



شبكة المعلومات الجامعية
التوثيق الإلكتروني والميكروفيلم

بسم الله الرحمن الرحيم



HANAA ALY



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شبكة المعلومات الجامعية التوثيق الإلكتروني والميكروفيلم



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جامعة عين شمس

التوثيق الإلكتروني والميكروفيلم

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Vaginal Misoprostol Prior to Intrauterine Contraceptive Device Insertion in Women Who Delivered Only By Elective Caeserean Section: Randomized Clinical Trial

Thesis

*Submitted For Partial Fulfillment of Master Degree in
Obstetrics and Gynaecology*

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2020





Acknowledgement

*First great thanks to **"Allah"** who gave me the power to complete this work. Without his care nothing could be achieved.*

*I wish to express my sincere thanks and gratitude to **Prof. Magdy Mohammed Mahmoud Abdel Gawad** Professor of Obstetrics and Gynaecology, Faculty of Medicine, Ain Shams University for his valuable guidance, instructive supervision and great support throughout this study.*

*I am profoundly grateful to **Assistant Prof. Noha Abd El-Sattar Sakna**, Assistant Professor of Obstetrics and Gynaecology, Faculty of Medicine, Ain Shams University for her constant guidance, valuable remarks and great support throughout this study*

*I am deeply thankful to **Dr. Ahmed Atik**, Lecturer in Obstetrics and Gynaecology, Faculty of Medicine, Ain Shams University, for his great help, active participation and guidance.*

*I would like to express my hearty thanks to all **my family especially my husband** for their support till this work was completed.*

Last but not least my sincere thanks and appreciation to all patients participated in this study.

Enas Mahmoud Mohammed Elshahid



List of Contents

<i>Title</i>	<i>Page No.</i>
List of Abbreviations.....	i
List of Tables.....	ii
List of Figures	iii
Protocol	iv
Introduction	1
Aim of the Work	5
<u>Review of literature</u>	
Female Reproductive System.....	6
Prostaglandins	10
Intrauterine Contraceptive Device	26
Patients and Methods	50
Results	64
Discussion	78
Summary	85
Conclusion	88
Recommendations	89
Reference.....	90
Arabic summary	--

List of Abbreviations

*Abbr.**Full term*

AIDs.....	Acquired Immune Deficiency Syndrome
AUC	Area Under Curve
cAMP	Cyclic Adenosine Mono Phosphate
CS	Caesarean Section
ECM.....	Extracellular matrix
EMB.....	Endometrial biopsies
HCP	Healthcare professionals
IUCDs.....	Intrauterine contraceptive devices
LARC.....	Long acting reversible contraceptive
LNG IUS.....	Levonorgestrel Intra Uterine System
MLCK.....	Myosine Light Chain Kinase
MLCP.....	Myosine Light Chain phosphatase
MPA.....	Misoprostolic Acid
MW	Molecular Weight
PGE	Prostaglandin E
PGF.....	Prostaglandin
PIDs.....	Pelvic Inflammatory Diseases
PKA	Protein Kinase A
RBCs.....	Red Blood Cells.
STD.....	Sexual transmitted diseases
Tmax.....	Peak Time Concentration
VAS.....	Visual Analogue Scale
WHO.....	World Health Organization

List of Tables

<i>Table No.</i>	<i>Title</i>	<i>Page No.</i>
Table (1):	Misoprostol dosage for different obstetric and gynecological indications by FIGO	25
Table (2):	Demographic characteristics of the women included in this study.....	65
Table (3):	Ease of insertion among the women included in this study	66
Table (4):	Insertion complications among the women included in this study	68
Table (5):	Misoprostol side effects among the women included in this study.....	70
Table (6):	Pain perception (VAS-10) among the studied groups.....	72
Table (7):	Satisfaction among the studied groups.....	74
Table (8):	Expulsion within 8 weeks among the studied groups.....	76

List of Figures

<i>Figure No.</i>	<i>Title</i>	<i>Page No.</i>
Figure (1):	The female reproductive system	6
Figure (2):	The female reproductive system	7
Figure (3):	Nulliparous vs. parous cervix.....	9
Figure (4):	Prostaglandin structure.....	11
Figure (5):	Prostaglandin structure.....	12
Figure (6):	Misoprostol structure	13
Figure (7):	Lippes loop.....	27
Figure (8):	Copper IUCD	28
Figure (9):	Mirena.	29
Figure (10):	Skyla.....	30
Figure (11):	Metraplant-E	31
Figure (12):	Correctly inserted IUCD	37
Figure (13):	Visual analogue scale (VAS) for assessment of children's pain perception.....	54
Figure (14):	The arms of the copper-releasing intrauterine device are folded into the insertion tube	58
Figure (15):	The arms of the copper-releasing intrauterine device are released.	58
Figure (16):	The insertion tube is advanced for placement of the copper-releasing intrauterine device	58
Figure (17):	The insertion rod of the copper-releasing intrauterine device is withdrawn	59
Figure (18):	Flow chart of the studied cases.....	64
Figure (19):	Ease of insertion among the studied groups.....	67
Figure (20):	Insertion complications among the studied groups	69

List of Figures

Figure (21):	Insertion complications among the studied groups	71
Figure (22):	Pain perception (VAS-10) among the studied groups.....	73
Figure (23):	Satisfaction among the studied groups.....	75
Figure (24):	Expulsion within 8 weeks among the studied groups	77
Figure (25):	Visual analogue scale (VAS) for assessment of children's pain perception.....	87



PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF
MASTER DEGREE IN
OBSTETRICS AND GYNEACOLOGY

**Role of vaginal misoprostol prior to IUCD insertion in
women who delivered only by elective caesarean section.**

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17/12/2018

1.INTRODUCTION/ REVIEW

Intrauterine contraceptive devices (IUCDs) are one of the reversible effective contraceptives (*Bahamondes et al., 2014*).

However its use is limited by the high cost in some settings and fear of pain at insertion time. For healthcare professionals (HCPs) the obstacles to its use include lack of training, fear of causing pain with the procedure and difficulties during the procedure that could end in insertion failure (*Marions et al., 2011*).

Many HCPs 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*).

Most IUCD insertions do not require pain control; however, a proportion of nulliparous (17%) and multiparous (11%) women experience significant pain and will require active pain management (*Marions et al., 2011*).

Misoprostol is an inexpensive prostaglandin E1 analogue, which is associated with few side-effects (*Wing and Gaffaney, 2006*) and has been used extensively for its cervical softening effect before induction of labour and surgical evacuation of the uterus (*Aronsson and Marion, 2007*), as it reduces the force required for cervical dilatation (*Cleary, 2010*).

2.Aim of the Work

The aim of study is to evaluate the role of vaginal misoprostol (400mcg) administration 3h prior to IUCD insertion in women delivered only by elective caesarean section.

Research hypothesis

In women who delivered by elective caesarean section undergoing IUCD insertion, vaginal misoprostol doesn't facilitate IUCD insertion.

Research question

In women who delivered by elective caesarean section undergoing IUCD insertion, does vaginal misoprostol facilitate IUCD insertion?

Primary outcome measures of this study are :

- 1) the proportion of failed IUCD insertions regardless of the reason (e.g. immediate expulsion or impossibility to sound the uterus or any resistance or need for dilatation will be recorded) .
- 2) the degree of difficulty of the IUCD insertion judged as the resistance of the internal cervical os experienced by the investigator and measured by a 5-point scale, as follow:
 - 5 \Longrightarrow Easy insertion.
 - 4 \Longrightarrow Moderately difficult insertion.

- 3 ➡ Difficult insertion.
 2 ➡ Extremely difficult insertion.
 1 ➡ Failed insertion.

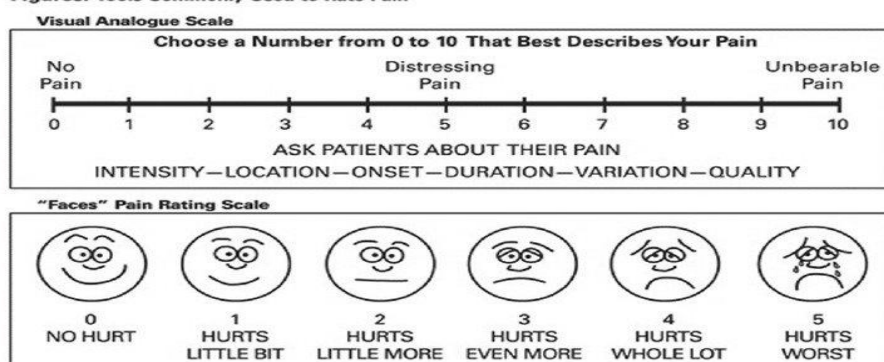
(Harry and Boone, 2012)

Secondary outcome measures are :

- 1) vasovagal-like reactions (dizziness, nausea and vomiting),
- 2) syncope,
- 3) partial- or total expulsion,
- 4) heavy bleeding,
- 5) uterine or cervical perforation,
- 6) pain during insertion, as estimated by the inserter.

Pain will be measured using a 10-cm visual analog scale (VAS) graded from 0 to 10.

Figures: Tools Commonly Used to Rate Pain



Visual analogue scale (VAS) for assessment of children's pain perception (*Faezeh et al., 2013*).

3.METHODOLOGY:

Patients and Methods/ Subjects and Methods/ Material and Methods

Study Design: Double blinded placebo randomized controlled clinical trial.

Place: The study will be conducted at family planning clinic of Ain-Shams University Maternity Hospital.

Sample size calculation:

Using STATA program setting alpha level at 5% and power at 80% result from previous study (*Abdella et al., 2017*) showed that 98.6% of misoprostol group showed successful insertion compared to 87.1% of placebo based on this we need 95 patient per group with taking in consideration on 10% drop out rate the needed sample size is 105 cases per group (210 total).

Population of study:

Two hundreds and ten women candidate for IUCD insertion will be enrolled in the study. Group A will receive 400 microgram of misoprostol vaginally 3 hours before IUCD insertion and group B will receive placebo.

Inclusion Criteria:

1. All women will be 20 to 40 years of age.
2. Desires IUCD placement and able to participate.
3. Negative pregnancy test.
4. Willing to follow- up in 6-8 weeks for a standard IUCD follow-up visit.
5. Delivered only by caesarean section.

Exclusion Criteria:

1. Active cervical infection.
2. Current pregnancy.