بسم الله الرحمن الرحيم

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تم رفع هذه الرسالة بواسطة / مني مغربي أحمد

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

ملاحظات: لا يوجد

Surgical Staples versus Absorbable and Non-Absorbable Subcuticular Suture for Skin Closure in Caesarean Sections: An Interventional Randomized Controlled Clinical Trial

Thesis

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

By

Shimaa Saiid Abd El Salam Ali

M.B.B.Ch - Faculty of Medicine – Ain Shams University (2005)
Current Job: Resident of Obstetrics & Gynecology – Abo El Nomros hospital - Giza

Under Supervision Of

Prof. Dr. Magdy Hassan Kolaib

Professor of Obstetrics & Gynecology
Faculty of Medicine – Ain Shams University

Dr. Aliaa Mohamed Aly Maaty

Lecturer of Obstetrics & Gynecology
Faculty of Medicine – Ain Shams University

Faculty of Medicine
Ain Shams University
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Shimaa Saiid Abd El Salam Ali

Surgical Staples versus Absorbable and Non-Absorbable Subcuticular Suture for Skin Closure in Caesarean Sections: An Interventional Randomized Controlled Clinical Trial

Abstract:
This interventional randomized controlled clinical trial was conducted at Ain Shams University Maternity Hospital (labor word) between March 2021 and august 2021 to compare the outcome of a cesarean wound regarding pain, infection and seroma with surgical staples versus absorbable and non-absorbable subcuticular sutures. A total of 150 patients were randomly allocated into three equal groups; staples group (A), vicryl group (B) and prolene group (C). Only 138 patients were followed-up and analyzed statistically ((47) patients in Staples group (A), (45) patients in vicryl group (B) and (46 patients in prolene group (C)).

Regarding demographics data; statistical analysis of current results showed that there was not statistically significantly difference between all groups regarding patient's age, parity and BMI; p= 0.153, 0.381 and 0.306 respectively. Regarding observational data in first 24 hours ,at hospital discharge and after one week from cesarean section; statistical analysis of current results showed that there was not statistically significantly difference between all groups regarding wound pain, need for extra dose of analgiscs, edema, echymosis, soaking of dressing , oozing (blood or serous),surgical site infection, allergy ,dehiscence, pigmentation, thickness, pliability, ; p= 0.645, 0.016 , 0.068 , 0.041 ,0.020 ,0.051 ,0.068 ,0.165 ,0.427 , 0.063 ,0.467 ,0.645 and 0.325 respectively. Regarding duration of intraoperative wound closure (minutes); statistical analysis of current results showed that it was significantly different among the three groups (P <0.001). Duration of closure was significantly lower in staples (7.00 ± 1.04) compared to vicryl (13.24 ± 1.23) (P <0.001) and prolene group (12.65 ± 1.18) (P =0.001). Also, it was significantly lower in prolene compared to vicryl group (P <0.001). In conclusion, the outcome of a cesarean wound regarding pain, infection and seroma was the same with no significant differences between surgical staples, absorbable and non-absorbable sub-cuticular sutures.

Key words: Surgical Staples, Absorbable and Non-Absorbable Subcuticular Suture, Caesarean Sections.

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List of Abbreviations

ACOG : American Committee of Obstetric Guidelines.

ACS : American College of Surgeons.

C.S. : Cesarean Section.

CDC : United States Centers for Disease Control and Prevention.

CT : Computed Tomography.

ERAS : Enhanced Recovery After Surgery.

MFMU : Maternal – Fetal Medicine Units.

NHSN : The National Health Care Safety Network.

NSQIP : The National Surgical Quality Improvement Program.

PDS : Polydioxanone.

POSAS : Patient & Observer Scar Assessment Scale.

PRCD : Planned repeat cesarean delivery.

R.R. : Relative Risk.

SIR : Standardized Infection Ratio.

SSI : Surgical Site Infection.

STS : The Society of Thoracic Surgeons.

TOLAC : Trial of Labor After Cesarean Delivery.

USSC : United States Surgical Corporation.

VTE : Deep Venous Thrombosis.

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

Title of the Protocol: Surgical Staples versus Absorbable and Non-Absorbable Subcuticular Suture for Skin Closure in Caesarean Sections: An Interventional Randomized Controlled Clinical Trial

Postgraduate Student: Shimaa Saiid Abd El Salam Ali
Degree: M.B.B.Ch - Faculty of Medicine – Ain Shams University (2005)
Current Job: Resident of Obstetrics & Gynecology – Abo El Nomros hospital - Giza

DIRECTOR: Prof. Magdy Hassan Kolaib
Academic Position: Professor
Department: Obstetrics & Gynecology – Ain Shams University

Co-DIRECTOR: Dr. Aliaa Mohamed Aly Maaty
Academic Position: Lecturer
Department: Obstetrics & Gynecology- Ain Shams University

Faculty of Medicine
Ain Shams University
2020

What is already known on this subject? AND

What does this study add?

Cesarean wound complications remain an important cause of post-cesarean morbidity. Basha et al study suggested increased rates of wound disruption or infection with staples skin closure when compared to suture closure. ***(Basha et al., 2010)***

1.INTRODUCTION/ REVIEW

Cesarean delivery is the most common major surgical procedure performed elsewhere. Currently, approximately 15% of pregnant women worldwide deliver by cesarean sections, and this prevalence is on the rise. (***Martin et al., 2011)***

Given these trends, cesarean wound complications, such as disruption or infection remain an important cause of post-cesarean morbidity at considerable costs to thepatient and health system. (***Ramsey et al., 2005)***

The skin is typically closed with surgical staples or sutures after cesarean delivery. Until recently there has been little evidence regarding the best cesarean skin closure material. (***Alderdice et al., 2003)***

It has been postulated that sutures act as a foreign body and damage tissue leading to increased infections. (***Tuuli et al., 2011)***

Prolene ®; is a synthetic, monofilament, non absorbable polypropylene suture. Its advantages include minimal tissue reactivity, durability and less infection. Disadvantages include fragility, high plasticity and high expense. (***Spano and Dimock, 2014)***

Vicryl ®; (polyglactin 910) is an absorbable, synthetic, usually braided suture. Its advantages include strength and better cosmoses. Disadvantages include low absorption by hydrolysis with more tissue reactivity and infection. ***(Spano and Dimock, 2014)***

Staple is made ofnon biodigradable titanium, its advantage is that it is easy to use & faster for closing wounds. Disadvantages include more cost & more surface tension. (***Tuuli et al., 2011***).

2.AIM / OBJECTIVES

This interventional randomized controlled clinical trial aims at compare the outcome of a cesarean wound regarding pain, infection & seroma with surgical staples versus absorbable & non absorbable subcuticular sutures.

Research Question: In skin closure at cesarean delivery, is there any difference between surgical staples, absorbable and non-absorbable subcuticular suture regarding wound complications (pain, wound infection and seroma)?

Research Hypothesis: In skin closure at cesarean delivery, there is no difference between surgical staples, absorbable and non-absorbable subcuticular sutures regarding wound complications (pain, wound infection and seroma).

3.METHODOLOGY:

Patients and Methods/ Subjects and Methods/ Material and Methods

Type of Study: Interventional randomized controlled clinical trial.

Study Setting: Ain Shams University Maternity Hospital (labor word).

Study Population: N=150 Pregnant women attending Ain Shams University Maternity Hospital scheduled for elective cesarean section with the following criteria:

Inclusion criteria:

1. Age between 20-40 years old.
2. BMI: 18.5 – 29.9 kg/m^2.
3. Cases include primigravidas & history of one previous cesarean section.
4. Scheduled to undergo elective lower segment cesarean section.
5. Hemoglobin level: ≥ 10 gm/dl.
6. Viable fetus.

Exclusion criteria:

1. Abnormal placental invasion (e.g., placenta previa).
2. Clinical signs of infection at the time of cesarean delivery including PPROMs and intra-amniotic infections.
3. Medical disorders (Diabetes, cardiac, hepatic or renal disorder).
4. History of endometriosis.
5. Uterine anomalies (e.g., septum, mullerian anomalies or fibroids).
6. Known hypersensitivity to any of the suture materials used in the protocol, or any disorders requiring chronic corticosteroids or immune suppressants.
7. Fetal demise.
8. Immune compromising disease (e.g. AIDS).
9. Contraindication to routine postpartum pain medications (ibuprofen, acetaminophen and narcotics).
10. Women refused to participate in the study or inability to obtain informed consent.

This patients while doing cesarean sections are divided into 3 goups :

Group A: 50 patients will use disposable skin stapler in skin closure.

Group B: 50 patients will use absorbable polyglactin 910 sutures (braided 2-0) (vicryl) in skin closure.

Group C: 50 patients will use non absorbableprolene sutures (2-0) in skin closure.

Sampling Method:

Systematic random sampling.

Sample Size: (N=150)

The study will be conducted on 150 women scheduled for elective lower segment cesarean section; they will be subdivided into 3 groups.

- **Group A:(**n=50) disposable skin staplers, 7.4mm × 4.6mm, (CSPF-35W®; Changzhou Medical Bioengineering Co, China) will be used in skin closure.
- **Group B:** (n=50) subcuticular sutures, coated, synthetic, absorbable, polyglactin 910, braided, 2-0, dyed, 75 cm, straight cutting needle (Vicryl®; TAISIER-MED, Egypt) will be used in skin subcuticular suturing.

- **Group C:(**n=50) subcuticular suture, synthetic, non-absorbable, prolene, 2-0, blue, 75 cm, straight cutting needle (PROLENE®; TAISIER-MED, Egypt)will be used in skin subcuticular suturing.

Sample Justification:
The required sample size was calculated using G*Power software version 3.1.0. The primary objective of the current study was to compare the incidence of wound complications between the three study groups (Absorbable Vs non absorbable Vs staple). Assuming a type I error of 0.05, and 80% power, a sample size of 47 patients in each study group will be neededto detect an effect size (w) of 0.2 in the primary outcome of interest between the 3 groups, with taking in consideration 20% drop out rate.

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 the written, signed informed consent of 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 to maintain subject confidentiality. The study will be based on the investigator self-funding.

Randomization:
Patients will be randomized using sequentially sealed opaque envelope method into three groups each including 50 patients, to ensure that every patient fulfilling the inclusion criteria has the same chance of participating in this study; randomization will be guided by a table of random members by a computer-based program (using www.randomization.com).

Allocation and concealment:
Women participating in the study will be randomized by a computer-generated randomization sheet using MedCalc version 13. 150 envelopes will be numbered serially and, in each envelope, the corresponding letter which denotes the allocated group will be put according to randomization table. Then all envelopes will be closed and put in one box. When the first patient arrives, the first envelope will be opened, and the patient will be allocated according to the letter inside and so on.

Study procedures and interventions:

- Pregnant women planning to undergo elective lower CS will be counseled to be enrolled in the study. The study will be conducted after approval from ethical committee of the department of Obstetrics and Gynecology, faculty of medicine, Ain shams University. After enrollment in the study, an informed written consent will be taken from all participants before recruitment in the study and after explaining the purpose, possible risks and complications e.g., wound dehiscence and blood transfusion.
- All participants will be subjected to:

A- History: Complete history taking including personal history (age, duration of marriage, occupation), history of present illness (any current medical or surgical diseases and any current medication), past history (any chronic medical disease or surgical procedures, known allergy, blood transfusions), obstetric history (parity, gestational age, obstetric complications), contraception and menstrual history.

B- Clinical Examination:

- **General Examination:**
  1. Assessment of the patients' general condition (chronic fatigue e.g., in anemic patients).
  2. Weight in kg, Height in m^2, Gait and Body mass index (BMI) measured in kg/m^2.
  3. Color of complexion e.g., pallor in anemic patients.
  4. Vital data: Pulse, blood pressure, temperature.

5. Cardiac and chest auscultation.
6. Lower limb assessment.

- **Abdominal Examination:** Assessment of (fundal level, fetal lie, presentation, liquor volume and previous abdominal scar).
- **Vaginal Examination:** to exclude cervical changes, rupture of membranes and cervical polyp or fibroids.

C- Investigations:

- **Laboratory investigations:**

1. Complete blood count.
2. Coagulation profile: PT, PTT, INR.
3. RH and blood group.
4. Viral markers (HBsAg, HCV-Ab, HIV).
5. Liver and kidney function tests.
6. Random blood sugar test.

- **Radiological Investigation:** Basic ultrasound examination will be done for all pregnant women to assess (fetal life, fetal parameters, amniotic fluid and placental location).

- All Caesarean deliveries will be performed by a senior registrar capable of performing elective caesarean delivery.
- All patients will receive prophylactic intravenous antibiotic (1st generation Cephalosporin e.g., Cefazoline® 2 gm) 30: 60 minutes before skin incision to be repeated if the operation lasts for more than 3 hours or blood loss is more than 1000 cc. Cephalosporin may be replaced by Ampicillin/Sulbactam in case of Cephalosporin hypersensitivity. (***ACOG Practice bulletin no. 199, 2018)***
- Women will be divided into 3 groups:
  - **Group A:** 50 disposable skin staplers, 7.4mm × 4.6mm, (CSPF-35W®; Changzhou Medical Bioengineering Co, China) will be used in skin closure.
  - **Group B:** 50 subcuticular sutures, coated, synthetic, absorbable, polyglactin 910, braided, 2-0, dyed, 75 cm, straight cutting needle (Vicryl®; TAISIER-MED, Egypt) will be used in skin closure.
  - **Group C:** 50 subcuticular suture, synthetic, non-