General Anesthesia

Drinking 300 mL of clear fluid two hours before surgery has no effect on gastric fluid volume and pH in fasting and non-fasting obese patients

[Le fait de boire 300 mL de liquide clair deux heures avant d'être opéré n'a pas d'effet sur le volume de liquide ni sur le pH gastriques chez des patients obèses à jeun ou non]

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Purpose: To determine whether, in obese [body mass index (BMI) > 30 kg·m⁻²] patients, oral intake of 300 mL clear liquid two hours before elective surgery affects the volume and pH of gastric contents at induction of anesthesia.

Methods: A single-blind, randomized study of 126 adult patients, age ≥ 18 yr, ASA physical status I or II, BMI > 30 kg·m⁻² who were scheduled for elective surgery under general anesthesia. Patients were excluded if they had diabetes mellitus, symptoms of gastroesophageal reflux, or had taken medication within 24 hr that affects gastric secretion, gastric fluid pH or gastric emptying. All patients fasted from midnight and were randomly assigned to fasting or fluid group. Two hours before their scheduled time of surgery, all patients drank 10 mL of water containing phenol red 50 mg. Those in the fluid group followed with 300 mL clear liquid of their choice. Immediately following induction of general anesthesia and tracheal intubation, gastric contents were aspirated through a multiorifice Salem sump tube. The fluid volume, pH and phenol red concentration were recorded.

Results: Median (range) values in fasting vs fluid groups were: gastric fluid volume 26 (3–107) mL vs 30 (3–187) mL, pH 1.78 (1.31–7.08) vs 1.77 (1.27–7.34) and phenol red retrieval 0.1 (0–30)% vs 0.2 (0–15)%. Differences between groups were not statistically significant.

Conclusion: Obese patients without comorbid conditions should follow the same fasting guidelines as non-obese patients and be allowed to drink clear liquid until two hours before elective surgery, inasmuch as obesity *per se* is not considered a risk factor for pulmonary aspiration.

Objectif: Déterminer si, chez des patients obèses [indice de masse corporelle (IMC) > 30 kg·m⁻²], la prise orale de 300 mL de liquide clair deux heures avant de subir une opération réglée a un effet sur le volume et le pH du contenu gastrique lors de l'induction anesthésique.

Méthode : Une étude randomisée, à simple insu, a été menée auprès de 126 patients adultes, ≥ 18 ans, d'état physique ASA I ou II, d'IMC > 30 kg·m⁻², devant subir une intervention chirurgicale réglée sous anesthésie générale. La présence de diabète, ou de symptômes de reflux gastro-œsophagien ou la prise de médicaments, dans les 24 h avant l'opération, pouvant affecter la sécrétion gastrique, le pH du liquide gastrique ou l'évacuation gastrique entraînaient l'exclusion du patient. Tous les patients, à jeun depuis minuit, ont été répartis en deux groupes : jeûne ou liquide. Deux heures avant l'heure prévue de l'opération, tous les patients ont bu 10 mL d'eau contenant 50 mg de rouge de phénol. Les patients du groupe «liquide» ont pris ensuite 300 mL d'un liquide clair de leur choix. Immédiatement après l'induction de l'anesthésie et l'intubation endotrachéale, le contenu gastrique a été aspiré au moyen d'une sonde multiorifice Salem. Le volume de liquide, le pH et les concentrations de rouge de phénol ont été notés.

Résultats : Les valeurs moyennes (étendue) du groupe de jeûne vs le groupe «liquide» ont été : volume de liquide gastrique 26 (3–107) mL vs 30 (3–187) mL, pH 1,78 (1,31–7,08) vs 1,77 (1,27–7,34) et repérage du rouge de phénol 0,1 (0–30) % vs 0,2 (0–15) %. Il n'y avait pas de différence intergroupe significative.

Conclusion : Les patients obèses, sans symptômes comorbides, devraient suivre les mêmes directives de jeûne que les patients non obèses. Ils peuvent boire un liquide clair jusqu'à deux heures avant une opération réglée, étant donné que l'obésité en elle-même n'est pas considérée comme un facteur de risque d'aspiration pulmonaire.

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PULMONARY aspiration of gastric contents during general anesthesia is a rare event in healthy patients undergoing elective surgery.¹⁻³ In ASA I and II patients, the incidence is one in 7,000 to 9,000, but increases to one in < 400 in ASA III to V patients undergoing emergency surgery.² Overall mortality from pulmonary aspiration is one in 45,000 to 70,000 and occurs almost exclusively in the latter group.¹⁻³

In 1999 a task force of the ASA, after an exhaustive review of randomized clinical trials and other scientific evidence, recommended that healthy patients undergoing elective surgery could safely drink clear liquids until two hours preoperatively and that routine pharmacologic antacid prophylaxis was not indicated.⁴ The task force cautioned that the guidelines may need to be modified for patients with co-existing disease that might affect gastric emptying or fluid volume (e.g., pregnancy, obesity, diabetes, hiatal hernia, gastroesophageal reflux disease, ileus or bowel obstruction, emergency care or enteral tube feeding) and patients in whom airway management might be difficult.⁵ No randomized clinical trials of fasting *vs* drinking on residual gastric fluid volume (RGV) and pH had been conducted in these conditions on which to give an evidence-based recommendation.

Obese patients have been considered to be at increased risk of pulmonary aspiration since Vaughan *et al.* in 1975⁵ observed that the risk factors of RGV > 25 mL and pH < 2.5 were present in a higher proportion of fasting [*npo* from midnight] morbidly obese than non-obese surgical patients. More recently, Harter *et al.* found a lower incidence of these risk factors in otherwise healthy, fasting obese than non-obese patients.⁶ Furthermore, Warner *et al.* were unable to identify obesity as a risk factor in their analysis of 67 cases of pulmonary aspiration in 215,000 general anesthetics.²

The prevalence of obesity among adults is 15% in Canada⁷ and 27% in the United States.⁸ Anesthesiologists may currently choose to include or exclude these patients from the ASA⁴ and similar Canadian Anesthesiologists' Society (CAS) fasting guidelines.⁹ In morbidly obese volunteers, the dual isotope technique for measuring gastric emptying of solids and liquids demonstrates delayed emptying of solids, but no delay for clear liquids.¹⁰⁻¹⁴ The purpose of this study was to determine, in obese patients, the effect of drinking 300 mL clear liquid two hours before elective surgery on the volume and pH of gastric contents at induction of anesthesia.

Methods

The University of Calgary Conjoint Health Research Ethics Board approved the study protocol and all patients gave written informed consent. This was a single-blind, randomized study of 138 (130 evaluable) patients, age ≥ 18 yr, ASA I or II, with body mass index (BMI) > 30 kg·m⁻² who were scheduled for elective surgery under general anesthesia. We excluded patients who had diabetes mellitus, proven hiatus hernia, symptoms of gastroesophageal reflux, those who had taken medication within 24 hr that affects gastric secretion or emptying. All data from eight patients whose surgery was delayed more than four hours from the time of phenol red ingestion were excluded from analysis.

Our research nurse explained the study to patients by telephone on the day before surgery. Those who agreed to participate had nothing to eat or drink after midnight. When they were admitted on the day of surgery, their demographic data and time of last oral intake were recorded. They were then randomized to the "drinking" or "fasting" group, using a computer-generated table of random numbers. Two hours before their scheduled time of surgery, all patients drank 50 mg phenol red (phenolsulfonphthalein, Sigma Chemicals, Oakville, ON, Canada, P4758 a non-toxic marker dye that is not absorbed from the stomach)¹⁵ in 10 mL water, followed in the drinking group by 300 mL clear liquid (water, apple juice, black coffee, clear tea, carbonated beverage) while those in the fasting group resumed their overnight fast. No premedication was given unless the patient requested an anxiolytic agent.

Immediately following induction of general anesthesia and tracheal intubation, a #18 multiorifice Salem sump® tube (Sherwood Medical, St. Louis, MO, USA) was passed orally through a Williams airway intubator (Anesthesia Associates Inc., San Marcos, CA, USA) into the stomach. An assistant massaged the patient's epigastrium while the tube was moved backwards and forwards in the stomach and the investigator aspirated gastric contents blindly into a 60-mL syringe. Gastric fluid volume was recorded and its pH measured using a calibrated Corning 150 pH meter. The phenol red concentration was measured using a Beckman DU-50 spectrophotometer at 560, 520 and 600 nm.¹⁶ The amount of phenol red retrieved in the gastric fluid was its concentration (mg·mL⁻¹) $\times$ RGV (mL). The ingested amount of phenol red was 50 mg. The portion of 300 mL ingested liquid in the gastric fluid samples in the drinking group was therefore (mg phenol red retrieved $\div$ 50) $\times$ 300.

We based our sample size on RGV results in non-obese patients.¹⁷ If RGV was 25 ± 10 mL in the fast-

ing group and 35 ± 20 mL in the drinking group, then a two-sided test with $\alpha = 0.05$ would have a power ($1 - \beta$) greater than 80% chance of detecting a statistically significant difference with 63 patients in each group. An independent groups *t* test was initially used to compare mean volume in the two groups. However, RGV within both groups showed such a skewed distribution with such a wide range that comparison of means was inappropriate. We therefore compared median values using a least absolute value model. As a secondary analysis, we used the same model to compare pH in the two groups. Covariates such as weight, BMI and ingestion-sampling interval were explored using the analysis of covariance.

Results

Complete data were obtained from 130 randomized patients. There were no statistically significant differences in sex distribution, age, weight or BMI between drinking and fasting groups (Table I). Median fast until induction of anesthesia was > 12 hr in the fasting group and < 2.5 hr in the drinking group.

Differences between groups for RGV ($P = 0.46$) or pH ($P = 0.91$) were not statistically significant (Table II). Median phenol red retrieval was $< 1\%$ in both groups. In the drinking group, this represented < 3 mL of the 300 mL ingested liquid. In only ten of the 65 drinking patients, the gastric fluid contained $> 5\%$ of the ingested phenol red, representing a residual of 15 mL of the ingested fluid. Phenol red concentration in the largest individual RGV aspirate (187 mL) in the drinking group was 9%. This amount of indicator would have come from a residual of 27 mL from the ingested fluid. The rest, to make up the volume of 187 mL, would be represented by 160 mL of the patient's own gastric secretions and saliva (see discussion below).

The least absolute value model showed no correlation between BMI or duration of fast and RGV at induction of anesthesia.

Discussion

This study demonstrates that obese patients who drank 300 mL of clear liquid two hours before their scheduled time of surgery had a similar range of RGV and pH to those who were 'npo from midnight,' many of whom fasted for > 12 hr. The small percentage of phenol red retrieval in the gastric contents in the drinking group demonstrates that nearly all of the 300-mL ingested liquid had emptied from the stomach before induction of anesthesia. Therefore, the measured RGV in both groups was almost entirely gastric secretions and swallowed saliva. Ingestion of 300 mL of clear liquid two hours before surgery does

TABLE I Demographic data

	Fasting <i>n</i> = 65	Drinking <i>n</i> = 65
Sex (m/f)	17/48	17/48
Age (yr)	45 ± 12 (20-74)	45 ± 13 (20-75)
Weight (kg)	99 ± 14 (75-141)	99 ± 14 (78-134)
BMI	36 ± 4 (31-50)	36 ± 4 (31-49)
Fast (hr)	12.7 (9.1 – 17.8)*	2.3 (1.1 – 4.0)*

BMI = body mass index. * $P < 0.05$ fasting *vs* drinking.

TABLE II Residual gastric fluid volume, pH and phenol red dye

	Fasting <i>n</i> = 65	Drinking <i>n</i> = 65
Volume ($P = 0.46$)	26 (3-107)	30 (3-187)
pH ($P = 0.91$)	1.78 (1.31-7.08)	1.77 (1.27-7.34)
% ingested dye recovered	0.1 (0-30.45)	0.23 (0-14.64)
Patients (<i>n</i>) with 0 to 5% dye	60	55
Patients (<i>n</i>) with 5.1 to 10% dye	2	9
Patients (<i>n</i>) with $> 10\%$ dye	3	1

Values are median (range).

not affect the 'risk' of regurgitation, nor of pulmonary aspiration. It does not exclude the possibility that all obese patients have a higher risk of aspiration, merely that drinking according to ASA and CAS guidelines does not increase that risk.

The stomach is a very distensible organ that accommodates 1,000 to 1,500 mL before the resting intragastric pressure rises.¹⁸ Despite the wide range of RGV in this study, the maximum RGV in each group was far below the volume at which intragastric pressure starts to rise. Gastric pressure must exceed the barrier pressure of the lower esophageal sphincter (LES) for regurgitation to occur. The barrier pressure of the LES does not appear to be as easily overcome under general anesthesia as is generally believed. Furthermore, a rise in intragastric pressure causes a reflex rise in barrier pressure. A rise in mean gastric pressure from 12.1 to 24.9 cm water, produced by external abdominal pressure, caused a rise in LES barrier pressure from 35.6 to 54.8 cm water in normal subjects.¹⁹ Similarly, a rise in mean gastric pressure from 5.2 to 15.7 cm water, during peritoneal insufflation for laparoscopy, caused a rise in LES barrier pressure from 31.2 to 47.0 cm water.²⁰

O'Mullane measured intragastric pressure with 500 to 1,000 mL saline in the stomachs of patients under

anesthesia with neuromuscular blockade.²¹ The pressure remained -5 to +5 cm water in supine, foot-down, Trendelenburg or lithotomy position in lean individuals. It ranged from +2 to +18 cm water in those with a distended abdomen including pregnancy. Neither sand bags placed on the abdominal wall to maintain intra-gastric pressure 15 to 20 cm water, nor the surgeon's manual compression of the stomach caused regurgitation. Plourde and Hardy demonstrated in anesthetized cats, whose LES is similar to that in humans, that a mean (range) intragastric volume of 21 (8–41) mL·kg⁻¹ was required to overcome LES barrier pressure and produce regurgitation of water tinted with methylene blue into the pharynx.²² This volume was at least 20 times greater than the volume (0.4 mL·kg⁻¹, pH ≤ 2.5) required to produce pulmonary damage by intratracheal injection. Hartsilver *et al.* measured gastric pressure and RGV in 20 women during emergency Cesarean section under general anesthesia.²³ Baseline mean gastric pressure following 30 mL sodium citrate 0.3 mol·L⁻¹, rapid sequence induction and tracheal intubation, was 11 mmHg (15 cm water), rising to 19 mmHg (25 cm water) during delivery. In one patient, gastric pressure rose to 65 mmHg (85 cm water) during fundal pressure. At the end of surgery, RGV was 112 (20–350 mL). There was no correlation between gastric pressure and gastric volume.

The belief that > 25 mL RGV with pH < 2.5 in the stomach is a surrogate marker for an increased risk of pulmonary aspiration was based on false premises. In their experiment on one monkey Roberts and Shirley did not measure volume or pH of the animal's stomach contents.^{24,25} They prepared their test liquids and injected them directly into the monkey's right main bronchus from a syringe. To be a valid surrogate marker, the incidence of > 25 mL RGV in the stomach must correlate with the true end-point, clinically significant pulmonary aspiration. The incidence of clinically significant pulmonary aspiration occurs in 0.014% (1 in > 7,000) of healthy patients undergoing elective surgery² whereas RGV > 25 mL with pH < 2.5 occurs in 40 to 80% (approximately one in two).^{26–28}

Schreiner marked the 25th anniversary of Roberts and Shirley's original paper by systematically challenging their surrogate marker.²⁹ Median RGV in fasting adults is 25 to 35 mL or 0.4 to 0.5 mL·kg⁻¹ with an upper limit of approximately 2 mL·kg⁻¹. He argued that, because high RGV is so common and clinically significant aspiration so rare, other pathways or mechanisms must be important. Warner *et al.*'s prospectively gathered data support this view. Sixty-seven aspirations occurred in their 215,488 general anesthetics. Increasing ASA physical status and emergency surgery

were associated with greater incidence of aspiration. The commonest predisposing condition was intestinal obstruction. There was no correlation with age, pregnancy, obesity with BMI ≥ 35 kg·m² or individual comorbid conditions. Furthermore, in patients undergoing elective procedures, risk factors were present in less than half (24 of 52) of those who aspirated.

Pulmonary aspiration coincided with gagging and vomiting (not passive regurgitation) in two-thirds of Warner *et al.*'s cases,² during airway manipulations of either laryngoscopy (33%) or tracheal extubation (36%). Vomiting differs from passive regurgitation because the squeezing action of the diaphragm and abdominal muscles causes a sudden increase in intra-gastric pressure to > 60 cm water.³⁰ This is accompanied by reflex relaxation of the LES and upper esophageal sphincter,¹⁸ to allow unimpeded flow of gastric contents. Herein lies the significance of Warner *et al.*'s analysis. During vomiting, relaxation of the sphincters facilitate escape of gastric contents, at all other times the barrier pressure of the normal LES prevents it. Other investigators have shown that episodes of gastroesophageal reflux (GER) during anesthesia are related to airway stimulation from straining on the endotracheal tube,³¹ and that the incidence of GER (not risk of aspiration) at induction of anesthesia is independent of RGV.³²

Gastric emptying of solids in obese subjects is faster, slower, or no different^{10–14} from non-obese patients. The rate may vary according the content of the test meal. There is no difference in the rate of gastric emptying of liquids between obese and non-obese subjects.^{10–14} A wide variation in RGV may be expected in obese patients as in non-obese patients.

In conclusion, obesity alone is an unproven risk factor for pulmonary aspiration during induction of anesthesia on the basis of RGV. However, associated GER may be present in some patients and coincidental difficult laryngoscopy may lead to gagging and vomiting. Median RGV in otherwise healthy obese patients who drink 300 mL of clear liquid two hours before their scheduled surgery is not statistically significantly greater than in those who remain *npo* from midnight. This study does not exclude the possibility that obese patients have a higher risk of aspiration. It merely shows that drinking according to the ASA and CAS guidelines does not increase that risk. Obese patients may therefore follow the same fasting guidelines as non-obese patients for clear liquids.

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