Research Proposal

A . Title:

PREOPERATIVE FREE ACCESS TO WATER AS OPPOSE TO FREE ACCESS TO CARBOHYDRATE DRINK UNTIL OPERATION THEATRE CALL TIME IN ELECTIVE GYNAECOLOGY SURGERY – RANDOMISED TRIAL

B. Executive summary of research proposal

Preoperative fasting guidelines allow clear liquids until two hours prior to anaesthesia and restrict solid food within six hours of anaesthesia.(1-4) However, in most busy hospitals, it is difficult to keep an operating list to exact schedule and the two-hour allowance is practically unenforceable leading to more prolonged fasting than is ideal. More recently, the British anaesthesia guideline committee is suggesting allowing free access to clear fluids down to 1 hour before anaesthesia. (5)

The objective of this study is to evaluate the effects of preoperative free access of water compared to free access of carbohydrate drink till Operation Theatre (OT) call time on pre-operative discomfort, satisfaction and postoperative recovery.

The study will be a single centre, prospective, randomised controlled trial, conducted in University Malaya Medical Centre, Kuala Lumpur.

Expected outcomes of this study are reported reduction in patient's hunger scores pre-operatively and higher patient satisfaction score with preoperative oral intake care. If statistically significant, these outcomes could potentially affect preoperative oral intake management for the better with improved patient satisfaction.

C. Research background

This study hypothesizes that pre-operative oral carbohydrate drinks in elective gynaecology surgery scheduled under general anaesthesia improves patients pre-operative discomfort, satisfaction and post-operative recovery.

Based on literature review done, pre-operative oral carbohydrate has been shown to reduce pre-operative thirst, hunger, anxiety, and nausea.(6, 7) It also reduces insulin resistance by 50%, as well as nausea, vomiting, pain, and nitrogen loss post-surgery.(8-11)

Clear liquids and gastric secretions move rapidly out of the stomach; the 50 percent emptying time of water is approximately 12 minutes.(12) Glucose-containing fluids initially leave the stomach more slowly, but after 90 minutes the stomach is empty of clear liquids regardless of type.(13) Gastric residual volume averages approximately 25 mL in patients fasted overnight prior to surgery.(14) Studies have shown that this is unchanged in patients who drink clear

liquids, water, clear juices, coffee, tea, or carbohydrate drinks up to two hours before surgery. (13, 15-19) In addition, pH values are also unchanged in patients drinking clear liquids.

One retrospective study has also demonstrated, permitting unrestricted clear oral fluids pre-operatively until transfer to theatre in scheduled day case anaesthesia reduces the rates of post-operative nausea and vomiting.(20)

Zhang et al demonstrated that patients taking carbohydrate drinks experienced significantly less hunger than patients taking water and concluded that the administration of oral carbohydrate beverage 2 hours before ambulatory surgery was safe and effective.(21)

D. Objectives

To evaluate the effects of preoperative free access of water compared to free access of carbohydrate drink till Operation Theatre (OT) call time

E. Methodology

This is a randomised controlled trial involving women who are planned for elective gynaecology surgery in University Malaya hospital. Eligible patients will be identified using the eligibility form and patient information sheet will be provided to those who fulfilled the eligible criteria. Those who agreed to participate will be asked to provide a written consent after which they will be recruited in this study.

Participants will receive usual care. Prior to operation they will be seen pre-operatively by the anaesthetic team, assessment will be done after which they will be given a date for elective admission to the ward 1 day prior to the surgery. Final eligibility for entry to the study will only be done on the day of admission. In the ward, they will be assessed by the anaesthetic and gynaecology team in charge, and confirmed for operation the next day. At this point is their final recruitment at which they will be given a sealed envelope with a number within, which will determine the study protocol. They will need to follow either – free access of water or free access of carbohydrate drink till up to OT call time

Randomisation

According to the time of pre-operative fasting, patients will be divided into 2 main groups.

A: Light meal up to 6 hours before surgery; No solid foods from 6 hours before the operation and allow carbohydrate drink till OT call time

B: Light meal up to 6 hours before surgery; No solid foods from 6 hours before the operation and allow water till OT call time

Patient is given assignment to record the volume and time of drinking up to OT call.

Hunger

Patients will be instructed to assess their hunger level with a VNRS score of 0 to10 at OT call time. (It is expected that the patients allowed to consume carbohydrate drink up to the time of OT call will be less hungry).

Patient's satisfaction

Patient's overall satisfaction with pre-operative oral intake care - to be assessed via a questionnaire at the time of OT call with the VNRS score 0 to 10. (It is expected that the patients allowed to consume carbohydrate drink up to the time of OT call will have a higher score of satisfaction).

BMI

Patient's admission weight and height will be recorded on recruitment of the study.

Refloflux

Patient's glucose levels will be monitored with refloflux upon OT call.

Vomiting Status – diary or observed

Patients will be observed for vomiting post-operatively and also till 24 hours post operation (as binary yes / no outcome)

Participants will keep a vomiting diary up to hospital discharge, recording date and time of each vomiting episode

Hydration Status – Thirst, Nausea, Ketonuria

Patients will be tested for ketonuria and glycosuria with ketone strips at OT call in the ward prior to being pushed to OT. Mid-stream urine sample will also be taken for analysis prior to patient being sent to OT. Patients also will be assessed on their thirst and nausea level with a VNRS score of 0 to10 prior to patient being sent to OT

Usage of Anti-emetics

The usage of anti-emetics will be recorded pre-operatively, intra-operatively and post-operatively

First Oral Feed

Post-operatively, patients will be encouraged to eat/drink as soon as possible (as per post-operative order) and the time from OT finish time to first oral feed time will be recorded and compared with each of the groups. (Patients who are allowed to take carbohydrate drink till OT call time are expected to take orally earlier as they are expected to have better nutritional status and less dehydration making it easier for them to start taking orally earlier).

Ambulatory status

Patient's first ambulatory time – time at which the patient first gets up to ambulate will be recorded.

Resting pain score

Post-op patients will be monitored for their resting pain score - day 1 post op before mobilisation with VNRS score 0 to 10

Time of discharge

Time of surgery until time of discharge will be monitored and documented. (It is expected that patients that were allowed to consume carbohydrate drink till the time of OT call time to have faster recovery, good hydration, earlier ambulation and earlier discharge).

Flow chart

Gantt chart

Milestones and dates

Apr 2021 – ethics submission and approval

July 2021 – expected start of recruitment

Jan 2022 – expected completion of recruitment and data collection

Feb 2022 – data analysis

Mar 2022 – thesis completion and submission

F. Expected Results/Benefit:

This study expects to show that patients who are allowed carbohydrate drink till OT call time will report improved pre-operative discomfort, satisfaction and post-operative recovery.

G. Expected Research Impact

If this study manages to prove our hypothesis with statistically significant results, it could potentially improve standard practice for pre-operative oral care in all women going for elective gynaecology surgery. As opposed to routine fasting pre-operatively, in the future, we hope this study will contribute towards patients being allowed to drink freely till OT call time with improved patient satisfaction and recovery.