects. Data from the remaining 512 subjects were analysed and presented. Thirty-two patients (6.2%) presented a full stomach. Of these, 9 patients (1.7% of the total cohort) had solid content and 23 (4.5%) had clear fluid in excess of 1.5 mL/kg. The remaining 480 patients had an empty stomach. Patients with a full stomach were younger than those with an empty stomach (p =0.0033) but were otherwise similar in all other demographic characteristics and co-morbidities and had fasted for similar periods of time (Table 5.1).

The distribution of antral grades in the cohort is presented on Table 5.2 and Figures 5.2 and 5.3. As expected, higher antral grades correlated with larger antral CSA and greater gastric volume (p<0.001) (Table 5.2, Figure 5.2). By definition, all patients with a grade 0 antrum had an empty stomach while 3.2% of those with a grade 1 and 70.4% of those with a grade 2 antrum had >1.5 mL/kg of clear gastric secretions (Figure 5.2, Table 5.2). Detailed information about the last ingestion for patients found to have solid gastric content is provided on Table 5.3. In addition, the individual values of gastric volume of patients with >1.5 mL/kg are provided on Table 5.4 . The anaesthetic management was changed in all 9 patients who presented solid gastric content and in 16 of the 23 patients who presented large volumes of clear fluid. In patients found to have solid content, the changes included surgical cancellation (n=1) surgical delay (n=2), conversion to a (loco)-regional technique (n=3) or tracheal intubation with a rapid sequence induction of anaesthesia (n=3). The changes in those patients who presented large volumes of clear fluid included delaying surgery for 2-4 hours until a second examination confirmed an empty stomach (n=10) and performing tracheal intubation with a rapid sequence induction (n=6). There was no change to the original anaesthetic plan in the remaining 7 subjects. No episodes of aspiration were documented.

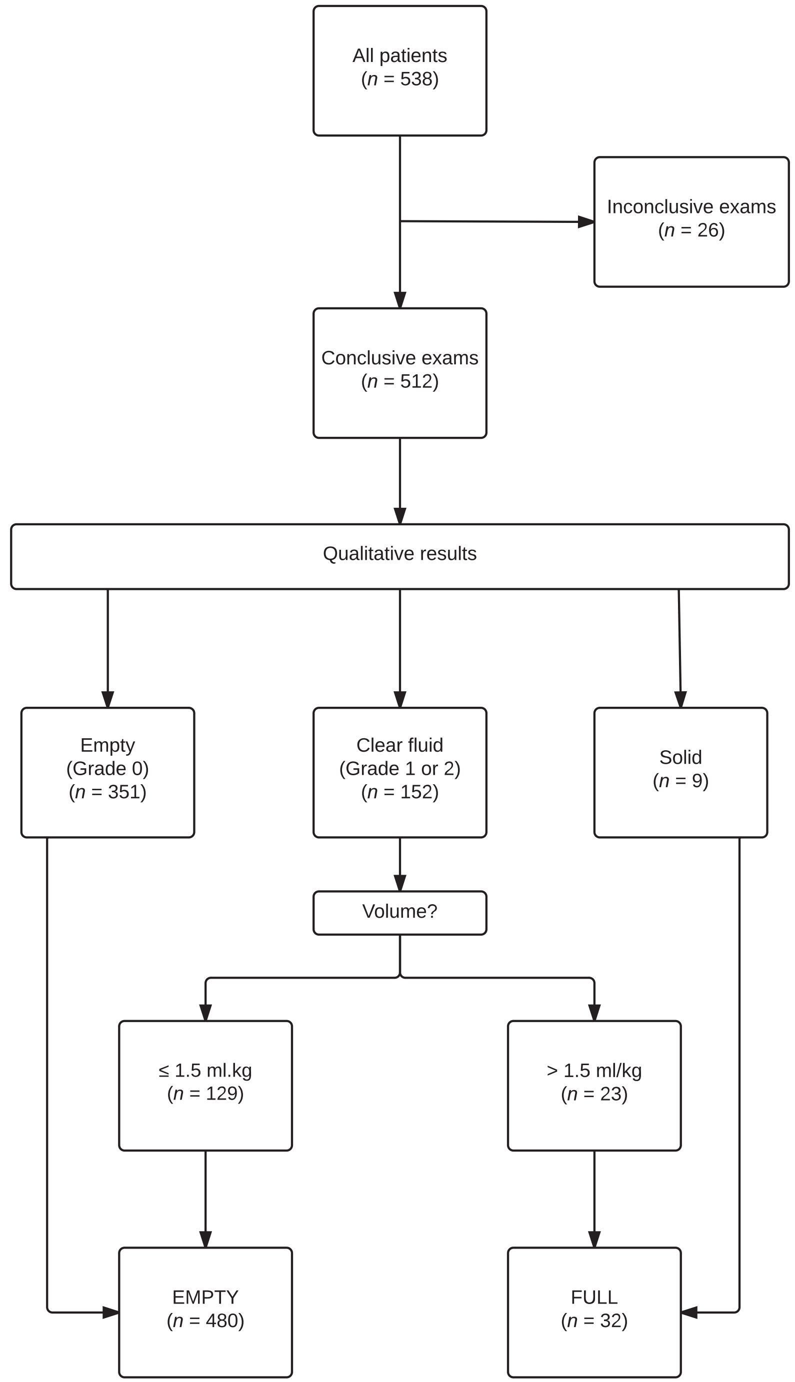

Figure 5.1: Flowchart

Table 5.1: Demographics. BMI body mass index; GERD gastro-esophageal reflux disease; MS multiple sclerosis. "Empty" corresponds to grade 0 antrum or ≤ 1.5 ml/kg of clear fluid. "Full" corresponds to solid content or > 1.5 ml/kg of clear fluid.

	Conclusive exams (n = 512)		**Inconclusive exams**	**All patients**	**P-value**
	Empty (n = 480)	**Full** (n = 32)	(n = 26)	(n = 538)	
Age (y)	47.8 ± 17.9	38.2 ± 15.9	56.2 ± 18.3	47.6 ± 18.1	0.0033
Gender (M:F ratio)	1.1 : 1	1.5 : 1	2.7 : 1	1.2 : 1	0.4684
Height (cm)	171.9 ± 9.9	172.6 ±10.3	176.1 ± 8.2	172.1 ± 9.9	0.7075
Weight (kg)	76.7 ± 15.6	74.5 ±15.4	80.0 ± 18.2	76.8 ± 15.8	0.4388
BMI (kg/m^2)	25.9 ± 4.6	25.0 ± 4.8	25.7 ± 5.0	25.8 ± 4.6	0.2842
Fasting interval solids (h)	13.9 ± 3.9	13.5 ± 3.2	13.6 ± 3.8	13.9 ± 3.9	0.5025
Fasting interval fluids (h)	10.8 ± 4.1	10.8 ± 4.3	10.4 ± 3.9	10.8 ± 4.1	0.9987
GERD, n (%)	49 (10.2)	2 (6.2)	0	51 (9.5)	0.7591
Diabetes, n (%)	16 (3.3)	1 (3.1)	0	17 (3.2)	1.000
Neurological disease (MS, stroke, Parkinson), n (%)	3 (0.6)	1 (3.1)	0	4 (0.7)	0.2281
Cannabis, n (%)	4 (0.8)	1 (3.1)	0	5 (0.9)	0.2768
Antabuse, n (%)	0	1 (3.1)	0	1 (0.2)	0.0625

Table 5.2: Results: gastric volume distribution. Legend: CSA = cross-sectional area; N/A = not applicable. All results are Mean ± SD.

	All conclusive exams (n = 512)				
	Empty	**Clear fluid** (n = 152)		**Solids**	**P-value**
	Grade 0 (n = 351)	**Grade 1** (n = 125)	**Grade 2** (n = 27)	(n = 9)	
Right lateral CSA (cm^2)	3.4 ± 1.4	6.7 ± 1.8	11.1 ± 2.3	N/A	<0.001
Gastric volume (mL)	18.8 ± 18.7	65.3 ± 30.2	138.1 ± 33.6	N/A	<0.001
Gastric volume (mL/kg)	0.3 ± 0.3	0.8 ± 0.4	1.8 ± 0.5	N/A	<0.001
Subjects >1.5 mL/kg, n (%)	0	4 (3.2)	19 (70.4)	N/A	<0.001

Table 5.3: Patients with solid gastric content.

Patient #	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Food	4 hamburgers w/ fries	2 pieces of toast	Full meal	Full meal	1 slice of bread w/ marmalade	Full meal	Full meal	Full meal	Full meal
Time interval (h)	14.0	6.5	17.0	11.3	8.4	10.8	16.1	14.4	15.3
Fluid	Coffee	Juice	Water Coffee	Water	Coffee	Water	Water	Water	Water
Time interval (h)	2.3	6.5	17.0	11.3	8.4	10.8	12.1	12.4	12.3
Comorbidities	None	None	Parkinson's disease	None	None	None	None	None	GERD +++
Proceed with surgery	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anesthetic management	Cancelled surgery	RSI	RSI	Surgery delayed	Locoregional anesthesia	RSI	Surgery delayed	Spinal anesthesia	Locoregional anesthesia

Legend: RSI = rapid sequence induction; Full meal = potatoes, vegetables, meat.

Table 5.4: Detailed gastric fluid volumes of patients with volume >1.5 mL/kg. CSA = cross-sectional area.

Patient #	Perlas grade	CSA (cm^2)	Volume (mL)	Volume (mL/kg)
1	1	11.6	146.44	1.68
2	1	10.39	155.65	2.32
3	1	10.5	152.14	2.17
4	1	6.18	92.91	1.52
5	2	8.67	99.8	1.75
6	2	12.23	123.64	1.65
7	2	16.5	219.26	2.92
8	2	14	176.36	1.86
9	2	12.3	127.22	1.57
10	2	9	127.68	1.62
11	2	7.86	103.36	1.62
12	2	9.05	130.97	2.18
13	2	13.8	188.8	1.78
14	2	8.19	123.53	1.99
15	2	11.8	166	2.77
16	2	16.72	230.15	1.97
17	2	10.58	139.23	1.58
18	2	9.3	128.22	2.14
19	2	10.58	132.83	1.62
20	2	13	137.44	1.6
21	2	9.37	135.64	3.15
22	2	10.5	147.02	2.13
23	2	11.9	140.58	2.1
Mean (SD)		**11.04 (2.61)**	**144.56 (33.79)**	**1.99 (0.45)**

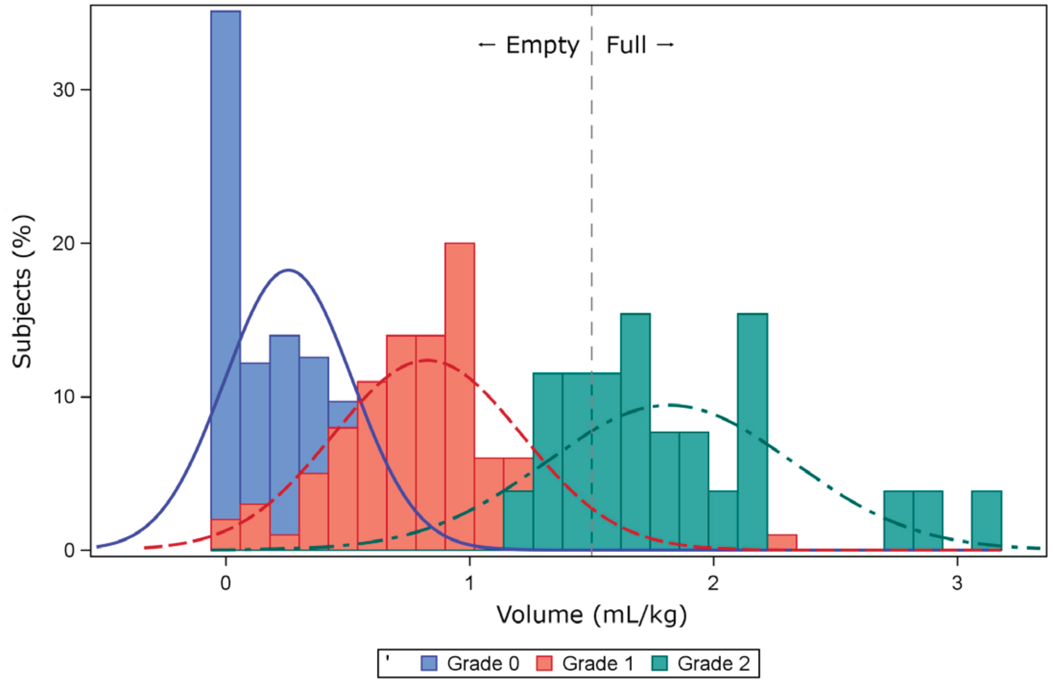

Figure 5.2: Distribution of gastric volume values. The percentage values represent the distribution of subjects within each grade group. Blue, grade 0; red, grade 1; green, grade 2.

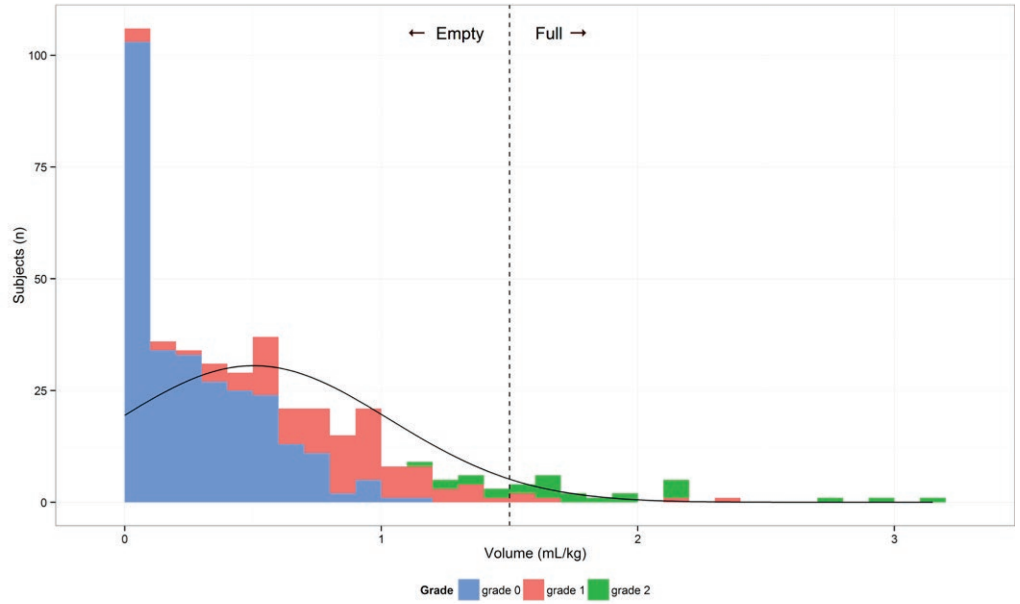

Figure 5.3: Gastric volume for overall population. Distribution of gastric volume values. The percentage represent distribution of subjects within each grade group. Blue, grade 0; red, grade 1; green, grade2.

5.5. Discussion

In this retrospective study, we found that 6.2% of an elective surgical population presented a full stomach (defined as solid content or fluid volume > 1.5 mL/kg) despite following current fasting guidelines. Patients with a full stomach were younger (by about 10 years) than those with an empty stomach, but were otherwise similar in all other demographic characteristics.

The finding of 9 patients (1.7%) presenting solid gastric content was particularly unexpected but may have been missed by earlier studies which measured gastric volume by aspiration through a gastric tube, the diameter of which would not necessarily have allowed solid material to be aspirated readily. Three of these nine patients had underlying conditions that could explain prolonged gastric emptying (one had severe GERD[15-17] and symptoms of chronic dyspepsia, one had severe Parkinson's disease[18] and a third one was on chronic disulfiram therapy[19], Table 5.3). A fourth patient had fasted during the day due to religious observance and had a particularly large meal 11 hours before presentation. Previous reports have suggested that the altered cycle of food intake during daily fasting practices may increase gastric acidity and peptic activity.[20] No risk factors for prolonged gastric emptying were identified in the remaining 5 subjects.

In contrast, the finding of 23 subjects (4.5%) with larger than commonly quoted fluid volumes is not particularly new. Most studies looking at the effect of varying fasting intervals have confirmed a wide range of residual gastric volumes, both in patients having a prolonged fluid fast and after ingesting fluids within two hours.[21-25] We now know that the average fasting gastric volume in healthy individuals is about 0.6 mL/kg with values of up to about 100-130 ml being frequently reported.[21-25] In addition, the National audit by the Royal College of Anaesthetists from the United Kingdom reported gastric residues of up to 200 mL in a study on the laryngeal mask supraglottic airway in fasted healthy subjects.[2] More recently, 3.5 % of 200 fasted surgical patients and 5.7% of 60 severely obese fasted patients were found to have a grade 2 antrum and fluid volumes of 2.8 ± 1.4mL/kg and 1.6 ± 0.2 mL/kg respectively.[10,26] There is indeed a plethora of clinical human data that demonstrates that normal baseline gastric volume is higher than that previously assumed based on animal data. Several decades ago and based on experimental observations of substances directly instilled into the tracheas of Rhesus monkeys, it was postulated that the aspiration of > 0.4 mL/kg (approximately 25mL in an average human adult) increased the risk of developing pneumonia.[27] Using a similar experimental setting, a more recent publication reported that instillation of more than 0.8mL/kg of filtered gastric secretions or hydrochloric acid (equivalent to 50 mL in the average adult human) directly into the tracheas of rhesus monkeys was more likely to result in pneumonia.[28,29] The same threshold was used by Bouvet et al. for the diagnosis of a full stomach.[11]

However, although these figures that stem from animal studies are widely quoted, they are not clinically meaningful definitions or thresholds. Already in 1998, Schreiner suggested[29] it was time to "lay to rest the myth" created by surrogate endpoints such as Roberts & Shirley's 0.4 mL/kg which have "failed to prove relevance to outcomes that matter to patients".[27] Even the larger volume of 0.8 mL/kg studied by Raidoo and colleagues is clinically irrelevant.[28] Assuming that the response in humans were similar to that in primates, these volumes represent the minimum amount of fluid required to be harmful when instilled directly into the trachea. Were this same volume present in the stomach, for pneumonia to occur, the stomach would have to empty completely and the entirety of these contents would have to pass the vocal cords and enter the trachea. Both seem very unlikely and hence the maximum "safe" gastric volume can be assumed somewhat higher than the minimum volume needed to damage the lungs. What is unknown is the margin of this difference, a factor likely to vary further by active vomiting or passive regurgitation, posture and the degree to which laryngeal reflexes are compromised. We therefore considered 1.5 mL/kg of gastric fluid volume to be a more realistic threshold that represents the upper end of normal baseline gastric secretions, although we still do not know if this is the correct value associated with meaningful patient outcomes.

Of the 23 patients with high baseline gastric volume, one had a diagnosis of diabetes,[30,31] one a history of GERD[15-17] and one used cannabis daily.[32,33] A fourth patient had fasted during the day due to religious observance and had consumed a very large meal 12 hours prior to presentation. No obvious risk factors were documented in the remaining 19 subjects with high gastric volume. As expected for a fasted population, the majority of subjects in our cohort either had a grade 0 (68.5%) or grade 1 (23.4%) antrum which represent low volume states.[10,26]

The clinical significance of our findings may be controversial. Aspiration is much less common in elective settings than in emergencies and several hundred times more rare (0.025%) than the incidence of "full stomach" as defined in the present study (6.2 %).[2] Additionally when it occurs, it rarely has the serious consequences seen in the non-elective setting. Therefore, our findings should be interpreted with caution and without raising undue alarm. The value of the present study is thus more on the informative and descriptive than on the decision side.

In our opinion, the small number of unexpected "full stomachs" documented in our series does not justify an ultrasound examination on every patient presenting for elective surgery. We must consider that all tests have a certain proportion of false positive and false negative results (albeit not yet fully defined for GUS) and may even be inconclusive in a small percentage of cases. Therefore, for patients that have either a low or high pre-test probability a gastric ultrasound examination will likely only provide a very small incremental precision in the diagnosis of full or empty stomach. We therefore concur with a recent editorial which suggests that routine ultrasound measurements of gastric contents will become part of our practice each time there is any doubt as to residual gastric volume and the optimum strategy to avoid aspiration[34] i.e. when there is clinical equipoise and the pre-test probability of having an empty stomach is the order of 50%.

Possible clinical scenarios where gastric ultrasound may be useful are urgent or emergency surgery, severe co-morbidities that may prolong gastric emptying (diabetes, renal or liver dysfunction, neurological disorders), unreliable or unclear history and lack of adherence to fasting instructions.[6,35] As the diagnostic value of gastric ultrasound becomes better defined and more established it is likely that its clinical applications will continue to grow.

Our study has several limitations. First, as a retrospective study it is subject to information bias, selection bias and measurement errors. We attempted to minimize information bias by following a standardized data collection protocol for the entire cohort. However, not all pertinent factors that influence gastric emptying had been captured in the source database. For example, no information was available regarding chronic alcohol abuse or smoking.[36-39] Additionally, previous studies on patient's compliance and understanding of fasting instructions reported that 8% considered fasting prior to a surgical procedure to be non-essential and that 4% would consider misrepresenting their fasting status.[40,41] A study in paediatric patients reported that 13% of parents might deliberately hide the actual fasting status of a child.[42] All ultrasound examinations were supervised by a single staff anaesthesiologist which minimized performance bias. Selection bias was minimized by including all patients identified in the source database, but not completely eliminated as this was not strictly a random sample. Measurement errors were minimized at the time of original data entry by using a standardized scanning protocol. Second, given the overall low incidence of full stomach in a fasted surgical population, our study lacks the power to correlate this incidence to specific comorbidities. Finally, our results are only applicable to similar patient populations, i.e., fasted elective, ASA 1-3, non-pregnant, adult patients.

Further research is warranted to define the normal distribution of baseline gastric volume in the general population and more clearly define a volume threshold over which aspiration risk increases significantly. Larger population-based studies could better define the relative risk associated with specific patient factors/comorbidities.

In conclusion, this retrospective cohort study suggests that a small proportion of elective surgical patients may present a full stomach despite recommended fasting. Further research is needed to establish the clinical implications of these findings in the elective setting. At the present time, the clinical role of gastric ultrasound continues to be for the evaluation of gastric contents to guide management when the risk of aspiration is uncertain or unknown.

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CHAPTER 6: Gastric ultrasound to guide anaesthetic management in elective surgical patients non-compliant with fasting instructions. A retrospective cohort study.

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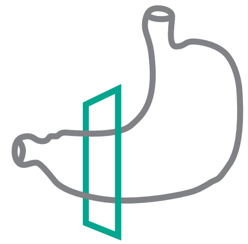

6.1. Abstract

BACKGROUND: Perioperative aspiration leads to significant morbidity and mortality. Standard fasting periods are used to ensure an empty stomach in patients. Anesthesiologists are frequently confronted with cases of dubious adherence to these guidelines. Point-of-care gastric ultrasound is a diagnostic tool that offers information on the type and volume of gastric contents.

METHODS: We performed a retrospective analysis of a departmental database containing clinical and sonographic information on elective surgical patients who had been non-compliant to the fasting guidelines. Primary outcome was the incidence of changes in aspiration risk stratification and anesthetic management when a point-of-care gastric ultrasound examination was added to a standard history-based clinical assessment. Secondary outcomes included a) types of changes (timing of the surgical procedure or change in anesthetic technique) b) the incidence of aspiration. Differences in the management plan (history-based versus gastric ultrasound) were tested with McNemar-Bowker's exact test of symmetry.

RESULTS: Thirty-seven patients met the inclusion criteria. Aspiration risk assessment and anesthetic management changed in 24 cases (64.9 %) following gastric ultrasound. Additionally, there was a non-significant difference in the distribution of the pre- and posttest changes in timing (delay, cancel, proceed)($p=0.074$) with a trend towards a lower number of surgical cancellations and a higher number of proceeds. No aspirations were documented.

CONCLUSION: This retrospective study suggests that gastric ultrasound may be a useful diagnostic addition to standard patient assessment in cases of non-compliance to fasting guidelines. It allows to personalize aspiration risk assessment and to tailor anesthetic management to the individual patient.

Keywords: NPO guidelines, stomach contents, gastric, ultrasound, patient non-compliance

6.2. Introduction

Pulmonary aspiration of gastric contents remains a serious perioperative complication seventy years after Mendelson's original publication.[1] According to the National Audit by the Royal College of Anaesthesists of the United Kingdom it is the single most common cause of death of airway management incidents and responsible for 50% of all airway-related deaths.[2] It has been suggested that a significant number of aspiration episodes occur due to failure to appreciate the true risk and to establish appropriate airway management.[2,3] The presence of gastric contents at the time of anesthetic induction is one of the main risk factors of pulmonary aspiration.[4,5]

To reduce the volume and acidity of these contents and to limit both the risk of aspiration and its sequelae, fasting guidelines have been developed.[6,7] However, when patient compliance is verified in the immediate preoperative period with a standard history-based clinical assessment, it is common to encounter cases of non-compliance with these instructions. This often results in changes to the planned anesthetic management and/or delayed or postponed surgical interventions.

Gastric ultrasound (GUS) is a point-of-care tool that evaluates gastric contents at the bedside both qualitatively and quantitatively.[8-15] We performed this retrospective cohort study to evaluate the changes in aspiration risk stratification and anesthetic management following a standard history-based clinical assessment compared to an assessment based on gastric sonography in elective surgical patients who had not followed fasting guidelines.

6.3. Methods:

After approval by the Institutional Ethics Board of Algemeen Ziekenhuis Monica, Deurne, Belgium, (OG 106, EC/313), we performed a retrospective observational cohort study. Inclusion criteria were: a) ASA physical status I-III patients, b) age 5 to 90 years, c) elective surgery under general anesthesia and d) non-compliance with institutional fasting guidelines (a minimum of 2 hours for clear fluids, 6 hours for a light meal, 8 hours for a meal that included fried or fatty food). Exclusion criteria were abnormal anatomy or previous surgery of the esophagus or stomach, hiatus hernia and current pregnancy.

The primary outcome was the incidence of changes in aspiration risk stratification and anesthetic management following gastric sonography compared to a standard history-based clinical assessment. Secondary outcomes included a) detailed changes in risk assessment and anesthetic management before and after GUS, more precisely the changes in timing (shorter, longer or avoided delays, cancelations) and anesthetic technique (more liberal or more conservative technique) b) the incidence of perioperative aspiration.

Data were obtained from an existing internal departmental database which was queried from November 2014 to January 2016 for the following information: a) demographic variables (age, height, weight, BMI), b) type of surgery, c) fasting interval for fluids and solids, d) details of last intake, e) initial clinical history-based aspiration risk assessment and management plan), f) gastric ultrasound examination results, g) aspiration risk assessment and management plan after gastric ultrasound, h) aspiration events, i) comorbidities.

Patients with suspected or certain non-compliance to the fasting guidelines were identified by the nursing team upon arrival in the preoperative unit. The anaesthesiologist responsible for the patient assessed and documented the aspiration risk based on the patient's history and made an initial management plan that could be: a) cancel the surgical intervention b) delay the intervention for a given number of hours c) proceed with the surgery with or without modified anesthetic plan. These modifications included a conversion to a) (loco)-regional anesthesia, b) neuraxial anesthesia, c) general anesthesia with no aspiration precautions (laryngeal mask, endotracheal intubation), d) general anesthesia with rapid sequence induction. All patients then underwent a gastric ultrasound exam performed by either a staff anesthesiologist with 5 years' experience in gastric ultrasound or a resident under direct staff supervision. This staff anesthesiologist was also in charge of direct patient care of some study subjects. A previously described standardized scanning protocol was followed.[8] A curved low-frequency (2-5 MHz) probe and a Philips HD11XE

(Philips Healthcare, Andover, MA, USA), or a GE Healthcare Logic E (General Electrics, Chicago, IL, USA) ultrasound system were used. All patients were first scanned in the supine position, followed by the right lateral decubitus (RLD) position. The gastric antrum was identified in a sagittal scanning plane in the epigastrium. The liver anteriorly and the aorta, inferior vena cava and pancreas posteriorly were used as anatomical reference points.[8-11] The stomach was deemed to be "empty" or "full" based on a combination of qualitative and quantitative findings. The stomach was considered empty if no content was visible in either position or if ≤ 1.5 mL/kg of clear fluid was present. The stomach was deemed to be full if solid content was observed or >1.5 mL/kg of clear fluid. The volume of clear fluid was calculated using a cross-sectional area (CSA) of the antrum measured in the RLD and a previously published mathematical model: *Volume (mL)= 27.0 + (14.6 x Right-lat CSA) – (1.28 x age.*[13]

Additionally, the antrum was classified according to a 3-point grading system (Perlas grade 0-2) that is based on the absence or presence of clear fluid in the supine and RLD positions.[10,13] Grade 0 refers to the absence of gastric content in the antrum in both supine and RLD positions. Grade 1 refers to antral clear fluid that is appreciable only in the RLD. Grade 2 refers to clear fluid that is documented in both the supine and RLD positions.

GUS results were presented to the referring anesthesiologist who confirmed or revised the initial aspiration risk assessment and anesthetic plan. This anesthesiologist also had the possibility to request a second gastric scan at a later time. All episodes of aspiration were recorded. There was no recording of episodes of nausea or vomiting.

Statistical analysis:

Descriptive statistics were used for continuous data. The assumption of normal distribution of continuous variables was checked with the Shapiro-Wilk test. If variables were normally distributed, central tendency was expressed as mean and standard deviation (SD). Categorical data are expressed as count and percentages or ratios. McNemar-Bowker's exact test of symmetry was used to test differences in the management plan (history-based versus gastric ultrasound). Changes in timing (shorter or longer delays, cancellations) and anesthetic technique (more liberal or conservative) were recorded. Differences were considered significant if $p < 0.05$. Statistical analysis was performed using SAS 9.4 for Windows (SAS Institute Inc.,Cary, NC).

6.4. Results:

Thirty-seven patients (22 male, 15 female) were identified as meeting the inclusion criteria. Demographic data are summarized in table 6.1 and were normally distributed. Patients presented for a variety of surgical procedures (orthopaedics 40.6%, general surgery 24.3%, maxillofacial surgery 8.1%, gynaecology 5.4%, urology 5.4%, otorhinolaryngology 5.4%, ophthalmology 5.4% and other 5.4%). The patients were cared for by ten different anesthesiologists (8 staff, 2 residents). Detailed information about the types of intake and fasting intervals is provided in table 6.2 (solid food intake n=25, thick fluid (milk) n=6, clear fluid n=4, unreliable intake n=2). An empty stomach was documented in 14 patients (37.8%). The remaining 23 patients (62.2%) presented a full stomach on gastric sonography (Figure 6.1, Table 6.3). Fourteen of these had solid content and 8 had clear fluid in excess of 1.5 mL/kg. The remaining patient presented a distended antrum in the supine position occupied by clear fluid. Although no volume could be measured in this patient due to the inability to scan in the RLD position, the presence of fluid in the supine position suggested a grade 2 antrum and the subject was therefore considered a full stomach. Nine of the 23 patients who presented a full stomach on initial scan (24.3%) had a subsequent repeat examination at a time requested by the attending anesthesiologist. All 9 subjects presented an empty stomach on repeat examination (6 subjects had a grade 0 antrum and 3 subjects had either a grade 1 antrum or a low volume (≤ 1.5 mL/kg) of clear fluid).

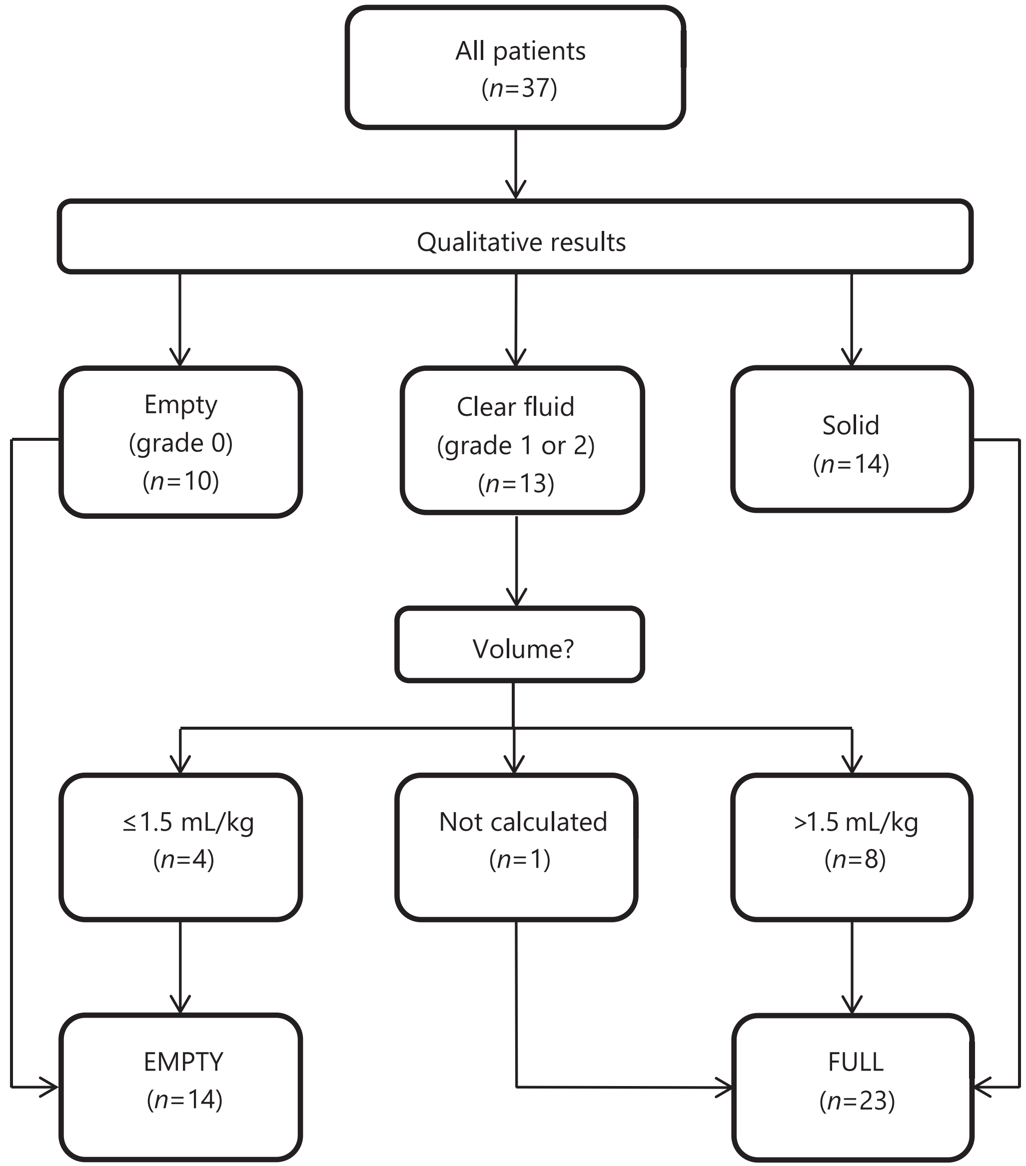

Figure 6.1: Results

Aspiration risk stratification and anesthetic management plan changed in 24 subjects (64.9%) following the gastric ultrasound exam compared to the pre-test clinical assessment and plan (Figure 6.2). Seventeen subjects (45.9%) were found to have a lower aspiration risk than anticipated by history. In 14 of them the timing of the surgery was changed (avoided surgical cancellations (n=7, #2, 8, 10, 16, 22, 26 and 35), shorter delay than initially planned (n=2, #19 and 25) or proceed at the scheduled time (n=5, #15, 28, 32, 33 and 36). In the remaining three subjects (#4, 6 and 13) the timing was not changed but a more liberal anesthetic technique was used (laryngeal mask airway instead of standard intubation). Conversely, 7 subjects were assessed as having a higher aspiration risk than anticipated by history (18.9%). In this subgroup, changes in timing included: surgical cancelation (n=1, #23) and longer delays (n=4, #12, 27, 30 and 31). In the remaining two patients (#5 and 9) the surgical timing was not changed but a more conservative anesthetic technique (rapid sequence induction) was used. The distribution of the pre- and posttest changes in timing (delay, cancel, proceed) was different (asymmetric) although not statistically significant (p=0.074, McNemar-Bowker's exact test of symmetry). There was a net trend towards a lower number of surgical cancellations and a higher number of proceeds (Table 6.4). No aspiration episode was reported.

Table 6.1: Demographics.

Patient demographics	**N=37**
Gender M / F	22 / 15
Age (y)	44.1 [24]
Height (cm)	172 [14]
Weight (kg)	72 [30]
Body mass index(kg/m^2)	24.9 [5]
Gastroesophageal reflux disease, n (%)	6 (16.2)
Diabetes, n (%)	2 (5.4)
Chronic neurological disease (MS, stroke, Parkinson's), n (%)	1 (2.7)

Table 6.2: Food intake details.

Patient number	**Time interval fluids**	**Time interval solids**	**Intake details**
1	1:30	8:00	Water (4 glasses)
2	6:00	6:00	Bread (1), salami, butter, orange juice (1/2 glass)
3	3:00	3:00	Bread (1), salami, butter, coffee (1 cup)
4	2:00	2:00	Soup (large bowl)
5	1:40	8:30	Softdrink (300 mL)
6	1:50	10:20	Water (2 large glasses)
7	4:30	4:30	Toast (1), water (1 glass)
8	5:00	5:00	Bread (2), fried egg, coffee
9	1:15	13:45	Coffee with milk
10	7:00	7:00	Bread (2), minced meat, butter, coffee
11	6:15	6:15	Bread (2), minced meat, meatball,softdrink(1/2L)
12	5:15	5:15	Bread (2), marmelade, coffee with milk
13	6:00	6:00	Oatmeal, yoghurt, water (2 glasses)
14	6:00	6:00	Bread, cheese, ham, meat salad, coffee
15	5:45	5:45	Cereals, milk, coffee, water
16	5:30	5:30	Bread (2), cheese, coffee, milk, water
17	?	?	Not sure
18	3:00	3:00	Bread (1), cheese, water (1 glass)
19	1:00	10:30	Coffee with milk
20	1:30	?	Coffee with milk
21	3:45	5:45	Hospital lunch, fruit juice, water
22	4:35	4:35	Bread (1), beetrootjuice, fruit
23	?	?	Not sure
24	5:45	5:45	Bowl of rice, water
25	1:50	12:00	Water (1 liter)
26	6:00	6:00	Pancakes (4), milk (2 glasses)
27	6:30	6:30	Pasta, strawberry, melon
28	6:20	6:00	Bread (1), cheese,meat, coffee
29	4:15	4:15	Cookies (4), yoghurt, water (1 glass)
30	7:00	7:00	Bread (1), salami,marmelade, water
31	7:00	7:00	Bread (2), fruitsalad, coffee, milk
32	2:15	?	Coffee with cream/milk
33	5:00	5:00	Cottage cheese (1 bowl), water
34	4:40	4:40	Coffee with milk, yoghurt
35	4:20	4:20	Yoghurt, berries, banana shake
36	2:00	2:00	Coffee with milk
37	6:00	6:00	Bread (1), cheese, water

Table 6.3: Gastric ultrasound results and anaesthetic plan changes. (Shaded cells correspond to those patients in which there was a change in anesthetic management. ETT RSI: endotracheal intubation, rapid sequence induction ETT SI: endotracheal intubation, standard induction LMA: laryngeal mask airway.)

Patient number	Anesthetic plan after clinical assessment	Gastric ultrasound			Anesthetic management after GUS
		Type of content	Perlas Grade	Conclusion	
1	Spinal	Clear Fluid	2	Full	Spinal
2	Cancel	Solid	/	Full	Delay for 3h
3	Cancel	Solid	/	Full	Cancel
4	ETT RSI	Empty	0	Empty	LMA
5	ETT SI	Clear Fluid	2	Full	ETT RSI
6	ETT RSI	Empty	0	Empty	ETT SI
7	Local	Clear Fluid	2	Empty	Local
8	Cancel	Empty	0	Empty	ETT SI
9	ETT SI	Solid	/	Full	ETT RSI
10	Cancel	Clear Fluid	0	Empty	ETT SI
11	ETT RSI	Clear Fluid	2	Full	ETT RSI
12	Delay for 1h	Solid	/	Full	Delay for 2h
13	ETT SI	Empty	0	Empty	LMA
14	Cancel	Solid	/	Full	Cancel
15	Delay for 2h	Empty	1	Empty	LMA
16	Cancel	Empty	1	Empty	ETT SI
17	ETT RSI	Clear Fluid	2	Full	ETT RSI
18	ETT RSI	Solid	/	Full	ETT RSI
19	Delay for 4h	Clear Fluid	2	Full	Delay for 1 h
20	Local	Clear Fluid	2	Full	Local
21	ETT RSI	Solid	/	Full	ETT RSI
22	Cancel	Solid	/	Full	Delay for 2h
23	ETT RSI	Solid	/	Full	Cancel
24	Delay for 2h	Solid	/	Full	Delay for 2h
25	Delay for 3h	Clear Fluid	2	Full	Delay for 1 h
26	Cancel	Empty	1	Empty	LMA
27	Delay for 1,5h	Solid	/	Full	Delay for 3h
28	Delay	Empty	0	Empty	Proceed (LMA)
29	Cancel	Solid	/	Full	Cancel
30	Delay for 1h	Solid	/	Full	Delay for 3h
31	Proceed	Clear Fluid	2	Full	Delay
32	Delay	Empty	0	Empty	Proceed (LMA)
33	Delay	Empty	0	Empty	Proceed (LMA)
34	ETT RSI	Clear Fluid	2	Full	ETT RSI
35	Cancel	Empty	0	Empty	LMA
36	Delay	Empty	0	Empty	Proceed (LMA)
37	ETT RSI	Solid	/	Full	ETT RSI

Table 6.4: McNemar-Bowker's test of symmetry.

Posttest	Pretest plan (n=37)			
	Cancel (n=10)	Delay (n=11)	Proceed (n=16)	P value[1]
Cancel (n=4)	3 (30%)	0 (0%)	1 (6.25%)	
Delay (n=9)	2 (20%)	6 (54.5%)	1 (6.25%)	0.074
Proceed (n=24)	5 (50%)	5 (45.5%)	14 (87.5%)	

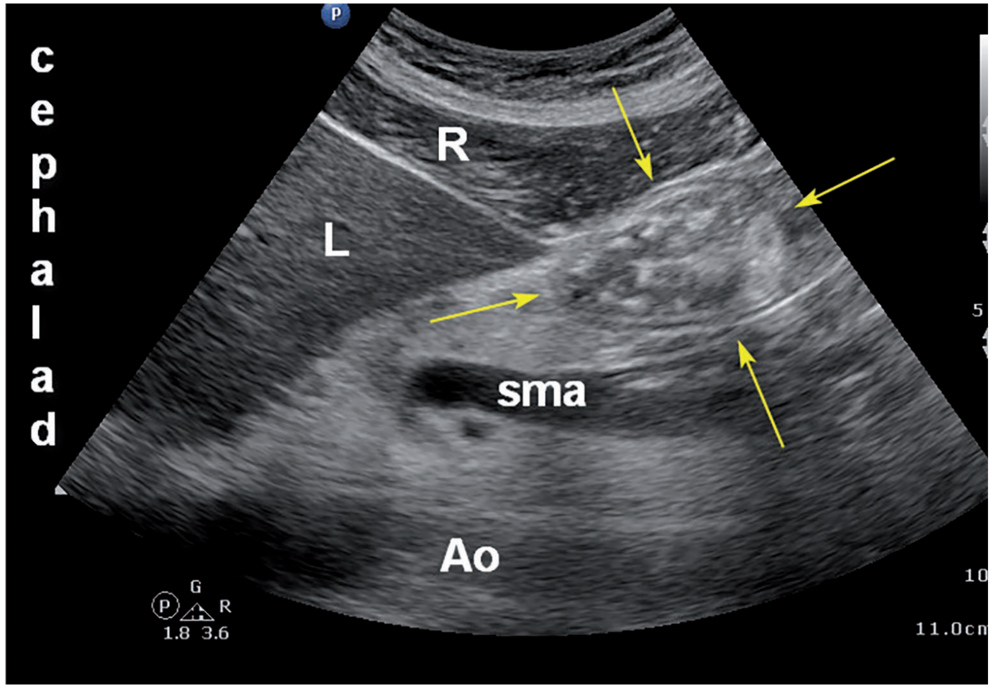

Figure 6.2: Gastric antrum filled with thick fluid / solid.

Ao: aorta; L: liver; Sma: superior mesenteric artery; R: rectus muscle.

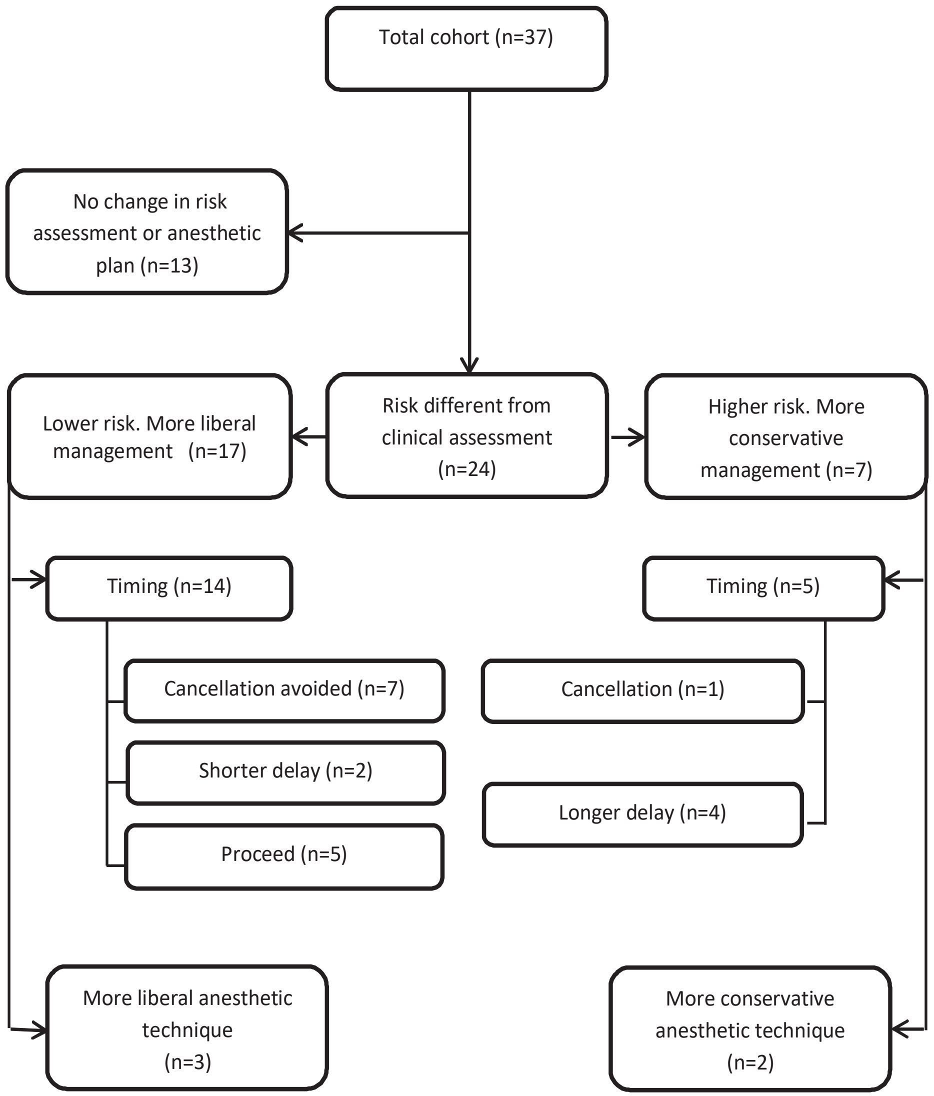

Figure 6.3: Patient management

6.5. Discussion:

In this retrospective study, gastric ultrasound changed the initial standard aspiration risk assessment and management plan in 24 (64.9 %) patients. The timing of the surgery was changed in 19 patients (51.3% of the total cohort) and the anesthetic technique was modified in 5 cases (13.5%). Our data suggest that point-of-care gastric ultrasound of elective surgical patients who have not complied with fasting instructions provides information about gastric content and aspiration risk that is often different from that suspected based on clinical history alone. Our findings are consistent with a previous prospective study (n=38) that reported a change in aspiration risk assessment and management in 72% of cases with a change in the timing of surgery in 55.3% and of 15.8% in the anesthetic technique.[16]

The management changes in our cohort were in both directions (towards more liberal and more conservative). Of the 10 patients whose surgery was initially planned to be cancelled based on clinical history alone, 5 were operated at the scheduled time (#8, 10, 16, 26 and 35) and 2 at a later time (#2 and 22). On the other hand, one patient (#23) who was originally planned to proceed with surgery based on history was cancelled after GUS showed a full stomach. The asymmetry in our cohort between the distribution of the pre- and posttest changes in timing, although not statistically significant (p=0.074), supports previous findings by Alakkad et al. (p=0.008).[16] However, they reported a net change towards a lower incidence of delays, whereas in our cohort the most significant trend was towards a lower number of cancelations (4 actual cancelations compared to the initial plan of 10 based on history alone) and a higher number of proceeds. Our results support previous findings that suggest that point-of-care GUS can help better individualize aspiration risk assessment and tailor anesthetic management to the needs of the individual patient rather than deciding management based on generic assumptions of risk.[16]

Preoperative fasting is an essential component of the strategy to reduce the risk of perioperative pulmonary aspiration. Different surveys estimate that approximately 1.5-3.9% of patients for elective surgery are non-compliant with fasting guidelines.[17-20] The ASA guidelines state that when fasting instructions are not followed, the practitioner should consider the relative risks and benefits of proceeding, with consideration given to the amount and type of liquids or solids ingested.[6] As a non-invasive, valid and reliable tool, GUS helps to better define risk by providing qualitative (empty, clear fluid, thick fluid/solid) information about stomach contents.[8-13, 21-23] Additionally, the volume of gastric fluid can be estimated based on a measurement of the cross-sectional area of the antrum.[10,12] The 3-point Perlas grading system is an easy system to discriminate between low and high gastric volumes.[10,13] Gastric ultrasound can be particularly useful in situations of clinical equipoise, where there is true uncertainty and the pre-test probability of having a full stomach is in the order of 50%.[15] A recent editorial supports the routine application of GUS each time there is any doubt as to residual gastric volume and the optimum strategy to avoid aspiration.[24]

Our cut-off value of 1.5 mL/kg to discriminate normal baseline gastric secretions from higher-than-baseline volumes deserves some comment. This value is based on a plethora of well-established human data. Although the threshold of gastric volume over which aspiration risk increases is not well-established, we know that the average fasting volume in adults is in the order of 0.6 mL/kg and values up to 100-130 ml (about 1.5 mL/kg) are common.[25-29] Previous lower thresholds of gastric volume considered to place patients at risk of aspiration (0.4 mL/kg and 0.8 mL/kg) were largely extrapolations from animal data of hydrochloric acid instilled directly into the tracheas of rhesus monkeys and have been put into question.[30,31] Even as early as 1998 Schreiner suggested that these extrapolations created a "myth" about what constitutes normal gastric volume in humans that should be put to rest.[32,33] Based on human data we know that baseline volumes of up to 1.5 mL/kg are normal and safe in healthy fasted individuals, and therefore we use this number as a conventional threshold to differentiate normal volumes (compatible with baseline gastric secretions) from higher-than-baseline volumes.[25-29] Although more research likely needs to be done in this area, it stands to reason that "risky" volumes have to be at least greater than normal baseline volumes.

Our study has several limitations. First, as a retrospective study it is subject to information bias, selection bias and measurement errors. We tried to minimize information bias by following a standardized data collection protocol. All ultrasound examinations were supervised by a single staff anesthesiologist which minimized performance bias, although qualitative and quantitative GUS results have been reported to be very reproducible with low intra- and interrater variability.[21] Selection bias was minimized by including every patient identified in the source database, but as this was not strictly a random sample not entirely eliminated. We tried to minimize measurement errors at the time of original data entry by using a standardized scanning protocol. Second, the principal investigator in this study who supervised or performed all scans was also in charge of some of the patient care decisions. This could possibly cause potential bias in the direction of patient-care decisions and study outcomes. However, one can argue that the clinical scenario in which the same physician performs the gastric scan and makes patient-care decisions is the most likely one. Finally, our findings are only applicable to similar patient populations, i.e., elective, ASA 1-3, non-pregnant patients who have been non-compliant to the fasting guidelines.

In conclusion, this retrospective cohort study suggests that gastric ultrasound is a useful diagnostic addition to standard patient assessment in cases of non-compliance to fasting guidelines. It allows to personalize aspiration risk assessment and to guide anesthetic management.

6.6. Key points

1) Anesthesiologists are frequently confronted with cases of dubious adherence to fasting guidelines. 2) Point-of-care gastric ultrasound offers information on the type and volume of gastric content. 3) Gastric ultrasound may be a useful diagnostic addition to standard patient assessment in cases of non-compliance with fasting guidelines. 4) It allows to personalize aspiration risk assessment and to tailor anesthetic management to the individual patient.

Acknowledgements

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CHAPTER 7: The link between gastric volume and aspiration risk. In search of the Holy Grail?

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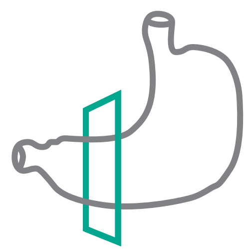

Prevention of aspiration pneumonitis has been a focus of anaesthesia practice ever since the dawn of the specialty [1]. For aspiration to occur there needs to be sufficient volume in the stomach to be regurgitated, the protective function of the lower oesophageal sphincter needs to be overcome and upper airway reflexes that close the glottis should be suppressed or absent [2]. General anaesthesia blunts both the lower oesophageal sphincter tone and upper airway reflexes rendering patients under anaesthesia susceptible to pulmonary aspiration [2]. Therefore, the presence of gastric contents is the main modifiable factor for aspiration prevention in anaesthesia practice [3]. Although the minimum volume of gastric contents that increases aspiration risk is not currently known, it is generally accepted that baseline gastric secretions in healthy fasted patients are safe and carry a very small risk in the order of 1: 4000 anaesthetics [4]. Several studies have reported mean baseline volumes of gastric contents in the order of 0.4 to 0.6 $ml.kg^{-1}$ when suctioning through a nasogastric tube after induction of anaesthesia, with the upper end of the normal range in the order of 1.0 to 1.2 $ml.kg^{-1}$ in healthy fasted individuals [5-8].

On the other end of the spectrum, patients who present for urgent or emergency surgery with a so-called 'full stomach' have a much higher risk of aspiration, and are susceptible to greater morbidity and mortality [4].

Plourde and Hardy evaluated adult cats under general anaesthesia to determine the minimum gastric volume that would result in spontaneous regurgitation of gastric fluid to the nasopharynx [9]. After ketamine induction and tracheal intubation, the animals underwent laparotomy and the distal duodenum was occluded to allow slow filling of the stomach with a water-base methylene dye solution. The minimum volume that resulted in passive regurgitation was surprisingly high, with a mean of 20 $ml.kg^{-1}$ and a range of 8-40 $ml.kg^{-1}$. This volume, equivalent to 1,400 ml in the average adult, is likely to be a gross overestimation of the true threshold of risk, since the authors relied on the observation of dye-tinted fluid in the nasopharynx to diagnose regurgitation.

On the other end of the spectrum, several animal studies have investigated the minimum volume of fluid that when directly instilled into the trachea of animals results in pneumonitis. For example, Roberts and Shirley reported that > 0.4 $ml.kg^{-1}$ of acid solution, instilled into the trachea of rhesus monkeys increased the risk of pneumonitis, equivalent to 25 ml in an average adult [10]. Similarly, Engelhardt et al. found that 0.8 $ml.kg^{-1}$ of filtered gastric secretions was more likely to result in pneumonitis, equivalent to about 50 ml in an average adult [2]. These two values are likely to be underestimations of the 'true' threshold. For these volumes of fluid in the stomach to pose a risk, the stomach would have to empty completely and all its contents enter the trachea. Not only is this an unlikely scenario, but a plethora of data from healthy human subjects shows that higher volumes than these (up to about 1.5 $ml.kg^{-1}$ or approximately 100-110 ml in the average adult) are normal and common in the fasting state, and are not associated with clinically significant aspiration [5-8,11]. We can therefore be quite certain that these lower thresholds based on animal data of direct tracheal instillation do not 'hold water' in humans. The true threshold of aspiration risk is somewhere in between a value of 0.8 $ml.kg^{-1}$ and 20 $ml.kg^{-1}$, but this huge range does not help the clinician!

Given the lack of a non-invasive tool to assess gastric volume in humans, there was little progress in this area of study for several decades [12]. The recent introduction of point-of-care gastric ultrasound has rekindled the interest and discussion adding new perspectives and fresh human data to our understanding [13,14]. There has been a burst of new publications recently, including two in this issue of *Anaesthesia* [15,16]. Ultrasound studies confirm that gastric volumes of up to 1.5 $ml.kg^{-1}$ are normal in healthy fasted individuals with baseline risk. For example, an analysis of our own raw data from previously published studies comprising over 800 adults show that mean baseline volume in a healthy fasted adult is about 0.5 - 0.8 $ml.kg^{-1}$, with a 95th percentile of 1.2 - 1.5 $ml.kg^{-1}$ [17-20].

The question of what constitutes a clinically insignificant or 'safe' baseline volume of gastric secretions has acquired greater relevance as we can now assess the type (nothing, clear fluid or thick fluid/solid), and the volume, of gastric contents non-invasively at the bedside to guide anaesthetic and airway management when fasting status is uncertain or unknown.

There are currently two different schools of thought when it comes to interpreting the results of bedside gastric ultrasound. The French group led by Dr. Bouvet uses cut-off values of antral cross-sectional area (CSA) measured in a 45º -degree semi recumbent position [21-25]. They have reported that CSAs greater than 3.4 cm^2 in non-pregnant, and 3.8 cm^2 in pregnant subjects correlate with gastric volume greater than 0.8 $ml.kg^{-1}$, which they consider a marker of a 'risk stomach'. However, given that 30-40% of all healthy fasted individuals have gastric volumes greater than 0.8 $ml.kg^{-1}$, it may be argued that this threshold is overly conservative, and could lead to a large proportion of false positives, where fasted individuals would be wrongly identified as being at risk.

Our research group has advocated a higher threshold of 1.5 $ml.kg^{-1}$ as a more appropriate cut-off for risk of aspiration [26-28]. This threshold corresponds to the 95^{th} - 97^{th} percentile of the healthy population and correlates with CSA between 9-10 cm^2 measured in the right lateral decubitus position. It is highly specific for ingestion of food or fluids since no more than 3-5% of fasted individuals will have a volume > 1.5 $ml.kg^{-1}$. Even this threshold may be rather conservative; the true value of gastric volume that increases aspiration risk in humans is not currently known and might be higher.

Having considered these two common approaches, we should point out that any cut-off value is ultimately somewhat arbitrary and should not be seen as a panacea, and specificity and sensitivity will change in opposite directions as the value is raised or lowered.

It is also important to point out that in the context of point-of-care ultrasound, gastric volume assessment is only required in a minority of cases [26-28]. More frequently, a positive assessment of 'empty' or 'full' stomach may be reached based on qualitative findings alone. No visible content in the gastric antrum in either the supine or right lateral decubitus (Grade 0 antrum) provides an unequivocal diagnosis of empty stomach. The presence of solid or thick fluid contents, are in and of themselves incompatible with an empty stomach, regardless of the volume [17,26,29,30]. It is in the remaining cases, when only clear fluid is observed, that a quantitative assessment and a reasonable threshold can differentiate a volume consistent with baseline secretions from a higher-than baseline volume (Fig. 7.1). Gastric ultrasound can provide more nuanced information than a simplistic dichotomy of 'empty' / 'full' stomach.

Compared to other well-established diagnostic applications such as lung assessment to rule out pneumothorax or cardiac assessment of the hemodynamically unstable patient, gastric ultrasound is relatively new. Despite current keen interest and growing literature several questions still remain to be answered.

First: when should gastric PoCUS be used? It seems reasonable to propose that a test of this nature is most useful when there is a high degree of clinical uncertainty (e.g. conflicting information regarding prandial status, urgent or emergency surgery, active labour or serious co-morbidities that can prolong gastric emptying despite otherwise 'appropriate' fasting). Two small cohort studies (n<40) suggest that gastric ultrasound changed aspiration risk stratification and led to changes in management in more than half of all adult elective surgical patients who did not fully comply with fasting instructions [27,31]. No such studies have yet been reported in the obstetric, paediatric or non-elective settings and should be encouraged. Furthermore, large prospective studies that randomize subjects with questionable prandial status into ultrasound or no ultrasound assessment and measure the incidence of perioperative aspiration would be ideal to conclusively prove a clinical outcome benefit. Given the low incidence of aspiration, these studies would be of a large scale, likely in the order of many hundreds if not thousands of patients and thus difficult to fund and perform.

Second: how should gastric ultrasound be performed? What are the best views and how should they be obtained? How should they be interpreted? And how should they be acted upon? We have proposed an I-AIM framework (Indication, Acquisition, Interpretation and Medical decision-making) as a logical step-wise approach to the performance and interpretation of this point-of-care test, but this needs to be considered within the context of national or local practice guidelines and best-practice protocols [28].

Third: who should perform and learn gastric ultrasound? It seems reasonable to propose that given the great importance of aspiration prevention in the practice of anaesthesiology, emergency and intensive care, gastric PoCUS should be part of the armamentarium of any clinician involved in these areas of patient care, similarly to lung or hemodynamic assessment. Indeed, several editorials have recently called for greater adoption of gastric and other PoCUS applications into clinical practice and residency training [13,32,33]. More studies are needed to determine the best methods to teach and learn this new skill, the most appropriate timing within the residency curriculum and the secondary impact on curriculum content overall. The degree of world-wide interest on gastric PoCUS is evidenced by the fact that it has been taught in over 100 Anaesthesiology continuing medical education events world-wide in the past 3 years. This, along with the fact that there is no current better alternative to objectively evaluate gastric content at the bedside suggests that gastric PoCUS is here to stay for some time and that significant growth and development may be expected in the short to medium term.

To conclude, perioperative aspiration continues to be an important challenge to anaesthesia patient safety, especially in non-elective surgeries. Gastric ultrasound is an emerging application of PoCUS that has rekindled the discussion around what constitutes 'normal' clinically insignificant gastric volume and what should be considered a volume of 'risk'. Growing data is starting to shed some new light into this very old question, and it is likely that before long, we will have a simple and clinically relevant bedside diagnostic tool available to all anaesthesiologists that may help accurately assess risk and guide safe anaesthetic management in otherwise complex clinical situations.

Keywords: gastric ultrasound; gastric volume; pulmonary aspiration; complications.

Right lat CSA (cm^2)	Age(y)						
	20	30	40	50	60	70	80
2	**31**	**18**	**5**	**0**	**0**	**0**	**0**
3	**45**	**32**	**20**	**7**	**0**	**0**	**0**
4	**60**	**47**	**34**	**21**	**9**	**0**	**0**
5	**74**	**62**	**49**	**36**	**23**	**10**	**0**
6	**89**	**76**	**63**	**51**	**38**	**25**	**12**
7	103	**91**	**78**	**65**	**52**	**40**	**27**
8	118	105	**93**	**80**	**67**	**54**	**41**
9	133	120	107	**94**	**82**	**69**	**56**
10	147	135	122	109	**96**	**83**	**71**
11	162	149	136	123	111	**98**	**85**
12	177	164	151	138	125	113	100
13	191	178	165	153	140	127	114
14	206	193	180	167	155	142	129
15	220	207	194	182	169	156	143
16	235	222	209	200	184	171	158
17	249	236	224	211	198	185	173
18	164	251	239	226	213	200	187
19	278	266	253	240	227	214	202
20	293	281	268	255	242	229	217
21	307	295	282	269	256	244	231
22	323	310	297	284	271	259	246
23	337	324	311	298	285	273	260
24	352	339	326	313	301	288	275
25	366	353	340	327	315	302	289
26	381	368	355	343	330	317	304
27	395	382	369	357	344	331	318
28	410	397	385	372	359	346	333
29	424	411	398	386	373	360	347
30	439	427	414	401	388	375	363

Figure 7.1: Gastric fluid volume as determined based on a cross-sectional area (CSA) of the gastric antrum measured in the right lateral decubitus and a validated model. With permission from www.gastricultrasound.org

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CHAPTER 8: Term pregnant women have similar gastric volume to non-pregnant females. A single centre cohort study.

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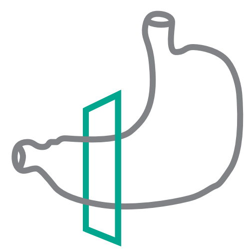

Editor's key points:

Pregnancy has been associated with increased gastric volume and risk of pulmonary aspiration but recent evidence suggests that gastric emptying is not delayed.

In a single centre prospective study, gastric volume in non-labouring pregnant patients at term was compared to that in non-pregnant females using ultrasonography.

Baseline gastric volume of pregnant patients was not significantly different from that of non-pregnant females.

These findings support recent data that suggest that the overall risk of aspiration in pregnant patients is relatively low and provide useful reference data for ultrasonographic evaluation.

8.1. ABSTRACT:

BACKGROUND: The physiologic changes of pregnancy can increase the risk of peri-partum pulmonary aspiration. There is limited objective information regarding gastric volumes in pregnant patients. The aim of this cohort study was to characterize prospectively the range of gastric fluid volume in term non-labouring pregnant patients compared to a historical cohort of non-pregnant females.

METHODS: Fasted non-labouring term pregnant patients scheduled for elective caesarean delivery underwent a standardized gastric ultrasound examination. Gastric content was evaluated qualitatively (type of content), semi-quantitatively (Perlas grades) and quantitatively (volume). Antral cross-sectional area and volume were compared to those of a retrospective cohort of non-pregnant subjects from the same institution. Descriptive statistics were used to describe the central tendency through mean and median values. Dispersion was evaluated with standard deviation and interquartile range and the higher end of the distribution as 95th percentile.

RESULTS: Non-labouring pregnant (59) and non-pregnant subjects (81) were studied. The range of estimated total gastric fluid volume ($p=0.96$) and volume per bodyweight ($p=0.78$) was not significantly different between cohorts. An estimated volume of 115 mL (102-143) versus 136 mL (106-149) and volume per unit body weight of 1.4 mL/kg (1.2-2.8) versus 2.0 mL/kg (1.5-2.7) corresponded to the 95th percentile (95% CI) values in the pregnant and non-pregnant cohort respectively.

CONCLUSIONS: Baseline gastric volume of non-labouring pregnant patients at term is not significantly different from that of non-pregnant females. This information will be helpful interpreting findings of gastric point-of-care ultrasound in obstetric patients.

Keywords: Fasting, gastric content, obstetric anaesthesia, pulmonary aspiration, ultrasonography.

8.2. INTRODUCTION

Pulmonary aspiration of gastric contents remains a rare but serious complication in obstetric anaesthesia and is associated with significant morbidity and mortality.[1-3] One of the main factors involved in the pathophysiology of pulmonary aspiration is the presence of gastric contents at the time of anaesthetic induction.[4] Studies suggesting that gastric emptying time is not prolonged by pregnancy have put into question the long-standing premise that every pregnant woman should be considered to have a "full stomach".[5-8] These data come from small samples[5-7] or heterogeneous non-obstetric control populations.[8] We therefore conducted a study to characterize the range of gastric fluid volume of non-labouring fasted term pregnant patients and compare it to that of non-pregnant fasted female surgical subjects. We hypothesised that term pregnancy was associated with a higher baseline gastric volume (by 50%) compared to non-pregnant female surgical patients.

8.3. METHODS

8.3.1. Study design

After approval by the Institutional Ethics Board (OG106/EC/263, 26.02.2015) and obtaining written informed consent, we conducted a single-centre prospective cohort study on fasting non-labouring pregnant patients at term. (Hospital AZ Monica, campus Deurne, Belgium) between March 2015 and October 2016. The study was designed and conducted following the STROBE guidelines.[9] Inclusion criteria were: 18 years of age and older, ASA physical status I-III, scheduled for elective caesarean delivery under neuraxial anaesthesia, ≥37 weeks gestational age having followed institutional fasting guidelines (a minimum of 2 h for clear fluids, 6 h for a light meal, 8 h for a meal that included fried or fatty food) and able to understand the rationale of the study. Exclusion criteria were: multiple gestation and pre-existing abnormal anatomy of the upper gastro-intestinal tract (previous lower oesophageal or gastric surgery, hiatal hernia, gastric cancer). Gastroesophageal reflux disease (GERD) or gestational diabetes mellitus were not exclusion criteria. Preoperative pharmacologic antacid aspiration prophylaxis was not routinely used.

8.3.2. Ultrasound assessment

Focused gastric ultrasound examinations were performed immediately preoperatively by one of 3 examiners: a staff anaesthesiologist with over 5 years' experience in gastric ultrasound or one of two residents under direct staff supervision. A previously described standardised scanning protocol was followed.[10,11] A curvilinear low-frequency (2-5 MHz) transducer and a Philips HD11XE or CX50 ultrasound machine (Philips Healthcare, Andover, MA, USA), were used. The gastric antrum was identified on a sagittal scanning plane in the epigastrium. The liver anteriorly and the pancreas posteriorly were used as anatomical reference points to obtain a standardized scanning level. The aorta or inferior vena cava served as additional reference points. All subjects were first scanned in the supine position, followed by the right lateral decubitus (RLD) position.[10-13] The examination was considered inconclusive if the antrum was not identified or if it was only visible in the supine position.

The examination included both a qualitative and a quantitative component. The stomach was characterized as "empty" (flat antrum with juxtaposed anterior and posterior walls in both supine and right lateral decubitus), to contain fluid (distended antrum with thin walls and hypoechoic content) or thick fluid/solid food (distended antrum with content of mixed echogenicity) based on qualitative findings. Gastric fluid volume was estimated using the cross-sectional area of the antrum (CSA) measured in the RLD (obtained with the free-tracing tool of the ultrasound equipment). The area was measured including the entire thickness of the antral wall and the following mathematical model : Gastric Volume (mL) = 27.0 + 14.6 x Right-lat CSA – 1.28 x age.[14] This model has been validated against endoscopically guided gastric suctioning for non-pregnant adults with a wide range of ages and weights and accurately predicts gastric volume up to 500 mL.[18] The pregnant patient's weight at term was used to calculate gastric volumes per weight (mL/kg). The antrum was classified according to a 3-point grading system (Perlas grade 0-2) based on the presence or absence of clear fluid in the supine and RLD positions (clear fluid refers to the presence of anechogenic non-particulate content).[13-14] Grade 0 refers to the absence of appreciable gastric content in the antrum in both supine and RLD positions. Grade 1 corresponds to clear fluid that is appreciable in the antrum in the RLD only. Grade 2 corresponds to clear fluid in the antrum in both the supine and RLD positions. The shortest distance between the skin and the anterior wall of the antrum was also measured.

8.3.3. Statistical analysis

A sample size was estimated to detect a 50% difference in mean gastric volume (expressed in mL/kg) between the two cohorts. The calculation was based on the assumption of mean gastric volume of 0.7 (0.59) mL/kg and 1.05 (0.59) in the non-pregnant[5] and pregnant cohorts respectively. A t-test was used for this calculation and then translated to the Mann-Whitney U-test assuming the worst-case asymptotic relative efficiency of 0.846. A minimum sample size of 53 pregnant subjects was required to test the hypothesis with 80% power and a two-sided 5% significance level. To allow for inconclusive examinations or loss-to-follow-ups we studied 59 subjects.

The primary outcome was to characterise the range of gastric fluid volume in fasting non-labouring pregnant patients at term. Secondary outcomes were: a) 95th percentile of antral CSA and gastric fluid volumes b) distribution of antral grades. These data were compared with those of a historic cohort of non-pregnant subjects from the same institution who had been evaluated by the same three examiners using the same ultrasound protocol.[15] From the 538 subjects originally studied we selected all females of child-bearing age (18-49 yr. of age) to use for comparison (n=81).

The Shapiro-Wilk test was used to test the assumption of normal distribution. When normally distributed, continuous variables are expressed as mean (SD) and compared using Student's t-test. If not normally distributed, continuous variables are expressed as median and interquartile range (IQR) and analysed with non-parametric tests (Mann-Whitney U-test). Categorical data are expressed as incidence (proportion) or ratios and analysed with the Fisher exact test. Differences were considered significant

if $P < 0.05$. For the purpose of comparison with the cohort of non-pregnant subjects, the distributions of the values of CSA and gastric volume were visually inspected with density and quantile-quantile diagnostic plots and tested with the Kolmogorov-Smirnov two-sample test. The 95th percentiles of antral CSA and gastric volume were calculated using a binomial-based method. Linear-regression analysis was used to evaluate the trend between antral grade and antral cross-sectional area, gastric volume, age, weight and BMI. Similarly, logistic-regression analysis was used to evaluate the trend between antral grade and incidence of diabetes and gastro-esophageal reflux. The statistical analysis was performed with R.3.4.1 statistical package (R development Core Team 2011. R: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria).

8.4. RESULTS

We enrolled 59 patients who consented to participate in the study. Subject characteristics are summarized in Table 1. Subjects had fasted for liquids for a median interval of 8 [IQR 5] h and 12 [4] h for solids. The ultrasound examination was inconclusive in 4 patients (antrum not identified n=2, visible in supine position only n=2). The 55 remaining subjects were included in the final analysis and their data were compared to those of 81 non-pregnant female surgical subjects (Figure 1).

Antral CSA and gastric fluid volume (expressed both in mL and mL/kg) were similarly distributed in both cohorts (Table 2 and Figure 2). The 95th percentiles in the pregnant cohort for antral CSA, gastric volume and gastric volume per weight were 8.7 cm^2 (95% CI, 7.6-10.8), 115 mL (95% CI, 101.6-143) and 1.4 mL/kg (95% CI, 1.2-2.8). Increasing antral grade was associated with greater CSA ($p < 0.0001$) and higher gastric volume ($p < 0.0001$) (Table 3). There was no linear trend between antral grade and age, weight, BMI, incidence of diabetes mellitus or gastroesophageal reflux (data not shown).

Of the 55 included subjects (Figure 1), 35 (63.6%) presented no appreciable gastric content (grade 0 antrum) and 18 (32.8%) had appreciable clear fluid. Two (3.6%) had thick fluid / solid despite adequate fasting and were excluded from gastric fluid volume calculation (n=53, 89.8%). One of these two subjects was obese (BMI=44), had a history of gastro-esophageal reflux disease, and had fasted for clear fluids for 2 h and solids for 8 h. The second subject with solid content had fasted for 8 hours for clear fluids and 12 h for solids and had no risk factors for delayed gastric emptying.

Of those that had clear fluid, 15 (27.3%) were classified as grade 1 and presented ≤1.5 mL/kg of clear fluid. The remaining 3 patients (5.5%) presented a grade 2 antrum and >1.5 mL/kg (Figure 1). These 3 subjects with a grade 2 antrum had fasted for 4-10 h for fluids and 10-16 h for solids and had no particular risk factors for prolonged gastric emptying.

Table 8.1: Subject characteristics. Data are represented by median [IQR] except where indicated. Age is represented by median [range]. BMI, body mass index; GERD, gastro-oesophageal reflux disease; N/A, not applicable

Characteristic	**Pregnant (*n* = 59)**	**Non- pregnant (*n* = 81)**
Age (years)	31 [20-41]	36 [18-49]
Weight (kg)	78 [18]	68 [19]
Height (cm)	164 [10]	167 [7]
BMI (kg/m^2)	28.8 [6.9]	24 [7.0]
GERD, *n* (%)	23 (38.9)	7 (8.6)
Gestational age (weeks)	39 [1]	N/A
Gestational diabetes, *n* (%)	4 (6.8)	N/A

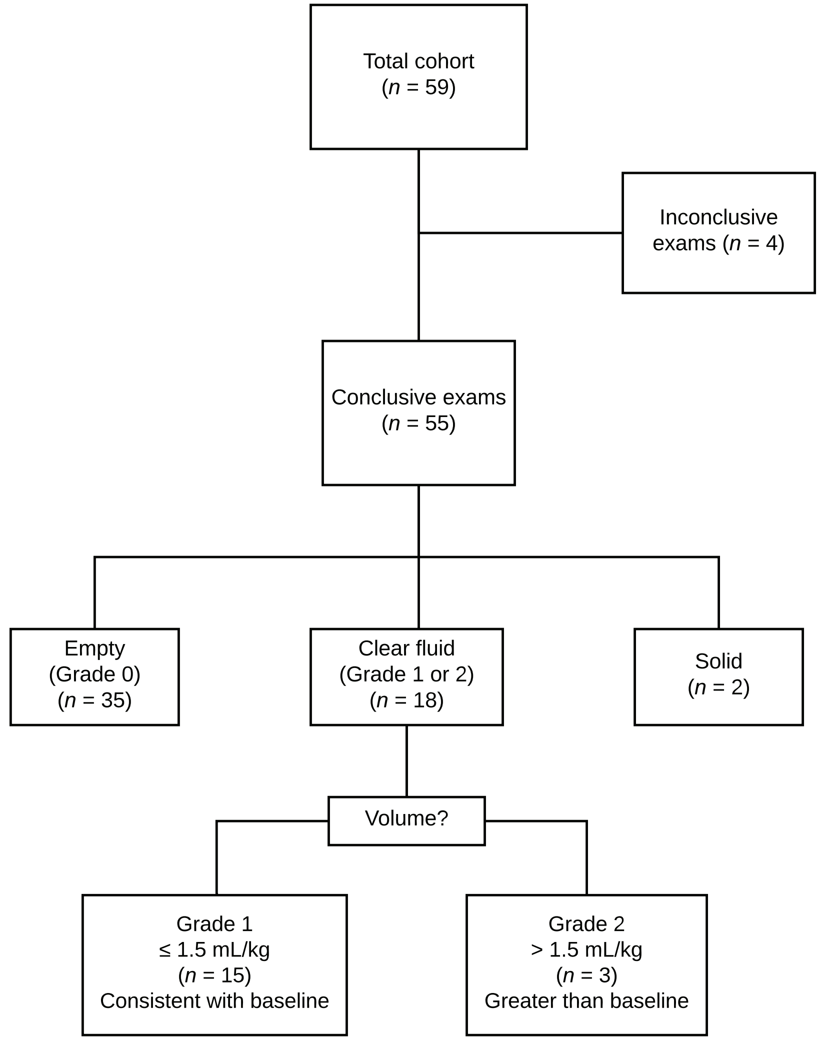

Figure 8.1: Patient flow. (Clear fluid refers to the presence of anechogenic non-particulate content)

Table 8.2. Results: Distribution of right lateral CSA and gastric volume in pregnant & non-pregnant adult females (excluding those with solid gastric content).

CI, confidence interval; CSA, cross-sectional area; IQR, interquartile range; SD, standard deviation

P-values: *, Kolmogorov Smirnov test; **, Student t-test; ***, Mann-Whitney-U test.
The P-values of the Kolmogorov-Smirnov test compare the *entire* distribution of the data in both cohorts

	Pregnant (*n* = 53)	**Non-pregnant (*n* = 81)**	**Pregnant – Non-pregnant Difference (95% CI)**	**P-value**
Right lateral CSA (cm²)				0.24*
Mean (SD)	4.2 (2.4)	4.7 (2.6)	-0.5 (-1.3; 0.4)	0.31**
Median [IQR]	4.1 [3.0]	4.0 [3.6]	-0.4 (-1.2; 0.4)	0.38***
95th percentile (95%CI)	8.7 (7.6 – 10.8)	10.2 (8.6 – 11.5)		
Gastric fluid volume (mL)				0.96*
Mean (SD)	49.8 (35.9)	49 (39)	0.6 (-12.4; 13.6)	0.93**
Median [IQR]	44.7 [48.5]	37.2 [48.5]	1.8 (-9.4; 13.2)	0.78***
95th percentile (95% CI)	115 (101.6 – 143.0)	135.6 (106.2 – 149.1)		
Gastric fluid volume (mL/kg)				0.78*
Mean (SD)	0.6 (0.5)	0.7 (0.6)	-0.1 (-0.3; 0.1)	0.40**
Median [IQR]	0.5 [0.5]	0.6 [0.7]	0.0 (-0.2; 0.1)	0.68***
95th percentile (95% CI)	1.4 (1.2 – 2.8)	2.0 (1.5 – 2.7)		

Table 8.3. CSA and gastric volume in subgroups by antral grade. Values are median [IQR]. CSA, cross-sectional area. P<0.0001 for right lat CSA, gastric volume (mL and mL/kg) in both cohorts.

	Pregnant (*n* = 53)			**Non-pregnant (*n* = 81)**		
	Grade 0 (n = 35)	Grade 1 (n = 15)	Grade 2 (n = 3)	Grade 0 (n = 54)	Grade 1 (n = 17)	Grade 2 (n = 10)
Right lateral CSA (cm²)	2.9 [2.2]	5.9 [3.1]	10.6 [1.1]	3.3 [1.9]	6.8 [1.7]	9.8 [1.7]
Gastric volume (mL)	32.8 [28.8]	77.3 [53]	139.7 [13.2]	29.5 [22.9]	76 [25.8]	132 [25]
Gastric volume (mL/kg)	0.4 [0.3]	0.8 [0.6]	1.6 [0.3]	0.4 [0.3]	0.9 [0.3]	1.9 [0.5]

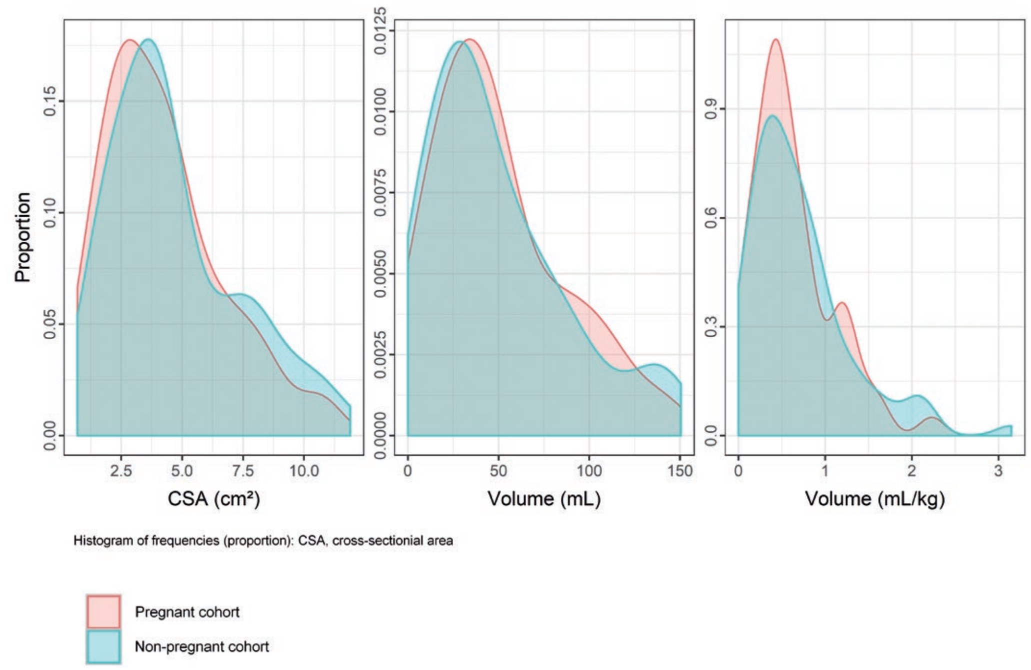

Figure 8.2: Histogram of frequencies (density) of antral cross-sectional area, total gastric fluid volumes and volume per body weight.

8.5. DISCUSSION

This study was designed to compare the estimated volume of baseline gastric secretions in fasting, non-labouring patients at term to that of non-pregnant female subjects.

We found that the median estimated fasting volume of 44.7 [48.5] mL was not significantly different from that of the non-pregnant cohort and remarkably similar to recent reports from other centres.[8,16] Arzola et al. reported a median volume 48 mL [IQR 45] and Rouget et al. found a median volume of 44 mL [IQR 49].[8,16] Similarly, Wong et al. reported mean antral CSA of 4 ± 2.5 cm^2 and 5.2 ± 2.1 cm^2 in non-obese and obese pregnant subjects respectively, which are also close to those in our cohort.[6,7] Whilst confirmatory of previous reports, the present study offers the added value of comparing obstetric patients to a similar cohort (in gender and age) of non-pregnant subjects. Rouget[16] and Wong[6,7] reported values on obstetric subjects only, while Arzola[8] used a historical comparative cohort of unselected elective surgical subjects.

Whilst mean and median values are useful to compare the central tendencies of the data, measures of dispersion (such as 95th and 99th percentiles) are required to illustrate the broader range of values in the sample and in particular to evaluate the "upper limits" of normal. The 97.5th percentile is commonly used to establish an upper limit of normal values in a population. For a normally distributed variable, the 97.5th percentile is equal to the mean plus 2 SD. Given that gastric volume in our sample is not normally distributed but rather positively skewed, the 97.5th percentile is larger than mean +2 SD. We therefore chose to report the 95th percentile of CSA (and volume) as the upper limit of normal, hence a CSA of 8.7 cm^2 (95% CI 7.6 – 10.8 cm^2) and a gastric volume of 115 mL (1.4 mL/kg) in the pregnant cohort (Table 2). Our findings are in keeping with the values reported by Arzola et al., also in obstetric patients (95th percentile of CSA = 9.6 cm^2 and gastric volume of 1.5mL/kg).[8]

Establishing these "upper limits" of normal values is important in the context of point-of-care ultrasound.[17-19] These values can help determine if an individual's gastric volume (or CSA) is compatible with baseline gastric secretions or suggests a

"full stomach". Such data had been difficult to obtain due to lack of a non-invasive method to study gastric volume in humans. Previous studies of volumes of acid directly instilled into the tracheas of animals likely overestimated the risk associated with otherwise insignificant baseline gastric fluid.[19,20] Our results align with more recent human data that suggests volumes of up to about 1.5 mL/kg are common in fasted individuals and otherwise clinically benign.[21-25]

Although recent data suggest that the overall risk of aspiration in pregnant patients is relatively low,[26-27] current standard of care is to consider all term pregnant women as having a "full stomach" and being at risk of aspiration.[27-30] Many centres still currently administer routine aspiration prophylaxis to all patients before Caesarean delivery.[31] Pregnancy-induced physiologic changes (such as upper displacement and increased pressure of the stomach by the gravid uterus, progesterone-mediated relaxation of the lower oesophageal sphincter and lower gastric pH) might conceivably increase aspiration risk in pregnancy, but clinical data on aspiration risk and its relation to gastric volume is scarce and mixed in this population.[26] The introduction of point-of-care gastric ultrasound has added new perspectives to this "old" question.[19,32,33] On one hand, one study suggests that gastric emptying is similar in non-labouring pregnant and non-pregnant patients.[8] However, this evidence is weak and comes from a study with a mixed pregnant/non-pregnant control cohort.[8] On the other hand, a recent case-control study that evaluated gastric emptying in term pregnant subjects after a standardised meal suggested that gastric emptying is indeed prolonged in late pregnancy.[34]

Two pregnant subjects in our cohort (3.6%) presented thick fluid/ solid content. There were no underlying conditions present that might explain delayed gastric emptying. Barboni et al. suggested that the transit of food after a standardised meal was slower in term pregnant than in non-pregnant subjects.[34] The presence of this thick fluid/solid content in these two subjects is in line with previous findings in 538 fasted non-pregnant patients for elective surgery where solid content was reported to be present in 1.7% of cases.[15] Two other studies in fasted term pregnant females before elective Caesarean section found no solid gastric contents.[8,16]

This study has several limitations. Firstly, it can be argued that the magnitude of the hypothesis that gastric volume is 50% higher in term pregnancy is too large, and therefore the study was not powered to detect smaller differences. However, the actual difference between the median gastric volumes (8 mL or 20%) is indeed very small and clinically negligible. Secondly, the fact that three different anaesthesiologists performed the ultrasound examinations might arguably lead to increased measurement variability. However it has been previously shown that when a standardised scanning protocol is used, both quantitative and qualitative gastric ultrasound assessments are highly reproducible with low inter- and intraobserver variability.[35,36] The mathematical model used to estimate gastric volume was developed and validated in non-pregnant adults and has not been fully studied in pregnant patients.[14] A different predictive model developed for the third trimester has been recently proposed by Arzola et al.[37] This latest model was not yet available at the time of planning and execution of this study, but we considered using the new model post hoc. However, we decided against it given that the new model[37] is based on ingested fluids only and unlike the pre-existing model does not take into account baseline gastric secretions.[14] The new model therefore, although derived from data on pregnant patients, significantly underestimates low volume states. For example, according to the new model[37], 6 of the 53 subjects in our cohort would be considered to have a gastric volume of 0 mL despite gastric fluid being clearly appreciable in the right lateral decubitus position (and estimated to be between 10 and 60 mL based on the previous model[14]). This discrepancy between the two models at low volume states is likely not a major shortcoming from a clinical perspective. However, for the purpose of this article we felt it fitting to apply the pre-existing model in order to study the overall distribution of total gastric volume values in fasting subjects, many of whom are expected to have low volumes at baseline.

A fourth limitation is that gastric ultrasound can be more technically challenging in pregnancy given the upward displacement of the stomach and its rotation into a more horizontal position, the moving fetus and an increase in respiratory rate. Probe placement can be difficult because of the steep angle between the xyphoid and the abdomen.[8,38] Nevertheless, ultrasound examination was conclusive in 93.2% of our

cohort which is similar to previous reports (82.5-100%).[8,38-40] Finally, a possible limitation is that the data on non-pregnant patients were obtained from a historical cohort. However, the two cohorts are comparable given the use of a standardised scanning protocol by the same authors from the same institution.[15]

Finally, we used gastric fluid volume per body weight as a variable to compare the pregnant and non-pregnant patient groups. The additional weight in pregnancy is not the same as in non-pregnant subjects as a proportion of the weight such as the fetus, placenta and amniotic fluid is not part of the patient's own body weight.

In conclusion, our data suggest that the 95th percentile of antral CSA in healthy fasting term non-labouring pregnant patients is 8.7 cm^2 which corresponds to a volume of 115 mL or 1.4 mL/kg. These values were not significantly different from those of a non-pregnant cohort. These upper limits of normal values may be helpful in the interpretation of individual findings when performing gastric point-of-care ultrasonography in the obstetric patient.

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Authors' contributions:

PVdP: study design, patient recruitment, data collection, wrote and approved the final manuscript.

LV: patient recruitment, data collection, designed the tables and figures, wrote and approved the final manuscript.

AP: study design, wrote and approved the final manuscript.

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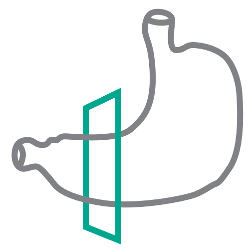
CHAPTER 9: Clinical applications



9.1. Bedside gastric ultrasonography to guide anesthetic management in a nonfasted emergency patient.

Peter Van de Putte

Journal of Clinical Anesthesia 2013 Mar;25(2):165-6.

9.1.1. Introduction:

Gastric ultrasound provides both qualitative and quantitative information about stomach contents [1,2]. This case illustrates the use of bedside ultrasonography for objective information regarding gastric contents and its impact on anesthetic management.

9.1.2. Case:

An 87-year-old woman presented for emergency incision and drainage of a spontaneous large hematoma of the left calf. She had a recent history of acute pulmonary embolism following total hip arthroplasty, for which she was anticoagulated with nadroparine (a low-molecular-weight heparin) 0.6 mL twice a day, warfarin 5 mg/day, and acetylsalicylic acid 80 mg/day. Her medical history included chronic obstructive pulmonary disease, which was treated with solumedrol 6 mg per day, and chronic heart failure, treated with bumetanide and lisinopril. She also had a documented difficult intubation, but on a previous occasion a Laryngeal Mask Airway (LMA) had been used successfully. Four hours before surgery, she ingested approximately a half cup of mashed potatoes, a half cup of applesauce, a piece of sausage, and 300 mL of water. She had several predictors for difficult intubation, including a Mallampati score of 3, small mouth opening, and decreased neck extension. She was hypotensive (blood pressure [BP] 76/50 mmHg) and tachycardic (heart rate [HR] 141 bpm). Chest auscultation was normal and oxygen saturation was 98% on room air. Preoperative laboratory values showed hemoglobin 9.9 g/dL, prothrombin time 35% (normal 70-100%), and INR 1.77. A regional anesthetic technique was considered contra- indicated for this urgent procedure due to her current coagulopathy. The 2011 practice guidelines for preoperative fasting by the ASA recommend 8 hours of fasting following a full meal with high calorie or fat content [3]. Therefore, a rapid-sequence induction and endotracheal intubation were indicated for our patient to protect her lungs from aspiration of gastric contents. However, her previous difficult intubation, her hemodynamic instability, the possible hemodynamic consequences of a rapid-sequence induction, and the contraindication of regional anesthesia prompted us to consider the possibility of a “smoother” anesthetic induction and use of a LMA. The key point in the decision making was evaluation of the patient's gastric contents.

Until recently, there was no bedside noninvasive test available to the clinician to examine stomach contents. However, ultrasound may be used not only for a qualitative examination of the stomach to detect the nature of the contents (empty, clear fluid, solid) but also for quantitative measurement of stomach contents [1,2].

We used bedside two-dimensional ultrasonography to examine the contents of her stomach, as previously described [1]. Using a Philips HD11XE ultrasound unit with a curvilinear array low-frequency (2-5 MHz) transducer (Philips Healthcare, Andover, MA, USA), we identified the gastric body and antrum in a sagittal/parasagittal plane in the epigastric area. The antrum of the stomach was scanned both in the supine and right lateral decubitus positions, following the technique described by Perlas et al [1,2]. While the patient was supine, the gastric antrum was not visualized. In the right lateral decubitus position, however, the gastric antrum and body were readily identified. The antrum appeared round, with a multi-layered wall located deep to the left lobe of the liver and superficial to the pancreas at the level of the abdominal aorta (Figure 9.1). The antrum appeared small, with no evidence of either solid or fluid contents, corresponding to a “grade 0” antrum [2,4]. We also quantitatively assessed the stomach contents by calculating a cross-sectional area (CSA) of the antrum. This was done by measuring the craniocaudal (CC) and anteroposterior (AP) diameters [5], and using the formula: CSA = (AP×CC×π)/4. The calculated CSA was 3.1 cm2, which also suggested an empty stomach (< 4 cm2) [1].

As a result of both the qualitative and quantitative assessments, we concluded that it was safe to proceed with our modified anesthetic plan. Prior to induction, her fluid status was optimized. She was induced with sufentanil (5 µg intravenously [IV]) and propofol that was slowly titrated until loss of consciousness (60 mg IV in total) while maintaining stable BP and HR within 20% of her preoperative values. On loss of consciousness, a size 3 Classic LMA was inserted uneventfully. Anesthesia was maintained with 0.6 minimum alveolar concentration sevoflurane for the duration of

the 35-minute surgical procedure, while maintaining spontaneous ventilation (inspired oxygen concentration 40%). She remained hemodynamically stable. The LMA was removed on emergence from general anesthesia. There was no evidence of regurgitation or aspiration of gastric contents.

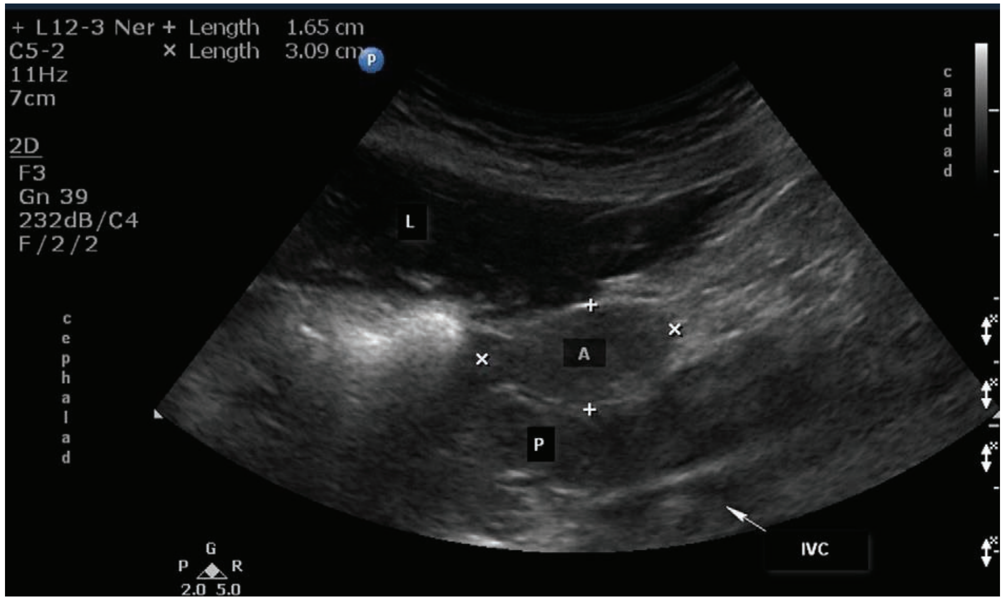


Figure 9.1: Sonographic image of the antrum of this nonfasted emergency patient. L, liver; A, antrum of the stomach P, pancreas; IVC, inferior vena cava.

Over the last decade, we have seen a dramatic increase in the use of ultrasound in the practice of anesthesia. Since it is readily available and relatively easy to use, bedside gastric ultrasonography may be another promising technique. Although it has proven to be a valid technique [1,6], it is not yet standard practice. More research needs to be done regarding the sensitivity and specificity of the assessments. The technique also has its limitations; the antrum is not identifiable in all patients and several steps need to be executed in a systematic way to obtain reliable results.

This case illustrates the use of gastric ultrasound for objective information about the gastric contents of an individual patient, rather than a general assumption based on hours of fasting, which may not reflect the individual patient's situation. This information allows us better to guide and to tailor our individual anesthetic management.

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9.2. Serial gastric ultrasound to evaluate gastric emptying following prokinetic therapy with domperidone and erythromycin in an elective surgical patient with a full stomach: a case report.

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Anesthesia Analgesia Practice. 2018 Aug;11(4):106-108.

9.2.1. Abstract:

Fasting guidelines are used to prevent perioperative aspiration but they are only reliable in healthy elective patients. Point-of-care gastric ultrasound (gastric PoCUS) allows qualitative and quantitative evaluation of gastric contents at the bedside. This case report describes the use of serial gastric PoCUS to evaluate the effect of pro-kinetic therapy with domperidone and erythromycin in an elective surgical patient with multiple co-morbidities who presented with a full stomach.

9.2.2. Introduction

According to the National Audit Project-4 study, pulmonary aspiration results in high morbidity and accounts for 50% of anesthesia-related deaths.[1] The presence of gastric contents is one of the risk factors for aspiration pneumonitis and pneumonia. Fasting guidelines are used for aspiration prevention but are only reliable in healthy elective patients.[2] Point-of-care gastric ultrasound (gastric PoCUS) is a recent tool that allows bedside qualitative and quantitative evaluation of gastric contents.[3] Erythromycin is a macrolide antibiotic whose gastroprokinetic properties have been studied in internal medicine, critical care and emergency surgery.[4-8] To our knowledge, this case report is the first one to describe the bedside evaluation of the gastroprokinetic effect of domperidone and erythromycin, administered to an elective surgical patient with delayed gastric emptying.

The patient provided written consent to publish this case report.

9.2.3. Case

A 48-y-old male was scheduled for repeat and complicated elective strabismus surgery. His past medical history included insulin dependent diabetes mellitus with high glycemic variability and post-traumatic seizure disorder. His medications included valproic acid, diazepam, alprazolam and prazepam. Upon presentation for this elective surgical procedure, the patient stated he had ingested a soda drink (300 mL) 2.5 hours earlier because he “felt hypoglycemic” but he didn’t check his blood glucose level. His last solid food intake was 9 h prior to arrival. A bedside gastric PoCUS exam following a previously described I-AIM protocol (Indication, Acquisition, Interpretation, Medical decision). was performed by the attending anesthesiologist (previous experience of ≥1000 gastric scans).[9] Using portable ultrasound equipment and a curvilinear array low-frequency (2-5 MHz) transducer (SonoSite X-porte, Fujifilm SonoSite), the antrum was identified in a sagittal plane in the epigastric area. The liver anteriorly and the aorta posteriorly were used as regional landmarks. The patient was examined in both the supine and right lateral decubitus position. The antrum appeared dilated with thin walls and content of mixed echogenicity, consistent with solid food / thick fluid suggesting a high aspiration risk (Figure 9.2). In view of the technical complexity of the surgery that required the presence of

several surgeons, the difficulties to manage his sugar levels and the possible side effects of disrupting his daily antiepileptic medication, cancelling the surgery was not considered the best option for the patient. The case was postponed and domperidone 10 mg was administered sublingually. A repeat gastric examination one hour later still showed a unaltered full stomach with solid content (Figure 9.3). It was decided to administer erythromycin intravenously in a dose of 3 $mg.kg^{-1}$. A third gastric PoCUS examination performed thirty minutes later revealed a small antrum with a prominent multilayered wall in both the supine and right lateral decubitus position and with no evidence of fluid or solid contents (Figure 9.4), corresponding to a “grade 0” or empty antrum, consistent with a low aspiration risk. We concluded it was safe to proceed with the procedure and after standard induction with endotracheal intubation, surgery was uneventful. There was no evidence of regurgitation or aspiration in the perioperative period and the patient experienced no side effects following the administration of erythromycin.

9.2.4. Discussion

Pulmonary aspiration of gastric contents carries significant morbidity and is the leading cause of death from anesthesia airway events.[1] Perioperative aspiration risk assessment and patient management are usually based on the patient’s history and compliance with fasting guidelines. However, recommended fasting intervals are only reliable in healthy patients. Several medical conditions, including diabetes may prolong gastric emptying beyond the recommended intervals.[2] In this case, a history of long-term Type I diabetes, chronic antiepileptic therapy and borderline compliance with fasting instructions for fluids, raised clinical uncertainty about his prandial status.

We admittedly could have taken several tactics when writing this case report (e.g. documented failure of domperidone at one hour versus success with erythromycin).

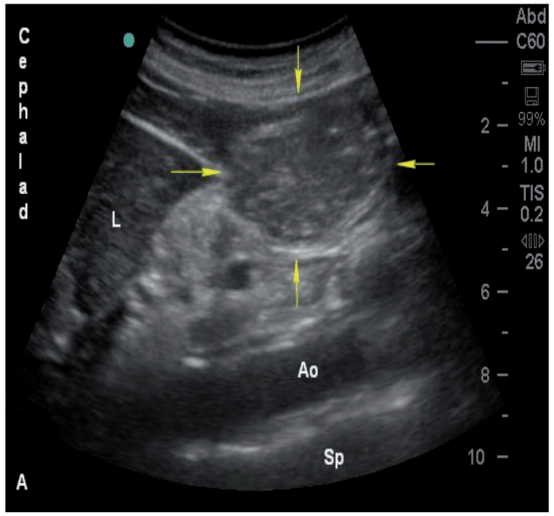

Figure 9.2: Sonographic findings consistent with a “full stomach” at baseline. The antrum (evaluated in the right lateral decubitus position) contains thick fluid/ solid content.

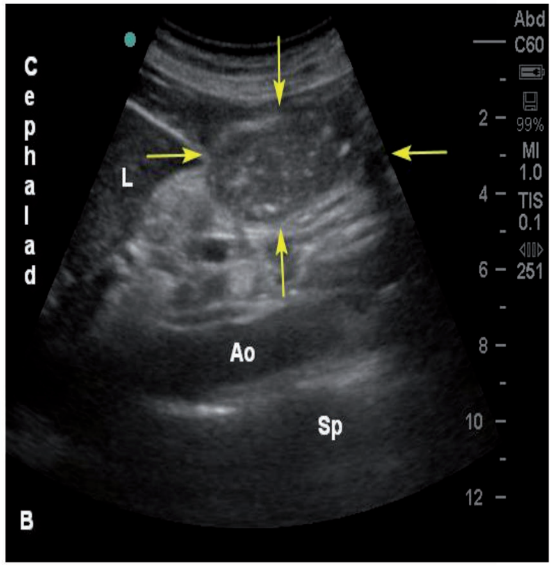

Figure 9.3: Sonographic findings consistent with a “full” stomach 60 minutes after administration of domperidone.

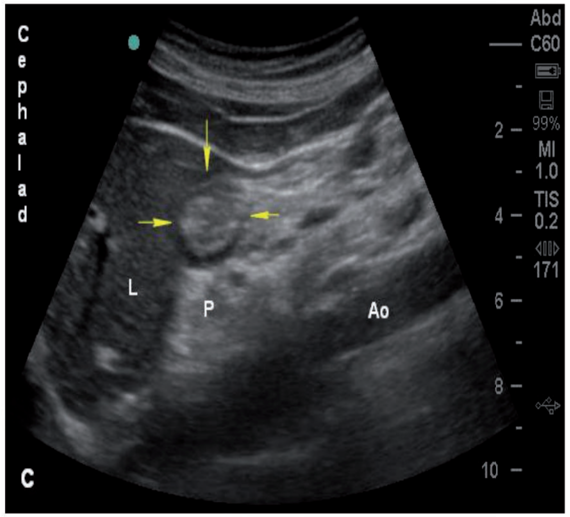

Figure 9.4: Sonographic findings consistent with an “empty stomach” 90 minutes after presentation following the administration of domperidone and erythromycin. The antrum (evaluated in the right lateral decubitus position) appears completely empty (bulls’ eye pattern) with no fluid or solid content.

Legend: Ao: Aorta P: Pancreas L: Liver Yellow arrows: antrum.

However, the serial use of gastric ultrasound to dynamically assess the stomachs’ content and to stratify individual aspiration risk and to tailor anesthetic management in a situation of clinical equipoise, was the most important and interesting fact. Gastric point-of-care ultrasound (PoCUS) is an emerging tool that provides bedside information on gastric content and volume.[3] It is a non-invasive, valid and reliable tool that offers qualitative (empty, clear fluid, thick fluid / solid) and quantitative (what is the volume of clear fluid) information based on a standardized scanning protocol and a validated mathematical model with high intra- and interrater reliability. Current evidence suggests that the addition of gastric PoCUS to the clinical history and physical exam, can add clarity to aspiration risk assessment and modify anesthetic management.[3,10] However, the diagnostic accuracy of gastric ultrasound to detect a full stomach (i.e. the sensitivity, specificity and positive and negative predictive values of gastric PoCUS) remains to be studied.[3]

The finding of a "full" stomach with solid content in this case was somewhat unexpected. Strategies to minimize the risk of aspiration in the presence of a full stomach include postponing or re-scheduling the surgical procedure in elective circumstances or performing a rapid sequence induction of anesthesia and endotracheal intubation in urgent or emergency situations.

Prokinetic agents are used to treat delayed gastric emptying. Metoclopramide is the only FDA approved prokinetic agent for the indication of gastroparesis in the United States and could have been a therapeutic possibility but was not readily available at our institution. For this reason we used domperidone, a dopamine D_2 antagonist, that acts as an antiemetic and is able to modulate gastric emptying of both liquid and solid meals.[11] Its peak plasma concentration is reached after 30 minutes. Therefore the one hour time frame between its per os administration and the second unaltered gastric scan with no signs of gastric emptying, seemed long enough for us to warrant the IV administration of erythromycin. No gastric volume calculations were made since this is only appropriate in the presence of clear fluid. Erythromycin is a macrolide antibiotic with gastroprokinetic properties that induces antral contractions and increases lower esophageal sphincter tone at smaller doses (3 $mg.kg^{-1}$) than used for antibiotic treatment.[12] The dose of 3 $mg.kg^{-1}$ is the dose required to obtain significant effect on gastric emptying postprandially. Side effects are dose-dependent and include abdominal pain, nausea, vomiting, liver disorder and QT prolongation.[12] Its effects have been described in patients with gastroesophageal reflux, endoscopic procedures, diabetes mellitus induced gastroparesis and critical care medicine.[4-8] Only one study investigated its pro-kinetic effect versus that of pantoprazole in elective surgical patients and concluded that both erythromycin and pantoprazole decreased gastric fluid volume to a similar extent but the decrease in gastric fluid acidity by pantoprazole was significantly greater than that by erythromycin.[13] The hastened gastric emptying we observed 30 minutes after the administration of erythromycin is consistent with previous reports by Bouvet in emergency non-fasting trauma patients.[7] Since the peak plasma concentration of oral domperidone is reached after 30 minutes, a late effect of the

earlier administered domperidone seems unlikely although it cannot be excluded since the effect lasts for 4-7 hours.[11]

The authors do not advocate for the routine administration of erythromycin as a pro-kinetic agent, but this case suggests that it could be considered when other first-line therapies have been ineffective. Combining a peripherally acting prokinetic agent such as erythromycin with a centrally acting adjunctive agent like domperidone could be a clinically appropriate and a practical approach for accelerating upper gastrointestinal motility.[11]

In conclusion, this case report describes the use of gastric PoCUS to evaluate gastric content serially in an elective surgical patient with multiple co-morbidities who presented to elective surgery with a full stomach, and to monitor the effect of pro-kinetic agents.

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CHAPTER 10: Point-of-care gastric ultrasound and aspiration risk assessment. A narrative review.

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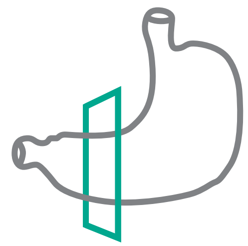

10.1. Abstract

This narrative review summarizes the current state of knowledge on Point-of-Care Ultrasound of gastric content with the purpose of informing aspiration risk assessment and guiding anesthetic management at the bedside. An I-AIM framework (Indication, Acquisition, Interpretation and Medical decision-making) is used to summarize and organize the content areas. This narrative review spans the breath of the literature on pediatric and adult subjects, and special patient populations such as obstetric and severely obese individuals. Areas that need to be further investigated include the diagnostic accuracy of gastric PoCUS from a Bayesian perspective, its impact on patient outcomes and health care economics and educational curricula.

10.2. Introduction:

The purpose of this narrative review article is to summarize the current state of knowledge on point-of-care gastric ultrasound. The manuscript targets the subject matter towards an international audience with the goal of raising interest in Point-of-Care Ultrasound (PoCUS) and providing a basic set of reference material that could be used to prepare oneself for a "hands on" training course.

10.3. Methods:

A broad literature search was performed on PubMed and Medline databases from inception to May 1st 2017, including the MeSH terms Stomach, Ultrasonography, Pneumonia, and Aspiration, and combined with AND. The abstracts were reviewed by two authors and selected by consensus according to relevance. The new information from the full-text articles was summarized and presented following an I-AIM framework (Indications, Acquisition, Interpretation and Medical decision-making).

10.4. Body of the Review

10.4.1. Rationale for use:

Pulmonary aspiration of gastric contents carries significant morbidity and mortality.[1-3] Aspiration is the leading cause of death from anesthesia airway events[4] and major morbidity (including pneumonitis, acute respiratory distress syndrome, multiple organ dysfunction and brain damage) is common among survivors.[5] Inaccurate risk assessment is often a root cause of aspiration events.[4] While a "full stomach" is a major risk factor for aspiration under anesthesia, the lack of an objective tool to assess gastric content at the bedside limits risk assessment and patient management is usually based on patient history alone. Although the risk of aspiration is highest in emergency situations, it can also rarely occur in patients who have followed fasting guidelines and are considered at low risk.[2] This baseline risk is in the order of 1:4,000.[2]

Gastric ultrasound is an emerging point-of-care tool that provides bedside information on gastric content and volume.[6-8] Similar to other more established PoCUS applications (such as cardiac or lung assessment) this diagnostic modality aims to answer a well-defined clinical question in a short period of time intended to guide patient management with the ultimate goal of improving patient outcome.[9] In the case of gastric ultrasound this is typically a dichotomous question. Does the patient have an "empty" or a "full" stomach? While the definition of a "full" stomach is controversial and my conceivably be open to interpretation, an acceptable working definition is one that describes any gastric content beyond what is normal for healthy fasted subjects (i.e. any solid or thick particulate content or clear fluid in excess of baseline gastric secretions of > 1.5 mL/Kg).[10,11] Gastric ultrasound has been studied in pregnant and non-pregnant adults, severely obese subjects, elective and non-elective situations and pediatric patients. Several recent editorials in major anesthesiology journals have called for greater adoption and teaching of gastric PoCUS in Anesthesia Practice.[12-14] Benhamou suggested that this skill should be part of the basic armamentarium of anesthesiologists for daily practice.[12] Mahmood et al. reported a PoCUS curriculum for anesthesiologists that includes gastric ultrasound along other more established applications such as lung and cardiac assessment.[13] Finally, Lucas et al have suggested the three most useful emerging ultrasound applications in obstetric anesthesia practice are a) ultrasound of the spine prior to neuraxial anesthesia, b) ultrasound for airway assessment and c) gastric ultrasound.[14]

All PoCUS applications are ultimately diagnostic tests. Although they are brief and focused, each needs to be studied from multiple angles. Not only their diagnostic validity needs to be determined (i.e.: do they evaluate what needs to be evaluated?) but also their reliability and diagnostic accuracy need to be established. Diagnostic accuracy refers to the global accuracy (the percentage of exams with a "correct diagnosis") as well as the sensitivity, specificity, positive and negative predictive values. Given the importance of correctly ruling out a full stomach for the prevention of aspiration, the negative predictive value of the test is arguably of outmost importance. Other aspects of relevance that need to be further studied are the clinical applicability, educational aspects and cost-effectiveness. As an emerging diagnostic tool, some, but not all of these aspects have been studied for gastric ultrasound thus far, and there is much room for development and change.

10.4.2. Clinical scenario

History of present illness: A 79 year old male presents for an internal fixation of a closed femoral shaft fracture that occurred 24 hours ago. The surgical procedure is relatively urgent but not immediately life-threatening. The timing of the last meal is unclear. While the patient's daughter states he has remained n.p.o, the patient insists he had a full lunch 3 hours ago.

Past medical history: The patient has hemodynamically significant severe aortic stenosis with a valve area of 0.8 cm^2 with recent episodes of exertional syncope. He has severe left ventricular hypertrophy with diastolic dysfunction but preserved systolic function. He also had an episode of transient ischemic attack (TIA) within the past year. He has mild carotid stenosis for which he is on antiplatelet therapy. His medications include metoprolol 25 mg twice daily, clopidogrel 75 mg daily and atorvastatin 20 mg daily and he received 5 mg of morphine intravenously 1 hour ago.

Physical examination: He is oriented to self, place and year but unsure of the month or exact day. He has a body mass index (BMI) of 38 Kg/m^2 and the upper airway looks normal. He is currently hemodynamically stable. An electrocardiogram shows signs of left ventricular hypertrophy but is otherwise unremarkable and routine blood work is within normal limits.

Anesthetic plan: The first decision is whether to proceed with semi-urgent surgery in a subject with questionable n.p.o status. The second decision pertains to the most appropriate anesthetic technique and it may impact the higher-order decision of whether to proceed. Given the contraindications for a neuraxial technique (severe aortic stenosis, and current antiplatelet therapy) a general anesthetic is planned. The clinical conflict here is between a) a "full stomach" that would dictate a rapid sequence induction of anesthesia but would pose a higher risk of hemodynamic instability and acute cardiac events and b) a slowly titrated induction of anesthesia which would be indicated for his severe aortic stenosis but possibly increase the risk of aspiration in the setting of a "full stomach".

10.4.3. The I-AIM framework

An I-AIM framework is a suitable paradigm for using and teaching gastric ultrasound. [15] When gastric content is unknown or uncertain based on clinical information (*Indication*), ultrasound images are acquired in a standardized manner (*Acquisition*). Once an adequate image is obtained it is interpreted based on qualitative and quantitative findings (*Interpretation*). This interpretation of the findings is then used to guide airway or anesthetic management (*Medical decision-making*). This framework succinctly describes the main conceptual steps for the clinical use of any point-of-care diagnostic ultrasound application and will be used in this review.[11]

10.4.4. Indication:

A gastric ultrasound exam is indicated to assess individual aspiration risk in the setting of unclear or undetermined n.p.o status. Similar to other tests with dichotomous results (yes or no, full or empty) and following a Bayesian diagnostic framework, gastric ultrasound is likely most useful when there is true clinical uncertainty, i.e., when the pre-test probability of having a full stomach is in the order of 50%.[11,16] Common such clinical scenarios include a) uncertain or contradictory information regarding n.p.o. status (e.g. due to language barrier or decreased level of consciousness), b) medical co-morbidities or physiologic conditions that may prolong gastric emptying despite adequate fasting (e.g. diabetic gastroparesis, achalasia, advanced renal or hepatic dysfunction, critical illness, multiple sclerosis, Parkinson's disease, substance abuse, recent trauma and labor).[10,17] Another interesting group of patients is those presenting for non-elective procedures who may not have had an opportunity to fast or may have delayed gastric emptying related to pain, sympathetic activation or recent opioid therapy. Bouvet et al. reported a prevalence of full stomach in 56% of emergency surgical patients and suggested that a preoperative ultrasound assessment of gastric content may be particularly useful in this setting.[17] The routine application of gastric PoCUS on patients with a low pre-test probability of a full stomach (i.e. fasted subjects for elective surgery) is somewhat controversial. The likelihood of an unexpected "full stomach" in these scenarios is very low [16,17] and the risk of aspiration rare (1:4,000). It is likely that in low-risk situations, the number-needed-to-test to change

anesthetic management and affect outcomes would be very high, and probably not cost-effective, although no clinical data is currently available to conclusively determine the optimal application of this diagnostic test.

10.4.5. Acquisition:

After adjusting the ambient light, the patient's upper abdomen is exposed and gel is used as an acoustic medium. The patient is scanned in the supine and the right lateral decubitus position (RLD) consecutively (Figure 10.1). In the latter position a larger proportion of the stomach's content flows towards the more dependent distal antrum and therefore scanning in the RLD increases the test's sensitivity.[6,8] When examination in the RLD is not possible (e.g. critically ill, trauma), a semi-recumbent position (head elevated 45 degrees) may be an acceptable "second best", with the supine position being the least sensitive and accurate patient position.[18-20]

In the adult patient, a curved array low-frequency abdominal probe (2-5MHz) with abdominal pre-sets is most suited to provide sufficient penetration to identify the relevant anatomical landmarks.[6-8] In pediatric patients under 40 kilograms a linear high-frequency transducer can be used.[21] The stomach is imaged in a sagittal plane in the epigastric area, immediately inferior to the xyphoid and superior to the umbilicus. The transducer is swept from the left to the right subcostal margin. Gentle sliding, rotation and tilting of the probe are used to locate the antrum and to optimize the image while avoiding oblique views from excessive probe rotation that could overestimate the antral size. The gastric antrum (the most distal portion of the organ) is particularly amenable to ultrasound examination given its superficial and consistent location in the epigastric area with a favorable soft tissue acoustic window through the left lobe of the liver.[6-8,10] Most importantly, an evaluation of the antrum provides accurate information about the content in the entire organ.[6-8,10] The gastric body usually has a greater air content that may interfere with the exam and the gastric fundus is of difficult ultrasound access.[6,10]

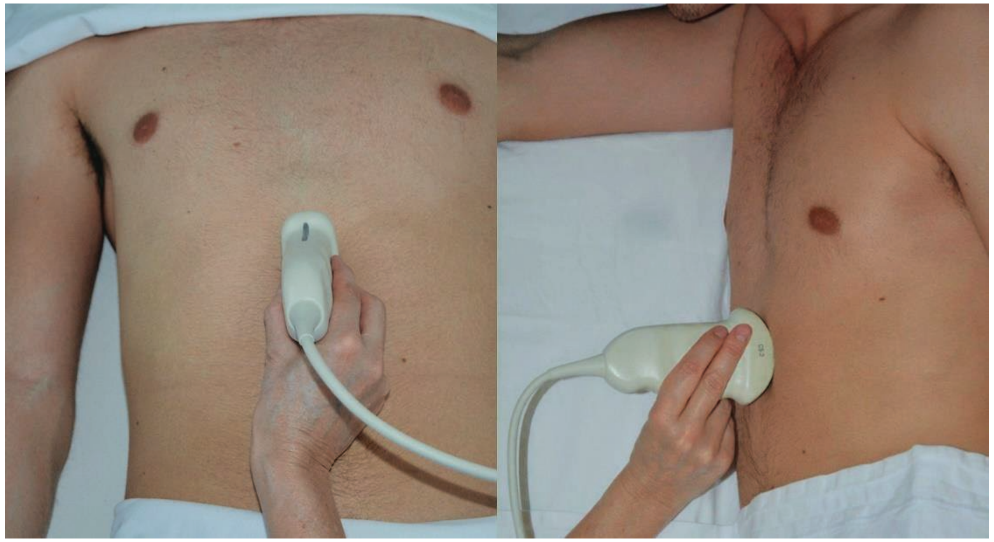

Figure 10.1: Scanning positions

The antrum appears as a superficial hollow viscus with a thick multilayered wall, immediately inferior to the left lobe of the liver and anterior to the body of the pancreas.[7] Both the inferior vena cava and the aorta lie posterior to the antrum and both can be identified in the course of the exam. However, for a quantitative evaluation of gastric fluid volume, a standardized plane at the level of the aorta is used.[8] Other vascular landmarks include the superior mesenteric artery or vein. The gastric wall is approximately 4-6 mm thick in the adult patient and has 5 distinct sonographic layers that are best visualized in the empty state with a high-frequency transducer. From inner to outer surface they are: a) mucosal-air interface, b) muscularis mucosa, c) submucosa, d) muscularis propria and e) serosa.[7] With a low-frequency transducer, only the muscularis propriae is consistently observed. This thick muscularis layer, along with the characteristic location of the antrum allows to distinguish the stomach from other portions of the gastrointestinal tract which have a thinner, less prominent smooth muscle layer.

10.4.6. Interpretation:

After identifying all relevant structures, the nature of the gastric content (empty, clear fluid, thick fluid/solid) may be established based on qualitative findings. When the stomach is empty, the antrum is either flat or round with juxtaposed anterior and posterior walls. When it is round or ovoid, its appearance has been compared with a "bull's eye" or "target" pattern (Figure 10.2). [6,7,10]

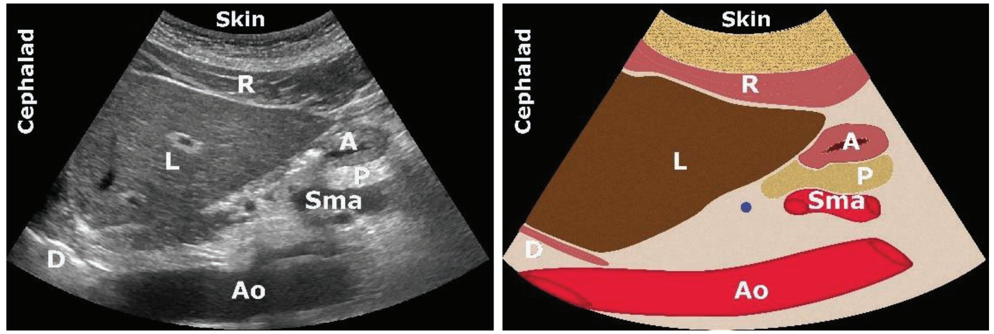

Figure 10.2: Empty antrum

Thick fluid, milk or suspensions have a hyperechoic, usually homogenous aspect. Following the ingestion of solid food, the air content mixed with the solid bolus during the chewing process forms a mucosal-air interface along the anterior wall of the distended antrum. This large area of "ring-down" air artefacts blurs the gastric content, the posterior wall of the antrum, the pancreas and the aorta and it is often referred to as a "frosted-glass" pattern (Figure 10.3).[7] After a variable time interval, this air is displaced and the antrum appears distended with a better appreciable content that is typically of mixed echogenicity (Figure 10.4).

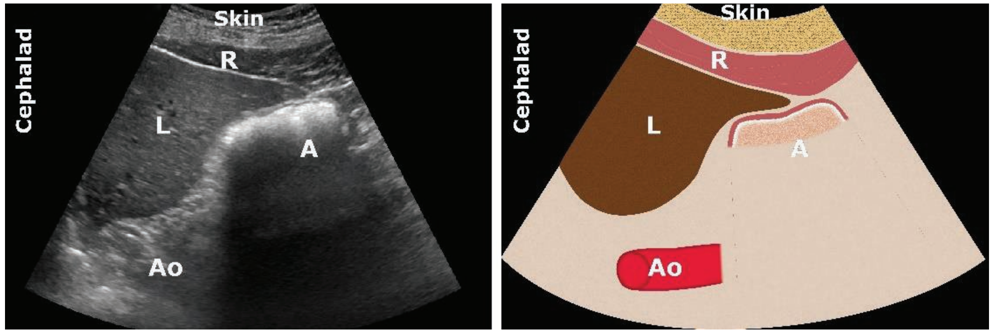

Figure 10.3: Solid food: early stage

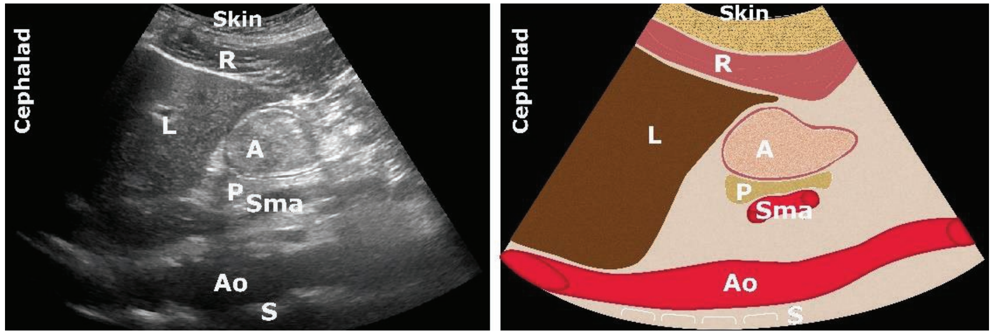

Figure 10.4: Solid food: late stage

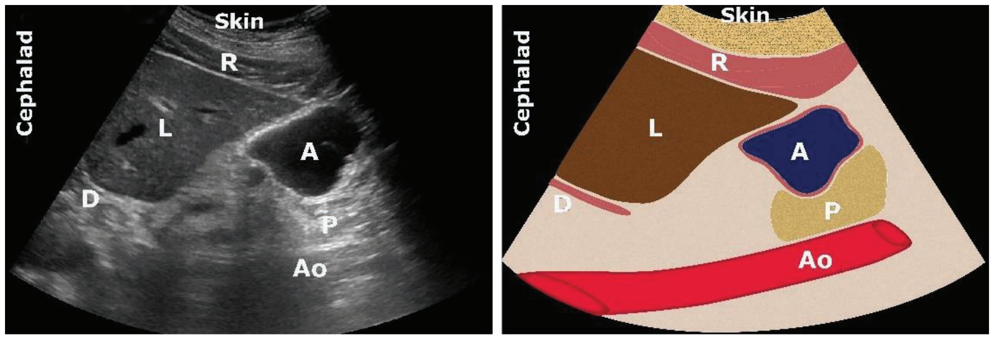

Figure 10.5: Clear fluid

A = antrum, Ao = aorta, D = diaphragm, L = liver, P = pancreas, R = rectus abdominis muscle, S = spine, Sma = superior mesenteric artery

Normal gastric secretions and clear fluids (e.g. water, tea, apple juice, black coffee) appear anechoic or hypoechoic. The antrum becomes round and distended with thin walls as the volumes increases (Figure 10.5). Gas bubbles can be appreciated as small punctuate echoes immediately after fluid intake but disappear rapidly within minutes of ingestion ("starry night" appearance, Figure 10.6).[7]

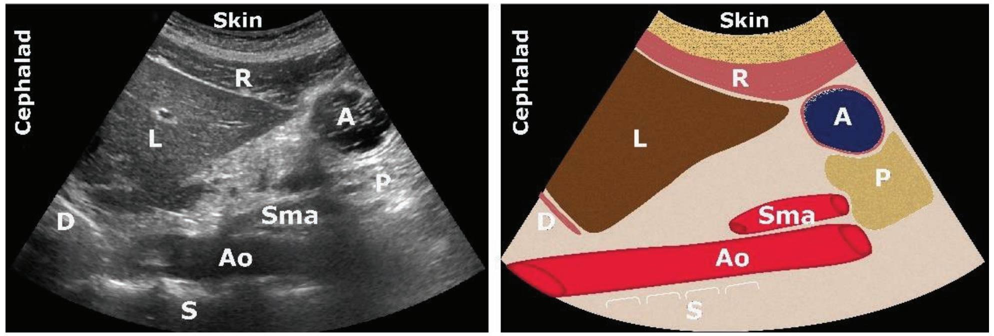

Figure 10.6: Starry night appearance

Healthy subjects that have fasted for elective surgery commonly present a completely empty antrum with no content visible in either supine or RLA position (Grade 0 antrum) or have a small, negligible volume of baseline secretions (typically ≤1.5 mL/Kg) that is usually only appreciated in the RLD (Grade 1 antrum) . [8,22] The upper limit of normal baseline gastric volume is still somewhat controversial. However, we know that the mean value is approximately 0.6mL/Kg and that volumes of up to 100-130 ml (about 1.5 mL/kg) are common in healthy fasted subjects and do not pose a significant aspiration risk.[23-25] Previously suggested thresholds of "risk" (0.4 mL/kg and 0.8 mL/kg)[26,27] were extrapolations from volumes of hydrochloric acid directly instilled into the tracheas of animals and are not supported by a plethora of human data that demonstrate that such volumes of gastric secretions are well within the normal range for healthy fasted individuals with low aspiration risk.

Conversely, a volume of clear fluid in excess of 1.5 mL/Kg or any amount of solid or particular content in the stomach suggests a non-fasting state (or a "full stomach") likely increasing the risk of aspiration. A grade 2 antrum (defined as clear fluid that is appreciable in both supine and RLD positions) is associated with grater fluid volumes, is uncommon in fasted healthy individuals and suggests a non-fasting state.[8,16,22]

Therefore, when the stomach contains clear fluid (homogeneous hypoechoic or anechoic), a volume assessment can help differentiate a negligible volume consistent with baseline secretions vs. a higher-than-baseline volume.[8,10,11]

It has been consistently shown that a single cross-sectional area (CSA) of the gastric antrum measured in a standardized manner correlates with the total gastric volume, and that this correlation is stronger in the RLD.[6,28-32] Several mathematical models have been reported that describe this numerical relationship.[6,8,29,33-37] One such model has been validated against endoscopically guided gastric suctioning for non-pregnant adults with a wide range of ages and weights and accurately predicts gastric volume up to 500 mL as follows (see figure 7.1, page 129):

Gastric Volume (mL) = 27.0 + 14.6 x Right-lat CSA – 1.28 x age[8]

This model has high intra-rater and inter-rater reliability.[38] For a volume evaluation, the antral area is obtained at the level of the aorta, with the antrum at rest (between peristaltic contractions), and measured using a free-tracing tool of the equipment following the serosa (or outer surface) of the antrum. Similar to other ultrasound measurements for other applications, it is recommended that a mean of three readings is used to minimize measurement error.

10.4.7. Medical decision-making:

Point-of-care gastric ultrasound is used to stratify individual aspiration risk and to tailor airway and anesthetic management in situations of clinical equipoise where prandial status is unclear.

An “empty” stomach (Grade 0 antrum) or a low volume of clear fluid within the range of baseline gastric secretions (Grade 1 antrum or ≤1.5mL/Kg) is consistent with a fasting state and suggests a low risk (see figure 3.6, page 60). In the absence of other risk factors, the ultrasound confirmation of an empty stomach would indicate that no special airway management precautions (intubation, rapid sequence induction) are required, and that supraglottic airway devices or deep sedation without airway

protection may be appropriate management choices. Conversely, solid content or a high volume of clear fluid that is not in keeping with a fasting state suggest a higher-than-baseline aspiration risk. These findings would indicate that the airway needs to be protected from aspiration with endotracheal intubation and possibly a rapid sequence induction of anesthesia.

The clinical context of each individual patient needs to be taken into consideration when making a medical decision.[11] Factors such as the patient’s history and physical exam, the type of procedure (elective or urgent), the nature of and the time interval since the last meal as well as other risk factors of aspiration need to be considered.[39] Ultrasound findings can help turn a 50% pre-test probability of a “full stomach” into a “likely full” or “likely empty” situation thus guiding anesthetic management accordingly. A growing body of evidence suggests that the addition of point-of-care gastric ultrasound to a patient’s history and physical exam can modify aspiration risk assessment and anesthetic management in a substantial proportion of cases when clinical data alone is uncertain.[16,17,40-42] A prospective study of 38 elective surgical patients who had not complied with fasting instructions reported a change in anesthetic management in 72% of the cases compared to that based on history alone and a trend towards a lower incidence of surgical delays.[40]

10.5. Morbidly obese patients

The incidence of obesity is growing globally. Obese subjects are usually considered to be at increased risk of aspiration and are therefore of particular interest. Although the greater depth of the antrum (around 7 cm), and the increased visceral adiposity can make the examination more challenging, gastric sonography is feasible in 95% of severely obese individuals .[43,44] The previously mentioned mathematical model for gastric volume assessment has been shown to be reasonably accurate in severely obese subjects (BMI > 40 Kg/m^2), with a trend towards an overestimation of the volume, particularly at low volume states (mean overestimation of 35 mL).[44] Overall, obese patients presented significantly larger baseline antral CSA and total gastric volumes than their non-obese counterparts.[43,44] However, the gastric volume per unit of body weight (0.57-0.7 mL/kg) and the relative distribution of antral grades were similar to those observed in non-obese subjects.[22,43,44]

10.6. Pediatric patients

A linear high-frequency transducer provides the best images through improved spatial resolution for children of less than 40 Kg while a low-frequency curvilinear transducer is recommended for best imaging in larger pediatric patients.[21] Similar to the adult population, most fasted children have either a Grade 0 or a Grade 1 antrum and the range of fasting gastric volume per unit of body weight is remarkably constant across all ages and body habitus, with an upper limit of normal in the range of 1.2-1.5 mL/Kg for pediatric patients.[21,30] A linear correlation between the antral cross-sectional area and the gastric volume was described in a study of 100 fasting children and this correlation was again stronger when measured in the RLD.[30] Point-of-care gastric ultrasound has been used to determine the most appropriate anesthetic technique for the management of hypertrophic pyloric stenosis.[45] In addition, a bedside gastric examination has been reported in children for a different diagnostic application: the detection and monitoring of ingested foreign bodies (batteries, hairclips, coin).[46-49] In this context it has been noted that the additional ingestion of water may aid in the positive identification of the foreign body as a hyperechoic structure within a hypoechoic background of clear fluid.[47]

10.7. Critically ill patients and emergency medicine

Two pilot studies have investigated the use of gastric PoCUS in critically ill patients.[19,20] A preliminary proof-of-concept study reported that novice examiners could identify the antrum in 65% of patients in the supine position following only 4 hours of training, and that antral CSA correlated well with tomographic volume assessment.[19] It has also been suggested that a cranio-caudal diameter may be a simple surrogate of CSA and residual gastric volume.[20]

Gastric ultrasound may be used for indications other than content and aspiration risk assessment. Confirmation of nasogastric tube placement in the stomach or duodenum has been reported either by direct imaging of the tip or indirect

confirmation through air instillation ("dynamic fogging") and it has also been used for the diagnosis of gastric outlet obstruction.[50,51]

10.8. Obstetric patients

Pulmonary aspiration remains one of the most feared complications in obstetric anesthesia.[52] Regardless of the anesthetic technique planned, an empty stomach is highly desirable prior to anesthetic induction. Gastric emptying in healthy non-laboring pregnant women is similar to that of non-pregnant patients, but it is significantly prolonged once labor begins, and appears to return to normal only many hours after delivery.[53,54] There are several clinical situations in obstetric anesthesia where knowing the status of the gastric content may be critical for clinical management.[11] Therefore, real-time ultrasound assessment may allow an opportunity to improve patient safety.[55] Although the general principles and anatomical landmarks of the ultrasound examination of pregnant women are similar to those of non-pregnant subjects, some technical details may differ. Identification of the gastric antrum can be more difficult in pregnant patients due to the gravid uterus and the moving fetus. The stomach is displaced more cephalad and to the right compared with non-pregnant subjects and dynamic characteristics such as a fast-shallow breathing and hyperdynamic circulation may pose additional challenges to the exam.[31,32,56] Finally, the presence of the gravid uterus will determine a slightly steeper angle between xyphoid and abdomen which may make probe placement more difficult.[31,32]

The nature of gastric contents for a qualitative ultrasound assessment was first evaluated by Carp et al. rendering promising but less than optimal results in 1992, when only a markedly distended stomach was appreciable and an empty stomach could not be consistently identified.[54] Recent advances in ultrasound imaging such as multi-beam technology and improved engineering now allow a much higher special resolution. Arzola et al. showed substantial agreement and reliable diagnosis when evaluating various gastric contents after a conventional fasting period of solids and clear fluids in the third trimester of pregnancy.[31] Although Barboni et al. suggested an initial slower gastric emptying of solid contents after a standardized meal in patients scheduled for elective cesarean deliveries, no ultrasound examination was carried out beyond 6 hours. [56] Nevertheless, no solid gastric contents were found in two cohort studies in term pregnant women before elective cesarean delivery after following current fasting guidelines (6-8 hours for solids and 2 hours for clear fluids) which suggests these guidelines are equally effective to ensure an empty stomach as in the non-pregnant population.[32,57] Clear fluids were initially assessed by Wong et. al in obese and non-obese pregnant women confirming normal gastric emptying during pregnancy. [58,59] Volume estimation based on a cross-sectional area of the gastric antrum has been the focus of multiple recent investigations. Several mathematical models have been described in various examining positions and different clinical scenarios.[60-63] Based on these models, there is currently a search for cut-off values of antral CSA to discriminate different levels of risk.[60-63] While a cut-off value has been reported to discriminate a completely empty stomach (grade 0 antrum) from one with low fluid volume (Grade 1 antrum), this type of threshold is of limited clinical applicability as both Grade 0 and Grade 1 antrums are common in fasted individuals and carry no significant risk. A more clinically relevant "cut-off" value of CSA would be one that differentiates a baseline volume state (Grade 0 or 1 antrum or $\leq$1.5 mL/Kg) from a greater-than-baseline condition (Grade 2 antrum or > 1.5 mL/Kg). Although Bataille et al.[60] and Jay et al.[61] reported antral size during labor, patients were not allowed to take any oral intake which deviates from most current recommendations in obstetric practice.[60] The report by Zieleskiewicz et al., on the other hand, was based on women during established labor under effective epidural analgesia which were allowed to drink water at their convenience.[62] A mathematical model to estimate gastric volume in pregnant women in the third trimester was proposed by Arzola et al.[63] Although the ingested volume of fluid rather than suction under gastroscopic examination was used as the reference standard, the resulting model very closely resembles the previous predictive model described by Perlas et al. in adult non-pregnant subjects.[8] Based on these data, an antral cross-sectional area of 9.6 cm^2 in the semi-recumbent right lateral position can discriminate a low from a high gastric volume (>1.5 $ml.kg^{-1}$).[63] This value of antral CSA could be a simple surrogate measure that could facilitate the interpretation of the examination findings when clear fluid is observed in the antrum.

Further research is warranted to develop decision-making strategies based on peri-partum gastric ultrasound assessment.

10.9. Limitations and areas of further research

It is important to consider both the technical limitations of this diagnostic test as well as the conceptual framework within which it is used. From a technical stand-point, gastric ultrasound has been validated in patients with normal gastric anatomy and may therefore not be reliable or accurate in subjects with previous gastric surgery (e.g. partial gastrectomy, gastric by-pass) or large hiatus hernias. Information on the nature of gastric content (clear fluid, solid) could still be useful in these settings but volume estimation in particular will likely be inaccurate in these subjects.

Regarding the conceptual framework for the use of point-of-care gastric ultrasound, it is first important to consider that this test evaluates only one of the determinants of aspiration risk: gastric content, nothing more and nothing less. The risk of clinically important aspiration is partly determined by the presence of gastric content at the time of anesthetic induction but it is also influenced by other independent factors such as a) co-existing diseases of the upper gastrointestinal tract (e.g. achalasia and gastro-esophageal reflux disease), b) the anesthetic technique and c) the events related to airway management (e.g.: unexpected difficult intubation requiring prolonged manual ventilation). So, point-of-care gastric ultrasound evaluates an important, but not the only, determinant of risk.

A second significant issue is that like any ultrasound examination (and any diagnostic test for that matter) gastric PoCUS is not infallible. In fact, up to 3-5% of all exams may be inconclusive and the diagnostic accuracy of gastric ultrasound to detect a full stomach (i.e. the sensitivity, specificity and positive and negative predictive values of gastric PoCUS) remains to be studied. [6,8,43]

Although both the positive and negative predictive values are important attributes of a test, given the implications of a correct "empty" stomach diagnosis for aspiration prevention, the negative predictive value of gastric PoCUS is arguably of outmost importance. Furthermore, the diagnostic accuracy of the test will be related to the experience of the sonographer. It has been established that approximately 33 practice examinations followed by expert feedback are needed on average for anesthesia fellows learning to perform gastric ultrasound to obtain an accurate diagnosis in 95% of cases, but the optimal way to learn and teach this skill has yet to be established.[64] Gastric content is dynamic and changes quickly over time. Therefore gastric PoCUS gives information that may only be accurate at the time of the test. For example, a stomach that is found to be "full" prior to induction of anesthesia may not be so at the end of a surgical procedure and vice versa. So, the test may be repeated as dictated by the clinical situation. Along those lines, ensuring an empty stomach prior to extubation in questionable cases (e.g. difficult airway; critically ill subjects) may be an appropriate additional indication.

An third important limitation is the difficulty to conclusively prove that the introduction of this test will lead to a reduction in episodes of clinically important aspiration and tangible improvements in patient outcomes. A randomized controlled trial of patients with unclear prandial status with enough power to answer this question would need be very large and logistically difficult to accomplish. This limitation is shared by other PoCUS applications and many current clinical recommendations are based on observational data. For example, the addition of lung ultrasound to a FAST protocol for evaluation or trauma victims is based on the fact that bedside ultrasound is more sensitive than chest X-ray to diagnose pneumothorax, but there is no clinical evidence that it improves survival or other important patient outcomes. Similarly, the American Heart Association currently recommends that bedside ultrasound may be considered during resuscitation to identify potentially reversible causes of cardiac arrest despite inadequate evidence to evaluate whether there is any survival benefit of cardiac ultrasound during ACLS. Furthermore, although the performance of a diagnostic test is not a therapeutic intervention itself, every diagnostic test is destined to potentially lead to clinical interventions that may themselves be beneficial or harmful. So far, we have scant evidence of the effect of gastric ultrasound on important clinical outcomes. The assertion that gastric ultrasound is beneficial in the management of perioperative patients is currently a hypothesis that needs to be tested with properly designed clinical studies examining clinical outcomes rather than just surrogate outcomes.

Given the above limitations and knowledge gaps, further research needs to define the diagnostic accuracy of gastric PoCUS from a Bayesian perspective, including determination of sensitivity, specificity and positive and negative predictive values as well as cost-effectiveness considerations. The above information will help define the clinical role of this test, including the determination of appropriate indications which is particularly relevant within the current "Choosing Wisely Canada" initiative.

10.10. Back to the clinical scenario:

In our case scenario an "empty" test result (no content at all or ≤ 1.5 mL/Kg of clear fluid) would be compatible with a fasting state. It would suggest the ingestion did not in fact occur and the "memory" of it may be related to confusion or delirium, highly prevalent in this clinical context. This negative result would suggest the risk of aspiration is low, and it may be safe to proceed with surgery with a slowly titrated induction of anesthesia as dictated by the patient's cardiac condition. Conversely, the documentation of solid or particulate content or a grossly distended stomach with >1.5 mL/Kg of clear fluid would suggest that the ingestion did likely take place, that the stomach has not fully emptied yet and that the risk of aspiration is higher than baseline. This finding would support postponing the surgery until either a) a recommended fasting interval has been achieved or b) the stomach is confirmed to have emptied on a repeat examination.

10.11. Conclusions:

Gastric PoCUS is an emerging application of sonography increasingly used in anesthesia education and practice. Its validity and reliability have been evaluated for a variety of patient populations including pregnant and non-pregnant adults, severely obese and pediatric patients. It is likely most useful to define risk and guide patient management when prandial status is uncertain or unknown. Further research is warranted to establish its diagnostic accuracy from a Bayesian perspective, determine the impact of this test on patient outcomes and on health care economics and establish how to best incorporate this new skill into existing educational curricula.[64-66]

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CHAPTER 11: Summary and conclusions

The present thesis sought to investigate and review the use of gastric Point-of-Care Ultrasound (PoCUS) as a perioperative tool to assess patient aspiration risk; to offer a framework for its implementation in daily clinical practice; to assess its feasibility in morbidly obese patients; to investigate the presence of a full stomach in healthy fasted patients for elective surgery; to investigate its influence on history-based aspiration risk assessment and management in patients who have been non-compliant to the fasting guidelines; to discuss what are gastric fluid threshold volumes that differentiate a normal from a risky stomach; to evaluate and to compare baseline gastric fluid volumes of term non-labouring pregnant and non-pregnant women; to illustrate its application in daily practice with two case reports.

Chapter 1

Aspiration of gastric contents is a rare but potentially devastating perioperative complication. This chapter offers a general introduction on its incidence, the conditions that must be fulfilled for it to occur and possible predisposing factors. Point-of-care gastric ultrasonography (gastric PoCUS) is a new way that allows the clinician to assess aspiration risk at the bedside.

Chapter 2

A systematic review of the scientific literature on gastric ultrasonography at the start of the PhD project anno 2013 shows that gastric PoCUS can determine the qualitative nature of gastric contents (empty, clear fluids or thick fluid/solid). It additionally allows to quantitatively estimate total gastric fluid volumes via a validated mathematical model. A semi-quantitative 3-point grading system has been reported as a simpler screening tool to differentiate low from high volume states. A possible algorithm for the clinical application is proposed.

Chapter 3

As every ultrasound exam, gastric PoCUS is operator dependent. The use of standardized protocols ensures consistency of the examination, correct image acquisition and accurate diagnosis. We therefore suggest an educational and clinical practice model for the implementation of gastric PoCUS and propose a stepwise framework based on the I-AIM model (Indication; Acquisition; Interpretation; Medical management). We additionally present a sample report template for standardized written communication of ultrasound findings and a refined version of the originally in chapter two presented clinical algorithm.

Chapter 4

Early studies on gastric PoCUS have focused on subjects with a normal to mildly obese body habitus and its feasibility in obese patients has not been documented systematically. We therefore studied the feasibility of gastric PoCUS in sixty fasted surgical patients with BMI > 35 kg/m². A full cross-section of the gastric antrum was identified in 95% of subjects in the right lateral decubitus and 90% of subjects in the supine position. The proportion of patients in which it was possible to use a 3-point grading scale (0-2) was 88.3%. We therefore concluded that gastric PoCUS was feasible in fasted severely obese subjects. The antral grade correlated with antral cross-sectional area and gastric volumes. Our results suggested, when compared to historical data, that severely obese patients have a larger baseline cross-sectional area and gastric volume than non-obese patients but a similar gastric volume per unit of weight.

Chapter 5

Preoperative fasting guidelines aim to limit the risk of aspiration but apply to healthy patients for elective surgery only. However, even in healthy individuals, standard fasting periods may not be sufficient to ensure an empty stomach in all patients and aspiration may complicate apparently low risk cases. This retrospective cohort study in a population of 538 fasted patients presenting for elective surgery, evaluated with gastric PoCUS the incidence of "full" stomach, defined by the presence of solid food or gastric fluid volume greater than 1.5 mL/kg. A small proportion of the study subjects (6.2%) presented a full stomach. Although the presence of patients with larger than commonly quoted fluid volumes (4.5%) was not new, the finding of nine patients (1.7%) presenting solid gastric content was unexpected and could only in 3 patients be explained by the presence of underlying risk factors. Since the value of the study was more on the descriptive than on the decision side, its findings and clinical significance must be interpreted with caution.

Chapter 6

It is common for anesthesiologists to encounter patients in the immediate preoperative period with dubious adherence to the fasting instructions. This results in changes to the planned anesthetic management and often surgical interventions are delayed or cancelled. This retrospective cohort study in 37 elective surgical patients who had not followed the guidelines, found that the initial standard history-based aspiration risk assessment and management plan was changed in almost 65% of patients, following gastric PoCUS. These management changes went in both directions, more liberal and more conservative. We concluded that the use of gastric PoCUS is a useful diagnostic addition to standard patient assessment in cases of non-compliance. It allows to personalize aspiration risk assessment and to guide anesthetic management.

Chapter 7

For aspiration to occur there needs to be sufficient volume in the stomach to be regurgitated. It seems reasonable to assume that the threshold for gastric volume that carries an increased risk of aspiration has to be higher than the volumes commonly seen in healthy fasted patients. However, the minimum volume of gastric contents that increases this risk is not currently known. This editorial discusses our current knowledge of animal and human data on gastric fluid volumes and describes the two different schools when it comes to interpret the results of gastric PoCUS. It addresses the discussion around what constitutes normal insignificant gastric volumes and what should be considered a volume of risk.

Chapter 8

Recent data suggest that the aspiration risk in term pregnant non-labouring women is low but many institutions still consider all term women as having a full stomach. However, the evidence is weak, comes from uncontrolled studies or studies with a mixed control cohort. We conducted this prospective study in 59 fasted term non-labouring pregnant patients scheduled for elective caesarean delivery and investigated antral CSA and volumes with gastric PoCUS and compared the data to data in non-pregnant women. Our results suggest that the upper limits of normal (95^{th} percentile) of antral CSA and volume did not differ between the pregnant and non-pregnant cohort.

Chapter 9

The application of gastric PoCUS in daily practice is illustrated in two case reports. *Chapter 9.1* describes how a rapid sequence intubation was avoided in a hemodynamically instable patient with a known history of very difficult intubation and unsure fasting status. *Chapter 9.2* illustrates the use of serial gastric PoCUS to evaluate the effect of pro-kinetic therapy with domperidone and erythromycin in an elective surgical patient with multiple co-morbidities who presents with a full stomach. The clinical cases presented, show that gastric PoCUS allows us to guide and to tailor individual anesthetic management.

Chapter 10

A systematic review of the scientific literature on gastric ultrasonography at the end of the PhD project anno 2017 shows there had been a substantial amount of publications on gastric PoCUS between 2013 and 2017. We describe and illustrate in detail the I-AIM framework (see Chapter 3), the use of gastric PoCUS in morbidly obese, paediatric, obstetric, critically ill and emergency medicine patients. We additionally discuss limitations and areas that need further research. Gastric ultrasound evaluates an important but not the only determinant of aspiration risk and additionally it is not infallible. It will remain difficult to prove that the introduction of this test will lead to a reduction in episodes of clinically important aspiration and tangible improvements in patient outcomes.

General conclusion

Point-of-Care gastric ultrasound is an emerging application of sonography that is increasingly used as an aspiration-risk assessment tool in anesthesia education and practice. Its validity and reliability have been evaluated for a variety of patient populations including severely obese, paediatric and pregnant and non-pregnant adults. It is most useful to define aspiration risk and to guide patient management when prandial status is uncertain or unknown. Further research is warranted to establish its diagnostic accuracy from a Bayesian perspective, to determine its impact on patient outcomes and on health care economics and to establish how to best incorporate this new skill into existing educational curricula. The current scientific knowledge and future research will help define the clinical role of this tool but we are confident it will become state of art and standard practice.

CHAPTER 12: Samenvatting en conclusies

Deze thesis onderzoekt en geeft een systematisch overzicht van het gebruik van Point-of-Care echografie van de maag (gastric PoCUS) als middel om het aspiratierisico van de patiënt in de perioperatieve periode in te schatten; ze biedt een framework aan voor de implementatie van gastric PoCUS in de klinische praktijk; onderzoekt de haalbaarheid van gastric PoCUS in morbied obese patiënten; onderzoekt de incidentie van een “volle maag” in electieve nuchtere chirurgische patiënten; bestudeert de invloed van gastric PoCUS op de inschatting van het aspiratierisico en op het anesthesiebeleid in patiënten die de richtlijnen omtrent het nuchterbeleid niet gevolgd hebben; bespreekt welke drempelwaarden van het maagvolume een normale van een “risicomaag” onderscheiden; onderzoekt en vergelijkt met gastric PoCUS maagvolumes tussen hoogzwangere (niet in arbeid) en niet-zwangere vrouwen; illustreert de toepassing in de dagelijkse praktijk met twee casussen.

Hoofdstuk 1

Aspiratie van maaginhoud is een zeldzame maar potentieel zeer ernstige perioperatieve verwikkeling. Dit hoofdstuk geeft een algemene inleiding op de incidentie van aspiratie, de voorwaarden onder dewelke het gebeurt en voorbeschikkende factoren. Point-of-care echografie van de maag is een nieuw hulpmiddel dat de arts toelaat om het aspiratierisico aan het bed van de patiënt in te schatten.

Hoofdstuk 2

Een systematisch overzicht en onderzoek van de wetenschappelijke literatuur bij de start van dit PhD project anno 2013 toont aan dat gastric PoCUS de kwalitatieve aard van maaginhoud kan bepalen (leeg, helder vocht of dik vocht/vast voedsel). Bovendien laat het toe om kwantitatief het totale volume maagvocht in te schatten met behulp van een gevalideerd mathematisch model. Er bestaat een makkelijker screeningsmiddel (het semi-kwantitatief 3-punt Perlas graderingssysteem) om lage van hoge volumetoestanden te onderscheiden. Tevens stellen we een mogelijk algoritme voor de klinische toepassing voor.

Hoofdstuk 3

Gastric PoCUS is zoals elk echografisch onderzoek uitvoerder-afhankelijk. Het gebruik van gestandaardiseerde protocollen garandeert consistentie van het onderzoek, het correct verkrijgen van de beelden en een juiste diagnose. Daarom stellen we een educatief en klinisch praktijkmodel voor om gastric PoCUS te implementeren en introduceren een stapsgewijs kader dat gebaseerd is op het I-AIM model (Indication; Acquisition; Interpretation; Medical management). Bovendien presenteren we een sjabloon om schriftelijke rapportering van de onderzoeksresultaten gestandaardiseerd weer te geven en een nieuwere versie van het klinisch algoritme dat origineel in hoofdstuk 2 voorgesteld werd.

Hoofdstuk 4

De eerste studies over gastric PoCUS onderzochten vooral personen met een normale lichaamsbouw. De haalbaarheid (feasibility) van de techniek in obese patiënten werd nog niet systematisch onderzocht. We onderzochten daarom de haalbaarheid van gastric PoCUS in zestig nuchtere chirurgische patiënten met een BMI (body mass index) >35 kg/m². In 95% van de gevallen kon, met de patiënt in rechter zijlig een volledige dwarsdoorsnede van het antrum van de maag gevisualiseerd worden en in 90% van de personen in ruglig. In 88.3% was het mogelijk een 3-punt graderingsschaal (0-2) (Perlas grading score) te gebruiken. We besloten daarom dat gastric PoCUS uitvoerbaar was in nuchtere ernstig obese subjecten. De antrale graad correleerde met de oppervlakte van de dwarse doorsnede van het antrum (CSA, cross-sectional area) en de maagvolumes. Onze resultaten suggereerden na vergelijking met historische data, dat ernstig obese patiënten in vergelijking met niet-obese patiënten statistische significant hogere grondwaarden hebben voor wat betreft antrale CSA en maagvolumes maar dat er geen statistisch significant verschil is tussen beide groepen als we kijken naar maagvolumes per eenheid van gewicht (mL/kg).

Hoofdstuk 5

De preoperatieve richtlijnen “nuchterbeleid” hebben tot doel het risico op aspiratie te beperken maar zijn enkel van toepassing voor gezonde patiënten die voor electieve heelkunde gepland zijn. Maar zelfs in gezonde personen zijn standaard periodes van niet eten en drinken onvoldoende om een lege maag te garanderen in alle patiënten. Aspiratie kan zelfs casussen met een ogenschijnlijk laag risico verwikkelen. Deze retrospectieve studie in een populatie van 538 nuchtere patiënten die gepland stonden voor electieve heelkunde, onderzoekt met gastric PoCUS de incidentie van een “volle” maag waarbij “vol” gedefinieerd is als de aanwezigheid van vast voedsel of van meer dan 1.5 mL/kg maagvocht. Bij een klein deel van de patiënten werd een volle maag aangetroffen (6.2%). Alhoewel de aanwezigheid van patiënten met grotere maagvolumes dan die meestal gezien worden (4.5%) niet nieuw is, was de vondst van negen patiënten (1.7%) met vast voedsel in de maag eerder onverwacht. Dit kon slechts in drie gevallen verklaard worden door de aanwezigheid van onderliggende risicofactoren. Vermits de studie eerder beschrijvend dan concluderend was, moeten de bevindingen en het klinisch belang met voorzichtigheid geïnterpreteerd worden.

Hoofdstuk 6

Anesthesisten worden tijdens de perioperatieve periode regelmatig geconfronteerd met patiënten waar het twijfelachtig is of ze de nuchterheidsregels gevolgd hebben. Dit leidt tot veranderingen van het anesthesiebeleid en vaak worden heelkundige ingrepen uitgesteld of geannuleerd. Deze retrospectieve cohortstudie in 37 patiënten voor electieve heelkunde die de nuchterheidsregels niet gevolgd hadden, concludeert dat het oorspronkelijke aspiratierisico en anesthesiebeleid dat gebaseerd is op een standaard anamnese, in bijna 65% van de patiënten verandert na point-of-care echografie van de maag. Deze beleidsveranderingen gaan in twee richtingen, meer liberaal en meer conservatief. We besloten dat het gebruik van gastric PoCUS in gevallen van het niet opvolgen van de richtlijnen een nuttige diagnostische toevoeging is aan de standaard anamnestische inschatting van het aspiratierisico en dat het toelaat om dit risico te personaliseren en het anesthesiebeleid stuurt.

Hoofdstuk 7

Opdat aspiratie zou voorvallen, moet er voldoende vocht in de maag zijn dat kan uitgebraakt worden. Het lijkt redelijk om aan te nemen dat de drempel van de hoeveelheid maagvocht die het aspiratierisico verhoogt hoger is dan de volumes die men meestal aantreft in gezonde nuchtere patiënten. Het minimale volume dat dit risico echter verhoogt, is momenteel niet gekend. Dit artikel (editorial) bespreekt onze huidige kennis van dierlijke en menselijke gegevens over maagvocht volumes en beschrijft de twee verschillende scholen als we het over interpretatie van de resultaten van maagechografie hebben. Het beschrijft en bespreekt welke hoeveelheid maagvocht als drempelwaarde kan dienen om het onderscheid te maken tussen een laag en hoog aspiratierisico.

Hoofdstuk 8

Recente data suggereren dat het aspiratierisico in hoogzwangere vrouwen die niet in arbeid zijn laag is maar vele instellingen beschouwen alle zwangere vrouwen als niet-nuchter (volle maag). Het bewijs is echter zwak, komt van ongecontroleerde studies of van studies die een gemengd controle cohort hebben. We voerden deze prospectieve studie uit in 59 nuchtere hoogzwangere vrouwen die niet in arbeid waren en die voor een keizersnede gepland stonden. We onderzochten met echografie van de maag antrale CSA en volumes en vergeleken de data met deze van niet-zwangere vrouwen. Onze resultaten suggereren dat de bovenste normaal-limieten (95ste percentiel) van antrale CSA en volumes niet verschilden tussen de zwangere en niet zwangere patiënten.

Hoofdstuk 9

De toepassing van gastric PoCUS in de dagdagelijkse praktijk wordt toegelicht aan de hand van twee casussen. De eerste casus beschrijft hoe een rapid sequence intubatie vermeden werd in een hemodynamisch onstabiele patiënt met een gekende voorgeschiedenis van zeer moeilijke intubatie en een onzekere

nuchterheidsstatus. De tweede casus illustreert het gebruik van seriële maagechografie om het effect van pro-kinetische behandeling (domperidone en erythromycine) te beoordelen in een niet-nuchtere heelkundige patiënt met epilepsie en diabetes én een volle maag. Deze klinische gevallen tonen dat gastric PoCUS ons toelaat om het anesthesiebeleid te sturen en op maat te maken.

Hoofdstuk 10

Een systematisch overzicht van de wetenschappelijke literatuur over gastric PoCUS aan het einde van dit PhD project anno 2018 toont dat er de laatste 5 jaar een substantiële hoeveelheid publicaties geweest is over dit onderwerp. We beschrijven en illustreren in detail het I-AIM kader (zie Hoofdstuk 3), het gebruik van maag PoCUS in morbied obese, pediatrische, obstetrische, kritisch zieke en spoedgevallen patiënten. Bovendien bespreken we beperkingen en onderwerpen die verder onderzoek behoeven. Echografie van de maag onderzoekt een belangrijke maar niet de enige determinant van aspiratierisico en is ook niet onfeilbaar. Het zal bovendien moeilijk blijven om te bewijzen dat de invoering van deze test tot een vermindering van klinisch belangrijke aspiratie en duidelijke verbeteringen in patiënten uitkomst zal leiden.

Conclusie

Point-of-Care echografie van de maag is een opkomende echografische toepassing die in toenemende mate binnen de anesthesiepraktijk toegepast wordt als middel om het aspiratierisico in te schatten. De waarde en betrouwbaarheid van de techniek werden voor een grote variëteit van patiëntengroepen zoals de morbied obese, de pediatrische, zwangere en niet-zwangere volwassenen onderzocht. Het is vooral nuttig om het aspiratierisico in te schatten en om het patiëntenbeleid te sturen als de mate van nuchterheid twijfelachtig of ongekend is. Verder onderzoek is aangewezen om de diagnostische accuraatheid te bepalen vanuit een Bayesiaans perspectief, om de invloed op “patient outcome” en op gezondheidskosten te bepalen en om uit te dokteren hoe dit nieuwe onderzoeksmiddel best in bestaande curricula te incorporeren. De huidige wetenschappelijke kennis en toekomstig onderzoek zullen helpen om de klinische rol van dit hulpmiddel te definiëren maar we zijn overtuigd dat het standaardpraktijk zal worden.

CHAPTER 13: Acknowledgements and curriculum vitae

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Curriculum vitae

Peter Van de Putte was born on January 29, 1966 in Bonheiden, Belgium. After completing his secondary school at the Sint-Romboutscollege in Mechelen in 1984, he studied medicine at the Catholic University of Leuven, Belgium where he obtained his degree in 1991. He received his specialty qualification in anaesthesiology in 1996. He was appointed a staff member of the department of Anesthesiology at the hospital AZ Monica, campus Deurne, Antwerp. He has been clinical director of the operating theatre and the one-day clinic and is responsible for the resident's training program. He will move to his new hospital, AZ Imelda, Bonheiden at the end of the summer. US-guided loco-regional anesthesia has always been his prime interest and especially continuous peripheral nerve blocks. Most of his current research involves point-of-care gastric ultrasound (gastric PoCUS) and its development as an application for assessment of aspiration risk in perioperative patients. He has given many lectures and workshops and published extensively on the topic. In collaboration with Prof. Dr A. Perlas, UHN, Toronto, Canada, he developed an educational website on the topic: *www.gastricultrasound.org*. He acted as a reviewer for the following journals: British Journal of Anaesthesiology, European Journal of Anesthesiology, Pain Medicine, Anaesthesia, International Journal of Obstetric Anaesthesia, Acta Anesthesiologica Belgica, Journal of Clinical Anaesthesia.

He is married to Kathy Bullaert and together they have a daughter Sara and a son Wouter.

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