Extended Antibiotic Prophylaxis for Prevention of Surgical Site Infections in Obese Diabetic Women Who Undergo Hysterectomy: A Randomized Controlled Trial

Thesis

Submitted for Partial Fulfillment of Master Degree
In Obstetric and Gynecology

By

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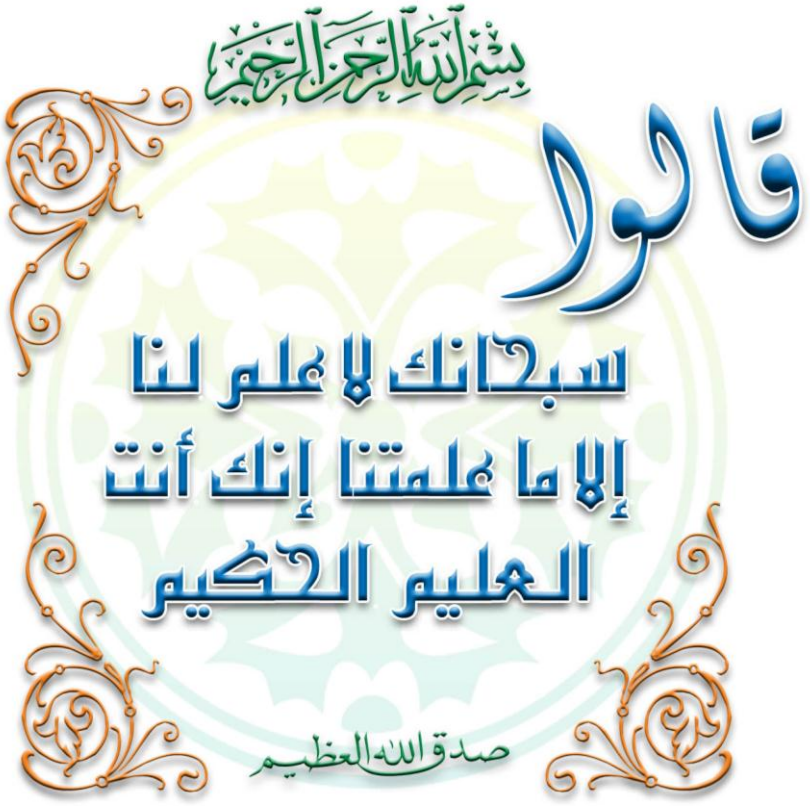

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List of Abbreviations

Abb.	Mean
ACOG	American College of Obstetric and gynecology
AH	Abdominal hysterectomy
BMI	Body mass index
CDC	The Centers for disease control and prevention
CI	Confidence interval
FI	Fold increase
FiO2	Fraction of Inspired Oxygen
GDM	Gestational diabetes mellitus
GWAS	Genome wide association study
HIV	Human immunodeficiency virus
HLA	Human leukocyte antigen
HS	Highly significant
IDDM	Insulin dependent diabetes mellitus
LADA	Latent autoimmune diabetes of adults
LH	Laparoscopic hysterectomy
MIC	Minimum inhibitory concentration
MRSA	Methicillin resistant S.aureus
MRSA	Methicillin resistant S.aureus
NIDDM	Non insulin dependent diabetes mellitus
NNIS	National nosocomial infection surveillance
NS	Non significant

Abb.	Mean
SIPGWW	Surgical infection prevention guideline workers work group
SPSS	Statistical program for social science
SSI	Surgical site infection
STAH	Subtotal abdominal hysterectomy
TLH	Total laparoscopic hysterectomy
USA	United States of America
UTI	Urinary tract infection
VH	Vaginal hysterectomy
WHO	World health organization

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Introduction

Surgical site infection (SSI) is the 2nd most common cause of nosocommial infection **(Burke, 2003 and National Nosocomial Infections Surveillance, 1996)**. Up to 2% to 5% of patients undergo clean extra abdominal operations and up to 20% undergo intra-abdominal operation will develop an SSI **(Auerbach, 2001).**

SSI compromise a major proportion of health care associated infections **(Klevens et al., 2007),** leading to increased morbidity and mortality as well as increased cost and length of the stay **(de Lissovoy et al., 2009**).

Obesity is associated with low subcutaneous oxygen tension preoperatively despite oxygen supplementation **(Kabon et al., 2004).**

Patients with body mass index (BMI) > 35 more likely than patients with lower BMI to have postoperative seromas (P < 0.0001, OR, 4.3, 95%, CI, 2.4-7.3) Seromas were associated with an increased risk of SSI and cellulites **(Kore et al., 2000).**

The impact of BMI on rate of SSI may be related to impaired wound healing and decreased tissue penetration of prophylactic antibiotics **(Walsh et al., 2009).**

In the American College of Surgeon National surgical quality improvement project, being overweight (BMI = 25-29) was shown to be associated with increased rates of superficial infections and being morbidity obese (BMI ≥ 35) was associated with superficial and deep infections and wound dehiscence **(Merkow et al., 2006).**

The contribution of diabetes to SSI risk is controversial because the independent contribution of diabetes to SSI risk has not typically assessed after controlling for potential confounding factors **(Gordon et al., 1997).**

Also increased glucose levels (> 200 mg/dL) in the immediate post operative period (≤ 48h) were associated with increase surgical site infection risk. More studies are needed to assess the efficacy of preoperative blood glucose control as a prevention measure **(Zerr et al., 1997).**

Efforts to reduce SSI gained momentum with the national implementation of the surgical prevention project

2004. These efforts focused on preoperative selection and administration including:

1. Timing of parentral antimicrobial administration.
2. Selection of a procedure appropriate antibiotic and
3. Discontinuation of the antibiotics within 24h of the end time of surgery.

(Bratzler and Hunt, 2006)

The widespread use of antimicrobial agents for prophylaxis has altered surgical practice markedly in the past 20 years and now represent one of the most frequent uses of antibiotics in hospital, accounting for as many as half of all antibiotics prescribed **(Bergquist and Murphey, 1987).**

Surgical antimicrobial prophylaxis has been shown in many randomized clinical trials to reduce the incidence of post operative wound infections **(Moleski and Andriole, 1986).**

In a cohort study, extended antibiotic prophylaxis with oral quinolones in addition to standard intravenous antibiotic prophylaxis administration before incisions was superior to the standard antibiotic regimen in the prevention of SSIs. There was reduction in rate of SSIs from 28 to 6% **(El-Nashar et al., 2010).**

Aim of the Work

Evaluation of the role of extended antibiotic prophylaxis for prevention of surgical site infections in obese diabetic women after hysterectomy.

Research Hypothesis:

In diabetic obese women undergoing hysterectomy, extended antibiotic prophylaxis may decrease the rate of SSI.

Research Question:

In women who are obese and diabetic undergoing hysterectomy. Does extended antibiotic prophylaxis decrease the rate of SSI?

Patients and Methods

Study design:

Randomized control trial.

Setting and population:

The study will be conducted in Ain Shams University Maternity Hospital on obese diabetic patients admitted for simple abdominal hysterectomy.

The patients will be distributed into 2 groups:

Group (A): will take standard antibiotic prophylaxis cefazolin (weight- based dose) IV within 60 minutes of incision, additional doses will be provided if operative time > 4 hours or if high blood loss documented, as guidelines).

Group (B): In addition to the standard antibiotic they will take extended antibiotic prophylaxis [oflaxacin (weight-based dose)] oral every 12 hours for 5 days.

Then follow up the patients for one month.

Inclusion Criteria:

1. Age of patients between 40- 65 years.
2. Diabetic (controlled on treatment).

3. BMI ≥ 30.
4. Simple abdominal hysterectomy.
5. The operation done by senior doctor.
6. 2 days post operative stay.

Exclusion Criteria:

1. Allergy to cephalosporin.
2. Allergy to quinolones.
3. Hysterectomy for obstetric cause as cesarean hysterectomy or vesicular mole.

Data collection and follow up:

1. History taken: detailed personal history, medical history (diabetes, hypertension, drug use), surgical history, obstetric history.
2. Examination: vital signs, general examination including BMI.
3. Indication of hysterectomy.
4. Operative time.
5. Blood loss.
6. Pathology.
7. The need for secondary sutures due to severity of infection.