## **Original Article**

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# Pre-operative gastric ultrasound in patients at risk of pulmonary aspiration: a prospective observational cohort study

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#### Summary

Point-of-care gastric sonography offers an objective approach to assessing individual pulmonary aspiration risk before induction of general anaesthesia. We aimed to evaluate the potential impact of routine pre-operative gastric ultrasound on peri-operative management in a cohort of adult patients undergoing elective or emergency surgery at a single centre. According to pre-operative gastric ultrasound results, patients were classified as low risk (empty, gastric fluid volume  $\leq 1.5$  ml.kg<sup>-1</sup> body weight) or high risk (solid, mixed or gastric fluid volume > 1.5 ml.kg<sup>-1</sup> body weight) of aspiration. After sonography, examiners were asked to indicate changes in aspiration risk management (none; more conservative; more liberal) to their pre-defined anaesthetic plan and to adapt it if patient safety was at risk. We included 2003 patients, 1246 (62%) of which underwent elective and 757 (38%) emergency surgery. Among patients who underwent elective surgery, 1046/1246 (84%) had a low-risk and 178/1246 (14%) a high-risk stomach, with this being 587/757 (78%) vs. 158/757 (21%) among patients undergoing emergency surgery, respectively. Routine pre-operative gastric sonography enabled changes in anaesthetic management in 379/2003 (19%) of patients, with these being a more liberal approach in 303/2003 (15%). In patients undergoing elective surgery, pre-operative gastric sonography would have allowed a more liberal approach in 170/1246 (14%) and made a more conservative approach indicated in 52/ 1246 (4%), whereas in patients undergoing emergency surgery, 133/757 (18%) would have been managed more liberally and 24/757 (3%) more conservatively. We showed that pre-operative gastric ultrasound helps to identify high- and low-risk situations in patients at risk of aspiration and adds useful information to perioperative management. Our data suggest that routine use of pre-operative gastric ultrasound may improve individualised care and potentially impact patient safety.

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#### Introduction

Despite its incidence ranging from 0.01% up to 0.8% [1-4], pulmonary aspiration is associated with significant morbidity and mortality [1] and accounts for a substantial proportion of legal claims [2], major airway complications and, ultimately, anaesthesia-related deaths [5]. Strategies to reduce the risk of pulmonary aspiration have, therefore, been developed and are continually adapted. Many of these have significant limitations. For example, thorough patient history and clinical examination may reveal obvious risk factors such as gastrointestinal obstruction [2], and clinical grading of various other conditions and procedures associated with an increased risk remains a challenge [6]. Furthermore, rapid sequence induction of anaesthesia as standard practice for emergency surgery in non-fasted patients or those at increased risk of aspiration carries the risk of haemodynamic instability and rapid desaturation where tracheal intubation and rescue mask ventilation fail [7, 8], and there is no convincing evidence that it reduces the incidence of pulmonary aspiration [9]. Finally, defined minimal durations of pre-operative fasting are considered standard practice for patients undergoing elective surgery [10, 11], even though prolonged fasting can lead to negative psychological, physiological and metabolic responses to surgery [11, 12]. Therefore, further tools to assess individual aspiration risk are urgently needed to provide personalised care.

Gastric point-of-care ultrasound (POCUS) offers a new diagnostic tool for the management of patients at risk of gastric regurgitation [13]. It can provide a simple, non-invasive and cost-effective strategy to assess a patient's risk of aspiration through an objective and reproducible evaluation [14]. There is a growing interest in pre-operative gastric sonography, particularly in patients at risk of pulmonary aspiration [15]. Recent guidelines even suggest the use of gastric ultrasound in children when fasting instructions have not been followed or before emergency surgery [16].

However, data from large cohorts of adult patients on the practical impact of routine pre-operative ultrasound on anaesthetic management remain scarce. Therefore, we aimed to routinely assess gastric content using POCUS in a large population of patients at potential risk of pulmonary aspiration. In addition, we intended to pre-operatively identify and quantify high- and low-risk patients in elective and emergency populations and to assess factors associated with higher risk. We hypothesised that routine gastric ultrasound adds decision-relevant information to pre-operative risk assessment and therefore influences anaesthetic management of individual patients.

## **Methods**

The pre-defined study protocol was approved by the local ethics committee and hospital board. Written informed consent was obtained from each participant. A data analysis and statistical plan was written and published on a trial registration site before data were accessed. While this plan included several population-based descriptive and educational descriptive outcomes, the current manuscript focuses on the population-based aspects. Further educational aspects are still under analysis and not part of this manuscript. Reporting adhered to the strengthening the reporting of observational studies in epidemiology (STROBE) statement.

In this single-centre, prospective observational study, adult patients were consecutively screened at the Cantonal Hospital Winterthur during a 12-month period from January to December 2021. Inclusion criteria were the presence of one or more risk factors for pulmonary aspiration according to a pre-defined catalogue in accordance with departmental standards, including: trauma within 24 h; chronic or acute opioid use; abdominal pathology; gastrointestinal obstruction; nausea or vomiting; irregular reflux (food dependent or asymptomatic on therapy); regular reflux (non-food dependent or uncontrolled on therapy); hiatus hernia; neurological disorders affecting swallowing or gastric motility; renal insufficiency with an estimated alomerular filtration rate < 30 ml.min<sup>-1</sup>.1.73 m<sup>-2</sup>, history of diabetes mellitus;  $BMI \ge 35 \text{ kg.m}^{-2}$ ; or non-fasted patients having emergency surgery. The anaesthetist in charge was allowed to indicate further risks if clinically relevant. Exclusion criteria were age < 18 y; previous gastric surgery; known pregnancy; obstetric surgery; or inability to give informed consent. Patients with life-threatening or timecritical emergencies were also excluded. For organisational reasons, patients could only be enrolled if staff adequately trained in gastric ultrasound were available and no significant delay in the care of other patients resulted.

After obtaining the patient's medical history and clinical findings, the anaesthetist responsible for pre-operative evaluation determined the patient's individual anaesthetic plan according to departmental standards. Upon arrival in the operating theatre, the anaesthetist responsible for perioperative care was then asked to rate the patient's risk of pulmonary aspiration on an integer scale from 1 (very low) to 10 (very high) using only clinical findings and patient history. Thereafter, gastric sonography was performed immediately before induction of anaesthesia. After sonography and before induction of anaesthesia, the anaesthetist responsible for peri-operative care reassessed the

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individual aspiration risk using the same integer scale, incorporating the newly available information from gastric sonography, and determined whether to adjust the original peri-operative management plan. A more conservative approach referred to additional measures taken to reduce the risk of aspiration (e.g. routine induction of anaesthesia to rapid sequence induction), in contrast to a more liberal management plan (e.g. tracheal intubation to a supraglottic airway device). A graphical description of possible changes is included in online Supporting Information Figure S1. The supraglottic airway device used in this study was the Ambu<sup>®</sup> AuraGain<sup>™</sup> (Ambu, Copenhagen, Denmark) in combination with double-lumen gastric tubes of various sizes. If gastric sonography revealed a serious threat to the patient's health, the responsible anaesthetist was allowed to adjust the induction plan accordingly to ensure a safe procedure. A graphical representation of the study design is presented in online Supporting Information Figure S2.

We developed a structured training programme for all 73 physicians in our anaesthesia department, combining theoretical and practical education. First, sonography experts with long-term experience in POCUS were selected and received extensive theoretical and hands-on training in gastric sonography, including tutoring by a radiologist specialising in abdominal sonography. The remaining physicians were then prepared for tuition by our experts with self-study, a step-by-step guide and educational videos. This was followed by 120 min of supervised practical training on healthy volunteers. It was structured in such a way that all sonographers had to perform at least 25 gastric scans on patients, which is in line with the current literature to achieve satisfactory results [17]. In addition, the first five scans were supervised by our experts to ensure high-quality performance.

Sonographic examination and determination of gastric content was performed using standard ultrasound machines (Venue and LOGIQ e, GE-HealthCare, Chicago, IL, USA) with a curved array, low-frequency transducer or a portable ultrasound device (iQ+, Butterfly Network Inc., Palo Alto, CA, USA). In accordance with current practice [18], qualitative assessment of gastric content was performed in the right lateral decubitus position. If this was not possible due to patient factors, sonography was done in a semiseated position at 45° or, as a last option, fully supine. Gastric contents were classified as empty, fluid (full stomach with homogeneous fluids) or solid (full stomach with solid material or mixed fluids and solid contents). If fluid content was detected, the antral cross-sectional area was measured with the antrum at rest in a parasagittal plane at the level of the aorta using serosal tracing [19]. Gastric volume was

estimated using the Perlas formula as described elsewhere [20, 21].

In line with current literature, all patients with solid or mixed gastric content were classified as high risk, while a cut-off of 1.5 ml.kg<sup>-1</sup> was used for fluid gastric content [18]. Patients with an empty stomach or fluid content below the cut-off were classified as low risk.

Descriptive statistics were used. When comparing emergency status univariately, hypothesis tests were applied as exploratory analyses. For continuous variables the t-test was used. Fasting time from last meal and last drink and aspiration risk score before and after POCUS variables were heavily skewed, so the non-parametric Mann-Whitney-U test was used. For categorical variables, either Chi-squared or Fisher's exact tests were used. Ordered categorical variables were analysed with a linear-by-linear association test. Adjustment for multiple testing was not done and all p values in descriptive tables should be interpreted in an exploratory way. Multivariable comparison of risk levels was done with multiple logistic regression models. Variables included were chosen by clinical reasoning. The model included all disease risk factors individually plus other relevant patient characteristics. To improve interpretability of coefficients, age was included in decades and fasting time from last meal in days in regression models. Coefficients of regression models are generally presented as point estimates with two-sided 95%Cl and twosided p values. All analyses were carried out with R version 4.2.2 (R Foundation for Statistical Computing, Vienna, Austria) and RMarkdown was used for dynamic reporting.

#### Results

A total of 2003 patients were included. Baseline characteristics are presented in Table 1. Median (IQR [range]) fasting time was 16 (12-18 [0-96]) h for solid meals and 5 (3-10 [0-72]) h for liquids. Distribution of aspiration risk factors overall and for both elective and emergency patients are presented in Table 2. Reflux (387/1246, 31%) was the most prevalent risk factor in elective settings, while abdominal pathology (358/757, 47%), nausea and vomiting (143/757, 19%) and recent trauma (185/757, 24%) were the most frequent in emergency settings. Other risks included: rare events such as elevated intracranial pressure; achalasia; sepsis; or non-adherence to fasting times. Gastric sonography could not be performed in 34 of 2003 patients (1.7%) for various reasons such as inability to correctly position the patient due to pain or inability to locate the anatomical landmarks.

In patients undergoing elective surgery, 61% (754/ 1246) had an empty stomach, 28% (352/1246) had fluid and onditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons I

 Table 1
 Baseline characteristics overall and for patients undergoing elective and emergency surgery. Values are mean (SD), number (proportion) or median (IQR [range]).

	Overall n = 2003	Elective n = 1246	Emergency n = 757	p value*
Age; y	60.5 (17.8)	63.2(15.9)	56.2 (19.9)	< 0.001
Sex; female	1010(50.4%)	640(51.4%)	370 (48.9%)	0.301
BMI; kg.m <sup>-2</sup>	27.50(5.7)	28.19(5.8)	26.36 (5.3)	< 0.001
Time since last meal; h	16(12–18[0–96])	14(12–16[0–96])	15(10-22[2-96])	
Time since last drink; h	5 (3–10 [0–72])	4 (3-8 [0-60])	7 (511 [0–72])	
ASA physical status				
1	95 (4.7%)	22 (1.8%)	73 (9.6%)	< 0.001
2	980 (48.9%)	569 (45.7%)	411 (54.3%)	
3	846 (42.2%)	608 (48.8%)	238 (31.4%)	
4	82 (4.1%)	47 (3.8%)	35 (4.6%)	
Type of surgery				
General	730 (36.4%)	356 (28.6%)	374 (49.4%)	< 0.001
Urology	251 (12.5%)	158(12.7%)	93 (12.3%)	
Trauma	238(11.9%)	72 (5.8%)	166 (21.9%)	
Orthopaedic	212(10.6%)	187 (15.0%)	25 (3.3%)	
Vascular	108 (5.4%)	88 (7.1%)	20 (2.6%)	
Gynaecology	122 (6.1%)	108 (8.7%)	14(1.8%)	
Neurosurgery	108 (5.4%)	88 (7.1%)	20 (2.6%)	
Ophthalmology	102 (5.1%)	101 (8.1%)	1 (0.1%)	
Reconstructive	89 (4.4%)	56 (4.5%)	33 (4.4%)	
Other	43 (2.1%)	32 (2.5%)	11 (1.5%)	
Anaesthetic technique				
Rapid sequence induction	1172 (58.5%)	582(46.7%)	590 (77.9%)	< 0.001
Standard induction	398(19.9%)	337 (27.0%)	61 (8.1%)	
Supraglottic airway device	300 (15.0%)	238(19.1%)	62 (8.2%)	
Regional anaesthesia	55 (2.7%)	32 (2.6%)	23 (3.0%)	
Awake tracheal intubation	32(1.6%)	25 (2.0%)	7 (0.9%)	
Spinal	32(1.6%)	23 (1.8%)	9(1.2%)	
Sedation	14(0.7%)	9 (0.7%)	5 (0.7%)	
Pre-operative nasogastric tube	34(1.7%)	6 (0.5%)	28 (3.7%)	< 0.001

\*p values calculated from log-transformed values and compare patients undergoing elective vs. emergency surgery.

9% (118/1246) had solid or mixed gastric content. In patients undergoing emergency surgery, 56% (421/757), 29% (218/757) and 14% (106/757) had empty, fluid or solid gastric sonographic appearances, respectively. This resulted in 14% (178/1246) of patients undergoing elective surgery and 21% (158/757) of patients undergoing emergency surgery being at high risk of pulmonary aspiration (Fig. 1 and online Supporting Information Table S1).

Multivariable logistic regression with binary sonographic risk classification (high risk vs. low risk) revealed the following factors with a strong association (p < 0.01) with increased risk of pulmonary aspiration: gastrointestinal obstruction (OR (95%CI) 11.69 (5.76–24.26),

p < 0.001); recent trauma (2.31 (1.44–3.69), p < 0.001); opioid use (2.02 (1.40–2.89), p < 0.001); ASA physical status 4 vs. 1 (3.93 (1.66–9.42), p = 0.002); and other risks (1.92 (1.20–3.01), p = 0.005), as displayed in Figure 2. All reported odds ratios are in online Supporting Information, Table S2.

Mean (SD) subjective aspiration risk estimated by the attending anaesthetist was 3.20 (1.57) overall, 2.94 (1.33) for patients undergoing elective surgery and 3.63 (1.81) for patients undergoing emergency surgery before gastric sonography (Table 3). After sonography, mean (SD) change in subjective aspiration risk was -0.33 (1.50), -0.27 (1.39) and -0.43 (1.67), respectively (Fig. 3). Overall, a more liberal

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 Table 2
 Pulmonary aspiration risk factors for overall and for patients undergoing elective and emergency surgery. Values are number (proportion).

	Overall n = 2003	Elective n = 1246	Emergency n = 757	p value*
Number of risk factors				< 0.001
0	5 (0.2%)	2 (0.2%)	3 (0.4%)	
1	1144 (57.1%)	760 (61.0%)	384 (50.7%)	
2	647 (32.3%)	380 (30.5%)	267 (35.3%)	
3	176 (8.8%)	90(7.2%)	86(11.4%)	
4	28 (1.4%)	14(1.1%)	14(1.8%)	
5	3 (0.4%)	3 (0.5%)	0	
Irregular gastric reflux $^{\dagger}$	483 (24.1%)	387 (31.1%)	96 (12.7%)	< 0.001
Regular gastric reflux $^{\dagger}$	432(21.6%)	358 (28.7%)	74 (9.8%)	< 0.001
Abdominal pathology $^\ddagger$	415 (20.7%)	57 (4.6%)	358 (47.3%)	< 0.001
Hiatus hernia	307(15.3%)	266 (21.3%)	41 (5.4%)	< 0.001
Diabetes mellitus	307 (15.3%)	248 (19.9%)	59(7.8%)	< 0.001
BMI≥ 35 kg.m <sup>-2</sup>	244(12.2%)	189 (15.2%)	55(7.3%)	< 0.001
Nausea or vomiting	210(10.5%)	67 (5.4%)	143 (18.9%)	< 0.001
Recent trauma	207 (10.3%)	22(1.8%)	185 (24.4%)	< 0.001
Opioid utilisation	194 (9.7%)	93 (7.5%)	101 (13.3%)	< 0.001
Renal insufficiency	86 (4.3%)	61 (4.9%)	25 (3.3%)	0.111
Gastro-intestinal obstruction	48 (2.4%)	10(0.8%)	38 (5.0%)	< 0.001
Neurological disorder	32(1.6%)	21 (1.7%)	11 (1.5%)	0.827
Other risks	128(6.4%)	67 (5.4%)	61 (8.1%)	0.022

\*p values compare patients having elective vs. emergency surgery.

<sup>†</sup>Irregular reflux (food dependent or asymptomatic on therapy); regular reflux (non-food dependent or uncontrolled on therapy). <sup>‡</sup>Abdominal pathology excludes gastrointestinal obstruction.

approach would have been possible in 15% (303/2003) of patients and a more conservative management necessary in 4% (76/2003) (Table 3).

#### Discussion

We have shown that pre-operative gastric sonography adds individualised, safety-relevant and management-changing information to the peri-operative care of patients undergoing elective or emergency surgery who are at risk of pulmonary aspiration. In our cohort, routine gastric ultrasound led to a substantial adjustment in individual risk assessment, enabling consequent changes in anaesthetic management in 19% of patients, with three-quarters of these being a more liberal approach.

Current estimation of aspiration risk and subsequent management is based on a combination of clinical assessment and fasting, which may identify populations at increased risk, but does not allow for individualised management planning. Despite fasting times being much longer than recommended by international guidelines [10], 14% of patients undergoing elective surgery presented to the operating theatre with a high-risk stomach. These results are comparable to another study in which 13% of patients scheduled for elective cholecystectomy had a full stomach even after the recommended fasting intervals [22]. Fasting times appear to correlate poorly with gastric volumes measured by sonography in children [23] and might not ensure an empty stomach in adults [24, 25]. This is not surprising, as current guidelines were designed for healthy patients undergoing elective surgery [10] and there is uncertainty about how they should be applied to other patient populations. Not unexpectedly, high-risk stomachs were even more common in patients scheduled for emergency surgery (21%). In both groups, gastric sonography could provide a fast and non-invasive individualised assessment of aspiration risk: patients presenting with a full stomach, despite adherence to fasting recommendations can be reliably identified [26] and gastric sonography helps to assess prandial status when it is unknown or unclear [27].

Consistent with these findings, the subjective aspiration risk score based on clinical assessment and medical history was adjusted in most cases with additional information from gastric ultrasound. This resulted in a



**Figure 1** Risk classification after gastric ultrasound. Overall values are shown, as well as elective and emergency patient groups separately. Risk categories results are displayed in waffle plots (a, overall; c, elective; e, emergency) and sonography findings in bar plots (b, overall; d, elective; f, emergency).

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**Figure 2** Association of pulmonary aspiration risk factors with sonographic risk classification. Multivariable logistic regression of risk levels. Forest plot where dots depict the point estimates, lines the 95%CI. Point estimates (odds ratios) are displayed in descending order, x-axis is on log scale.

clinically relevant change in anaesthetic management. While a more conservative approach was needed in a relatively small but clinically relevant proportion of patients undergoing elective surgery (4.2%), 13.6% could have been eligible for more liberal management. In the emergency surgery population, 78% presented with a low-risk stomach despite one or more risk factors including the emergency setting itself, which is associated with a higher risk of aspiration [28]. Accordingly, only 3% of patients having emergency surgery needed a more conservative approach, but 18% could have been managed more liberally after sonography. This is important, as they might benefit from less invasive techniques such as routine induction of anaesthesia rather than rapid sequence induction or

	Overall n = 2003	Elective n = 1246	Emergency n = 757	p value*			
Aspiration risk before ultrasound	3.20(1.57)	2.94(1.33)	3.63(1.81)	< 0.001			
Aspiration risk after ultrasound	2.87 (1.74)	2.67 (1.54)	3.20(1.98)	< 0.001			
Change in aspiration risk	-0.33 (1.50)	-0.27 (1.39)	-0.43 (1.67)	0.020			
Change in patient management							
More liberal	303 (15.2%)	170(13.7%)	133 (17.7%)	0.011			
No change	1612 (81.0%)	1016(82.1%)	596 (79.2%)				
More conservative	76(3.8%)	52 (4.2%)	24(3.2%)				

 Table 3
 Subjective aspiration risk score before and after gastric ultrasound and change in anaesthetic management. Values are mean (SD) or number (proportion).

\*p values compare patients undergoing elective vs. emergency surgery.

second-generation supraglottic airway device rather than tracheal intubation, which may be associated with fewer complications in a variety of settings [29, 30]. Our data show that use of gastric ultrasound adds information to the preoperative strategy. Similar results have been observed in non-elective paediatric surgery, where the use of gastric ultrasound led to an appropriate induction of anaesthesia technique in 85% of children, compared with 49% when relying on clinical assessment alone [31].

In an exploratory analysis, we identified a number of factors associated with high-risk stomachs in our population. While abdominal pathology or gastrointestinal obstruction are traditionally considered to be risk factors for pulmonary aspiration [2] and usually require additional precautions, gastric ultrasound may identify those patients who could benefit from early nasogastric tube placement, a common measure in patients with gastrointestinal obstruction before induction [32]. Pain, stress and opioid use, on the other hand, have been less extensively studied but are known causes of delayed gastric emptying [33–35].

Limitations of our study include the observational design, which does not allow us to infer the causal relationship of effects. Pulmonary aspiration is a rare event and the definitions of aspiration, regurgitation, aspiration pneumonia and pneumonitis are heterogeneous. Therefore, we did not systematically define and assess aspiration and related complications (i.e. patient-centred outcomes) as this trial was not designed or powered to do so. However, no obvious aspiration was witnessed in this setting. Study design allowed management-change towards a more conservative approach when patient safety was at jeopardy. In addition, the association of residual gastric content with aspiration risk remains unclear and controversial due to the rarity of this complication, as is the case for the Perlas formula and the 1.5 ml.kg<sup>-1</sup> high risk cut-off for gastric fluid content [36]. According to the literature, this is the most widely accepted upper limit for gastric fluid content and correlates with the 95th centile for fasted patients undergoing elective surgery [37]. Furthermore, we cannot exclude inter-observer variability while performing pre-operative gastric ultrasound, which we have tried to minimise through extensive training, and thus believe represents a real-life clinical teaching scenario. Nevertheless, sonography and, in particular, gastric content estimation remains an investigator-dependent examination with limitations in technique, applicability and indications. In addition, scanning was only performed pre-operatively and not before tracheal extubation, therefore the risk of postoperative aspiration was not addressed. We also emphasise that the subjective risk score we used is not a validated tool for assessing pre-operative risk of aspiration. The scale was introduced to approximate a synthesis of the global risk assessment by the anaesthetist responsible for patient management and to demonstrate that additional sonographic assessment changes the overall interpretation of the circumstances present. Nevertheless, these results should be interpreted with caution. Results may have also been biased by the unblinded design of this study, which was chosen to increase usability in an authentic clinical setting. Further, although gastric sonography has been extensively studied in pregnancy and obstetric surgery [38], those patients were excluded from our study to ensure a high quality, standardised protocol in line with previous training. However, this high-risk population might especially benefit from pre-operative gastric ultrasound and further investigation is warranted. Finally, we relied on the fasting times reported by our patients. These were not independently verified.

In conclusion, we have demonstrated that preoperative gastric ultrasound helps to identify high- and lowrisk situations in patients at risk of aspiration, adds information to peri-operative airway management and can

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**Figure 3** Subjective pulmonary aspiration risk score. Change in subjective aspiration risk score before and after gastric sonography (US) is shown with proportions for (a) overall; (b) patients having elective surgery; and (c) patients undergoing emergency surgery. Risk score definition, 1 (very low) to 10 (very high).

lead to changes to patient care. Therefore, our data suggest that routine use of pre-operative gastric ultrasound may improve individualised care and possibly impact patient safety.

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#### **Supporting Information**

Additional supporting information may be found online via the journal website.

**Figure S1.** Liberal and conservative anaesthetic management.

Figure S2. Study design.

**Table S1.** Patient position, sonographic findings for gastric content and risk classification after sonography.

**Table S2.** Association of aspiration risk factors with sonographic risk classification.