The effect of carbohydrate loading on gastric residual volume and hunger score: A single blind, randomised controlled trial study

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Introduction

ERAS (enhanced recovery after surgery) protocol is a standardised perioperative care procedure which aim to improve patient outcome(Carmichael *et al.*, 2017). It can be divided into preoperative, intraoperative and postoperative components. One of the measures in preoperative care component is carbohydrate loading. Carbohydrate loading is usage of carbohydrate rich beverage prior to operation to improve insulin resistance post operation(Faria *et al.*, 2009). Body response to surgery and prolong fasting by releasing of stress hormone and inflammatory marker(Kratzing, 2011). This led to insulin resistance and catabolic state(Kratzing, 2011). Production of glucose via gluconeogenesis and inability of usage of glucose by peripheral tissues due to insulin resistance cause hyperglycaemia post operation(Kratzing, 2011). This catabolic state and insulin resistance are associated with increased morbidity and mortality postoperatively(Gustafsson *et al.*, 202308; Tran *et al.*, 2013). By giving carbohydrate loading prior operation shift body metabolic from fasted state into fed state(Tran *et al.*, 2013).

Recent guideline had recommended to allow solid food until 6 hours prior to and clear fluid 2 hours prior to operation in replace to fasting of minimum of 6 hours(Kratzing, 2011). However, most of the centres still practice nil by mouth for minimum of 6 hours due to worried of pulmonary aspiration. According to previous study, patient are at risk of develop pulmonary aspiration if the gastric content >25ml (>0.4ml/kg) and the pH<2.5(Dalal *et al.*, 2010). Pulmonary aspiration is a fatal complication for patient undergoes general anaesthesia. It is due to aspiration of acidic gastric content during intubation and subsequently leads to pneumonitis(Nason, 2015). There are several normal physiological reflex mechanism to prevent aspiration of gastric content but they were abolished by

the drugs used during general anaesthesia(Robinson and Davidson, 2014). Apart from residual gastric volume and pH, delay gastric emptying in patient who has diabetic mellitus, dyspepsia, history upper gastrointestinal surgery or intestinal obstruction can predispose to pulmonary aspiration also(Asai, 2004).

According to study, amount of carbohydrate that can stimulate insulin release is 50g(Kratzing, 2011). Carbohydrate rich beverage contained polymer (maltodextrin) is used as carbohydrate loading currently because its low osmolality compared with other monomer beverage(Nygren *et al.*, 1995). Low osmolality leads to increase gastric emptying rate(Nygren *et al.*, 1995). However, absorption of small bowel for glucose from digested maltodextrin is rapid, which affect blood sugar level especially in diabetic patient(Hofman *et al.*, 2016).

There is still no proper guideline regarding usage of carbohydrate loading in diabetic mellitus patient prior to operation in view of possibility of delay gastric emptying and poor glycaemic control after loading(Gustafsson *et al.*, 2008).

Other than metabolic effect, carbohydrate loading also improve patient's wellbeing in the aspect of thirst, hunger and anxiety in most of the study(Gustafsson *et al.*, 2008; Hausel *et al.*, 2001).

Most studies conducted showed carbohydrate loading prior to operation is safe and benefit. However, most of studies conducted to measure gastric volume is through aspiration via nasogastric tube. This study conducted is to assess effect of carbohydrate loading (maltodextrin with whey protein) to gastric volume 2 hours after ingestion via aspiration while doing OGDS (direct visualisation) and patient's wellbeing (hunger, thirst, weakness, tiredness, anxiety) for all patient planned for OGDS.

Literature review

Enhanced recovery after surgery (ERAS) protocol is also known as fast track protocol. It is an evidence-based protocol with multimodal perioperative care pathway(Carmichael *et al.*, 2017). It is designed to improve patient outcome after treatment and care. There are several standardised practices can be done preoperatively, intraoperatively and postoperatively in order to achieve pain free postoperation, return bowel function in shorter time, improve wound healing and shorten hospitalisation(Carmichael *et al.*, 2017; Noblett *et al.*, 2006). With the ERAS protocol developed, overall complication rate and length of hospitalisation reduced as compared to conventional practice(Adamina *et al.*, 2011). Patient's satisfication is also improved and cost of hospitalisation is reduced(Carmichael *et al.*, 2017; Kratzing, 2011). Apart from surgeon, cardio-thoracic surgeon or gynaecologist also practice according to this protocol(Kaska *et al.*, 2010).

Body response towards injury or surgical trauma can be divided into ebb and flow phase(Faria *et al.*, 2009). Ebb phase is response of body in order to maintain hemodynamic stability. After ebb phase, body enter flow phase, where catabolic state started. This response is mediated by stress hormone and release of cytokines(Kratzing, 2011). Stress hormones and cytokines cause consumption of glycogen reservoir, increase gluconeogenesis and insulin resistance of peripheral tissues(Faria *et al.*, 2009). All of these contribute to hyperglycaemic after injury. Peripheral insulin resistance also leads to proteolysis, inability to utilise glucose as source of energy and subsequently reduced muscle function(Kratzing, 2011). All of these happened even after minor operation(Helminen *et al.*, 2009) and the condition worsen if added prolonged fasting(Faria *et al.*, 2009; Weledji *et al.*, 2017). Hyperglycaemia and insulin resistance are associated with post operation complication. Intensive insulin therapy had shown to give a better outcome(Kratzing, 2011).

Carbohydrate loading is recommended as preoperation measure in ERAS protocol because it induce insulin release and shift body metabolism from fasting to feed state(Tran *et al.*, 2013). Previous study showed that 50g of carbohydrate is needed to produce this effect. Hence, carbohydrate loading with 100g carbohydrate on the night before operation and 50g of carbohydrate 2 hours prior operation were used (Kratzing, 2011).

Traditionally, adequate fasting time with a minimum of 6 hours is required before operation in order to prevent pulmonary aspiration during general anaesthesia. Lately, allow clear fluid for up to 2 hours prior operation is recommended as it improve patient's wellbeing and it is safe(Kratzing, 2011). However, not all solution is safe to be used as carbohydrate loading. Type of food (solid or fluid), the volume of fluid, particle size and composition of the fluid can affect gastric emptying rate (Dalal *et al.*, 2010; Nygren *et al.*, 1995). With the presence of carbohydrate and protein, gastric emptying rate is shorter than fluid contain fat or cellulose(Dalal *et al.*, 2010). Polymer carbohydrate such as maltodextrin has low osmolality which cause rapidly passage of fluid through stomach if compare with monomer fluid(Nygren *et al.*, 1995). According to previous study, 400cc of carbohydrate rich solution (12.0% carbohydrate, maltodextrin) was used and it took about 90minutes to pass through stomach (Nygren *et al.*, 1995). Hence, carbohydrate loading with polymer is recommended in order to provide large dose of carbohydrate which able to stimulate insulin release and not produce significant gastric residual volume prior to anaesthesia.

Kaska et al. (2010) conducted a randomized, prospective and blinded clinical trial, in which patients were randomized into three groups: overnight fasting group as control group, intravenous administer glucose preoperatively and preoperative oral consumption of 400cc a specifically composed solution (principally maltodextrin and electrolytes). Gastric residual volume was examined by aspiration of juice with the aid of a gastric tube inserted temporarily at the beginning of surgery. It showed that the residual volume was 5 ml in all groups without statistically significant differences. However, the values

of gastric residual volume perioperatively was smallest in preoperative carbohydrate drink group. Yagci et al. (2008) had conducted similar study, in which patient was randomized into 2 groups that were overnight fasting and carbohydrate drink(800cc on the evening before and 400cc 2 hours prior to operation), it showed no statistically significant difference between two groups with respect to gastric residue contents. Itou et al. (2011) conducted a study which randomized patient into 2 group that were fasting group and ORS group showed similar result. However, study conducted by Dalal et al. (2010) randomized patient into 2 groups that were fasting (group I) and water (group II). It showed that the gastric fluid volume was found to be lesser in Group II (5.5 ± 3.70 ml) than Group I (17.1 ± 8.2 ml) which was statistically significant.

Significant gastric residual volume can predispose to pulmonary aspiration for patient undergo general anaesthesia. Pulmonary aspiration is defined of inhalation of solid or liquid into respiratory tract(Nason, 2015). It occurs 1 in 900 to 1 in 10000 of patient underwent general anaesthesia(Robinson and Davidson, 2014). General anaesthesia is considered safe in most of the cases, but pulmonary aspiration can cause significant airway related mortality and morbidity(Nason, 2015). Entry of acidic gastric content into lung leads to pneumonitis. The severity of the injury to lung parenchymal is depend on gastric volume, pH level of aspirated gastric content and content of the aspirated fluid which cause infection or mechanical airway obstruction(Nason, 2015). Traditionally, patient is considered as high risk of aspiration pneumonia if gastric volume aspirated more than 25cc and pH less than 2.5(Dalal *et al.*, 2010). There are several normal physiological reflex mechanism presences in order to prevent aspiration which include gastroesophageal junction, upper oesophageal sphincter and protective laryngeal reflex(Robinson and Davidson, 2014). However, these protective reflexes abolished after general anaesthesia due to the drug used during anaesthesia. Apart from the causes above, systemic disease such as diabetic mellitus also affect gastric emptying time.(Asai, 2004)

In addition to metabolic effect due to carbohydrate loading, patient's well being such as hunger, thirst, anxiety can be improved also(Hausel *et al.*, 2001).

Hausel et al. (2001) consucted a randomised control trial. 252 elective abdominal surgery patients were randomized to preparation with a 12.5% carbohydrate drink (CHO), placebo (flavored water), or overnight fasting. The CHO and Placebo groups were double-blinded and were given 800 mL to drink on the evening before and 400 mL on the morning of surgery. 11 different discomfort variables(anxiety, depression, hunger, inability to concentrate, malaise, nausea, pain, thirst, tiredness, unfitness, and weakness) were scored via Visual analog scales. During the waiting period before surgery, the CHO-treated group was less hungry and less anxious than both the other groups ($P \leq 0.05$). CHO reduced thirst as effectively as placebo ($P < 0.0001$ versus Fasted). Trend analysis showed consistently decreasing thirst, hunger, anxiety, malaise, and unfitness in the CHO group ($P< 0.05$). The Placebo group experienced decreasing unfitness and malaise, whereas nausea, tiredness, and inability to concentrate increased ($P < 0.05$). In the Fasted group, hunger, thirst, tiredness, weakness, and inability to concentrate increased ($P < 0.05$).

Helminen et al. (2009) conducted a prospective, randomized study, in which 210 patients undergoing general or gastrointestinal surgery were randomly assigned to three groups: overnight intravenous 5% glucose infusion (1000 ml), carbohydrate-rich drink (400 ml) at 6–7 a.m., or overnight fasting. Visual analogue scale was used to assess the subjective feelings of thirst, hunger, mouth dryness, weakness, tiredness, anxiety, headache and pain preoperatively. During the waiting period before surgery, the carbohydrate-rich drink group was less hungry than the fasting group ($P=0.011$). No other differences were seen in visual analogue scale scores among the study groups. Trend analysis showed increasing thirst, mouth dryness and anxiety in the intravenous glucose group ($P<0.05$). The carbohydrate-rich

drink group experienced decreasing thirst but increasing hunger and mouth dryness ($P<0.05$). In the fasting group, thirst, hunger, mouth dryness, weakness, tiredness and anxiety increased ($P<0.05$).

Glucose from maltodextrin is rapidly reabsorb by intestine and cause elevation of blood glucose rapidly(Hofman *et al.*, 2016). It may impair blood glucose level in diabetic mellitus patient. There is a study about use of carbohydrate loading in diabetic mellitus patient, which showed higher peak glucose level which occur later and take longer time for blood glucose to return to baseline if compare to healthy subject(Gustafsson *et al.*, 2008). Because of the possibility impair blood surgar and delay gastric emptying in diabetic mellitus patietn, use of carbohydrate loading in diabetic mellitus paitent still debate.

Product detail

Resource

Description

Fruit flavoured beverage designed for dietary management in malnutrition and peri-operative to enhance outcomes and recovery. It is lactose and gluten free

Age

≥4 years old

Feature

100% high quality whey protein

Fat free

Clear fluid

Low residue

Indications

carbohydrate loading for peri-operative management

fat intolerance/ malabsorption

clear liquid diet

fat free diet

cancer with treatment

Usage

Oral/tube feeding

Caloric density

1.05kcal/ml

Osmolality

77OmOsm/kg H2O

Flavour

Fruit flavoured

Nutritional information

	Per 100ml	Per 237ml
Energy	105 kcal	250 kcal
Protein	3.8 g	9.0 g
Fat-total	0 g	0.0 g
Carbohydrate	22.6 g	53.6 g
- Sugars	145 g	34.4 g
Dietary Fibre	0 g	0 g
Sodium	32 mg	76 mg
potassium	-	-
phosphorous	72 mg	171 mg
Calcium	-	-
iron	1.3 mg	3.1 mg

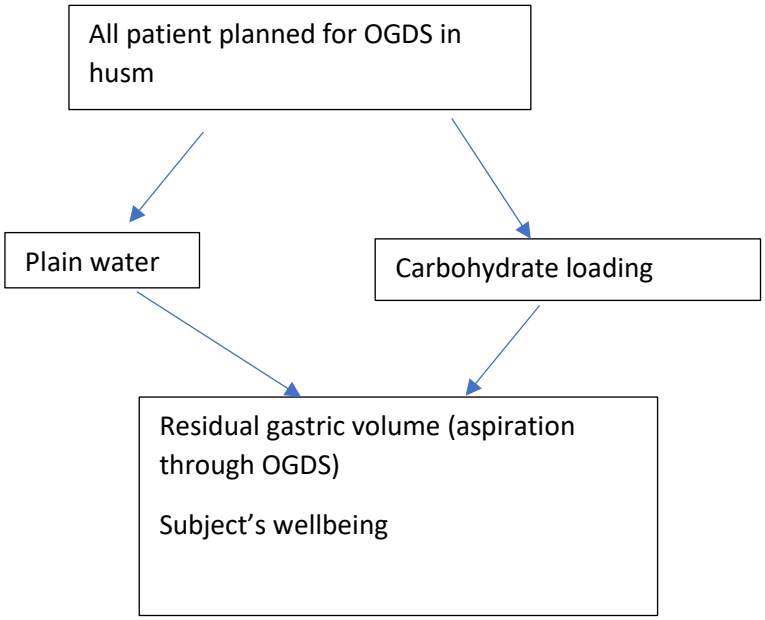
Preparation per serving

237ml

Pack size

237ml

Conceptual framework



Subject planned for OGDS in HUSM will be randomised into 2 group. Plain water is given to group1 of subject and carbohydrate loading is given to group 2 subjects 2 hours prior to OGDS. Residual gastric volume is measure through aspiration via OGDS and subject's wellbeing are assessed for both group of subject prior and after clear fluid have given.

Problem statement & Study rationale

There are a lot of study were conducted to look for the effect of carbohydrate loading worldwide. However, there is limited data about used of carbohydrate and protein as carbohydrate loading. This study conducted by using maltodextrin with whey protein as carbohydrate loading. Method to measure gastric residual volume is via aspiration from direct visualisation with OGDS. This study also assesses effect of carbohydrate loading (polymer+ whey protein) to patient's well being.

Research Question(s)

1. What is gastric residual volume 2 hours after carbohydrate loading group and control group?
2. What is the effect of carbohydrate loading and control group on subject's wellbeing?

Objectives

General:

- To assess effect of carbohydrate loading in patient planned for OGDS in HUSM

Specific:

- to determine residual gastric volume 2 hours after carbohydrate loading and plain water group
- to explore patient's wellbeing after carbohydrate loading and control

Research hypothesis

First Hypothesis

H1: There is significant association between carbohydrate loading with residual gastric volume

H0: there is no significant association between carbohydrate loading with gastric residual volume

Second hypothesis

H1: there is significant association between carbohydrate loading with subject's wellbeing

H0: there is no significant association between carbohydrate loading with subject's wellbeing

Methodology

Research design

This is a stratified (female, male) with balanced randomisation (1:1), single-blind (blind endoscopist, researcher enrolling and assessing participants), placebo-controlled, parallel-group study

Study area

This study will be conducted in endoscopy room in Hospital University Sains Malaysia in Kubang Kerian

Operative definition

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Study population

Reference population:

- patient who has planned for OGDS

Source population

- Patient planned for OGDS and attend endoscopy room in HUSM

Study population

- Patient planned for OGDS, attend endoscopy room for in HUSM, fulfilled inclusion criteria and exclusion criteria from April 2019 until December 2019

Subject criteria

Inclusion criteria

- Patient more than 18 years old

Exclusion criteria

- History of upper gastrointestinal surgery
- Intestinal obstruction
- Patient with vomiting
- Mentally disable or who cannot give an informed consent

End points

Primary end point

- Amount of gastric residual volume (ml) that has been aspirated via OGDS 2 hours after plain water or carbohydrate loading group

Secondary end point

- Score (mm) of each parameter from visual analogue scale (VAS) before drink and before OGDS for plain water and carbohydrate loading group

Sample size estimation

Sample size is calculated for all the objectives. However, the one that yield the biggest number is taken as the sample size.

objective 1 is to identify the gastric residual volume between subject with plain water (group A) and carbohydrate loading (group B). Sample size was calculated using comparing two means formula. Sample size is calculate using http://www.openepi.com/SampleSize/SSMean.htm. The ratio between group A and group B was set as 1. According to article, standard deviation was 18.46. Means difference was set as 12.5.sample size for objective 1 is 35 per group.

Objective 2 is to determined patient's well being for group A and group B. sample size was calculate using comparing paired difference formula. Sample size calculate using http://statulator.com/SampleSize/ss2PM.html#. Expected standard deviation of the paired

differences is set as 2 times the expected mean of the paired differences. The sample size is 34 per group

For all sample size calculation, type I error was set at 5% (two tailed), Type 2 error was 20% (to achieve 80% power of study).

Corrected sample size is calculated after included 10% of dropout rate. Corrected sample size = calculated sample size/ (1-anticipated drop out rate).

After considering both objective, 1st objective give biggest number of sample size. Hence, 35 subject per group with a total number of 70 subjects are needed to study both objectives. after consider dropout rate, minimum sample size in this study is 39 subjects per group with a total number of 78 subjects.

Sampling method and subject recruitment

Patient scheduled for elective OGDS in HUSM from April 2019 to December 2019 with the complaint of one or more of the following symptoms: Bothersome postprandial fullness, early satiation, Epigastric pain or Epigastric burning are eligible to participate in the study. Patients who fulfilled exclusion criteria (History of upper gastrointestinal surgery, intestinal obstruction, patient with vomiting or mentally disable or who cannot give an informed consent) are ineligible.

If a patient fulfils the inclusion criteria, a suitable medical officer will discuss the trial with patient while reviewing patient in surgical outpatient clinic prior to OGDS. Patient will be approached again on the day of OGDS, if patient agree to participate in study, a written consent will be obtained. If patient refuse to participate in study, appropriate treatment and care still will be provided to patient. The consent form will provide information about the purpose of the study, the procedures to be followed,

risks and benefits of participation. If patient agree to participate in the trial, subject will be enrolled in the study. Method of recruitment in this study is direct recruitment of potential study participants.

Stratified permuted block randomization was used. Randomization sequence was created using https://www.sealedenvelope.com/simple-randomiser/v1/lists and is stratified by gender (female and male) with 1:1 allocation. Random block sizes of 6 is used. Subjects are randomized into either preprocedure plain water (group A) or preprocedure carbohydrate loading group (group B). Patients randomized into group A consume 250ml plain water and patients in group B consume 1 packet of resource (237ml, 53.6g carbohydrate and 9g whey protein). Both groups of patients consume the drink over 10 minutes. 2 hours after that, OGDS will be carried out.

Research tools

1. Data collection pro forma
2. Resource beverage (53.6g carbohydrate and 9g whey protein), plain water
3. Visual analogue scale for assessment of patient well being
    - Each scale consisted of ungraded, horizontal lines anchored at two ends.
    - The left end of the scale represented “not at all” which score: 0 and the right end represented and “the most imaginable” which score: 100
    - patients mark an X somewhere along the horizontal line to complete the scale
4. OGDS
5. 2 Suction systems (include suction reservoir, yankauer sucker)

Data collection method

All subjected planned for OGDS with the complain of one or more of the following symptoms: Bothersome postprandial fullness, early satiation, Epigastric pain or Epigastric burning and fullfill inclusion criteria are selected. Patients will be approached and be explained regarding the study in

surgical outpatient clinic prior to OGDS. Patient will be approached again on the day of OGDS, if agree to participate, an informed consent will be obtained. Informed consent will be obtained after explanation regarding the study and procedure again by researcher nurse

Allocation sequence is according computer generated random number list, it was prepared by an investigator with no clinical involvement in the trial. Allocation sequence was concealed from researcher enrolling and assessing participants. Allocation sequence will be sealed in sequentially numbered and opaque envelopes. A manila card will be placed inside envelop to render it impermeable to intense light. To prevent subversion of the allocation sequence, the name and I/C of the participant will be written on a book together with the series number on envelopes. The details in the book will be kept confidentially. After enrolled subject complete all baseline assessment, corresponding envelope will be enclosed by staff (who not involve in study) who prepare the drink. The staff need to ensure that the envelop still sealed when receive it. The staff will prepare the drink into identical container according to the assignment.

Subjects are randomised into 2 group: 1 group with 250cc plain water and another group give 1 packet resource(237ml). Subjects need to finish the drink over 10minutes. After that, subjects are not allow to leave endoscope room before OGDS done to prevent consumption of other drink or food**.**

2 hours after that, subject undergo OGDS. OGDS is done follow standard protocol.

1. Patient lies in left lateral position
2. Medication to numb the back of throats (spray) will be given to prevent gagging during the passage of the instrument
3. A plastic mouth guard is placed between the teeth to prevent damage to the teeth and endoscope.
4. The endoscope (also called a gastroscope) will be inserted through the mouthpiece

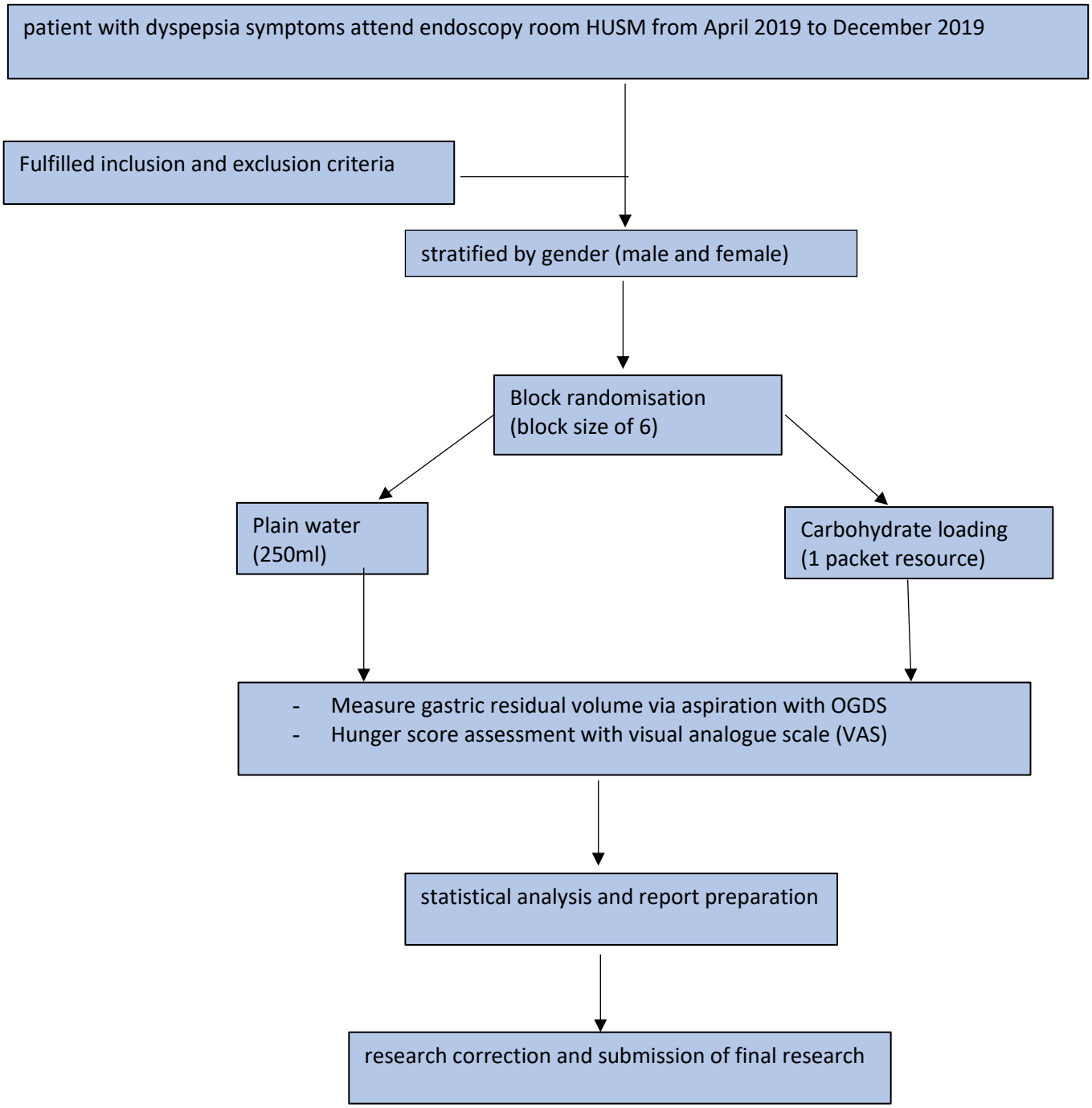
5. A small container or yankauer suction is placed close to the mouth of a patient to collect saliva during and after the esophagogastroduodenoscopy
6. Endoscope will be inserted along the middle line of the soft palate.
7. Once endoscope advanced, patient may be asked to swallow to facilitate advancement of scope.
8. Throughout the procedure, no water flushing is allowed, only air inflation is allowed
9. visualised pooling of fluid in the stomach is aspirated until dry via direct visualization with endoscope. Aspirated fluid will be collected in suction reservoir and the fluid will be measured.

Subject's wellbeing is assessed via visual analogue scale (VAS) which consist of 5 parameters: hunger, thirst, anxiety, tiredness and weakness. This scale will be used repeatedly during this study to assess patient's wellbeing. Trained staff nurse will ask patient regarding level of 5 parameters and subject need to mark X somewhere along the horizontal line given before drink and before OGDS procedure.

All subjects are advised to inform assessor if there is adverse reaction. Medical personnel are available to manage any adverse events that might occur throughout the procedure.

The possible risk that may arise in the study include injury to the gastrointestinal's wall, aspiration and bleeding which is the similar risk for all patient going through OGDS procedure. Small volume of the drink will not cause psychological distress to subject, but its taste may not be palatable.

Flow of study



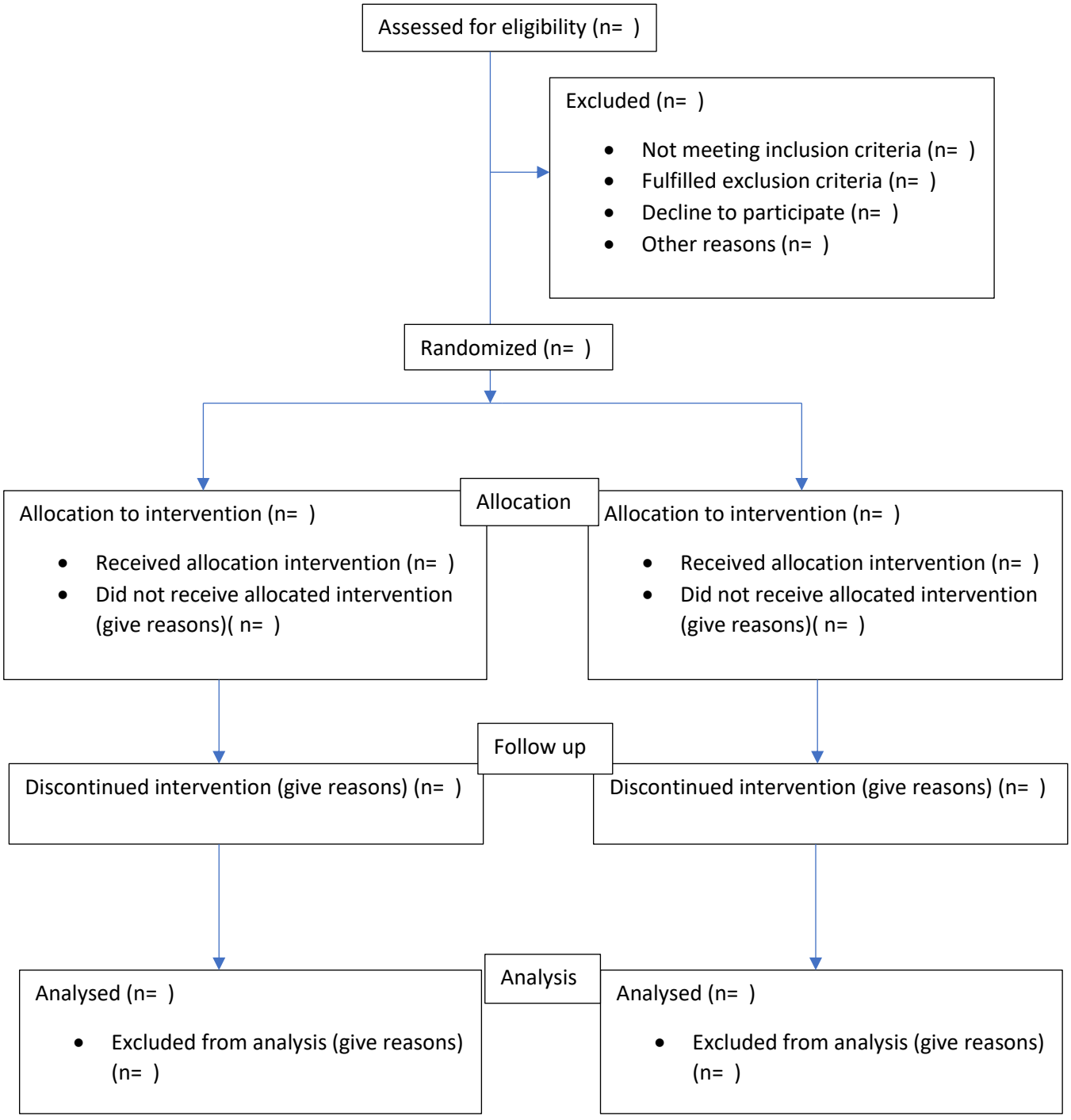
Data analysis

The collected data will be entry and analyzed using SPSS version 24 (SPSS Inc., Chicago, IL, USA)

Objective 1 is to determine and compare gastric residual volume between group A and group B subjects. Independent T test is used to interpret the date.

Objective 2 is to determine and compare subject's well being before and after drink in between group A and group B. paired t test is used to determine effect of drink on subject's wellbeing before and after in each group. ANOVA is used to compare effect of the drink in both groups.

Expected result



Patient's characteristic

	Group 1 (plain water) (n=)	Group 2 (resource) (n=)
Age (y)		
Gender (female/male)		
Body mass index (kg/m^2)		

Data presented in means (SD) or number of subject)

Residual gastric volume in both group

	Group 1 (plain water) (n=)	Group 2 (resource) (n=)
Residual gastric volume (ml)		

Data presented in means (SD)

Visual analogue scale data for preprocedure discomfort variables

VAS variable		Before drink mm, median (IQL)	Before OGDS mm, median (IQL)
Hunger	Group 1		
	Group 2		
Thirst	Group 1		
	Group 2		
Anxiety	Group 1		
	Group 2		
Weakness	Group 1		
	Group 2		
Tiredness	Group 1		
	Group 2		

Gantt chart and milestone

year	2018							2019											2020					
month	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**
Proposal presentation																									
Ethics approval																									
Grant approval																									
Data collection																									
Data analysis and report presentation																									
Submission of draft and revision																									
Submission of final research																									

Budget proposal

Resource costs RM10 per pack.

Ethical consideration

Approval will be obtained from the Research and Ethics committee of Universiti Sains Malaysia (USM) and Ministry of Health before starting the study.

Declaration

There is no conflict of interest.

Privacy and confidentiality

All forms are anonymous and will be entered SPSS software. Only research team members can access the data, confidentially of the data will be maintained strictly. Data will be presented as grouped data and the participant individually or the involved patient will not be identified.

Community sensitivities and benefits

This study finding may benefit the community by knowing the effect of carbohydrate drink before procedure on patient's well being and its safety to be used in future.

Honorarium and incentives

Endoscopy procedure provide to each participant with free.

Subject vulnerability

Appropriate treatment and care still will be provided to patient who refuse to participate in study. Patient has the right to refuse to participate in study.

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Pro forma

Demographic

ID number	:_____	Randomization	:_____
Age (years old)	:_____	Gender	○ Male ○ Female
Weight (Kg)	:_____	Height (cm)	:_____
BMI (kg/m^2)	:_____		

End point evaluation

Time of drink given	: ____:____H	Time of scope	: ____:____H
Residual gastric volume (cc)		:_____	

Visual analogue scale

Please place X along the line where you think you fit

Before drink

1. Current level of hunger

Not at all — The most imaginable

2. Current level of thirst

Not at all — The most imaginable

3. Current level of anxiety

Not at all — The most imaginable

4. Current level of tiredness

Not at all — The most imaginable

5. Current level of weakness

Not at all — The most imaginable

Before scope

1. Current level of hunger

Not at all The most imaginable

2. Current level of thirst

Not at all The most imaginable

3. Current level of anxiety

Not at all The most imaginable

4. Current level of tiredness

Not at all The most imaginable

5. Current level of weakness

Not at all The most imaginable

ATTACHMENT B

RESEARCH INFORMATION

Research Title ***:*** **The effect of carbohydrate loading on gastric residual volume and hunger score**

Name of main and co-Researcher:
Dr. Bee Chen Lua (MPM 61885),
Dr. Michael Wong Pak Kai (General surgeon HUSM, MPM 45546)
Dr. Mohd Nizam Bin Md Hashim (General surgeon HUSM, MPM 41057)

INTRODUCTION

You are invited to take part voluntarily in a research. This research is about Effect of carbohydrate loading on gastric residual volume and patient's wellbeing.

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate.

Your participation in this study is expected to be about 3 hours. This study is estimated to include up to 78 participants.

PURPOSE OF THE STUDY

The purpose of this study are to determine and compare effect of carbohydrate drink and plain water towards gastric residual volume and patient's well being.

PARTICIPANTS CRITERIA

The research team members will discussed your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history [if relevant ONLY].

This study will include individual who are above 18 years old

This study will not incude individual who had history of upper gastrointestinal surgery, symptoms of intestinal obstruction such as vomiting, abdominal distension and mentally disabled subject.

STUDY PROCEDURES

All subjected planned **for scope of stomach (oesophagogastroduodenoscope**) with the complain of one or more of the following symptoms: Bothersome postprandial fullness, early satiation, Epigastric pain or Epigastric burning and fulfil inclusion criteria are selected. Patients will be approach and invited to join the study. Informed consent will be obtained after explanation regarding the study and procedure. They are randomised into 2 group:

- Group 1 will be given 250cc plain water
- Group 2 will be given 237cc resource (1 pack resource).

2 hours after that, subject undergo scope. Scope is done follow standard protocol. Fluid remain in the stomach is aspirated until dry via endoscope and residual gastric volume is measured.

Subject's wellbeing is assessed via visual analogue scale (VAS) which consist of 5 parameters: hunger, thirst, anxiety, tiredness and weakness. This scale will be used repeatedly during this study to assess

patient's wellbeing. Subject need to mark "X" somewhere along the horizontal line given before drink and before scope procedure.

RISKS

The possible risk that may arise from your participation in the study include injury to the gastrointestinal's wall, aspiration and bleeding which is the similar risk for all patient going through oesophagogastroduodenoscope procedure.

REPORTING HEALTH EXPERIENCES.

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.

Dr. Bee Chen Lua **[MMC Registration No. 61885]**
at +60 127107200

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled.

Your participation also may be stopped by the research team without your consent if in any form you have violated the study eligibility criteria. The research team member will discussed with you if the matter arises.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

The procedure undergo in this study will be provided to you with free. You will be informed about result of the endoscope and treatment provided.

This study finding may benefit the community by knowing the effect of carbohydrate drink before procedure on patient's well being and its safety to be used in future.

You will not recieve any compensation from this study.

QUESTIONS

If you have any question about this study or your rights, please contact;

Dr Bee Chen Lua & No. MMC 61885
Department of general surgery
School of medicine
USM Health Campus
+60 127107200

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my or jepem@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and data the signature page **[ATTACHMENT S and ATTACHMENT P]**

ATTACHMENT S

Subject Information and Consent Form
(Signature Page)

Research Title: **The effect of carbohydrate loading on gastric residual volume and hunger score**

Researcher's Name: **Dr. Bee Chen Lua (MPM 61885), Dr. Michael Wong Pak Kai (General surgeon HUSM, MPM 45546), Dr. Mohd Nizam Bin Md Hashim (General surgeon HUSM, MPM 41057)**

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____

Participant I.C No

_____ _____

Signature of Participant or Legal Representative **Date** (dd/MM/yy)

_____

Name of Individual
Conducting Consent Discussion

_____ _____

Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

_____ _____

Name & Signature of Witness **Date** (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

ATTACHMENT P

Participant's Material Publication Consent Form
Signature Page

Research Title: **The effect of carbohydrate loading on gastric residual volume and hunger score**

Researcher's Name: **Dr. Bee Chen Lua (MPM 61885), Dr. Michael Wong Pak Kai (General surgeon HUSM, MPM 45546), Dr. Mohd Nizam Bin Md Hashim (General surgeon HUSM, MPM 41057)**

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there has been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____

Participant Name

_____ _____ _____

Participant I.C No. **Participant's Signature** **Date** (dd/MM/yy)

_____ _____

Name and Signature of Individual **Date** (dd/MM/yy)
Conducting Consent Discussion

Note: i) All participants who are involved in this study will not be covered by insurance.