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بسم الله الرحمن الرحيم

HANAA ALY

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جامعة عين شمس

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قسم

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Sublingual versus Vaginal Misoprostol for Medical Termination of Second Trimesteric Pregnancy

A Thesis

Submitted for partial fulfillment of Master degree
in Obstetrics and Gynecology

By

Dina Fawzi Mansour
M.B.B.Ch

Under Supervision of

Prof. Dr. Amr Hassan El-Shalakany
Professor of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Dr. Amr Helmy Yehia
Assistant Professor of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Faculty of Medicine
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Dina Fawzi Mansour

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List of Abbreviations

Abbr.	Full-term
CBC	**:** Complete blood count
HCT	**:** Hematocrit
Hb	**:** Hemoglobin
CS	**:** Cesarean Section
D&C	**:** Dilatation and curettage
DM	**:** Diabetes mellitus
FDA	**:** Food and Drug Administration
FHR	**:** Fetal heart rate
GTD	**:** Gestational trophoblastic disease
hCG	**:** Human chorionic gonadotropin
IUFD	**:** Intrauterine fetal death
MTP	**:** Medical Termination of Pregnancy
NAF	**:** National Abortion Federation
NSAIDs	**:** Non-steroidal anti inflammatory drugs
PG	**:** Prostaglandin
PID	**:** Pelvic inflammatory disease
PROM	**:** Premature rupture of membrane
Rh	**:** Rhesus
SD	**:** Standard deviation
SPSS	**:** Statistical package for social science
TB	**:** Tuberculosis

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Introduction

Miscarriage is defined as termination of pregnancy before the period of viability, which occurs at 20 weeks of gestation and the foetus weighing 500 g according to the definition of World Health Organization (WHO), but here in Egypt, age of fetal viability is 28 weeks; so, miscarriage is considered before this gestational age. About 40-60 million abortions occur per year globally. Medical abortion is a safe alternative to surgical methods ***(Stabile et al., 2000).***

Abortion is done according to the laws of any country. Legally, therapeutic abortion means ending a pregnancy by a physician due to illness of the mother or the fetus ***(Hasanzadeh et al., 2009).***

Mid-trimester abortion constitutes 10–15 % of all induced abortions but is responsible for two-thirds of all major complications. There is a gradual increase in second trimester abortions because of the wide-scale introduction of prenatal screening programs detecting women whose pregnancies are complicated by serious fetal abnormalities. During the last decade, medical methods for mid-trimester induced abortions have shown a considerable development and have become safe and more accessible ***(Borgatta et al., 2011).***

Cervical priming prior to surgical termination of pregnancy reduces the risks of cervical injury, uterine perforation,

haemorrhage and incomplete uterine evacuation. Risk factors for cervical damage include patient age (more common in younger patients) and increasing gestation (especially among multigravida women), which is associated with an increased risk of uterine perforation ***(Aronsson et al., 2004).***

The Royal College of Obstetricians and Gynaecologists recommends that cervical preparation is beneficial prior to suction termination and should be routine when the woman is under 18 or at gestation of >10 weeks ***(O'Shea et al., 2020).***

The commonly used methods for cervical priming include laminaria tent in the United States and the prostaglandin analogues in the United Kingdom. In the United Kingdom, the prostaglandin E1 analogue gemeprost is most commonly used although studies have shown that misoprostol is an effective alternative ***(Ashok et al., 2000).***

Various management protocols have been used for second trimester pregnancy termination. These includes surgical techniques (D&E) and medical approaches such as intra-amniotic prostaglandin (PG) F2 α instillation, PGE2 vaginal suppositories, PGE2 and high-dose oxytocin ***(Tang et al., 2005).***

All these methods require hospitalization and have disadvantage of surgical trauma and anaesthetic complication. PGE1 analogue, misoprostol, originally used for the treatment of peptic ulcer, has been found to have uterotonic effect as well and is used for termination of pregnancy for great success ***(Guix et al., 2005).***

Aim of the Work

The aim of this study is to compare the effectiveness, and safety of sublingual versus vaginal routes of administration of misoprostol in the medical treatment for termination of the second trimesteric abortions.

Overview of Miscarriage

The incidence of clinically obvious miscarriage is considered to be between 10% and 15% of all pregnancies, although the real incidence may be considerably higher ***(Grudzinskas 1995; Howie 1995; Simpson, 1991).***

The wide spread use of ultrasound in early pregnancy for either specific reasons (for example, vaginal bleeding) or as a routine examination ***(Neilson, 1998)*** reveals 'non-viable pregnancies' destined inevitably to miscarry in due course. These are termed 'anembryonic pregnancies' (formerly called 'blighted ova') if no embryo has developed within the gestation sac, or 'missed abortions' if an embryo or fetus is present, but is dead.

Misoprostol has been shown to be an effective myometrial stimulant of the pregnant uterus, selectively binding to EP-2/EP-3 prostanoid receptors ***(Senior, 1993).*** It is rapidly absorbed orally and vaginally. Vaginally absorbed serum levels are more prolonged and vaginal misoprostol may have locally mediated effects ***(Zieman, 1997).***

Although clotting problems occasionally occur in women with prolonged retention of a dead fetus, this is rare and does not usually happen within the first month after fetal death. There are, therefore, not pressing medical reasons to

terminate non-viable pregnancies. Although, anecdotally, many women favour early termination, so-called 'expectant management' (that is, awaiting spontaneous miscarriage) is alegitimate alternative and this policy should be considered in clinical care and in planning trials.

Misoprostol has emerged as a critical component of these regimens both as a stand-alone method and in combination with other medications like mifepristone. The combination of mifepristone and misoprostol is the most effective and fastest regimen ***(Borgatta et al., 2011).***

However, mifepristone is not widely available and is expensive. Misoprostol is being more widely used because it is inexpensive and stable at room temperature. It can be absorbed via oral, vaginal, sublingual, buccal, and rectal routes. Initially, misoprostol was used orally for medical abortion. Many clinical trials have found vaginal administration to be more effective than oral administration ***(Ashok et al., 1998).***

There has been suggestive evidence showing that absorption through vaginal route is inconsistent ***(Singh et al., 1999).***

Recently, the use of sublingual misoprostol has been explored for medical abortion. A pharmacokinetic study has demonstrated that sublingual administration could achieve