Does adding milk to tea delay gastric emptying?

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Background. Many preoperative fasting guidelines suggest that hot tea or coffee with milk added should be considered similar to solid food, allowing an interval of 6 h before commencing anaesthesia. There is little evidence to support these instructions, with recent guidelines undecided on the issue. This study aimed to establish whether there was a clinically significant delay in gastric emptying associated with adding a modest amount of milk to tea.

Methods. This randomized controlled crossover study was conducted in 10 healthy volunteers. The paracetamol absorption technique and real-time ultrasound measurement of the cross-sectional area of the gastric antrum were used to assess gastric emptying after ingestion of 300 ml of black tea or 300 ml of tea with milk (250 ml black tea plus 50 ml of full fat milk).

Results. The mean difference in the time to reach the peak paracetamol concentration (tmax) was −8 min [95% confidence interval (CI) −23.1 to 7] in favour of tea with milk. Ultrasound assessment indicated that the geometric mean of the half-time to gastric emptying (T1/2) after tea without milk was 22.7 (95% CI 12.7–40.9) min and after tea with milk 23.6 (95% CI 13.5–41.0) min (ratio 1.04) (95% CI 0.47–2.29).

Conclusions. This study demonstrated no difference in gastric emptying times when a modest amount of milk was added to tea. These findings suggest that it may be acceptable to allow patients to add a small quantity of milk to their tea or coffee and follow the same fasting restrictions applied to clear fluids.

Keywords: gastric emptying; paracetamol; preoperative care; ultrasound

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Ethics Committee 2, and was conducted between November 2011 and January 2012. After completion of written informed consent, 10 healthy volunteers were entered into this randomized controlled crossover trial. Exclusion criteria included: medical conditions with a predisposition to delayed gastric emptying (e.g. diabetes or gastric disease), ingestion of paracetamol within the previous 24 h, ingestion of solids or non-clear liquids in the previous 6 h, and ingestion of clear liquids in the previous 2 h.

Each participant took part in both arms of the trial, drinking black tea and tea with milk, the order of which was determined by a computerized random number generator and concealed from the investigators by opaque brown paper envelopes. In each arm of the study, the procedure was as follows. The subject sat in a semi-reclined position at a 45° angle, a 16 g i.v. cannula was sited in an upper limb, and baseline blood samples were obtained. The initial cross-sectional area of the gastric antrum was then measured by ultrasound (MicroMaxx C60e/5-2 MHz Probe, Sonosite, Inc., Bothel, Washington, DC, USA). The investigating anaesthetist then left the room, the subject opened their randomization envelope and drank, as directed, either 300 ml of black tea or 300 ml of tea with milk (250 ml black tea plus 50 ml of full fat milk) over 3 min, followed by 1.5 g of dispersible paracetamol dissolved in 30 ml of water.

Venous blood samples were obtained every 10 min for the first hour, then every 30 min until 150 min had elapsed. Each sample was obtained after aspirating and discarding a 5–10 ml waste blank. Paracetamol concentrations in each sample were measured using an enzymatic assay on the ADVIA 2400 analyser (Siemens Healthcare Diagnostic, Frimley, Surrey, UK), which had a sensitivity of 1 mg litre⁻¹ and a daily coefficient of variation of <5%. The peak paracetamol concentration (Cmax) and time to peak concentration (tmax) were thus determined. Values were plotted against time to calculate the area under the curve (AUC) at 60, 90, 120, and 150 min; and to infinity by the cubic spline method.

The cross-sectional surface area (CSA) of the gastric antrum was measured by ultrasound in RUS at baseline, every 10 min for 60 min and then at 30 min intervals for 150 min. These measurements were performed by two of the investigators who had been trained by a radiologist specializing in abdominal ultrasound. The CSA was calculated as described previously, by determining the maximal anteroposterior (D1) and longitudinal diameter (D2) in the sagittal plane. For every time point, three measurements were taken of D1 and D2 and the average values used in the following formula to calculate the antral CSA.

\[
\text{Antral CSA} = \pi \times D1 \times \frac{D2^2}{4}
\]

A consistently reproducible position for scanning the gastric antrum was achieved using the abdominal aorta and left lobe of the liver as anatomical landmarks, as detailed in earlier studies. Antral CSA was plotted against time and gastric emptying expressed as half-time to gastric emptying (T1/2). This was defined as the time from baseline to the time the gastric antrum returns to half the maximal value (CSA1/2 max), with CSA1/2 max calculated as below:

\[
\text{CSA}_{1/2\ max} = \text{CSA}_{\max} - \frac{\text{CSA}_{\max} - \text{CSA}_{\text{baseline}}}{2}
\]

Statistics
The primary outcome was tmax. Previous studies have shown the mean or median tmax values for paracetamol to vary from 25 to 60 min after ingestion of clear fluids, with standard deviation up to 38 min. In this study, we considered that a delay of gastric emptying of under 60 min would not be clinically important; and that we would be able to declare that the two regimes were equivalent if the (two sided) 95% confidence interval (CI) for the mean difference (MD) in tmax, between black tea and tea with milk included only times <60 min. Using these assumptions and taking (pessimistically) a correlation between repeated measurements of 0.0, power analysis determined nine participants would be required (with 90% power) to show equivalence. Power will be greater if there is a positive correlation.

A 95% CI for the MD in tmax that lay entirely within 60 min of no effect would confirm the hypothesis that tea with milk was clinically equivalent to black tea.

For each subject, the AUC of the paracetamol concentration was estimated as the weighted average of all measurements up to 150 min, following standard procedures. Since this time point was somewhat arbitrary, sensitivity analysis also considered AUC values calculated for all measurements up to 60, 90, and 120 min, and linear extrapolation of the curve to final elimination, to confirm that changing the basis of the test did not change the result. The AUC of the drug concentration is a standard summary score used in many circumstances. A single value is calculated for each subject under each condition across all time points, as described by Matthews and colleagues. Treatment effects for all continuous outcomes were estimated using linear regression, correcting for the order of presentation; standard errors were adjusted for repeated observations using robust standard errors. Analysis was conducted using Stata (StataCorp, College Station, TX, USA), version 11.2.

The secondary outcome was the RUS-determined T1/2. For this, no clinically important difference was pre-specified.

Results
Ten participants (five males, five females) consented to, enrolled, and completed the study; their characteristics are given in Table 1. It was possible to measure the CSA of the gastric antrum in both arms of the study in nine of the subjects.

<table>
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<th>Table 1 Participants’ characteristics</th>
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<tr>
<td>Median (inter-quartile range)</td>
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<td>Gender (male/female)</td>
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<td>Body mass index (kg m⁻²)</td>
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It was difficult to visualize the gastric antrum in one participant after drinking both black tea and tea with milk; this subject was therefore excluded in the final analysis of the US data. Figure 1 illustrates a typical image generated during the study. The interval between the two test days ranged from 1 to 42 days. All 10 subjects were able to provide a complete data set for assessment of paracetamol levels.

Figure 2 shows the results of the mean plasma paracetamol concentrations plotted against time, indicating that there was little difference in gastric emptying after drinking either black tea or tea with milk. Further analysis of these data (Table 2) yielded a MD in $t_{\text{max}}$ in favour of tea with milk, of $-8$ min (95% CI of $-23.1$ to 7.1), demonstrating non-inferiority of gastric emptying for tea with milk when compared with black tea. The result remains essentially the same if the basis of comparison is only the first 60, 90, or 120 min; or if the curve is extrapolated to infinity.

The difference in the gastric emptying times assessed using RUS was not significant. The geometric mean $T_{1/2}$ after drinking black tea was 22.7 (95% CI 12.7–40.9) min and after tea with milk 23.6 (95% CI 13.5–41.0) min (ratio 1.04) (95% CI 0.47–2.29). After drinking black tea or tea with milk, the mean antral CSA returned to below baseline values within 90 min, as shown in Figure 3.

**Discussion**

The current ASA preoperative fasting guidelines state that ‘It is appropriate to fast from intake of a light meal or nonhuman milk 6 h or more before elective procedures requiring general anesthesia, regional anesthesia, or sedation/analgesia (i.e., monitored anesthesia care)’. ‘Because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period’. The recent ESA guidelines did not reach a firm conclusion about the addition of milk to tea/coffee, noting that no studies had examined this practice specifically. Milky drinks have traditionally been discouraged because of their high fat and protein content, which can delay gastric emptying. The main practical and clinical issue is the need to differentiate between a drink containing a modest quantity of milk (15–20% of the total volume) and a drink consisting almost exclusively of milk. Unfortunately, the current situation is such that surgery is often postponed or even cancelled because the patient admitted to drinking tea/coffee with some milk. Ironically, enhanced recovery programmes are now followed by many surgical disciplines, in particular colorectal surgery, where high carbohydrate drinks are consumed within 2 h of surgery, the aim being to mitigate the patient’s metabolic response to surgery. While allowing tea/coffee with milk to be consumed before an operation is unlikely to alter the metabolic
Pulmonary aspiration became widely accepted. This claim was introduced into clinical practice. However, at a time when pulmonary aspiration was one of the leading causes of anaesthetic morbidity, it is uncertain why a long period of fasting from liquids was ever mandated to prevent the aspiration of a significant pneumonitis. Subsequent studies on preoperative fasting have suggested that larger volumes are required to produce a significant pneumonitis. It is known that there is significant between-subject variation in the absorption, distribution, and response, it might improve patient satisfaction and wellbeing and reduce unnecessary cancellations of surgery.

The physiology and time scale of gastric emptying of solids mandates a preoperative fasting time of at least 6 h. The same is not true for clear liquids, which leave the stomach exponentially and volume of the gastric contents aspirated through a nasogastric tube. Arguably, it might have been difficult to aspirate toast 2–4 h before surgery, demonstrated no difference in pH and volume of the gastric contents aspirated through a nasogastric tube. Arguably, it might have been difficult to aspirate toast through a nasogastric tube, but the results will have been valid for the emptying of the liquid phase of the meal. In the context of this study, it is not surprising therefore that we failed to demonstrate a difference between gastric emptying of black tea or tea with a modest quantity of milk.

The severity of pulmonary aspiration correlates with gastric volume, pH, and the presence of particles in the aspirate. Neither the volume nor the pH of the gastric contents was measured in this study. However, it can be presumed that the stomach would be relatively empty after an overnight fast. Since this study demonstrated that the stomach had returned to a similar size 60–120 min after consuming black tea or tea with milk, it can be assumed that the stomach was again relatively empty by that time. These results could possibly be extended to obese patients as healthy, fasting, obese subjects have a similar gastric volume and pH to lean subjects. While the situation in obstetrics might be considered to be more complex, Wong and colleagues demonstrated that the gastric emptying of both 50 and 300 ml of water is not delayed in either normal or obese parturients at term. Therefore, it is likely that the emptying of tea with milk would not be delayed at term.

Both gastroenterologists and anaesthetists use the paracetamol absorption technique to evaluate gastric emptying of liquids. The technique is based on the assumption that, as paracetamol is absorbed almost exclusively from the small intestine, its rate of appearance in the systemic circulation will reflect the rate of gastric emptying. The safety and simplicity of the technique make it acceptable to patients/volunteers when they are asked to take part in a study. The reliability of the paracetamol absorption technique is also well established and has been shown to correlate significantly with scintigraphically measured gastric emptying time, the acknowledged ‘gold standard technique’ for measuring gastric emptying. The indices used for measuring gastric emptying include pharmacokinetic parameters such as the maximum concentration (Cmax), the time it occurs (tmax), and the area under the time concentration curve (AUC). It is known that there is significant between-subject variation in the absorption, distribution, and

| Table 2 Paracetamol pharmacokinetics. Data are mean (so) and as MD, between tea with milk and black tea (95% CI). AUC150, area under the curve from 0 to 150 min; Cmax, maximum plasma concentration; tmax, time to maximum plasma concentration. *The AUC is the weighted average of all measured paracetamol concentrations during the 150 min of observation; the weightings depending on the spacing between observations. |
|---------------------------------------------|-----------------|-----------------|-----------------|-----------------|
| Tea with milk (n = 10)                      | Black tea (n = 10) | MD (95% CI)     | P-value         |
| AUC150 (µg min m⁻¹)                         | 1886 (309)       | 1779 (355)      | 107 (−127 to 341) | 0.32 |
| Cmax (µg ml⁻¹)                              | 21.4 (5.0)       | 19.5 (4.5)      | 1.9 (−2.8 to 6.6) | 0.39 |
| tmax (min)                                  | 30 (17.6)        | 38 (23.9)       | −8 (−23.1 to 7.1) | 0.26 |

Fig 3 Change in antral CSA over time after drinking 300 ml of tea with milk or 300 ml of black tea. The data are mean (so) (n=9 in each group).
elimination of paracetamol, whereas the intra-subject variation is minimal. Therefore, crossover studies, such as the present one, are useful to minimize the inter-subject variation in absorption, distribution, and elimination.\(^{32}\)

The frequency of blood sampling is important with this technique and a higher sampling frequency has been shown to result in a significantly higher \(C_{\text{max}}\) and an earlier identification of the start of the elimination phase. Sampling every 10 min for the first hour is needed to identify the initial phase of emptying. Reassuringly, the results of the measured parameters in our study are similar to those in other studies of a similar design.\(^{10, 11}\)

One participant had a baseline paracetamol concentration of 3 \(\mu g\) ml\(^{-1}\) on the first occasion. When questioned after the assay results were available, she agreed that she had taken a headache remedy the evening before the study, which she had not thought to contain paracetamol. As the level was extremely low and a significant time had elapsed since ingestion, we considered it appropriate to include her results in the final analysis.

In the studies that lead to the liberalization of preoperative fasting, gastric volume was usually determined by measuring the volume of aspirated gastric contents shortly after the induction of general anaesthesia. In a study in which the emptying of a caloric liquid meal was evaluated with the paracetamol absorption technique, the total contents of the stomach were aspirated after 45 min, the estimated time point at which most subjects would have emptied between 40% and 60% of the meal.\(^{33}\) This estimation proved to be correct as the median percentage emptied at 45 min was close to 50%. This study demonstrated both the accuracy of the paracetamol absorption technique for measuring gastric emptying and in addition highlighted the importance of ongoing gastric secretion, as the volume ingested and the volume aspirated after 45 min were similar. This suggests that assessing the rate of emptying by changes in gastric volume, for example, by RUS may not give an entirely accurate picture of the gastric volume/secretion/emptying interaction. Thus, using two methods to estimate gastric emptying should improve overall assessment of the process of gastric emptying.

RUS is another very useful non-invasive technique for measuring gastric emptying. Its advantage is that it is relatively easy to perform, is acceptable to patients, and avoids both gastric intubation and exposure to radiation. It has been shown that for volumes up to 300 ml, measurements of the CSA of a single section of the gastric antrum reflect the intragastric volume.\(^{34}\)

The accuracy of RUS has been validated against gold standard techniques such as scintigraphy.\(^{16, 35}\) In one early study comparing scintigraphy and RUS, they were equally effective in evaluating liquid gastric emptying, demonstrating that saline emptied significantly faster than semi-skimmed milk (1.8% fat).\(^{16}\) More recently, it has been suggested that two-dimensional ultrasonography is sufficiently sensitive to be used as a bedside test to determine gastric content and volume before emergency surgery.\(^{36}\) This observational study in 183 patients, undergoing either elective or emergency surgery, measured the antral CSA immediately before induction of anaesthesia. After tracheal intubation, an 18 Fr multiorifice Salem tube was inserted into the stomach and the contents were aspirated during the ensuing 15 min. There was a significant positive correlation between the antral CSA and the aspirated gastric volume. The correlation coefficient was 0.72 (\(P<0.0001\)). However, in our study, the relatively wide CI for the effect of the intervention on the half-life for stomach emptying demonstrates the difficulty of accurately estimating this quantity, particularly given the relatively small changes in stomach volume involved.

Position is known to affect the rate of gastric emptying, in particular the left lateral position has been shown to delay gastric emptying relative to the right.\(^{37}\) These studies were performed in the semi-upright position as necessitated by RUS measurements and is the position in which oral fluids are normally consumed.

The results of this study in healthy volunteers support our hypothesis that the addition of a small to moderate volume of full fat milk to tea/coffee would not significantly delay gastric emptying. There was no significant difference in the mean maximum concentration of paracetamol (\(C_{\text{max}}\)) and mean time maximum concentration (\(t_{\text{max}}\)) between black tea and tea with milk. In addition, RUS measurements showed that at 60 min, the stomach had returned to a size similar to that before the drink was consumed. This suggests that current preoperative fasting guidelines, which recommend only black tea/coffee before surgery, could be altered to allow patients to add a modest quantity of milk (up to 50 ml) to these drinks. Full fat (4%) milk was used in this study, but in today’s health conscious world, it is likely that most people drink tea/coffee with semi-skimmed milk (1.8–2% fat) and that the emptying profile of tea with semi-skimmed/skimmed milk will be similar to that seen in this study. Limitations of this study are that it was performed in healthy volunteers with presumed normal gastric emptying. None were obese and the presumed anxiety that may accompany the wait for surgery was not an issue. Therefore, further observational studies are required to verify the safety of allowing patients to consume tea/coffee with milk before elective surgery.

**Authors’ contributions**

S.H. assisted in the study design, collected data, and drafted the manuscript. S.C. assisted in study design and gained the ethical approval. R.R. collected data. P.S. was the trial statistician and assisted in drafting the manuscript. G.O. was the principal investigator, conceived this study, and assisted in drafting the manuscript.

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**Declaration of interest**

G.O.’s was an unpaid member of the task force involved in producing the European Society of Anaesthesiology’s guidelines...

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