A Comparative Study of Surgical versus Medical Management of Cases of First Trimesteric Missed Abortion

Thesis

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

By

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List of Abbreviations

µg, mcg	Micro-gram
ACOG	American college of obstetrics and gynaecology
APS	Antiphospholipid syndrome
BMI	Body mass index
BP	Blood pressure
BV	Bacterial vaginosis
CBC	Complete blood count
CRL	Crown rump length
CS	Cesarian section
CT	Computerized tomography
D&C	Dilatation and currettage
DES	Diethylstilbestrol
DNA	Deoxyribose nucleic acid
E&C	Evacuation and currettage
ERPC	Evacuation of retained products of conception
EVA	Electric vacuum aspiration
FDA	Food and drug administration
FL	Fetal life (cardiac activity)
FSH	Follicular stimulating hormone
gm	Gram
Gy	Gray (unit for measurement of ionizing radiation)
h	Hour
Hb	Hemoglobin level
HCG	Human chorionic gonadotropin
IgG	Immunoglobulin g
IgM	Immunoglobulin m
IU	International unit
KFT	Kidney function tests
Kg	Kilogram
LFT	Liver function tests

LH	**Lutenizing hormone**
LMP	**Last menestrual period**
LPD	**Luteal phase defect**
m	**Meter**
mg	**Milligram**
min	**Minute**
ml	**Milliliter**
mm	**Millimeter**
MVA	**Manual vacuum aspiration**
NCRP	**National council on radiation protection and measurment**
NSAIDs	**Nonsteroidal anti-inflammatory drgugs**
^{o}C	**Celsius**
PCO	**Polycystic ovary**
PGE2	**Prostaglandin E2**
PT	**Prothrombin time**
PTT	**Partial thromboplastin time**
RBS	**Random blood sugar**
RCOG	**Royal college of obstetrics and gynaecology**
RH	**Rhesus factor**
RM	**Recurrent miscarriage**
RSA	**Recurrent spontaneous abortion**
SLE	**Systemic lupus erythomatous**
TPO	**Thyroperoxidase**
TSH	**Thyroid stimulating hormone**
U/S	**Ultrasonography**
β-hCG	**Beta subunit of human chorionic gonadotropin**

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Abstract

This study is aiming to compare the effectiveness and the outcome of two different regimens for the management of first trimester missed abortion using misoprostol followed by evacuation and curettage versus a home regimen of misoprostol.

This study is a randomized controlled open labelled clinical trial, which was conducted at Maternity hospital, Ain Shams University. The study included ninety patients suffering from first trimestric missed abortion. The patients were randomly divided into two equal groups; the first group **(Group A) the hospital regimen group,** using a single dose of 400 mcg. Misoprostol vaginally followed by 3 hours expectancy then will be evacuated by E&C. The second group **(Group B) the home regimen group**, who will receive misoprostol in the following manner:

- **Dose:** 800 mcg
- **Route of administration:** vaginally
- **Frequency:** every 8 hours for 48 hours & if failed it will be repeated after 24 hours

  Maximum dose: 2400 mcg / 24 hours.

Keywords: First trimesteric missed abortion, surgical evacuation, misoprostol.

Protocol

PROTOCOL OF A THESIS FOR PARTIAL FULFILLMENT OF MASTER DEGREE IN OBSTETRICS AND GYNECOLOGY

Title: **A Comparative Study of Surgical versus Medical Management of Cases of First Trimesteric Missed Abortion**

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What is already known on this subject? And What does this study add?
Traditionally, missed abortion occurred at 1st trimester is managed by evacuation and curettage (E&C) either directly or after medical preparation with misopristol tablets inside the hospital. Since uncomplicated cases of missed abortion are in need for more sense of comfortable, convenience and the least surgical intervention; in this study, the effectiveness and safety of using medical treatment by misopristol at home will be evaluated in comparison to surgical evaluation.

1. INTRODUCTION/ REVIEW:

Missed abortion is defined as the natural death of an embryo or fetus before it is able to survive independently ***(Wahabi et al.,2018)***.

Some use the cutoff of 28 weeks of gestation, after which fetal death is known as a still birth.***(Gardosi, J et al., 2013).***

Missed abortion can occur before 12 weeks of gestation and it so called 1st trimestric abortion or called as early pregnancy loss ***(Maconochie et al.,2007)***.

In some cases of first trimester pregnancy failure, arrest of embryonic or fetal development occurs some time

before the expulsion (miscarriage). When this occurs, the cervix is closed and there is no or only slight bleeding. Ultrasound shows an empty gestational sac or an embryo\fetus without cardiac activity. **(Gemzell-Danielsson *et al;* 2007).**

Missed abortion in the first trimester is a common obstetric problem which may be followed by serious complications. It can be managed by different methods including expectant, surgical, and medical methods **(Hooker, A. B *et al;* 2013).**

An expectant management may result in serious complications resulting from the presence of dead tissue of the fetus inside the uterus for several days which may produce a severe infection or release of tissue thromboplastin materials into the circulation which will initiate the coagulation cascade consuming the coagulation factors resulting in a hemocoagulopathy and DIC which may end fatally (**Wallace *et al;* 2010**).

The medical method for evacuation by using prostaglandins PGE2 either alone or in combination with mifepristone can be used safely but it has the disadvantage of being expensive for many patients as well as time consumption (**Neilson *et al;* 2010**).

Surgical evacuation of uterine contents by D&C or aspiration is commonly accepted by many practitioners,

however, it has several complications including cervical tears, uterine perforations, bleeding and complications of anesthesia ***(Tristan, & Gilliam, 2009).***

Now, ***Misoprostol*** (PGE2 analogue) a drug that was originally developed and approved for the prevention of gastric ulcer, showed itself to be a safe, effective and an acceptable drug used for uterine evacuation with good preparation of the cervix facilitating surgical evacuation of the uterus and it has the advantage of being inexpensive ***(Clark & Shannon, 2007)***.

2. AIM/ OBJECTIVES :

Hypothesis:

In women with 1st trimestric missed abortion, induction of abortion using misopristol in home may be as safe & convenient as E&C

Question :

In women with 1st trimestric missed abortion, is induction of abortion using misopristol in home safe & convenient as E&C?

Aim of the study :

This study is aiming to compare the effectiveness and the

outcome of two different regimens for the management of first trimester missed abortion using misoprostol followed by evacuation and curettage versus a home regimen of misoprostol.

1ry outcome:

Success rate (Occurrence of complete abortion whatever surgically or medically without complications).

2ry outcome:

- Patient's satisfaction.
- Occurrence of complications like sepsis, uterine perforation & massive bleeding
- Time needed to induce abortion.

3. METHODOLOGY:

- **Types of study:** randomized controlled open labelled clinical trial
- **Study setting :** Maternity hospital, Ain Shams University
- **Study period** : for six months from 1st of March 2019 to 31st of August 2019
- **Sample Size Justification**: Using (PASS©) version 11.0.10 **(NCS©S, LLC. Kaysville, Utah, USA)**. The primary outcome is occurrence of complete abortion. A previous study, ***Annelise Gronlund et al, 2002*** reported that the rate of occurrence of complete abortion in group 3 (surgical evacuation) was 90.%; while it was 72% in group 2 (medical management with misoprostol only). So, in our study, it was estimated that group sample size of 45 in group A (who will undergo E&C) and 45 in group B (misoprostol regimen at home) achieve power to detect the difference between

the group proportions of 11% lost to follow up we're taken into consideration while calculating sample size.

(Ref. of program) Hintze,J.(2011). PASS 11. NCSS,LLC.Kaysville, Utah, USA.

- **Sample size :** 90 patients divided into 2 equal groups
- **Study population :** Women who have uncomplicated 1st trimesteric missed abortion

- **Patient & method :**

After detailed discussion with the patients, all will be accurately informed about the steps of this study and a written informed consent will be taken from all the patients.

Women will be randomizely chosen.

- Inclusion criteria :

1- Gestational age : 7 to 9 weeks of gestation

2- Maternal age : 20 to 35 years old

3- Absence of fetal cardiac activity confirmed by ultrasonography(U/S)

4- Body mass index (BMI) : 20 to 30 kg/m^2

- Exclusion criteria:

1- Known allergy or contraindication to misoprostol.

2- Suspected ectopic pregnancy.

3- Unstable hemodynamics and shock.