Transverse Versus Longitudinal Uterine Incision in Abdominal Myomectomy: A Randomized Controlled trial

Thesis

Submitted for partial fulfillment of the MD Degree in Obstetrics and Gynecology

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List of Abbreviations/Acronym

ALT : Alanine aminotransferase AUB : Abnormal uterine bleeding

BMI : Body Mass Index

COC : Combined Oral Contraceptive

ESHRE-ESGE: Does the European Society of Human

Reproduction and Embryology – European Society for Gynaecological

Endoscopy

FDA : Food and Drug Administration

FIGO : International Federation of Gynecology

and Obstetrics

GnRH : Gonadotropin Releasing Hormone

Hb : Hemoglobin

HBV : Hepatitis B virusHCV : Hepatitis C virus

INR : International normalized ratio

IUCD : Intrauterine Contraceptive Device

MRI : Magnetic Resonance Imaging

NSAIDs : Nonsteroidal Anti-Inflammatory Drugs

PALM-COEIN: Polyp, Adenomyosis, Leiomyoma,

Malignancy and Hyperplasia, Coagulopathy, Ovulatory Disorders, Endometrial Disorders, Iatrogenic

Causes, and Not Classified

PRMs : Progesterone Receptor Modulators

PTT : Partial thromboplastin time

SD : Standard deviation

sm : submucosal

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ABSTRACT

Objective: The Aim of the study is to compare between transverse and longitudinal uterine incision in abdominal myomectomy regarding intraoperative blood loss **Design:** A randomized Controlled interventional study. Setting: Ain Shams Maternity teaching hospital. Patients 52 patients undergoing methods: abdominal myomectomy for single myoma were involved The patients were randomized into two groups that showed no significant difference in demographic data, characters of myoma or indication of surgery Results: Our results proved that there was no significant difference between both incisions regarding intra-operative blood loss, need for blood transfusion, post-operative Hgb drop, operative time incidence of postoperative fever. Conclusion: Transverse uterine incision for myomectomy does not cause more blood loss than longitudinal incision. There is no difference between both incisions in operative time or identifier: complications postoperative Trial NCT03009812, MY-789 Key Words: Myomectomy uterine incisions

Transverse Versus Longitudinal Uterine Incision in Abdominal Myomectomy

Protocol of a Thesis

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Introduction

Myomectomy, the surgical removal of the uterine fibroid leaving the uterus in place, is one of the most commonly encountered operations in gynecologic practice. This can be performed through an abdominal (open), laparoscopic, hysteroscopic or vaginal approaches. It is indicated for women in the child-bearing age desiring to preserve fertility with symptomatic myomata; causing abnormal uterine bleeding, bulk related symptoms or infertility (*Parker et al, 2014*).

Successful abdominal myomectomy was recorded as early as 1845 by the Atlee brothers, but did not gain popularity due to high mortality rates (approaching 40%) caused by excessive blood loss (*Speert, 1980*). It was popularized by Victor Bonney in the 1920s (*Hutchins, 1995*).

Since then, many interventions have been developed to reduce blood loss, the major problem, during myomectomy (Kongnyuy and Wiysonge, 2014). These measures include intraoperative application of tourniquets or loop ligations around the cervix or infundibulopelvic ligaments, chemical dissection or application of drugs such as procoagulants (gelatin-thrombin matrix or tranexamic acid), vasoconstrictors (epinephrine or vasopressin) or misoprostol to stimulate myometrial contractions (Kongnyuy and Wiysonge, 2014).

It has been classical teaching to perform a vertical uterine incision for myomectomy to prevent transection of the arcuate arteries of the uterus that run transversely. However, it was proved that fibroids distort normal vascular architecture, thus avoiding these vessels is not feasible (*Discepola et al*, 2007).

Moreover, in a trial comparing transverse versus longitudinal uterine incisions in laparoscopic myomectomy, transverse incision was shown to reduce blood loss and operative time (*Morita et al, 2004*).

Hence, we propose that there is no significant difference between transverse and longitudinal uterine incisions in abdominal myomectomy regarding blood loss.

Aim of the Work

The Aim of the study is to compare between transverse and longitudinal uterine incision in abdominal myomectomy regarding intraoperative blood loss.

Research Question

In women undergoing abdominal myomectomy, is there a difference between transverse and longitudinal uterine incisions regarding blood loss?

Research Hypothesis

There is no significant difference between transverse and longitudinal uterine incisions in abdominal myomectomy regarding blood loss.

Patients and Methods

Study Design

Prospective, comparative, non-inferiority study.

Study Setting

Ain Shams University Maternity Hospital.

Study Population

Fifty-two patients will be recruited from those attending the outpatient gynecologic clinic and casualty of Ain Shams University Hospital, who will be candidates for myomectomy.

A written informed consent will be obtained from each patient before participation in the study.

The study protocol and patient informed consent will be reviewed and approved by the Ethics Committee of the Obstetrics and Gynecology Department Ain Shams University.

Sample size justification

Sample size was calculated using the Power & Sample Size Calculator®, setting the power $(1-\beta)$ at 0.8 and the type-1 error (α) at 0.05. The primary outcome of the current study is the mean intraoperative estimated blood loss (EBL). Reviewing the literature revealed no direct comparison between vertical and transverse uterine incision for abdominal myomectomy, however, a trial comparing the two types of incision in *laparoscopic* myomectomy was found. This latter trial showed that the mean values for intraoperative EBL in transverse versus vertical uterine incision in laparoscopic myomectomy were 110.5 ± 81.7 mL and 136.4 ± 108.5 mL, respectively (*Mariota et al.*, 2004). Therefore, transverse uterine incision would be assumed to reduce the mean intraoperative EBL by almost