COVER LETTER

Title:
"Implementation of Enhanced Recovery After Surgery (ERAS) Pathways in Gynecologic Oncology"

This research study was developed in the context of my dissertation.

Its purpose is to study the benefit in women with gynecological cancer who undergo major gynecological surgeries, and follow a protocol of enhanced recovery after surgery compared to conventional postoperative care.

The study is performed in a public oncology hospital in Greece, and is licensed by the scientific committee of the hospital, with the number 24111/16-10-2019.

The Doctoral theses is approved by the scientific committee of the University of West Attica, Nursing Department, with no 8/11-09-2019.

University of West Attica
Nursing Department &
Anticancer Oncology
Hospital of Athens "Saint Savvas"

DOCTORAL THESES

Title:

"Implementation of Enhanced Recovery After Surgery (ERAS) Pathways in Gynecologic Oncology"

MARIA BOURAZANI, RN, MSc, PhDc

Supervising Professor: Martha Kelesi

ATHENS 2019

Implementation of Enhanced Recovery After Surgery (ERAS) Pathways in Gynecologic Oncology

Abstract

Background

Gynecological cancer is comprised of cancer of the female reproductive system, which includes the cervix, vulva, uterus, fallopian tubes, ovaries, and vagina [1]. The therapeutic approach to gynecological cancers involves surgical resection, with chemotherapy and/or radiation, and should always be scheduled and performed in specialized oncology centers [2] (European Society for Medical Oncology- ESMO, 2014).

Major gynecological oncology surgeries (MGOS) cause moderate to severe postoperative pain and discomfort [3]. Patients undergoing MGOS need a multimodal approach to postoperative pain management, which provides great analgesic results with minimal side effects.

Opioid regimens are commonly used in postoperative analgesia with often many side effects. In recent years, there has been a global effort to reduce the use of opioid regimens, in order to reduce their side effects (opioid-sparing multimodal analgesia).

Various alternative postoperative pain approaches have been studied that reduce the need for high doses of opioids postoperatively, such as the use of coxib and gabapentin (Alayed et al., 2014).

The last decade, the need to reduce the hospital stay (LOS) and the hospital cost have been developed new pathways of fast track surgeries, known as Enhanced Recovery after Surgery (ERAS) protocols. ERAS pathways have been reported to promote earlier recovery and be beneficial for patients.

ERAS pathways involve evidenced based approaches in three phases: preoperative, intraoperative and postoperative, by an interdisciplinary team including surgeon, anesthesiologist and perioperative nurse. The combination of these techniques reduces the postoperative stress response, relieves acute postoperative pain, promotes early feeding and mobilization, thus reducing LOS and hospitalization cost and increasing patient satisfaction (Barber & Van, 2015).

Aim

The hypothesis of this theses was if the ERAS pathway could reduce the length of stay (LOS) in hospital for patients undergoing MGOS. The study aims to compare the effectiveness of ERAS protocol and the conventional non-ERAS clinical practice of recovery, of patients who will undergo MGOS.

Objectives

The objectives of the present study comparatively in the two groups are:

1. Hospital leght of stay (LOS)

Measuring how many days will stay in hospital for recovery. It is defined as the time frame from the day of operation to discharge from the hospital (unit: days)

2. Pain levels

Evaluation of analgesia and correlation of requirements with opioid analgesics; by recording of postoperative pain levels and the evaluation of the effectiveness of analgesic

treatment of patients. Using Numbered Pain Scale. As lower the number on pain scale as better the outcome.

3. Hospital Complications

The evaluation of postoperative complications such as bleeding, thrombosis and inflammation.

4. Mobilization

Mobilization time, which is defined as the time frame from the end of operation to the ability to walk without external assistance (unit: hours). Patients will perform a 6 minutes walking test.

5. Depression-Stress- anxiety

The evaluation of the presentation or not, of the patients 'depression, of the patients' emotional state (anxiety-depression) for their current state of health. Using HADS scale. Scores for each sub scale (depression and anxiety) are summed-up and range from 0-21. Values from 0-7 indicate normal levels, 8-10 are border values and from 11-21 are considered as pathologicals.

6. Readmission rate by 30 days after discharge of the hospital.

Method

This is a randomized study.

The study will be carried out at a General Oncology Hospital of Athens.

Study population: The study sample will include patients with gynecological cancer who undergo tumor resection surgery, and they will be randomly divided into two groups.

Group A will include patients who will follow the ERAS protocol, and the group B will include patients who will follow conventional postoperative care.

Randomization: Based on the results of the pilot research, a power analysis will be performed and the final number of the sample with the hypotheses with a significance level of 0.05 will be determined.

Next, the total number of n patients in the study sample will be randomly divided into two groups in the two intervention categories A (ERAS) and B (Classical) with a fixed number of individuals each.

Data analysis:

The processing and statistical analysis of the data will be done using the software package IBM SPSS 21.0 (Statistical Package for Social Sciences). The level of statistical significance (value a), in all statistical tests, will be equal to 0.05. Thus, a value of $p < 0.05$ will be considered statistically significant. The statistical analysis will include the following (Galanis 2015):

(a) Univariate analysis. Frequency distributions of the variables to study the values of each variable separately and independently of the others. The continuous variables will be expressed as mean (standard deviation), while the nominal variables as absolute (n) and relative frequencies (%).

(b) Variable analysis. Appropriate statistical controls will be used depending on the type and distribution of variables, such as e.g. the x2 (chi-square test), the t (student's t-test), the analysis of variance, the Pearson correlation coefficient, the Spearman correlation coefficient etc.

(c) Multivariate analysis. Multivariate linear and logistic regression models will be implemented to neutralize confusers.

Research tools: The numerical scale of pain will be used to assess the intensity of pain (Sarakatsianou, 2012).
The HADS scale (Michopoulos et al., 2008) will be used to assess patients' emotional state and is designed to assist in the assessment of anxiety and depression in patients in general hospitals.
For the collection of medical parameters, data will be collected from the anesthesia charts, the surgery minutes, the patient's personal file, the protocol data and from interviews with patients.

Inclusion Criteria:
Greek language speakers
Have complete mental clarity
Age >18 years

Exclusion Criteria:
Refusal to sign consent
Patients receiving treatment for chronic pain
Patients receiving antipsychotic therapy, Psychopathy
They have acute or chronic kidney and / or liver disease
History or family history of malignant hyperthermia
Known allergy to propofol, desflurane, or any other anesthetic agent
Impairment of cognitive function or communication
History of postoperative delirium

ERAS PROTOCOL		
Post-operation day	Informed conset Informing the patient about the ERAS program Surgical plan - Targeting Intestinal preparation with fleet-enema Thromboprophylaxis Cleaning bath	 Elastic anticoagulant socks Clexane 20-40mg SC daily
Intraoperatively	Normothermia parecoxib 40mg IV paracetamol 1000mg IV Morfine 0,1mg/kg Magnesium	
Operation day, Day-0	liquids PO after 4-6 h PONV mobilization after 4 h diuresis <30 ml/h Paracetamol 1000mg	 ondansetron 4mgX2 Metoclopramide 10mgX3

	parecoxib 40mg Morfine 0,1mg/kg Diet clear fluids and jelly	 Water, coffee, apple juice, tea
Day 1	Mobilization out of the room Incentive spirometer Thromboprophylaxis diuresis <30 ml/h Intestinal function Cleaning bath Light Diet 1 Oxycodone / paracetamol (Depalgos) PO q: 4-6 prn Lornoxicam 8mgX2 Removal of drains	 <30 ml/h Emollients or Senna Diet 1: Soup, jelly, puree, boiled chicken
Day 2 & 3	Full diet Full mobilization Incentive Spirometer Thromboprophylaxis Diuresis Intestinal function Cleaning bath Oxycodone / paracetamol (Depalgos) PO q: 4-6 prn Lornoxicam 8mgX2	Emollients or Senna
Discharge criteria	Full diet Full mobilization Help at home Great analgesia management Understanding the instructions	
Discharge instructions	Thromboprophylaxis Normal functionality of the digestive system Oxycodone / paracetamol (Depalgos) PO q: 4-6 prn	
Follow-up	Contact via phone Appointment for reassessment	

NON-ERAS PATHWAYS		
Post-operation day	Intestinal preparation with fleet-enema Thromboprophylaxis Cleaning bath	Elastic anticoagulant socks Clexane 20-40mg SC daily
Intraoperatively	Normothermia parecoxib 40mg IV paracetamol 1000mg IV Morfine 0,1mg/kg	
Day 0	On nausea ondansetron 4mg X2 Mobilization at will Diuresis 30ml/h Paracetamol 1000mgX4 Tramadol 50mgX4 or Morphine 0.1mg / kg Parenteral fluid IV 2-3Lt / 24h NPO	
Day 1	Mobilization at will Thromboprophylaxis Diuresis Intestinal function Cleaning bath Diet: hydrated and jelly Paracetamol 1000mgX4 Tramadol 10mg/kgX4	
Day 2 until Discharge day	Mobilization Thromboprophylaxis Diuresis <30 ml/h Intestinal function Cleaning bath Paracetamol 1000mgX4 Tramadol 50-100mgX4 Removal of drains	emollients
Discharge criteria	Full diet Full mobilization Help at home Great analgesia management Understanding the instructions	
Discharge instructions	Thromboprophylaxis	

Follow-up	After 15 days from the surgery	

Ethics

The researcher undertakes to follow the national and international principles of research ethics. The anonymity and confidentiality of the data collected will also be ensured and will not be made known at any stage of the study.

The patient who want to take part in the research will fill in the consent form for her participation in the study, after being informed about the aims of the research (informed consent).

The study will be conducted in accordance with the Declaration of Helsinki and with the approval of the Scientific Committee of the Hospital and Ethics Committee of the Nursing Department of University of West Attica.

The participation in the research will be optional and anonymous and it will not be possible to identify the participants. Therefore, there is no risk to the safety of patients, and the health care they have received is not affected.

Expected results from the research

The present research is expected to assess the contribution of enhanced recovery after surgery programs and their benefits to both the patient individually and the health system in general. The importance of these programs is expected to emerge in the days of hospitalization, in postoperative pain, in perioperative stress and in the mobilization of patients who will have undergone major gynecologic oncological surgeries. In addition, conclusions will be drawn about the quality of life of women with gynecological cancer that will help health professionals understand the needs of these patients and their care. While, from the study of the complications and the estimation of the financial health expenses, for the patients with gynecological oncological problem who will undergo surgical treatment, it is expected that future measures will be taken to reduce and prevent the complications but also to minimize the health care expenses.

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Title: ***"Implementation of Enhanced Recovery After Surgery (ERAS) Pathways in Gynecologic Oncology".***

Purpose: To investigate the effectiveness of the ERAS pathways on postoperative recovery in patients undergoing major gynecological oncology surgery.

Consent:

Name: ..... Age…….

I understand that the results of the research can be used in the future in conference announcements and / or publications in scientific journals. The research data will not be disclosed to anyone other than the researcher.

All research data that will be used in conference announcements and / or publications in scientific journals, will remain anonymous and I should not be identifiable.

I understand that my participation is voluntary and I am not required to answer all questions. I can withdraw from the study at any time, even after the signing of this statement, without giving an explanation or the reason for my withdrawal, without affecting the level of service to me, and with the obligation to destroy the data.

The researcher will keep the research data until the completion of the project, for a period of 5 years and then they will be destroyed. The data will be destroyed in accordance with the regulations of the Personal Data Protection Authority.

The procedure as well as the intended results of the research have been explained to me by the researcher.

I understand that any of my information about this research will be anonymous and I will not be identifiable.

I confirm that I read and understood the Patient Information Form today __ / __ / __ and that I had the opportunity to ask questions.

I have read the above information and agree to participate in the research.

Sign……..Date……..