Topical Application of Antibiotic prophylaxis in the prevention of Surgical Site Infection After Elective LSCS: RCT

Thesis

Submitted for Partial Fulfillment of the Master Degree
in Obstetrics and Gynecology

By

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Hassan Helmy Mohamed

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aPPT	:	Activated partial thromboplastin time
ARDS	:	Acute respiratory distress syndrome.
BMI	:	Body Mass Index
CT	:	Computed tomography.
CCT	:	Controlled cord traction
CDC	:	Centers for Disease Control
ERCD	:	Elective repeat caesarean delivery
HAI	:	Healthcare-associated infection
HIV	:	Human immunodeficiency virus
LSCS	:	Lower segment cesarean section
NHSN	:	National Healthcare Safety Network
NICE	:	National Institute for Health and Clinical Excellence
RCOG	:	Royal College for Obstetricians and Gynecologists.
RCTs	:	Randomized controlled trials
SOC	:	System Organ Class
SSI	:	Surgical site infection'
TOLAC	:	Trial of labor after cesarean delivery
TTN	:	Transient tachypnea of the newborn
VBAC	:	Vaginal birth after caesarean section

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Protocol of Thesis

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Introduction

In 2010, an estimated 16 million operative procedures were performed in acute care hospitals in the United States ***(CDC, 2010)***. A recent prevalence study found that SSIs (surgical site infection) were the most common healthcare-associated infection, accounting for 31% of all HAIs (healthcare-associated infection) among hospitalized patients ***(Magill, 2012)***. The CDC healthcare-associated infection (HAI) prevalence survey found that there were an estimated 157,500 surgical site infections associated with inpatient surgeries in 2011 ***(Magill, 2014)***. National Healthcare Safety Network (NHSN) data for 2006-2008 (16,147 SSIs following 849,659 operative procedures) showed an overall SSI rate of 1.9% ***(Mu, 2011).***

While advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis, SSIs remain a substantial cause of morbidity, prolonged hospitalization, and death. SSI is associated with a mortality rate of 3%, and 75% of SSI associated deaths are directly attributable to the SSI ***(Awad, 2012).***

Amongst the many interventions advocated to prevent SSI, the effectiveness of pre-operative intravenous administration of antibiotic prophylaxis has been extensively studied and has been shown to be effective ***(McHugh, 2011).***

Topical antibiotics have been employed for the treatment of infected wounds. Some antimicrobial agents have also been used topically to reduce SSI rates. Topical antibiotic application has many potential advantages over systematic use, though some specific disadvantages also exist. The clinical benefits of topical antibiotic prophylaxis have not been extensively documented for general surgical cases. Commonly used antibiotics for topical prophylaxis are cephalosporins, aminoglycosides, glycopeptides, chloramphenicol, and bacitracin; the doses, delivery methods, and pharmacological profiles vary ***(McHugh, 2011).***

The benefits of local application include high and sustained concentrations at the site of infection where local physiological changes may hinder the efficacy of systemic antibiotics **.**Other benefits include the limited potential for systemic absorption and toxicity, reduced volumes of antibiotic use, and, possibly, less potential for the development of antibiotic resistance (as there is likely to be less of an effect on, e.g. bowel flora). Novel agents that are not available systemically may also be used .While local hypersensitivity or contact dermatitis reactions and interference with local wound healing may be problematic, a major disadvantage of local antibiotics is that there are no specific efficacy criteria for agents in this setting that have been standardized and approved by any official oversight agency for evaluating their efficacy ***(Lipsky and Hoey, 2009)***.

Aim of the Study

This study aims at establishing benefit from the use of topical antibiotics prophylaxis after skin closure to decrease rate of surgical site infection in women undergoing elective LSCS.

Research question:

In women undergoing elective LSCS, does topical fusidin cream applied to surgical site after skin closure decreases the rate of surgical site infection?

Research hypothesis:

In women undergoing elective LSCS, topical antibiotics applied to surgical site may decrease rate of surgical site infection.

Patients and Methods

Study design: randomized controlled trial.

Setting: This study will be held at Ain shams Maternity hospital.

Population under study:

The study will include 122 subjects divided into 2 groups:

Group A: Patients will have topical fusidic acid immediately after subcuticular stitches followed by dry dressing.

Group B: Patients will have simple dressing with povidone- iodine.

The study will include all pregnant females undergoing elective LSCS with the following inclusion and exclusion criteria:

Inclusion criteria:

1- Women with BMI at or under 30 Kg/m^2.

2- Women having pfannensteil incision.

3- Women with gestational age more than 38 weeks with viable fetus.

Exclusion criteria:

1- Women having Rupture of membranes more than 6 hours.

2- Women with BMI more than $30kg/m^2$.

3- Diabetics or on long term steroids.

4- Patients with known any local hypersensitivity to any chemical product, and any previous history of septic wound.

5- Patients with preoperative systemic infection (e.g., chorioamionitis) or those that will need systemic antibiotics for preoperative fever.

6- Women having midline incision or women with previous more than 2 cesarean sections.

Sample size justification:

In The study that was undertaken to see the infection rate of wound following emergency caesarean section with and without the use of topical fusidic acid. The study was carried out at Himal Hospital from April 2006 to Jan. 2008. A total of 70 child bearing patients who underwent emergency caesarean sections were included. All of the patients were given absorbable subcuticular stitches. Out of the 70 patients, 35 patients had topical fusidic acid immediately after subcuticular stitches followed by dry dressing. The other 35 patients had simple dressing with povidone- iodine. Six patients (17.1%) out of the 35 patients who had dressing with povidone-iodine developed wound infection at the surgical site and only 1 patient (2.8%) out of the 35 patients with fusidic acid developed wound infection. The use of fusidic acid reduced the infection rate by six times. The relation of fusidic acid to wound infection was statistically significant ($p = 0.0460$) ***Pradhan and Agrawal (2009).***

Accordingly:

Group sample size of 61 in group A "patients will have topical fusidic acid immediately after subcuticular stitches followed by dry dressing" and 61 in group B "patients will have simple dressing with povidone- iodine.

Sample size was calculated at 80% power and with a significance level (alpha) of 0.05 using PASS 11 sample size calculator program; based on a study finding carried out by ***Pradhan and Agrawal (2009).***

Methods:

All patients will be subjected to:

History: personal (age, duration of marriage), present (any current medical or surgical diseases and any current medication) and obstetric history (including Parity, Gestational age, obstetric complications).

Clinical examination:

- ***General examination***: assessment of vital data (temperature), cardiac and chest auscultation to exclude contraindications for anesthesia.
- ***Abdominal examination***: assessment of fundal level and previous scar if present.

Investigations:

Routine preoperative investigations will be done e.g., Full blood count and Random blood sugar.

In cases with suspected SSI culture will be taken using aseptic technique and will be sent to Ainshams maternity hospital lab.

Steps:

- Informed consent will be obtained form parents or guardians of patients who are invited to participate in the research after explanation of benefits and risks of this trial.
- All caesarean sections will be performed by a surgeon who has at least 2 years experience in both groups.
- Both Groups will receive intravenous antibiotic zenol one hour before skin incision.
- Scrubbing the abdomen as usually.
- Any scar of previous section will be removed in both groups.
- The skin will be close with non-absorbable polyprolyne suture 2.0.
- Followed by application of fusidine cream over the scar in Group A followed by dry dressing and betadine dressing only in (Group B).
- Wound dressing will be removed after 24 hours postoperatively then cleaning with alcohol 70% antiseptic solution for 5 days for both groups.