Diet Modification Based on Enhanced Recovery After Surgery in Patients undergoing Elective Abdominal Hysterectomy for Benign Gynecologic Lesions: A Randomized Controlled Trial*

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ABSTRACT

Objective. Enhanced Recovery After Surgery (ERAS) represents an evidenced-based approach to surgical management challenging traditional paradigms with the goal of maintaining normal physiology perioperatively, hence, these benefits were replicated across the spectrum of gynecologic surgeries. The study aims to determine if there is a significant difference in patient's outcome between ERAS and standard diet who will undergo elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic lesions.

Method. This study is a single blind, superiority, randomized controlled trial design. Participants were group as ERAS and standard diet. A total of 15 cases in each study arm was judged sufficient to ensure confidence interval of 95%, 80% power (beta error), 5% margin of error, 50 % of exposed with outcome and 0.5% percent of unexposed with outcome generated from OpenEpi Version 3.01. It utilized descriptive and inferential analysis. Comparative analysis was done using Z-test of proportion for categorical variables and Mann-Whitney test for continuous variable. Two-tailed with values of $P < 0.05$ were concluded statistically significant.

Results: Between January 2021 to December 2021, there were 30 cases participated in this study. ERAS shown better result such as shorter length of hospital stay ($p < 0.019$), early return of bowel function (time to first flatus ($p<0.006$) time to first defecation ($p<0.002$), less post-operative complications in terms of post-operative nausea and vomiting with 24 hours ($p<0.014$) and patient's subjective well-being: hunger ($p<0.001$) and thirst ($p<0.001$). Analysis showed BMI, age, ASA score and preoperative diagnosis were not associated with patient's outcome.

Conclusion: The study showed better patient's outcome, postoperative complications and subjective well-being who underwent elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic lesions under ERAS. Our findings may contribute in the standardization of guidelines for perioperative nutritional care in elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic conditions.

Keywords: Abdominal Hysterectomy, Enhanced Recovery After Surgery, Fasting, Postoperative complications, Preoperative carbohydrate supplements

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INTRODUCTION

In the era of evidenced-based medicine, there were no scientific reasons to keep a patient in prolonged preoperative fasting. This routine was questioned and shown to be unnecessary for most patients. As a result, many anesthesia societies have changed their guidelines and currently recommend intake of clear fluids up until 2 hours before surgery and anesthesia. Accordingly, the European Society for Clinical Nutrition and Metabolism (ESPEN) recommended, with grade A of evidence, a carbohydrate-rich drink 2 hours before anesthesia (1). The main reason for the traditional prescription of 6-8 hours of preoperative fasting for either gastroscopy or elective operations was to reduce the volume and acidity of stomach contents, thus decreasing the risk of regurgitation and aspiration recognized as Mendelson's syndrome. In the 1980s, it was already known that gastric emptying of water and other non-caloric fluids followed an extremely fast exponential curve in volunteers.

Conventionally, patients who underwent elective hysterectomy in our institution fasted from midnight the day before surgery. In addition, the postoperative diet starts on general liquid, then after confirming the passage of flatus on soft diet and normal regular diet once with bowel movement. The ERAS program aimed to maximize the recovery of patients by minimizing pre- and postoperative complications and stress. The program recommends providing preoperative carbohydrate (CHO) supplements and an early postoperative diet to reduce the fasting duration (2). It allows patients to eat a light meal up until 6 hours, and consume clear fluids including oral carbohydrate drinks up until 2 hours, before initiation of anesthesia (3). Post-operatively, the program recommends starting a regular diet within 24 hours after surgery (3). In our institutions, majority of gynecologic surgeons used the standard diet. There were no previous studies or available researches that compared ERAS and standard diet for benign gynecologic hysterectomies.

This study aimed to determine the significant difference in patient's outcome between ERAS and standard diet who underwent elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic lesions. Specifically, in terms of length of hospital stay, return of bowel function: time to first flatus and defecation, post-operative complications: post-operative nausea and vomiting within 24 hours, post-operative pain and readmission within 30 days and patient's subjective well-being: anxiety states, hunger and thirst. The result of this study was geared towards providing optimum health and cost savings while preserving patient's satisfaction and quality of life.

OBJECTIVES

General Objectives

To determine a significant difference in patient's outcome between ERAS and standard diet who will undergo elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic lesions

Specific Objectives

1. To compare the following patient's outcome between ERAS and standard diet in terms of:
    a. Length of hospital stay
    b. Return of bowel function
        1. Time to first flatus
        2. Time to first defecation
    c. Post-operative complications in terms of:
        1. Post-operative nausea and vomiting within 24 hours
        2. Post-operative pain
        3. Readmission within 30 days

2. To compare the patient's subjective well-being between ERAS and standard diet in terms of:
    1. Anxiety states
    2. Hunger
    3. Thirst

METHODS OF RESEARCH

This is a single blind, superiority, randomized controlled trial design involving women with benign gynecologic lesions who underwent elective abdominal hysterectomies with or without salpingo-oophorectomy.

Study Population

This study included benign gynecologic surgical patients admitted for elective surgery in this institution from January 2021 to December 2021.

Inclusion criteria:

All women more than 19 years old, American Society of Anesthesiologists (ASA) I-II and scheduled as elective procedure.

Exclusion criteria:

All patients underwent emergency hysterectomies, documented delayed gastric emptying or gastrointestinal motility disorders such as gastroparesis, mechanical obstruction of the gastrointestinal tract, gastro-esophageal reflux, malignant diagnosis, obese (BMI >30 kg/m2), diabetic patients, ASA class >III and pregnant.

Sample Size and Sampling Design

The sample size was based on a previous study which 80 % of patients has less than 25 mL of RGV after either an overnight fast or 2-3 hours after the ingestion of a carbohydrate alone or in addition to peptides enriched drink. (15) A quantity of 15 cases in each study arm was judged to be sufficient to ensure confidence interval of 95%, 80% power (beta error), 5% margin of error, 50 % of exposed with outcome and 0.5% percent of unexposed with outcome generated from OpenEpi Version 3.01. (Figure 1)

This study used a simple random sampling. The population elements were assigned based on the diet modification. Then, they were assigned chronologically from 1 to n in each group. The sample size in each group were taken through a computer program generated random numbers. The patients were randomized to Group A, preoperatively, light meal up until 6 hours before the surgery, and on the day of surgery, consumed oral carbohydrate drink (Gatorade/Powerade 20 oz. (4)) up until 2 hours before initiation of anesthesia; post-operatively, clear liquid diet such as ice chips, jello, immediately after surgery at PACU (4) then on regular diet within 24 hours of surgery. The patients of Group B, preoperatively, fasted from midnight up until initiation of anesthesia; postoperatively, general liquids then soft diet once with flatus, then, diet as tolerated once with bowel movement.

Materials and Procedure

Eligible patients were recruited at Out Patient Department and Emergency room as scheduled by the researcher. Consent was secured by the researcher attested by a third-party co-service surgeon at the time of admission.

Patient's participation in this study was entirely voluntary. Once the consent was secured, the participants received the appropriate treatment or intervention of her condition according to national guidelines. The risk and benefits was explained by the surgeon to the participants.

Pre-operatively, patients were given standard antibiotic prophylaxis protocol. The patients under Group A, in the event that the patient was not able to tolerate the carbohydrate drink, it was stopped immediately and put patient into nothing per orem. Hence, patient will be given Ranitidine 50mg 1 ampule intravenously and Metoclopramide 10 mg 1 ampule intravenously prior to operation.

Both groups received Paracetamol 300 mg intravenous every 6 hours and Ketorolac 30 mg

intravenous every 8 hours, unless contraindication exists for postoperative pain. If nausea and vomiting will arise, Metoclopramide 10 mg 1 ampule was given.

After discharged, participants of the study were asked to follow up after 1 week. Follow-up was done pro-actively. All means were exhausted to contact the recruited patients. Patients who were lost to follow-up were documented.

Statistical Analysis

This study utilized both descriptive and inferential analysis. Data was described using median for central tendency and range for dispersion. Comparative analysis was done using Z-test of proportion for categorical variables and Mann-Whitney test for continuous variable. There is a need to set a risk level to test the significance and a 5% level was adopted for significance. Two-tailed with values of $P < 0.05$ were concluded as statistically significant. Data analysis was performed using the SPSS software package version 26.

RESULTS

Between January 2021 to December 2021, a total of 30 patients participated in this study, 15 cases in each group, Group A, ERAS and Group B, standard diet.

Patient Demographics

This shows that there are no significant differences on the characteristics of patients in both groups which implies that there is not a lot of intervening factors to consider in terms of age, BMI, ASA score and preoperative diagnosis that might affect the results of other statistical tests done. (Table C.1.)

Patient Outcome

There is one-day difference on the median length of hospital stay between groups, Group A shows a shorter hospital stay than in Group B.

Group A has a median of 12 hours when the first flatus occurred. The difference between the hours to first flatus between experimental and standard group is highly significant as concluded from the p-value of 0.006.

In terms of the length of time it took for the patient to defecate, both groups have the same minimum (12 hours) and maximum (84 hours' time). However, there is a high significant difference among the two groups with a p-value of 0.002. (Table C.2.)

Post- operative Complications

There is a significant difference in the proportion of patients experiencing post-operative nausea and vomiting based on the p-value of 0.014. There are no patients who experienced nausea and vomiting within 24 hours in the experimental group as compared to five (5) patients who experienced it in the standard group.

On the other hand, there is no significant difference on the postoperative pain among the two groups. There is also no significant difference on the readmission status of patients although there is one patient readmitted in Group A. (Table C.3.)

Subjective Well-Being

There is no significant difference in the experience of anxiety between the two groups. Although there are more patients from Group B who admitted to experiencing anxiety.

There is a significant difference among the experience of both hunger and thirst between both groups with a p-value of less than 0.001. (Table C.4.)

DISCUSSION

ERAS pathways were developed with the goal of maintaining normal physiology in the perioperative period, thus optimizing patient outcomes without increasing complications or

readmissions (5). Herein, we compared the patient's outcome between ERAS and standard diet who underwent elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic lesions.

Perioperative diet of the patients is an important component of ERAS protocol. Our study showed there was one day difference on the median length of hospital stay, it shows that ERAS resulted to shorter hospital stay. This result was comparable to the study done by Kim et al., wherein patient under pre and post-operative ERAS has a shorter hospital stay (7).

Surgery and anesthesia are both associated with loss of normal bowel function for multiple reasons. The study done by Ezelle,J.K. their study concluded that preoperative carbohydrate drinks were effective in accelerating the return of bowel function (9). This is true in our study in terms of return of bowel function.

Post-operative complications remains the major medical challenge. In this study, there are no patients who experienced nausea and vomiting within 24 hours in the experimental group as compared to five patients who experienced it in the standard group, which is consistent in one randomized controlled trial, which showed less post-operative nausea and vomiting, metoclopramide consumption, and improved patient satisfaction within 24 hours after abdominal myomectomy (5).

A retrospective study done by Jidong Zuo et al., post-operative pain incidence under the ERAS protocol was decreased with 63.7 %, particularly 6.3 % for moderate- to-severe pain (11). However, in our study, there is no significant difference on the postoperative pain among the two groups with a higher number of patients stating that they did not experience any postoperative pain.

Notably, implementation of ERAS program has not been shown to increase readmission rate (12). Of special interest, in our study, there is no significant difference on the readmission status of patients.

In this study, which is consistent with the study done by Asiye Gul et al., there are less of those who experienced anxiety, hunger and thirst among those under ERAS.(14)

Overall, as shown in our study, ERAS presents a better result in patient's outcome measured in terms of length of hospital stay, return of bowel function, post-operative complications in terms of post-operative nausea and vomiting within 24 hours, post-operative pain and readmission within 30 days and patient's subjective well-being: anxiety states, hunger and thirst.

CONCLUSION

This study showed that there is a significant difference in patient's outcome between ERAS and standard diet who underwent elective abdominal hysterectomies with or without salpingo-oophorectomy for benign gynecologic lesions. With this in mind, implementation of ERAS reduced rates in post-operative complications, faster recovery, decreased length of hospital stay, and overall cost savings.

LIMITATIONS OF THE STUDY

The study did not include factors such as delayed in scheduled time of operation and length of operating time that is affected by the skills of the surgeon, degree of surgical difficulty and surgical complications that may affect the result of this study.

RECOMMENDATION

Since the study was done in a single institution, it is recommended that a multi-center study be conducted, enrollment of more patients and external subgroup analyses such as focusing

on evaluations of more patient-related outcomes, such as patients' experience of the process, quality of life aspects and long-term consequences for further improvement of the care of patients undergoing gynecological surgery.

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Table and Illustrations

Figure 1. Sample Size Computation

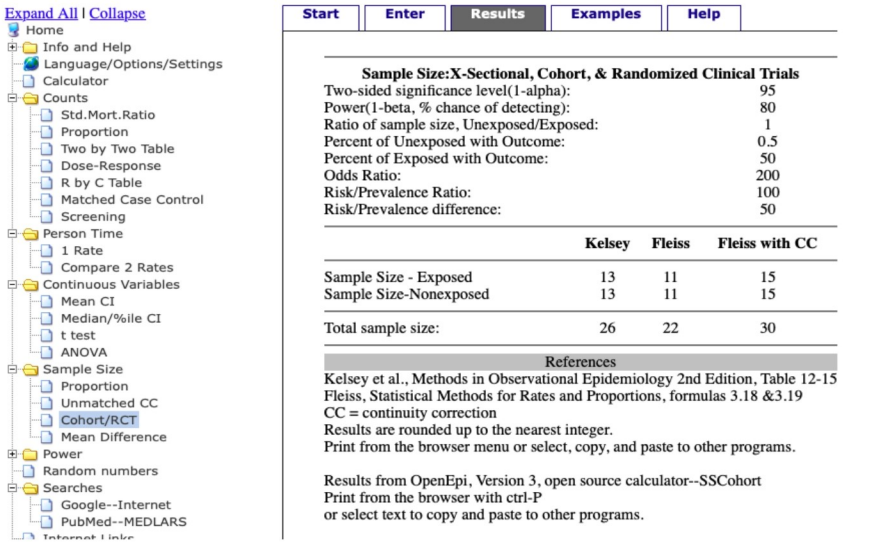

Table C.1: Clinicodemographic Characterics of the Population

POST-OPERATIVE COMPLICATIONS	GROUP A: EXPERIMENTAL (ERAS) (n =15)	GROUP B: STANDARD (n =15)	MANN-WHITNEY U/ Z-TEST	P-VALUE [b]
A. Age (years)	Median = 47 (37-62)	Median = 48 (41-72)	118.5	0.803^{ns}
B. BMI	Median = 23.81 (18.29-29.34)	Median = 23.81 (20.66-29.33)	110	0.917^{ns}
C. ASA Score	ASA score II	ASA score II	No statistics computed because ASA score is the same for both groups.	
D. Pre-operative Diagnosis [(A)]	Adenomyosis = 1_a Leiomyoma = 10_a Ovarian New Growth = 4_a	Adenomyosis = 0_a Leiomyoma = 13_a Ovarian New Growth = 2_a	1.435	0.357^{ns}

Legend:(a) The same subscript letter denotes that proportions do not differ significantly from each other at the set level of significance (b); ns – not significant at 0.05 level of significance

Table C.2: Patient's Outcome

PATIENT OUTCOME	GROUP A: EXPERIMENTAL (ERAS) (n =15)	GROUP B: STANDARD (n =15)	MANN-WHITNEY U	P-VALUE
A. Length of hospital stay (days)	Median = 4 (3-6)	Median = 5 (4-11)	165.00	0.019*
B. Return of bowel function				
B.1. Time to first flatus (hours)	Median = 12 (8-72)	Median = 24 (11-96)	177.5	0.006**
B.2. Time to first defecation (hours)	Median = 24 (12-96)	Median = 72 (12-96)	186.0	0.002**

Legend: * - significant at 0.05 level of significance
** - Highly significant at 0.01 level of significance

Table C.3: Post Operative Complications

POST-OPERATIVE COMPLICATIONS	GROUP A: EXPERIMENTAL (ERAS) ^ (n =15)		GROUP B: STANDARD ^ (n =15)		Z-TEST	P-VALUE
	No	Yes	No	Yes		
Post-operative nausea and vomiting within 24 hours	15_a	0_b	10_a	5_b	2.45	0.014*
Post-operative pain	10_a	5_a	10_a	$5b_a$	0.00	1.000^{ns}
Readmission within 30 days	14_a	1_b	15_a	0_b	1.016	0.309^{ns}

Legend:(a) The same subscript letter denotes that proportions do not differ significantly from each other at the set level of significance. Different subscript letter denotes that proportions across that category are statistically different (b); ns – not significant at 0.05 level of significance
* - significant at 0.05 level of significance

Table C.4: Subjective Well Being

SUBJECTIVE WELL BEING	GROUP A: EXPERIMENTAL (ERAS) (n =15)		GROUP A: STANDARD (n =15)		Z-TEST	P-VALUE
	No	Yes	No	Yes		
Anxiety	10_a	5_a	5_a	10_a	1.824	0.068^{ns}
Hunger	14_a	1_b	2_a	13_b	4.391	<0.001**
Thirst	14_a	1_b	2_a	13_b	4.391	<0.001**

Legend:(a) The same subscript letter denotes that proportions do not differ significantly from each other at the set level of significance. Different subscript letter denotes that proportions across that category are statistically different (b); ns – not significant at 0.05 level of significance
** - highly significant at 0.01 level of significance