Title: How do you take your coffee before anesthesia? A randomized controlled crossover study comparing gastric emptying with black coffee vs coffee with cream.

NCT: 04786691

Date: 12/29/2020

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Background and Rationale

An important component in the pre-operative patient evaluation is to establish the duration of time a patient has been fasting in order to reduce the risk of pulmonary aspiration.[1] An inadequate fasting time may prompt a change in anesthetic plans or result in the delay or cancellation of a case altogether. The risk of anesthetic-related pulmonary aspiration is rare due to current anesthetic practices, with the incidence in adults cited around 0.05% or less.[2, 3, 4] However, the sequelae of aspiration can lead to aspiration pneumonitis, prolonged mechanical ventilation and unanticipated intensive care.[4]

There is no established gastric volume definitively known to increase anesthetic risk of aspiration but it has been observed that the gastric volume in most healthy, fasted patients can be up to 1.5 ml/kg.[5]

Current guidelines recommend a minimum fasting period of 8 hours for fatty foods, 6 hours for nonhuman milk and non-fatty solid foods, and 2 hours for clear liquids. Acceptable examples of clear liquids include water, black coffee or tea, carbonated beverages, and fruit juices without pulp.[1] However, about 68% of adults in the United States consume coffee with add-ins such as cream and/or sugar.[6] One study by *Larsen et al.*[7] found that adding up to 50% full fat milk to coffee led to no or minimal increase in gastric volume measured by Magnetic Resonance Imaging after 2 hours. *Hillyard et al.*[8] examined the addition of milk to tea and found no difference in gastric emptying times using the paracetamol absorption technique and ultrasound measurement of the gastric antrum. These studies provide some useful insight on gastric emptying times but are not generalizable to beverage consumption in the United States. Typically, the volume of coffee consumed is larger than that in Europe and half and half is preferred to milk. Half and half is a mixture of milk and cream and has a fat content ranging from 10.5-18% compared to 3.25% fat in whole milk.[9] Non-dairy coffee creamer is another popular addition to coffee, which consists of vegetable oil and corn syrup. This adds both fat and sugar to coffee. Therefore, the effects of larger quantities of coffee with the addition of high fat content milk products on gastric emptying is unknown. We propose a volunteer cross-over study in healthy individuals to assess the effects of milk additives to coffee and its effects on gastric emptying. In this study we will compare two separate additions to the coffee using half and half and liquid non-dairy coffee creamer.

Objectives

The primary objective of this study is to compare gastric volume using bedside ultrasound in volunteers 2 hours after consumption of black coffee, coffee with half and half, and coffee with non-dairy creamer.

Study Design and Procedures (sometimes called "Methods")

This study is a randomized controlled crossover study with 3 arms. One arm is the consumption of a 12 ounce (354.8 ml) brewed black coffee. The second is a 12 ounce brewed black coffee plus 1 ounce (30 ml) of half and half. The third arm is a 12 ounce brewed black coffee plus 1 ounce (30 ml) of non-dairy coffee creamer. Each subject will participate in all 3 arms of the study and serve as their own control.

The order of which arm they will be assigned to will be determined by a computerized random number generator which will create a unique sequence from 1 to 3. The number 1 will be attributed to black coffee without additives. The number 2 will be attributed to coffee with half and half and the number 3 will be attributed to coffee with non-dairy coffee creamer. For example, a random generation of the sequence 2 1 3 will result in the order of arms to be coffee with half and half, black coffee, then coffee with non-dairy creamer. The investigator performing the gastric ultrasound will be blind as to which drink was consumed. In order to maintain blinding and anonymization during the study, each participant will be assigned a unique study number which will not be associated with any identifying information. This study number will be associated with the randomized number sequence of their coffee arm order and will be used each time the participant returns for the next study measurement.

Each study participant will be instructed to consume nothing by mouth for at least 6 hours prior to the commencement of the study. An investigator will measure the cross-section of the gastric antrum using bedside ultrasound with the participant in the right lateral decubitus position as a baseline measurement. The participant will then consume one of the 3 prepared coffee options. They will be instructed to return 2 hours post consumption for the investigator to repeat the gastric antrum cross-section measurement with ultrasound. There must be a minimum of 2 days between repeat measurements with the other arms of the study.

Study Population

The study population will be composed of volunteers between the ages of 18 and 65 and will include 30 total subjects. Recruitment will be via an email to the Department of Anesthesia at the University of Arkansas for Medical Sciences asking for volunteers to participate in the study. In order to minimize coercion, it will be emphasized that participation is voluntary and that there is no reward or negative consequence for participating or not. A total of 2 reminder emails will also be sent 1 week apart from each other and the initial recruitment email. No recruitment will occur in person to avoid potential pressure from a colleague/peer.

<u>Inclusion Criteria</u>

- Age between 18-65

Exclusion Criteria

- History of diabetes, delayed gastric emptying, previous gastric surgery, lactose intolerance, currently pregnant, consumption of solid/liquids in 6 hours prior to commencement of ultrasound study

Risks and Benefits

A risk to study participants is the potential for loss of confidentiality of study data. Measures to protect the confidentiality of study data will be implemented as described in the Data Handling and Recordkeeping section below.

There are no direct benefits to participants.

Data Handling and Recordkeeping

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. De-identified data will be initially recorded on paper on a data collection form then transcribed to Excel and kept on UAMS-maintained servers. The paper records will be destroyed by confidential shredding. All collected data will be completely anonymized with no way to relink it to individual participants. Each participant will be assigned a unique study number which will not be associated with any identifying information. This study number will be associated with the randomized number sequence of their coffee arm order and will be used each time the participant returns for the next study measurement. Only investigators will have access to the collected data. At the conclusion of the study, the data which is permanently de-identified will be retained for seven years after completion of the project.

Data Analysis

Point of care bedside ultrasound will be used to measure the cross-sectional area of the gastric antrum of participants at baseline prior to consumption of coffee and 2 hours after consumption of coffee. Three measurements will be taken and recorded each time and the mean of these measurements will be used to calculate the predicted gastric volume. The difference between gastric volume at baseline and after coffee consumption will be compared across all three study arms. We will analyze the data using standard statistical methods such as mean, median, mode, standard deviation and statistical significance. We will also determine if the gastric volumes after consumption of coffee in each arm exceeds 1.5 ml/kg.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

Study participants will be provided with information outlining the process of the study in the recruitment email. They will be fully informed that their participation requires the consumption of three different coffee drinks on three separate occasions along with ultrasound examinations by one of the study investigators. They will be informed that the data collected will be de-identified. This is a minimal risk study and a waiver of documentation of consent is requested. The research involves no more than minimal risk to the subjects and the research involves no procedures for which written consent is normally required outside of the research context.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

References

1. American Society of Anesthesiologists. Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures: An Updated Report by the American Society of Anesthesiologists Task Force on Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration. *Anesthesiology.* 2017;126:376–393. doi: https://doi.org/10.1097/ALN.0000000000001452

2. Neillipovitz DT, Crosby ET. No evidence for decreased incidence of aspiration after rapid sequence induction. *Can J Anaesth.* 2007;54:748-764. doi: https://doi.org/10.1007/BF03026872

3. Sakai T, Planinsic RM, Quinlan JJ, et al. The incidence and outcome of perioperative pulmonary aspiration in a university hospital: a 4-year retrospective analysis. *Anesth Analg*. 2006;103(4):941-947. doi: https://doi.org/10.1213/01.ane.0000237296.57941.e7

4. Warner MA, Warner ME, Weber JG. Clinical significance of pulmonary aspiration during the perioperative period. *Anesthesiology*. 1993;78(1):56-62. doi: https://doi.org/10.1097/00000542-199301000-00010

5. Van de Putte P, Perlas A. The link between gastric volume and aspiration risk. In search of the Holy Grail? *Anaesthesia*. 2017;73(3):274-279. doi: https://doi.org/10.1111/anae.14164

6. An R, Shi Y. Consumption of coffee and tea with add-ins in relation to daily energy, sugar, and fat intake in US adults, 2001-2012. *Public Health.* 2017;146:1-3. doi: https://doi.org/10.1016/j.puhe.2016.12.032.

7. Code of Federal Regulations, Title 21, Volume 2, Chapter 1, Part 131 Milk and Cream. Electronic Code of Federal Regulations. https://www.ecfr.gov/cgi-bin/text-idx?SID=b76a4695ab22c8cfa98ea7a934ac0bee&mc=true&node=se21.2.131_1180&rgn=div8. Published March 15, 1977. Updated October 8, 2020. Accessed October 12, 2020.

8. Larsen B, Larsen LP, Sivesgaard K, et al. Black or white coffee before anaesthesia? A randomized crossover trial. *Eur J Anaesthesiol*. 2016;33(6):457-462. doi: https://doi.org/10.1097/eja.0000000000000457

9. Hillyard S, Cowman S, Ramasundaram R, et al. Does adding milk to tea delay gastric emptying? *Br J Anaesth*. 2014;112(1):66-71.

Appendices

1. Data Collection Form

Study: How do you take your coffee before anesthesia? **Date: _____**

Data Collection Form

ID #	Session #	Age	Gender	Height	Weight	BMI	Time coffee consumed	Time US exam	Baseline Antrum CSA			Post coffee Antrum CSA		