Role of Subcutaneous Suction Drain of Midline Incision on Wound Healing in Obese Women Undergoing Laparotomy for Ovarian Cancer: RCT

Thesis

Submitted for Partial Fulfillment of Master Degree in Obstetrics & Gynecology

By

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Ola Mohamed Abd El Hamid

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List of Abbreviations

BMI	Body mass index
ECM	Extracellular matrix
PDGF	Platelet-derived growth factor
TGF-β	Transforming growth factor beta
FGF	Fibroblast growth factor
TNFa	Tumor necrosis factor alpha
TIMP	Tissue inhibitor of metallo-protease
TGFa	Transforming growth factor alpha
EGF	Epidermal growth factor
VEGF	Vascular endothelial cell growth factor
Bfgf	Basic fibroblast growth factor
HIF	Hypoxia-inducible factor
PO_2	Partial pressure oxygen tension

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Protocol of Thesis

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INTRODUCTION

Wound complications are troublesome not only to the patients and doctors, but also to hospitals and insurers. Wound complications impact clearly the patient's quality of life, and furthermore are associated with an increase of hospital stay and a significant socioeconomic burden ***(Perencevich et al., 2003).***

Midline incision is the most common incision for laparotomy. It implies a vertical incision for skin, subcutaneous fat, linea alba and peritoneum. Most of the fibers, crossing the linea alba in a mediocaudal and medioproximal direction are cut transversely. The incision is easy to perform and results in minimal blood loss, because of the vascular nature of linea alba. The incision can be made quickly, taking 7 minutes on average. Moreover, exposure of the abdomen is excellent extensions when required, can be easily made superiorly and inferiorly, providing access to the whole abdominal cavity, including the retroperitoneum. These qualities make the midline approach especially suitable for ovarian cancer surgery either for staging or cytoreduction ***(Guillou et al., 1980).***

In gynecological malignancy requiring adjuvant treatment, such as chemotherapy after cytoreductive surgery in ovarian cancer or radiotherapy and/or chemotherapy after radical hysterectomy in cervical cancer, wound complications could be related to a delayed treatment schedule, ultimately impacting the disease course ***(Wechter et al., 2005).***

In an attempt to reduce seroma formation in obese patients, previous studies have elucidated preoperative and intraoperative risk factors and others have validated several interventions which may reduce wound complications at the time of operation. Alongside skin preparation methods or subcutaneous closure techniques, intraoperative placement of subcutaneous drainage is one of the most investigated interventions ***(Gallup et al., 1996).***

A subcutaneous wound drain has its merit in the reduction of subcutaneous tissue dead space by preventing accumulation of fluid and enabling its regress ***(Panici et al., 2003).***

Incisional SSI has some of the following causes: bacterial load, hematoma formation, subcutaneous effusion, subcutaneous dead space, and local ischemia of the skin or subcutaneous tissue. In addition to stitching the dermic

layer and sufficient irrigation of the wound, the use of the Drainage System was effective in reducing the incidence of incisional SSI not only because of the continuous suction of the subcutaneous effusion, hematoma, and bacteria, but also because of reduction in the dead space of the subcutaneous wound area ***(Murray et al., 2011).***

AIM OF THE WORK

To evaluate the role of subcutaneous negative pressure suction drain on wound healing in obese women undergoing midline laparotomy in ovarian cancer surgery.

PATIENTS AND METHODS

Study Aim:

The effect of subcutaneous negative pressure suction wound drain on post laparotomy wound healing in obese women undergoing laparotomy for ovarian cancer.

Study Settings:

Ain Shams University Maternity Hospital

Study Design:

Randomized controlled trial using computer automated program.

Study Population:

The current study will include obese patient undergoing abdominal surgery for gynecologic indications.

Inclusion Criteria

1. BMI > 30kg/m^2
2. Midline incision in ovarian cancer surgery either for cytoreduction or surgical staging.

Exclusion Criteria:

1. Patients with severe renal or cardiac dysfunction
2. Patients with uncontrolled diabetes mellitus
3. Patients with autoimmune disease
4. Patients with immune deficiency disease

5. Patients with previous radiotherapy on the pelvis
6. Patients with pelvic inflammatory disease

SAMPLE SIZE JUSTIFICATION

The required sample size has been calculated using the G*Power Software (Universität Düsseldorf, Germany).

The primary outcome measure is the proportion of patients with clear wound healing, defined as surgical wound healing without any problems such as disruption, infection, or seroma formation ***(Kim et al., 2013).***

There is at present no clear information regarding the expected difference in the outcome measure in patients undergoing surgery for removal of pelvic malignancies. So, the present study will target an effect size that would be clinically relevant.

So, it is estimated that a sample size of 44 patients in each study group (total 88 patients) would achieve a power of 80% (type II error, 0.2) to detect a statistically significant difference between the two groups for a medium effect size *(w)* of 0.3 using a two-sided chi-squared test with a confidence level of 95% (type I error, 0.05). The effect size *(w)* is calculated as follows:

$w = \sqrt{\frac{\chi^2}{N}}$, where χ^2 is the chi-squared statistic and N is the total sample size.

A medium effect size equivalent to a w of 0.3 has been chosen as it could be regarded as a clinically relevant difference to seek in this exploratory study.

STATISTICAL METHODS

Data will be collected, tabulated, then analyzed using IBM© SPSS© Statistics version 22 (IBM© Corp., Armonk, NY).

Normally distributed numerical data will be presented as mean and SD, and skewed data as median and interquartile range. Qualitative data will be presented as number and percentage. Comparison of normally distributed numerical data will be done using the unpaired Student *t* test. Skewed data will be compared using the Mann-Whitney U test. Categorical data will be compared using the chi-squared test or Fisher's exact test, when appropriate.

A two-sided p-value <0.05 will be considered statistically significant.

Ethics and Patients' rights:

The study will be approved by the ethical and research committee of council of Obstetrics and Gynecology Department, Ain Shams University.

The study purpose will be explained and enrolled women and a written informed consent will be obtained from all participants prior to enrolment.

Procedures

All women will be subjected to:

1. Full History Taking
2. Clinical Examination (General and Abdominal)
3. Investigations
    1. Complete blood count
    2. Complete Urine Analysis
    3. Liver and Kidney function tests
    4. Abdominal Ultrasound
    5. Abdominal CT or MRI.
    6. Tumor markers (e.g., CA125,CA 19.9, AFP, βhCG, CEA).

Surgical Preparation:

1. Bowel preparation.
2. Skin preparation using Povodine iodine.