UNIVERSITI PUTRA MALAYSIA

EFFECTIVENESS OF ENHANCED RECOVERY AFTER SURGERY WITH WHEY PROTEIN-INFUSED CARBOHYDRATE LOADING ON POSTOPERATIVE OUTCOMES AMONG GYNAECOLOGIC CANCER PATIENTS

HO CHIOU YI

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By

HO CHIOU YI

Thesis Submitted to the School of Graduates Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Master of Science

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Master of Science

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September 2020

Chair : Zuriati binti Ibrahim, PhD
Faculty : Medicine and Health Sciences

Background: Enhanced Recovery after Surgery (ERAS) with preoperative sole carbohydrate (CHO) loading is widely proven in reducing the length of postoperative hospital stay (LPOHS) without increasing complications among gastrointestinal and gynaecologic cancer (GC) patients. However, ERAS with preoperative whey protein-infused CHO loading among GC patients is unexplored. This randomised controlled trial aimed to determine the effectiveness of ERAS with preoperative whey protein-infused CHO loading on postoperative outcomes among GC patients. **Method**: The trial recruited 62 subjects as intervention group (CHO-P), who received preoperative whey protein-infused CHO loading and 56 subjects as control group (CO), which were given conventional care. Postoperative outcomes including surgical outcomes, postoperative complications, nutritional (body composition, dietary intake and biochemical profile) and functional status (handgrip strength) were studied. Body composition involved in this study were muscle mass, fat percentage, fat-free mass and fat mass, while biochemical profile assessed were full blood count, albumin and C-reactive protein. Body composition was measured via TANITA body composition analyser, nutritional status via PG-SGA, dietary intake via 24-hour diet recall, handgrip strength via Jammar Dynamometer. Pearson Chi-square, paired t-test, independent t-test and two-way mixed model ANOVA were used to analyse the data. One-way ANCOVA was used to detect for any covariates. **Result**: The mean age for CHO-P was 49.5 ± 12.2 years and CO was 51.2 ± 11.9 years. Majority of the subjects were Malay (70%), followed by Chinese (19%) and India (11%). Subjects' diagnosis distribution was 42% ovarian cancer, 34% endometrial cancer, 18% cervical cancer and 6% uterine

cancer. Total energy intake of subjects was 1385 ± 327 kcal/day, while total protein intake was 56.7 ± 16.6 g/day. Percentage weight loss within 1 month were -4.5 ± 6.8% and -5.3 ± 7.2% for CHO-P and CO, while PG-SGA scores were 6.7 ± 5.2 and 7.0 ± 5.5, respectively. CHO-P showed significantly positive results in the trial, which included shorter LPOHS (78.13 ± 33.05 hours vs. 99.49 ± 22.54 hours, $p<0.01$), less postoperative nausea and vomiting (17% vs 24%, $p<0.01$), a lower readmission rate within one-month postoperative (6% vs. 16%, $p<0.05$), lower weight loss (−0.3 ± 2.3 kg vs. −2.1 ± 2.3 kg, $p<0.01$), lower C-reactive protein–albumin ratio (0.3 ± 1.2 vs. 1.1 ± 2.6, $p<0.05$), more preserved muscle mass (0.4 ± 1.7 kg vs. −0.7 ± 2.6 kg, $p<0.01$), and better handgrip strength (0.6 ± 4.3 kg vs. −1.9 ± 4.7 kg, $p<0.01$) as compared with CO. However, there were no significant differences in mid-upper arm circumference and serum albumin level upon discharge. **Discussion and conclusion**: ERAS with preoperative whey protein-infused CHO loading not only assured better surgical outcomes without increasing postoperative complications and readmission rate, but also achieved a superior preservation of nutritional status and muscle strength, as well as suppression of postoperative acute phase inflammatory marker among GC patients. This approach with a multidisciplinary involvement and collaboration is recommended to be integrated into routine perioperative nutritional intervention management in surgical oncology to ensure better postoperative outcomes.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk Ijazah Sarjana Sains

KEBERKESANAN *ENHANCED RECOVERY AFTER SURGERY* DENGAN MINUMAN BERKARBOHIDRAT MENGANDUNGI PROTEIN-WHEY KE ATAS HASIL PEMBEDAHAN DALAM KALANGAN PESAKIT KANSER GINEKOLOGI

Oleh

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Latar belakang: *Enhanced Recovery after Surgery* (ERAS) dengan pemberian minuman berkarbohidrat sahaja semasa pra-pembedahan telah terbukti dapat mengurangkan tempoh berada di hospital selepas pembedahan (LPOHS) dan komplikasi dalam kalangan pesakit kanser perut usus dan ginekologi (GC). Namun, ERAS dengan pemberian minuman berkarbohidrat yang mengandungi protein belum dikaji dalami kalangan pesakit GC. Kajian percubaan kawal secara rawak ini bertujuan untuk mengkaji impak ERAS dengan minuman berkarbohidrat yang mengandungi protein yang diberikan sebelum pembedahan ke atas hasil pembedahan dalam kalangan pesakit (GC). **Kaedah**: Kajian ini melibatkan 62 subjek sebagai kumpulan intervensi (CHO-P) yang diberikan minuman berkarbohidrat yang mengandungi protein sebelum pembedahan manakala 56 subjek sebagai kumpulan kawalan yang menerima penjagaan konvensional. Hasil pembedahan termasuk hasil pembedahan klinikal, komplikasi, pemakanan (komposisi tubuh dan profil biokimia) dan fungsi (kekuatan cengkaman tangan) dikaji. Komposisi tubuh yang terlibat dalam kajian ini adalah jisim otot, peratus lemak, jisim bebas lemak dan jisim lemak, manakala profil biokimia adalah kiraan darah penuh, albumin dan protein C-reaktif. Komposisi tubuh diukur dengan analisis komposisi badan TANITA, status pemakanan dengan PG-SGA, pengambilan makanan dengan ingatan diet-24 jam, kekuatan genggaman tangan dengan *Jammar Dynamometer*. Khi-square Pearson, ujian T-berpasangan, ujian T-tidak berpasangan dan model ANOVA dua-hala bercampur digunakan untuk analisa data. ANCOVA satu-hala digunakan untuk mengesan kovariat**. Keputusan**: Min umur untuk CHO-P adalah 49.5 ± 12.2 tahun dan CO adalah 51.2 ± 11.9 tahun. Majoriti subjek

adalah Melayu (70%), diikuti oleh Cina (19%) dan India (11%). Pertaburan diagnosis subjek adalah 42% kanser ovari, 34% endometrium kanser, 18% kanser serviks dan 6% kanser rahim**.** Jumlah pengambilan tenaga adalah 1385 ± 327 kcal/hari manakala jumlah pengambilan protein adalah 56.7 ± 16.6 g/hari. Peratus penurunan berat badan dalam 1 bulan adalah -4.5 ± 6.8% dan -5.3 ± 7.2% untuk CHO-O dan CO, dan skor PG-SGA adalah 6.7 ± 5.2 dan 7.0 ± 5.5 masing-masing. CHO-P menunjukkan keputusan yang positif secara signifikan, termasuk LPOHS yang lebih pendek (78.13 ± 33.05 jam vs. 99.49 ± 22.54 jam, $p<0.01$), kurang simptom loya dan muntah selepas pembedahan (17% vs 24%, $p<0.01$), kurang kemasukan hospital semula selepas pembedahan (6% vs 16%, $p<0.05$), kurang penurunan berat badan (-0.3 ± 2.3kg vs -2.1 ± 2.3kg, $p<0.01$), pengekalan jisim otot badan (0.4 ± 1.7kg vs -0.7 ± 2.6kg, $p<0.01$), nisbah protein C-reaktif albumin yang lebih rendah (0.3 ± 1.2 vs 1.1 ± 2.6, $p<0.05$) dan kekuatan genggaman tangan yang lebih baik (0.6 ± 4.3kg vs -1.9 ± 4.7kg, $p<0.01$) jika dibandingkan dengan CO. Namun, kajian ini tidak dapat menunjukkan perubahan yang nyata antara kumpulan bagi ukurlilit pertengahan lengan atas dan aras albumin semasa discaj. **Perbincangan dan kesimpulan**: ERAS yang melibatkan pemberian minuman berkarbohidrat yang mengandungi protein bukan sahaja memberikan hasil pembedahan yang lebih baik tanpa meningkatkan komplikasi, malah juga mencapai pemeliharaan yang unggul dari segi status pemakanan dan kekuatan otot, serta menindas penanda keradangan fasa akut selepas pembedahan dalam kalangan pesakit GC. Pendekatan dengan penglibatan dan kolaborasi pelbagai disiplin ini disarankan untuk diintegrasikan dalam pengurusan intervensi pemakanan pembedahan rutin dalam onkologi pembedahan untuk mencapai hasil selepas pembedahan yang lebih baik.

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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Master of Sciences. The members of the Supervisory Committee were as follows:

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LIST OF ABBREVIATIONS

UPM	Universiti Putra Malaysia
Alb	Albumin
ASPEN	American society of Parenteral and Enteral Nutrition
ASA	American Society of Anaesthesiologist score
BMI	Body Mass Index
CAR	C-reactive Protein-Albumin Ratio
CHO	Carbohydrate
CHO-P	CHO-protein
CRP	C-reactive Protein
CO	Control
CONSORT	Consolidated Standard of Reporting Trials
DNA	Deoxyribonucleic acid
ERAS	Enhanced Recovery after Surgery
ESPEN	European Society of for Clinical Nutrition and Metabolism
FFM	Free Fat Mass
FM	Fat Mass
FTR	Fast Track Recovery
GC	Gynaecologic cancer
GLOBOCAN	Global Cancer Statistics
Hb	Haemoglobin
IARC	International Agency for Research on Cancer
JKE	*Jawatankuasa Etika untuk Penyelidikan Manusia*
LOCF	Length of clear fluid toleration
LOSDT	Length of solid diet toleration
LOBFR	Length of bowel function return
LOBO	Length of bowel open
LOHS	Length of hospital stays
LOS	Length of stays
LPOHS	Length of postoperative hospital stay
MNCRR	Malaysian National Cancer Registry Report
MREC	Medical Research and Ethics Committee
MUAC	Mid-Upper Arm Circumference
NMRR	National Medical Research Registry
NMSC	Nonmelanoma skin cancer
NG	Nasogastric
ONS	Oral Nutrition Supplement
PG-SGA	Patient Generated Subject Global Assessment
POD	Postoperative day
RCT	Randomised control trial
RECOvER	Reporting on ERAS Compliance, Outcomes and Elements Research
SGA	Subjective Global Assessment
TAHBSO	Total abdominal Hysterectomy Bilateral Salpingooperectomy

CHAPTER 1

INTRODUCTION

1.1 Background

Cancer is defined as a diseases which involves uncontrolled growth of abnormal cells that neglects the normal rules of cell division (Um, 2015). Normal human body cells share similar molecular networks whereby there are constant signals to grow, divide, differentiate into other cells or die. Changes in the molecular structure, biochemical and cellular cause the uncontrolled growth and proliferation of cancer cells to happen (Um, 2015). Cancer involves mutation in the cell genome where its protein, produced by Deoxyribonucleic acid (DNA) mutation, disrupts the appropriate cellular balance cycle from cell division to death, consequently causing the cells to keep on dividing to form cancers (Hesketh, 2012).

Gynaecologic malignancies is a field clinically specialised in the female reproductive system cancers, while gynaecologic cancers (GC) are cancers that affect women's reproductive system such as cervical cancer, ovarian cancer, endometrial cancer, uterine cancer, vaginal cancer, and vulvas cancer from all demographic and cultural backgrounds (Di Saia et al., 2018a).

The International Agency for Research on Cancer (IARC) compiled the Global Cancer Statistics (GLOBOCAN) 2018 database and reported that there were 18.1 million new cancer cases worldwide. From the database, GLOBOCAN 2018 reported that there is about 20% risk of getting a cancer before the age of 75, and 10% of death is caused by cancer (Bray et al., 2018). The percentage of cancer deaths in Asia is higher (57.3%) than the percentage of incidence (48.4%) because of the different distribution of cancer types and higher mortality rates (Siegel et al., 2018).

Although breast cancer is the most common cancer in female population around the world, there are three GC (cervix, corpus uteri, and ovarian cancers) listed as part of the top ten cancers in the world (Bray et al., 2018). According to the Malaysian National Cancer Registry (MNCR), there is a similar trend whereby cervix, uterine and ovarian cancers are listed as the top ten most common leading cancers among Malaysians. Cervix, uterine and ovarian cancers were ranked at third and fifth places of the top five most common cancers in Malaysian females from years 2012 to 2016 (Azizah et al., 2019).

Clinical and pathological assessments are the first approaches of GC diagnosis and management. After diagnosis, oncologists and oncology surgeons would

determine the appropriate treatment options based on prognosis. Surgery, chemotherapy and radiotherapy are the primary cancer treatments (Jammer et al., 2015). Oncologists and surgeons would prioritise surgery as the first treatment for those cancers which are well margined and operable (Saito et al., 2018).

Optimum nutritional status of patients at pre-, during and post-operation is of importance to speed up the postoperative wound healing process, enhance immunity and assure better post-operation outcomes (Arends et al., 2017). However, the prevalence of malnutrition is high among cancer patients, including GC patients (Laky et al., 2006; Obermair et al., 2017). This phenomenon is due to the alteration of energy metabolism by cancer cells, whereby it involves an increase in basal metabolic rate that subsequently increases metabolism of sugar, protein and lipid (Baracos et al., 2018). With increased energy and nutrient needs but inadequate oral intake, cancer patients, including GC patients, have a high risk of being malnourished before the start on any treatment (Laky et al., 2006). Operation not only leads to body skeletal muscle tissue catabolism in order to release amino acids, but also raise the rate of protein anabolism to heal the damaged cells and regenerate new blood vessels (Sandrucci et al., 2018).

Higher nutritional requirement for surgery is essential to support a speedy recovery and minimise postoperative nutritional depletion (Arends et al., 2017). Macronutrients including CHO, protein and fat are the main sources of calories providers. Other than fat and CHO, protein is an essential macronutrient to boost anabolism, slow down muscle catabolism and decrease the inflammatory phase during postoperative recovery stage (Arends et al., 2017). Protein food sources such as milk protein is categorised as a potential ingredient in oral supplement support formula or functional food for chronic diseases such as cardiovascular disease, diabetes mellitus and cancer (Petrotos et al., 2014). There are two major types of milk protein, which are casein micelles and whey protein. In comparison, the quality and bioavailability of whey protein is higher whereby it records 3.2 in protein efficacy ratio, 104 in biological value and has 99% protein digestibility (Petrotos et al., 2014). With these features, whey protein is easier to be digested, absorbed by the gastrointestinal tract and increase muscle protein synthesis (Teixeira et al., 2019).

Conventional surgery approach recommends prolonged fasting before and after operation. Preoperative fasting is to starve the patient from having any foods and liquids within a specified period of time before anaesthesia induction and/or initiation of surgery. Preoperative fasting aims to equip the patient with an empty or near empty stomach for emergency and elective surgery (Francisco et al., 2015; Maltby, 2006). Physiologically, the intention of a preoperative fasting is to reduce regurgitation, vomiting, aspiration, and complication risks during anaesthesia or surgery (Murray et al., 2018; Nunes et al., 2006). However, patients might fast longer than the expected period on the operation day due to the unforeseeable nature of a packed operating theatre or unavoidable delays. Sometimes, elective operations might be cancelled in the late afternoon.

Subsequently, there would be a rescheduling of the elective operation and another round of preoperative fasting for patients. Prolonged and even repeated preoperative fasting deplete patients' nutritional status even prior to operation and delay patients' recovery progress as an organic response to surgical trauma (Chon et al., 2017). Preoperative fasting can lead to dehydration and increase the need for fluid replacement during anaesthesia, and the potential for blood lost replacement during surgical procedures. Reduction in blood volume and drugs kinetics alternation resulting from the surgical procedure-related dehydration and blood loss can cause more side effects (Li et al., 2014).

Postoperative management of conventional surgery approach practise nasogastric (NG) decompression and delayed oral feeding after a major abdominal operation (Petrini, 2005). The progression of postoperative feeding in conventional surgery is slow, which is a stepwise manner following patient's progression. Patient is only allowed to eat orally after bowel function has returned with passage of flatus or stool. Diet pattern is then expanded gradually from full liquid to normal diet. With this diet transition stage, postoperative oral feeding is usually delayed for 4–5 days (Aguilar-Nascimento et al., 2007). Delayed oral feeding causes inadequate oral intake and further nutritional depletion. With this condition, catabolism would happen whereby energy is generated from protein source of the human body (muscle) in order to compensate for energy expenditure. Hence, inadequate oral intake due to delayed oral feeding postoperatively causes patients to experience unintentional weight and muscle mass loss (Balayla et al., 2015).

Henrik Kehlet and Mogensen (1999) realised the problem of a unimodal intervention as in conventional surgery approach, thus they established the protocol for a multimodal perioperative care, named the Enhanced Recovery After Surgery (ERAS) or Fast Track Recovery (FTR) Surgery (Kehlet et al., 1999). This is a multidisciplinary metabolic strategy aimed to abbreviate the length of hospital stay (LOHS), reduce perioperative stress and enhance surgical outcomes, attain better pain control, faster normal gastrointestinal function return, and early mobilisation (Arends et al., 2017; Ariffin et al., 2016; Ariffin et al., 2014; Balayla et al., 2015; Eberhart et al., 2008; Obermair et al., 2017; Sandrucci et al., 2018).

Nutritional intervention approach is one of key elements in ERAS protocols. To shorten the preoperative fasting period, ERAS protocols recommend a beverage containing CHO as a CHO loading approach (Kehlet et al., 1999). Preoperative sole CHO loading using a sole CHO drink is frequently used among gastrointestinal cancer patients with proven positive and beneficial outcomes (Ariffin et al., 2014; Carter, 2012; Kalogera et al., 2013; Marx et al., 2006; Modesitt et al., 2016; Rizvanović et al., 2019). Postoperative early oral feeding is recommended because the suspension of nutritional support therapy and delayed oral feeding increased the risk of malnutrition post-operation (Balayla et al., 2015). Studies suggest starting at the relevant references as proof of citation on ERAS with preoperative sole CHO loading have shown to significantly shortened LOHS without increasing readmission and complication rates.

The integration of ERAS protocols has shown to reduce LOHS and postoperative complications in patients undergoing vascular surgery (Dinic et al., 2018). On the other hand, ERAS surgical stabilisation with epidural analgesia was able to shorten intensive care unit and hospital stay (Golic et al., 2018), with similar findings reported among urologic surgical patients (Dinic et al., 2018).

1.2 Problem statement

As per the recommendations in ERAS and the European Society for Clinical Nutrition and Metabolism (ESPEN) 2017, the shortening of preoperative fasting via carbohydrate (CHO) loading and early initiation of postoperative oral feeding are preferable, with improved postoperative surgical outcomes and without increased postoperative readmission rates (Arends et al., 2017; Kehlet et al., 2002). To date, carbohydrate loading with solely carbohydrate drink is broadly used and has been shown to have beneficial outcomes (Modesitt et al., 2016; Rizvanović et al., 2019; Smith et al., 2014).

Over the decades, ERAS has increasingly been practised in colorectal surgeries (Pexe-Machado et al., 2013), gastrointestinal surgery (Lewis et al., 2001), pancreaticoduodenectomy (Ariffin et al., 2014), and various other fields (Dock-Nascimento et al., 2012; Kim et al., 2012). Studies highlighted that ERAS with preoperative sole CHO loading allows for postoperative early oral feeding with clear fluid, followed by solid foods (Kalogera et al., 2013; Kehlet et al., 2002; Knott et al., 2012; Makuuchi et al., 2017; Modesitt et al., 2016; Rizvanović et al., 2019).

ERAS protocols with preoperative CHO loading and postoperative early oral feeding in GC surgeries also showed similar findings whereby it significantly shortened the length of stay (LOS) without increasing readmission and complication rates (Balayla et al., 2015; Kalogera et al., 2013; Modesitt et al., 2016; Renaud et al., 2019). In Malaysia, surgeries which implemented the ERAS protocols with preoperative CHO loading showed positive surgical outcomes, including in colorectal resection (Ho, 2018), pancreaticoduodenectomy (Ariffin et al., 2014), and liver resection (Ariffin et al., 2016). However, the impact of the ERAS protocols in surgical GC remains unclear in Malaysia.

Protein is a macronutrient which promotes anabolism and minimises catabolism (Kiela et al., 2016). To explore the role of protein in CHO loading under the ERAS protocols, studies in cholecystectomy (Dock-Nascimento et al., 2012), gastrointestinal cancer (Perrone et al., 2011), and oral and maxillofacial surgery (Singh et al., 2015) resulted in shortened postoperative length of stay and reduced postoperative inflammatory reactions. A study demonstrated that preoperative CHO loading in the form of protein-infused with CHO drinks in cholecystectomy patients preserved postoperative muscle strength, improved patients' satisfaction by reducing fatigue, anxiety and discomfort, and reduced trauma-induced inflammatory responses (Perrone et al., 2011).

Guidelines for preoperative CHO loading in GC patients under the ERAS setting have been updated (Nelson et al., 2019) and consistent with the defined ERAS protocols which consist of 16 items, including preoperative CHO loading and postoperative early feeding (Elias et al., 2019; Ljungqvist et al., 2017a). However, the effectiveness of ERAS with whey protein-infused CHO loading drinks as preoperative CHO loading among surgical GC patients is less explored. Thus, there is a need to fill the research gap regarding the effectiveness of ERAS with preoperative whey protein-infused CHO loading in surgical GC patients.

Moreover, most ERAS protocol studies were focused on postoperative clinical outcomes such as LOS, complication, and readmission rates (Ariffin et al., 2016; Ariffin et al., 2014; Balayla et al., 2015; Eberhart et al., 2008; Kehlet et al., 1999; Lewis et al., 2001; Mathur et al., 2010). However, the role of ERAS protocols in changes of nutritional aspects [body composition, biochemical profile (acute phase inflammatory marker) and postoperative total daily energy protein intake), and functional status (handgrip strength)] were not emphasized. On top of surgical outcomes, this study aims to investigate the effectiveness of ERAS with a preoperative whey protein-infused CHO loading on postoperative nutritional status and handgrip strength outcomes among GC patients.

1.3 Research questions

i. Is there any difference in the surgical outcomes and postoperative complications in GC patients between CHO-P and CO?

ii. Is there any difference in the nutritional outcomes (anthropometry, dietary intake and biochemical data) and functional outcome (handgrip strength] in GC patients between CHO-P and CO?

1.4 Objectives

1.4.1 General objective

To determine the effectiveness of ERAS with a preoperative whey protein-infused CHO loading drink on postoperative outcomes (surgical outcomes and postoperative complications, as well as nutritional and functional outcomes) among GC patients.

1.4.2 Specific objectives

i. To determine the overall characteristics [socio-demographic, clinical, nutritional status (anthropometry, dietary intake and biochemical profile) and functional status] in GC patients prior to elective operation.

ii. To determine and compare the surgical outcomes [length of postoperative hospital stay (LOPHS), length of clear fluid toleration (LOCF), length of solid diet toleration (LOSDT), length of bowel function return (LOBFR), and length of bowel opening (LOBO)] and postoperative complications (postoperative nausea and vomiting, ileus, aspiration pneumonia, infection, and post-discharge readmission within 30 days) of GC patients between CHO-P and CO.

iii. To determine and compare the nutritional outcomes (anthropometry, dietary intake and biochemical data) and functional outcomes (handgrip strength) of GC patients between CHO-P and CO.

1.5 Research hypotheses

i. CHO-P has significantly better surgical outcomes [length of postoperative hospital stays (LOPHS), length of clear fluid toleration (LOCF), length of solid diet toleration (LOSDT), length of bowel function return (LOBFR), and length of bowel opening (LOBO)] and less postoperative complications (postoperative nausea and vomiting, ileus, aspiration pneumonia and infection, and post-discharge readmission within 30 days)] compared to CO.

ii. CHO-P has significantly better nutritional outcomes (anthropometry, dietary intake and biochemical data) and functional outcome (handgrip strength) compared to CO.

1.6 Conceptual framework

Figure 1.1 shows the dependent and independent variables in the present study. The dependent variables included postoperative outcomes such as surgical outcomes (length of postoperative hospital stay, length of clear fluid toleration, length of solid diet toleration, length of bowel function return, and length of bowel opening); postoperative complications (postoperative nausea and vomiting, aspiration pneumonia, ileus, infection, and post-discharge readmission within 30 days), nutritional outcomes (anthropometry – weight, muscle mass, fat mass, free-fat mass and mid-upper arm circumference; dietary intake; biochemical profile – acute phase inflammatory marker), and functional outcome (handgrip strength).

Independent variables were ERAS with preoperative whey protein-infused CHO loading (intervention group, CHO-P) and conventional surgery approach (control group, CO). The potential confounding factors were surgical approach (laparotomy versus laparoscopic), preoperative co-morbidities and cancer stage. The differences in these dependent variables within each group and the difference between intervention and control groups before and after intervention approach were evaluated.

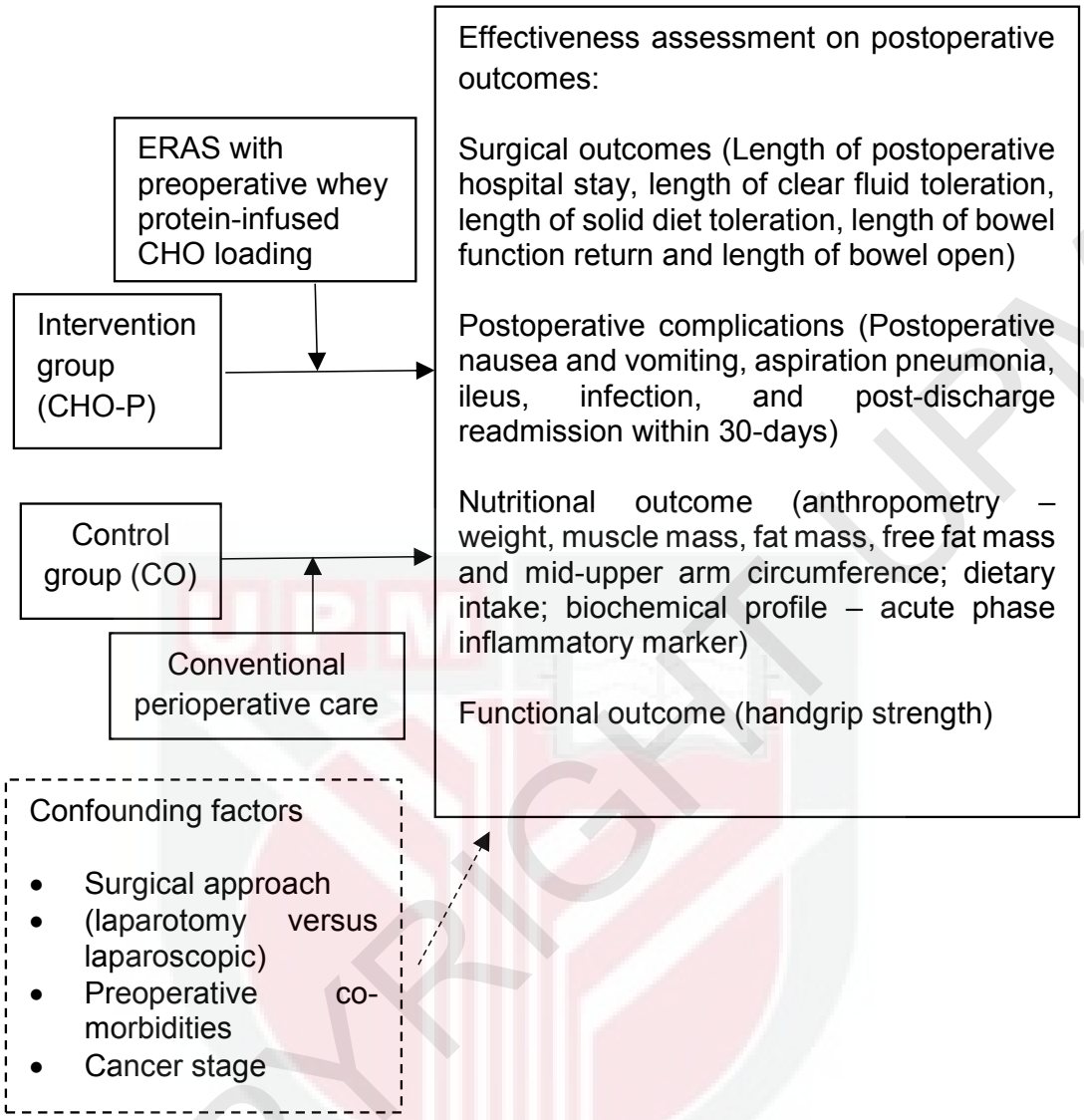

Figure 1.1: Conceptual framework of study

1.7 Definition of Terms

i. ERAS

Conceptual and operational definition: A multimodal perioperative protocol with the aim to promote an early recovery after operation by preserving preoperative organ functions and diminishing surgery-related metabolic stresses. The ERAS protocol elements include preoperative counselling, optimisation of nutrition, preoperative CHO loading, standardised analgesic and anaesthetic regimens, postoperative early oral feeding and early mobilisation (Elias et al., 2019; Kehlet, 2015; Ljungqvist et al., 2017b).

ii. Conventional perioperative care

Conceptual and operational definition: A unimodal surgical approach where a surgeon is the main decision maker in patient management. It involves prolonged fasting during the perioperative period, standard fluid resuscitation, drain or line insertion, opioid optimisation, delayed postoperative oral feeding and mobilisation. Patients are asked to fast from midnight on the day of operation, thus their last meal is normally dinner, which would be a minimum of 12 hours before an operation. Patients would then follow a diet transition stage whereby he/she is allowed clear fluid once there is bowel sounds. After patient has tolerated clear fluid, he/she would proceed with nourishing fluid, then soft diet, and then receive a regular solid diet after tolerating the soft diet (Abebe et al., 2016; Maltby, 2006).

iii. Carbohydrate loading

Conceptual and operational definition: A part of the ERAS perioperative feeding approach to shorten preoperative fasting period where patient consumes 100g carbohydrate-containing drinks in the evening before operation day and 50g carbohydrate-containing drink up to 2 hours before operation (Elias et al., 2019; Kehlet et al., 1999; Ljungqvist et al., 2017b).

iv. Postoperative outcomes

Conceptual and operational definition: The measurements of patient's outcomes after an operation (Jammer et al., 2015).

v. Surgical outcomes

Conceptual and operational definition: The measurements of clinical outcomes after an operation, which include length of hospitalisation, length of postoperative hospital stay, length of clear fluid toleration,

length of solid diet toleration, length of bowel function return, and length of bowel opening (Jammer et al., 2015).

vi. Postoperative complications

Conceptual and operational definition: The measurements of unfavourable results or adverse effects that happened after surgery, which might worsen the condition, or the development of signs, symptoms or pathological changes. These complications would affect other organ systems (Jammer et al., 2015).

vii. Nutritional outcomes

Conceptual and operational definition: The measurements on the changes in nutritional status, which include anthropometry, body composition, biochemical profile, and dietary intake after a nutritional or clinical intervention or approach (Mahan et al., 2020).

viii. Functional outcome

Conceptual and operational definition: The measurement of a patient's physical ability to perform a task or physical movement which involve muscle mass and strength. The ability to perform a specific task is measured by using a tool (Garcia, 2012).

1.8 Significance of the study

The findings from this study may contribute to the body of knowledge on ERAS with nutrition care to enhance recovery rate among surgical cancer patients. In addition, these findings perform the function of a fundamental research evidence on ERAS approach to ensure better postoperative outcomes for surgical GC patients in Malaysia.

The current study might inspire future studies on ERAS with preoperative whey protein-infused CHO loading among other types of cancer patients. The present study findings will turn out to be an elemental guideline for practising healthcare professionals, especially surgeons, allied health professionals including dietitians, as well as dietetic guideline developers in integrating the ERAS multidisciplinary approach into routine practice and further modifying perioperative nutritional interventions, especially for surgical cancer patients.

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