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Comparison of Gastric Volume After 6-hour and 8-hour Fasting in Patient Scheduled for Elective Surgery

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Background

The incidence of perioperative aspiration associates with significant morbidity and mortality for patients who will undergo surgery, especially in the length of hospitalizations and use of mechanical ventilation.¹ Perioperative aspiration is an undesirable risk although the incidence is rare. The incidence of aspiration ranges from <0.1% to 19% depends on patient factors and factors of surgery performed.² Sedation and anesthesia reduce or even eliminates physiological reflexes that protect the risk of aspiration, such as *lower esophageal sphincter* muscle tone and upper airway reflex.³

One of the risk factors of aspiration is the amount and type of gastric content so that elective surgery patients will fast before the operation. ASA guideline recommends 8 hours of fasting after eating for patients who will undergo elective surgery.⁴ 8-hours fasting after consumption of fatty foods or fried foods are considered adequate by ASA guideline for the elective surgical patient.⁴ However, special conditions such as diabetes patients, critical patients, digestive disease, and other diseases cause variations in the duration of gastric emptying.^{2,4} The longer patients do the fasting increase the risk of dehydration, hypoglycemia, and other problems, especially in patients with metabolic disorders. RSCM recommends 6-hours of fasting before undergoing elective surgery to reduce the period of prolonged fasting. Moreover, the types of food consumed in Indonesia have a lower fat content compared to ASA guidelines.

Ultrasound examination is an invasive examination and easy to administer performed which can show the volume of the hull in *real-time* to predict aspiration risk. Gastric volume resulting in an increased risk of aspiration remains controversial, but healthy patients who do fasting often have a residual gastric volume of about 1.5 ml/kg without an increased risk of aspiration.^{2,4}

Until now, several studies have stated that ultrasound examination can predict gastric volume. This examination is useful for assessing the patient who in an emergency condition with an unclear fasting condition that requires medical treatment soon. A study assessing gastric contents in fasting patients using ultrasound has not been done in Indonesia. Ultrasound of gastric contents has become an option in many countries such as Sweden, and Canada to assess the risk of perioperative aspiration.

Research Problems

Prolonged fasting can negatively affect the patient, especially the patient with a high risk of anesthesia. Currently, in RSCM, 6 hours of fasting is considered sufficient as preparation for elective surgery. There are differences from the ASA guidelines that state recommendations for 6-hours fasting after snacks and 8-hours fasting after solid foods. This research aims to analyze the difference in gastric volume after 6-hours of fasting compared with 8-hour fasting in patients undergoing elective surgery.

Research purposes

This study aims to compare gastric volume in fasting patients as preparation for elective surgery. Prolonged fasting has a negative impact on the patient's condition, especially patients with risk factors such as sepsis, diabetes, and various other conditions. If there is no significant difference in gastric volume after 8 hours of fasting compared to gastric volume after 6 h of fasting, then a 6-hour fasting period may be considered to reduce the risk of aspiration in the patient who will undergo elective surgery.

Research Methods

Research design

This is a cohort study of patients undergoing non-digestive elective surgery. This research was conducted in the hospital ward RSUPN dr. Cipto Mangunkusumo from January to February 2019. The estimated number of samples with an estimated *drop out* of 10% are 35 subjects. Sampling is done after obtaining approval from the Ethics Committee of the Faculty of Medicine, University of Indonesia.

Inclusion and Exclusion Criteria

The inclusion criteria were patients aged 18-60 years, ASA 1-2 who would undergo non-digestive elective surgery in RSCM with a body mass index between 20-30 kg/m². Exclusion criteria were a patient who is not willing to enter the study, patients with diabetes mellitus, pregnancy, abdominal distension, intestinal motility disorders, history of dyspepsia, or patients who do not receive the standard RSCM diet and changes of the surgery schedule in which the patient is unable to do 8-hours fasting before surgery, the patient who has an emergency in the perioperative period and the patient was unable to consume the standard food provided.

Sampling technique

Samples were obtained consecutively. Subjects were recruited based on an elective operating schedule recorded at the RSCM one day before the procedure. Subjects who met the inclusion criteria and did not have exclusion criteria will be explained regarding the research procedure in the ward by researchers. A sign of consent to be included in the research will be written on the informed consent sheet if the subject is willing to take part in the research. If the subject cannot sign the informed consent sheet, the signature can be represented to the patient's main family.

Data collection techniques and variables to be measured

After the subjects agree to take part in the research, an initial examination will be carried out for obtaining subject demographic data, including age, weight and height, type surgery to be performed, and preoperative examinations. The subject will start 8 hours of fasting before the surgical planning time. Before fasting, the subjects were given standard food RSCM with standardized nutritional levels. Subjects were given 1 hour to consume the standard RSCM food. 6 hours after the standard meal is consumed, an ultrasound examination will be performed with the right lateral decubitus position to obtain ultrasound imaging of the antrum after 6 hours of fasting. After that, the subject continues fasting for up to 8 hours after consumption of solid food. Furthermore, an Ultrasound examination is performed using the same technique to obtain images of ultrasound imaging of the antrum after 8 hours of fasting. Imaging pictures are taken at the time relaxation of the antrum, between two contractions. The results of this imaging are stored and assessments of antrum craniocaudal (CC) and anteroposterior (AP) diameters were performed by research assistants who don't know when the image was taken. The volume of the stomach was calculated with the formula $GV = 27.0 + 14.6 \times CSA - 1.28 \times age$.

Statistical analysis

The data collected is processed using the Statistical Package for Social Scientist program (SPSS) version 23.0. Numerical data with normal distribution will be analyzed using the T-test

in pairs. If the data has an abnormal distribution, the data will be analyzed using the Wilcoxon test. The data obtained is the result of repeated examinations, so that the

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analysis will be adjusted using the Bonferonni correction factor. Categorical data will be analyzed using the McNemar test. The results of data processing are displayed in tabular form. The CSA can be calculated with the formula $CSA = \frac{\pi \times CC \times AP}{4}$. The gaster volume was grouped into sufficient and insufficient with a border value of 1.5ml/kg.

Participant initials :

Comparison of Gastric Volume After 6-hour and 8-hour Fasting in Patient Scheduled for Elective Surgery

This research information sheet explains the purpose, procedure, and usefulness of the research, so that you understand what research is going to be about and can decide whether to participate or not. This sheet also contains patient rights and our responsibility as researchers in conducting this research.

Research purposes

Aspiration is a rare, but fatal, risk of anesthesia. Currently, there are various efforts to reduce these risks, such as fasting. Prolonged fasting can have a negative impact on patients, especially in patients at high risk of anesthesia. This study aimed to compare the gastric volume after 6 hours of fasting versus 8 hours of fasting in patients undergoing elective surgery.

Research procedure

If you have decided to participate in this research, then you can sign a consent form stating that you have been given an explanation of this research and voluntarily agree to participate. Your stomach will be examined using ultrasound to determine the volume of the stomach. This examination will be carried out four times, namely before you eat the food that is given, after eating the dinner that has been provided, after fasting for 6 hours, and after fasting for 8 hours.

Possible benefits and Confidentiality

This examination is useful for knowing the volume of the stomach, where it will be a measure of whether your fasting is enough before surgery. Sufficient fasting is useful for reducing the incidence of aspiration associated with anesthesia. The confidentiality of the results of this examination will be guaranteed and used for research following the permission of the Ethics Committee of the Faculty of Medicine, University of Indonesia.

Contact

This research was conducted by dr. Jefferson, Sp.An-KAKV in the Department of Anesthesiology and Intensive Therapy FKUI / RSCM.

Thank you.

dr. Jefferson, Sp.An-KAKV

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**RESEARCH PARTICIPATION AGREEMENT
(INFORMED CONSENT)**

I the undersigned hands at the bottom of this:

Name :
Age :
Gender :
Address :

With full awareness and without coercion, has been given an adequate and stated explanation

AGREE / DO NOT AGREE

To participate as a research subject entitled:

**"Comparison of Gastric Volume After 6-hour and 8-hour Fasting in Patient
Scheduled for Elective Surgery"**

which is (self / husband / wife / parent / child *)

Name :
Age :
Gender :
Address :
Medical Record No :

I understand the purpose of this research and the reasons why I was asked to participate.

I declare that my participation in this research is voluntary and without coercion from any party.

Jakarta, _____ 2019

Investigator

Patients, parents or guardian

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RSUPN Dr. Cipto Mangunkusumo

Jl. Diponegoro No. 71 Jakarta 10430

Tel: (021) 3918301 Fax : (021) 3148991

Med Rec No :
Name :
Age :
Date of Birth :

RESEARCH PARTICIPATION AGREEMENT (INFORMED CONSENT)			
Principal Investigator		: dr. Jefferson, Sp.An-KAKV	
Informant		: dr. Meliani Anggreni	
Recipient of Information			
Name		:	
Date of Birth / Age		:	
Gender		:	
Address		:	
Contact		:	
No	Type of Information	Content	Check
1	Title of research	Comparison of Gastric Volume After 6-hour and 8-hour Fasting in Patient Scheduled for Elective Surgery	
2	Research purposes	This study aimed to evaluate gastric contents after 6 hours of fasting versus 8 hours of fasting as a preparation for patients undergoing elective surgery.	

3	Research procedure	<p>If you are aged 18-65 years who are going to undergo surgery that is not related to the digestive organs and meet the selection criteria, then you are expected to participate in this study.</p> <p>In this study, you will be examined the contents of the stomach using an ultrasound machine. The examination will be carried out four times, namely before consuming the RSCM standard food, after finishing the food provided, after 6 hours of fasting, and 8 hours of fasting. The duration of fasting will be adjusted to the scheduled operating hours.</p> <p>All research data will be kept confidential so that it is not possible to be misused by others. In addition, your participation in research is voluntary (no coercion). You have the right to refuse to participate or not.</p>	
4	Number of subjects	35 subjects	
5	Research time	January – June 2019	
6	The benefit of the research	This study aimed to evaluate gastric volume after 6 hours and 8 hours of fasting. You will also find out whether your fast is long enough to prepare for pre-surgery.	
7	Risks and side effects in research	Nothing	

8	Subject's discomfort	At the time of the gastric ultrasound examination, you will feel a little discomfort.	
9	Compensation for side effects	There is no compensation. You will be treated following applicable hospital procedures.	
10	Alternative treatment (if any)	Nothing	
11	Data confidentiality	All research data will be kept confidential.	
12	The name and address of the researcher that can be contacted	dr. Jefferson, Sp.An-KAKV Department of Anaesthesiology and Intensive Therapy	

After listening to the explanation regarding the research that will be conducted by dr. Jefferson, Sp.An-KACV with the title: " Comparison of Gastric Volume After 6-hour and 8-hour Fasting in Patient Scheduled for Elective Surgery" I understand this information well.

By signing this form, I agree to be included in the research voluntarily without coercion from any party. If at any time I feel harmed in any form, I have the right to cancel this agreement.

Signature

Date

Subject's name

Signature of the Guardian

Date

Name of the guardian:

I have explained to the patient truthfully and honestly the purpose of the study, the benefits of the study, the research procedures, as well as the potential risks and inconveniences that may arise (detailed explanations correspond to the items I marked above). I have also best answered research-related questions.

Investigator Signature

Date