بسم الله الرحمن الرحيم

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تم رفع هذه الرسالة بواسطة / هناء محمد علي

بقسم التوثيق الإلكتروني بمركز الشبكات وتكنولوجيا المعلومات دون أدنى مسئولية عن محتوى هذه الرسالة.

ملاحظات: ....

The Effect of Subcutaneous Saline Irrigation on Wound Complication after Cesarean Section: a Randomized Controlled Trial

Thesis

Submitted for Partial Fulfillment of
Master Degree in ***Obstetrics & Gynaecology***

By

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Elsayda Mohamed Mohamed Eltalbanty

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List of Abbreviations

Abb.	Full term

ACOG.....American College of Obstetricians and Gynecologists

CBC.....Complete blood count

CDC.....Centers for Disease Control

EGW.....External genital warts

FPR.....False positive rate

MEOWS.....Maternal Early Obstetric Warning System

NHSN.....National Healthcare Safety Network

PRCD.....Planned repeat cesarean delivery

PSI.....Per square inch

SPSS.....Statistical Package for the Social Sciences

SSI.....Surgical site infection

TOLAC.....Trial of labor after cesarean delivery

TPR.....True positive rate

VTE.....Venous thrombo embolism

WHO.....World health organization

NICE.....,.....National Institute for Clinical Excellence

ACCP..... American College of Clinical Pharmacology

PROTOCOL

PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF MASTER DEGREE IN OBSTETRICS & GYNAECOLOGY

Title of the Protocol: The Effect of subcutaneous Saline Irrigation on Wound Complication after Cesarean Section: a randomized controlled trial.

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What is already known on this subject? AND

What does this study add?

One of the most serious complication after cesarean section is wound complication it varies from 3 to 30%. This prospective randomized controlled study will assess the effect of subcutaneous saline irrigation of the wound on postoperative complication after cesarean section.

1.INTRODUCTION/ REVIEW

Cesarean delivery is the most common major operation preformed worldwide. In daily obstetric practice. It account for up to 60% of all births in some countries ***(Gibbons et al., 2010)***. .

One of the most serious complications after cesarean section is wound complication it varies from 3 to 30% ***(Corbacoiglu et al., 2014)***.

It may be infectious as surgical site infection or non-infectious as hematoma, seroma, and wound separation ***(Makeen and Vats et al., 2014)***.

These complications cause increase hospital stay or readmission also, maternal morbidaty & cost are increased ***(Cardoso et al., 2010; Johnson et al., 2006).***

Many preventive methods have been investigated as prophylactic use of antibiotics skin preparation ***(Kawakita et al., 2017)***.

One of the preventive method is prophylactic incisional irrigation with various solution as povidone-iodine solution, normal saline or topical antibiotic to reduce surgical site

infection ***(Mueller et al., 2015)***.

Normal saline (0.9% sodium chloride) is the most commonly used solution for wound irrigation due to its safety. One of the earliest trials on wound irrigations with saline after surgery reported a reduction in surgical site infection (SSI) from 25% to 8.7% ***(Aslan Çetin et al., 2018)***.

Prophylactic wound irrigation of subcutaneous and deep soft tissue by saline or any antiseptic solution is an easy an economic option to reduce surgical site infection (SSI) ***(Barnes et al., 2014)***.

2.AIM / OBJECTIVES

To assess of the efficacy of subcutaneous saline irrigation of the wound on post-operative surgical site complications.

3. Patients and Methods

Type of Study: Prospective randomized controlled study

Study Setting: The study will be conducted at Ain Shams University Maternity Hospital, (operative theater of labor ward).

Study Population: Women attending for elective cesarean section will be enrolled.

Inclusion criteria:

1. Age: 20-40 years.
2. Elective cesarean section.

Exclusion criteria:

1. Body mass index ≥ 30KG/m2.
2. Diabetes mellitus.
3. Immunocompromised patient using corticosteroid as SLE.
4. Anemic patient (Hb <10.5g/dL).
5. Thrombocytopenia or bleeding tendency.
6. History of lower abdominal operations.
7. Placenta Previa and placenta accreta.
8. Rupture of membranes and chorioamnionitis.
9. Multiple pregnancies.
10. Any medical disorder interfere with wound healing as hypertension and liver diseases.

Method of randomization: Patients undergoing elective caesarean sections will be randomized using a computer-generated sequence 1:1 either to subcutaneous saline irrigation group or to no irrigation group .

Randomization: Will be done using computer generated randomization sheet using MedCalc© version 13.

Allocation and Concealment: By use of sealed opaque envelopes that will be given to a third party (anurse) who will assigne the women to study arms. Each woman will be invited to pull out an envelope. According to the number inside her envelope, women will be allocated to either group 1 or group 2 using a computer generated random list.

Sample Size: The study will be conducted on (2890) women; they will be subdivided into 2 groups.

- **Irrigation group:1445** women with subcutaneous irrigation by 200cc saline before closure of the skin.

- **Non irrigation group:** 1445 women without irrigation before closure of the skin

Sample Justification:

Sample size was calculated using PASS® 15.0 4 Power Analysis and Sample Size Software (NCSS® LLC, USA), setting the power (80%) at 0 2 and the significance level (a)at 0.05. On reviewing the Literature, few research papers addressed the effect of saline irrigation of wound in the setting of cesarean section **(Aslan Cetin et al., 2018).** They, all used non standardized definitions for diagnosis of surgical site infection with even one of them labeling culture negative in flamed • wounds as having surgical site infection. This resulted in a rather perplexing results regarding the effect size of saline wound irrigation.

According to **Opoien and his colleagues**, the incidence of SSI following cesarean delivery according to the CDC definition was estimated to be 8.90/b Assuming a minimal clinically relevant • reduction in SSI rates of 33.3° o; calculation according to the previous data produced a minimal total sample size of 2456 women undergoing cesarean section • Assuming a dropout rate of 15%," this produces a drop out • inflated sample size of approximately 2890 women to be randomized equally into two groups.

Ethical Consideration: This study will be done after approval of the ethical committee of the department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University. Informed consent will be taken from all participants before recruitment in the study, and after explaining the purpose and procedures of the study. The investigator will obtain a written, signed informed consent from each subject prior to performing any study specific procedures on the subject. The investigator will retain the original signed informed consent form. All laboratory specimens, evaluation

forms, reports, video recordings and other records that leave the site will not include unique personal information to maintain subject confidentiality. The study will be based on the investigator self-funding.

Study procedures and interventions:

- All women will receive 1-2 gram intravenous 1st generation cephalosporin (Zinol 1 g vial, Pharco, Egypt) or 3 gram Ampcillin, sulbactam (unasyn 1.5 gram vial, pfizer, USA), if there is pencillin allergy, 900mg clindamycin (Dalacin 600 amp, pifzar, USA) plus 5mg/kg Gentamycin(Gentamycin 80mg/2ml, CId, Egypt) 30 minute before the procedure. All cases will be performed by experienced obstetricians (the same level surgeon).
- After skin disinfection using(povidone iodine 10%), catheterization and drapping, a transverse skin incision (Pfannenstiel) will be done.
- At all stages of the cesarean procedure,a scalpel will be used for sharp dissection, rather than an electrocautery device.
- Blunt dissection (with fingers) over sharp dissection (with the knife) will be done.
- The abdominal cavity will be inspected before closing the abdomen to ensure that hemostasis has been achieved.
- Facial closure will be done using a continuous number 1 (ETHICON®, coated, Vicryl™, polyglactin 910, violet braided absorbable suture, Johnson & Johnson International) placed approximately 1 cm from the edge of the incision and 1 cm apart, without excessive tension.
- Subcutaneous tissue hemostasis will be achieved using an electro-monopolar cautery device .
- Before the skin closure in the saline group the

subcutaneous saline irrigation will be performed with a 200cc .saline (0.9%NaCl) using 50 CC syringe. No subcutaneous irrigation will be applied in the non irrigation group before the skin closure.

- Skin closure will be done using a subcuticular suture using 2-0 (ETHICON®, PROLENE™, Polypropylene, blue monofilament non-absorbable suture, ETHICON, LLC).

The patients will be discharged from the hospital 24 hours upon surgery completion. Participants will be asked to come to the hospital for routine inspection of the skin incision on day 7 and day 30 postoperatively.

All wounds will be inspected for hematoma, seroma, separation and signs of superficial infection such as (tenderness, redness, hotness, swelling, purulent discharge) ***(Arnold Press, 2008).***

A swab will be taken from any wound suspected to be infected.

An abdominal ultrasound will be performed to inspect the subcutaneous tissue hematoma and/or seroma using Samsung H 60 linear probe **(1≈8 MHz made in korea)** The participants, primary investigator and care providers evaluating skin incisions will be blinded to the intervention (saline/control).

Outcomes:

- **1ry outcome:** Superficial site infection (tenderness, redness, hotness, swelling, purulent discharge) rate between both groups 30 day after operation.

Superficial incisional SSI must meet the following criteria:

Date of event occurs within 30 days after any operative procedure (where day 1 = the procedure date) **AND** involves only skin and subcutaneous tissue of the incision **AND** patient