بسم الله الرحمن الرحيم

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تم رفع هذه الرسالة بواسطة / حسام الدين محمد مغربي

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

ملاحظات : لا يوجد

Two Different Doses of Self-Administered Vaginal Misoprostol for Successful Copper Intrauterine Device Insertion in Parous Women Previously Delivered By Cesarean Section. A Double Blinded Randomized Clinical Trial

Thesis

Submitted for Partial Fulfillment of Master Degree in Obstetrics & Gynaecology

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Sherif Naguip

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List of Abbreviations

Abb.	Full term
ACOG	American College of Obstetricians and Gynecologists
BMI	Body mass index
BV	Bacterial vaginosis
CDC	Centers for Disease Control and Prevention
CS	Cesarean section
FDA	Food and Drug Administration
IM	Intramuscular
IUCD	Intrauterine contraceptive device
IUD	Intrauterine device
IV	Intravenous
LNg	Levonorgestrel
MPA	Misoprostol acid
NSAID	Non-steroidal anti-inflammatory drugs
PGE	Prostaglandin E
PID	Pelvic inflammatory disease
PPH	Postpartum hemorrhage
STIs	Sexually transmitted infections
USMEC	United States Medical Eligibility Criteria
VAS	Visual analog scale
WHO	World Health Organization

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ABSTRACT

Background: The main reasons associated with a low IUCD use are high cost in some settings and fear of pain at insertion by women. This double blind randomized controlled clinical trial study will evaluated and compare the efficacy and safety of misoprostol 200 mcg versus 400 mcg administered vaginally prior to IUCD insertion regarding the success and ease of insertion procedure among parous women beside the rate of occurrence of adverse effects.

Objective: To evaluate and compare the efficacy and safety of misoprostol 200 mcg plus placebo versus 400 mcg administered vaginally prior to IUCD insertion in regard to the success and ease of insertion procedure among parous women previously delivered by cesarean section beside the rate of occurrence of adverse effects.

Patients and Methods: This double blind randomized controlled clinical trial was conducted at Ain Shams University Maternity Hospital (Family planning clinic) during the period from January 2020 till July 2020, to evaluate and compare the efficacy and safety of misoprostol 200 mcg plus placebo versus 400 mcg administered vaginally prior to IUCD insertion in regard to the success and ease of insertion procedure among parous women beside the rate of occurrence of adverse. One hundred parous women previously delivered by cesarean section were randomized into 2 equal groups; group (1): 50 women received misoprostol 400 mcg (2 tablets) vaginally 3 hours prior to IUCD insertion and group (2): 50 women received misoprostol 200 mcg plus placebo vaginally 3 hours prior to IUCD insertion (the placebo tablet has the same color, size and shape of tab of misoprostol).

Results: Regarding baseline patient's characteristics (Age, BMI, parity, previous miscarriages, previous CS, previous use of contraceptives and previous insertion of IUD); statistical analysis of current results showed that there were insignificantly different between both groups. Statistical analysis of current results showed that VAS ranged between 1 and 5 with a mean value of 2.16 ± 0.93 in group 1 and between 1 and 5 with a mean value of 2.55 ± 1.21 in group 2. It was insignificantly different between both groups. However, needing for analgesia was significantly lower in group 1 than group 2 ($P = 0.004$). Successful IUD insertion was insignificantly different between both groups. Woman's level of satisfaction was insignificantly different between both groups. All side effects were insignificantly different between both groups except abdominal cramping and shivering were significantly lower in group 2 than group 1.

Conclusion: In cases of intrauterine contraceptive devices (IUCDs) insertion, there was between different doses of misoprostol (400 vs. 200) regarding degree of pain, success of insertion, women's satisfaction or pharmacological side effects However needing for analgesia was significantly lower and adverse effects as abdominal cramping and shivering were significantly higher in women received higher doses of misoprostol.

Keywords: Intrauterine contraceptive device, cesarean section

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

Title of the Protocol: Two Different Doses of Self-Administered Vaginal Misoprostol for Successful Copper Intrauterine Device Insertion In Parous Women Previously Delivered By Cesarean Section. A Double Blinded Randomized Clinical Trial.

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What is already known on this subject? AND What does this study add?

The main reasons associated with a low IUCD use are high cost in some settings and fear of pain at insertion by women. This double blind randomized controlled clinical trial study will evaluate and compare the efficacy and safety of misoprostol 200 mcg versus 400 mcg administered vaginally prior to IUCD insertion regarding the success and ease of insertion procedure among parous women beside the rate of occurrence of adverse effects.

1.INTRODUCTION/ REVIEW

The intrauterine contraceptive device (IUCD) is one of the most effective contraceptive methods available in addition to one of the safest Long-acting reversible contraception ***(Winner et al., 2012).***

Intrauterine contraceptive devices (IUCDs) are safe, reliable and highly effective forms of long-acting reversible contraception ***(ACOG 2017).***

IUCD is globally used by 15% of women aged 15–49 years. In Egypt, the percentage of women using IUCD according to Demographic and Health Surveys 2014 is 52.9% ***(Family Planning, 2016).***

These high rates of IUCD usage are due to its advantages such as reversible fertility immediately after removal, no need to daily reminder, no effect on breastfeeding, lack of hormonal effects, no interference with sexual activities and medications. But despite all these advantages; it doesn't always succeed ***(Aoun et al., 2014).***

The main reasons associated with a low IUCD use are high cost in some settings and fear of pain at insertion by women. For healthcare professionals the obstacles to use

include lack of training in insertion, fear of causing pain with the procedure and difficulties during the procedure that could end in failure of insertion ***(Bahamondes et al., 2011).***

Many health care providers believe that failure or difficulty of insertion is common in adolescents and nulligravidas and this is one of the reasons that restrict IUCD use, despite the evidence and recommendations supporting use in these groups ***(Berenson et al., 2013).***

Insertion was associated with anxiety in 86% of women and discomfort in 41% ***(Akintomide et al., 2015)***.

Failure of insertion occurs in up to 14% and 20% of parous and nulliparous women, respectively ***(Dermish et al., 2013).***

Insertion-associated pain is related to speculum insertion, tenaculum traction on the cervix, sounding of the uterus, passing of the insertion tube through the cervix and placement of the device within the uterine cavity ***(Pergialiotis et al., 2014).***

Extensive researches have been published aiming to decrease the perception of pain during IUCD insertion with no consensus on an effective method ***(Lopez et al., 2015).***

Misoprostol is a synthetic and inexpensive prostaglandin estrone analogue. It may be administered orally or vaginally the night before and, if needed, again in the morning before minimally invasive gynaecological procedures such as hysteroscopy, to assist cervical softening. Its use, however, is associated with side effects such as abdominal cramps, uterine bleeding, shivering, nausea, vomiting and diarrhoea ***(Khalaf et al., 2017).***

2.AIM / OBJECTIVES

The aim of the study is to evaluate and compare the efficacy and safety of misoprostol 200 mcg plus placebo versus 400 mcg administered vaginally prior to IUCD insertion in regard to the success and ease of insertion procedure among parous women beside the rate of occurrence of adverse effects.

Research Hypothesis:

In our study, we postulate that vaginal administration of 200 mcg misoprostol is as useful as administration of 400 mcg of misoprostol 3 hrs prior to IUCD insertion among parous women.

Research Question:

Is there a difference between pretreatment with two different doses of misoprostol in insertion of intrauterine contraceptives (IUCs)?

3.METHODOLOGY:

Patients and Methods/ Subjects and Methods/ Material and M

Type of Study:

A double blind randomized controlled clinical trial study.

Study Setting:

The study will be conducted on all women seeking intra uterine device insertion at Ain Shams University Maternity Hospital (Family planning clinic) during the period from January 2020 Till end of sample size.

Study Population: (N = 100)

All women who come to the family planning clinic during the study period require an insertion of IUCD insertion with the following criteria:

Inclusion criteria:

1. Women at reproductive age group between 18 - 45 years old.
2. Parous women previously delivered by cesarean section.
3. Non pregnant.
4. Timing: at the last day of menstruation, during puerperium or 2 weeks after abortion.
5. Did not receive any analgesics in the 24 h prior to IUCD insertion.
6. Have no contraindications for IUCD insertion in accordance with WHO eligibility criteria.

Exclusion criteria:

1. Nulligravidas.
2. Previous vaginal delivery.
3. Women with contraindications for misoprostol use (pregnancy, prostaglandin allergy)
4. Women with a contraindication for IUCD insertion (e.g., less than sex weeks post-partum, gynecologic malignancy, uterine bleeding of undetermined origin, fibroids or other uterine abnormalities, active vaginitis or cervicitis, a history of PID or puerperal sepsis).
5. Women on anticoagulant therapy or having any coagulopathy.
6. Uterine fibroid with distortion of the cavity.
7. Anatomical abnormality with distortion of the cavity.
8. Current pelvic inflammatory disease.
9. Current purulent cervicitis (chlamydia or gonorrhea).
10. Pelvic tuberculosis.

11. Puerperal sepsis.
12. Immediately after septic abortion.
13. Cancer cervix and cancer endometrium.
14. Women who refused to participate.

Sampling Method:

Simple random sample.

Sample Size:

The study will be conducted on (100) women. They will be subdivided into 2 groups:

- **Group 1 (control):** 50 women will receive misoprostol 400 mcg (2 tablets) vaginally 3rh prior to IUCD insertion.
- **Group 2 (experimental):** 50 women will receive misoprostol 200 mcg plus placebo vaginally 3hr prior to IUCD insertion (the placebo tablet has the same color, size and shape of tab. Of misoprostol)

Sample Justification: The required sample size has been calculated using the IBM© Sample Power© Software (IBM© Corp., Armonk, NY, USA). The primary outcome measure is the success rate for IUCD insertion. A previous study reported that following previous IUCD insertion failure, the success rate associated with pre-emptive vaginal misoprostol or placebo was 87.5% or 61.9%, respectively ***(Bahamondes et al., 2015)***. So, it is estimated that a total sample size of 100 patients equally randomized into either study group (n=50 patients per group) will achieve a power of 80% (type II error, 0.2) to detect a statistically significant difference between the two groups as regards the success rate for IUCD insertion using a two-sided chi-squared test with a confidence level of 95% (type I error, 0.05). The success rate is assumed to be identical in both