

**Randomized controlled trial between vaginal
misoprostol alone versus weighted intrauterine
Foley's catheter and vaginal misoprostol in
termination of mid-trimester abortion**

Thesis

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By

Ebtisam Ashour Ahmed Desoky

M.B.B.CH (2011)

Faculty of Medicine, Ain shams University

Resident of Obstetrics & Gynecology

Nasser general Hospital

Under Supervision of

Dr. Alaa Eldin Hamed El Feky

Professor of Obstetrics and Gynecology

Faculty of Medicine – Ain Shams University

Dr. Amr Abd Al Aziz El Sayed

Assistant Professor of Obstetrics and Gynecology

Faculty of Medicine – Ain Shams University

**Faculty of Medicine
Ain Shams University**

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List of Abbreviations

<i>Abbr.</i>	<i>Full-term</i>
D&C	: Dilatation and curettage
D&E	: Dilatation and evacuation
D&X	: Dilatation and extraction
EASI	: Extra-amniotic saline infusion
FCB	: Foley's catheter balloon
Hr	: Hour
IEI	: Induction to expulsion interval
IP3	: Inositol triphosphate
IUFD	: Intra uterine fetal death .
PG	: Prostaglandin
PGE1	: Prostaglandin E1
PGsE1	: prostaglandin synthetase enzyme
PROM	: premature rupture of the membranes
POC	: Products of conception
RCT	: Randomized Controlled Trial
SNOSE	: sequentially numbered opaque sealed envelopes
TOP	: Termination of Pregnancy
µg	: Microgram

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Abstract

Background: Termination of pregnancy (TOP) is defined as elective expulsion or extraction of products of conception from the uterus instead of spontaneous onset of the process irrespective of duration of pregnancy. **Aim**

of the Work: to investigate whether the insertion of a weighted fluid filled trans-cervical Foley's catheter in women undergoing midtrimester termination of pregnancy for various reasons; may further improve the effectiveness of vaginal misoprostol in terminating their pregnancies.

Patients and Methods: A prospective, interventional, randomized controlled trial was conducted on a total number of 50 patients, divided into two groups; the first group (I) included 25 patients who received vaginal misoprostol, two tablets each contains 200 microgram misoprostol (Segma pharmaceuticals, Egypt), in the posterior vaginal fornix every four hours.

Results: The use of a weighted trans-cervical Foley's catheter filled with 30 ml saline improve the effectiveness of 400 µg vaginal misoprostol in terminating mid trimester pregnancies as reflected by a shorter induction to delivery interval with no significant increase in the incidence of side effects.

Conclusion: The use of a weighted trans-cervical Foley's catheter filled with 30 ml saline improve the effectiveness of 400 µg vaginal misoprostol in terminating mid trimester pregnancies as reflected by a shorter induction to delivery interval with no significant increase in the incidence of side effects.

Key words: vaginal misoprostol, Foley's catheter, termination of mid-trimester abortion

Introduction

Abortion is defined as termination of pregnancy (TOP) by any means before the fetus is viable. Viability is now considered to be reached at 23–24 weeks of gestation, Second trimester, or midtrimester, is a period ranging from 13 to 28 weeks of gestation, which again is subdivided into early midtrimester abortion between 13 and 20 weeks and a late midtrimester abortion between 20 and 28 weeks (*Lalithkumar et al., 2007*).

Mid trimester uterine evacuation is a process in which the contents of the uterus are removed during the second trimester of pregnancy. It can be performed electively, for fetal or pregnancy complications, or for maternal medical indications (*Whitley et al., 2011*).

Termination of pregnancy (TOP) is defined as elective expulsion or extraction of products of conception from the uterus instead of spontaneous onset of the process irrespective of duration of pregnancy.

Worldwide;mid-trimester abortion constitutes 10–15% of all induced abortions but is responsible for two-thirds of all major complications (*WHO,1997*).

Although the majority of abortions are performed in the first trimester, the ability to identify foetal abnormalities at an early stage by using ultrasonography and modern prenatal diagnostic techniques has increased the number of women requiring TOP (*Bryant et al., 2011*).

Indications for second trimester termination of pregnancy:

Are variable, they are usually performed for:

Anticipated benefits to the mother, such as improving a medical condition which is caused or aggravated by pregnancy, including pre-eclampsia, placental abruption and certain respiratory, hepatic and cardiac disorders; or any other medical disorder affect the mother health.

However, congenital fetal malformations; which are incompatible with life also constitute a major indicator for TOP. (*Yapar et al., 1996*).

Several regimens for second trimester medical abortion have been published. Most of these are based on Misoprostol, which is a synthetic prostaglandin E1 analogue (PGE1) and is either used alone, or combined with Mifepristone, other regimens used mechanical methods as intracervical catheters for termination of pregnancy in second trimester. (*Wildshut et al., 2011*).

Several studies have described that the Foley's catheter is an effective method in ripening the cervix. These studies showed that it increased the Bishop's score in women with unripe cervixes and Foley's catheter appears to be superior to prostaglandins for pre-induction cervical ripening (*Sciscione et al., 2004*); (*Obed and Adewole, 1994*).

So, in this study I will compare between Foley's catheter with vaginal misoprostol versus the use of misoprostole alone to shorten the duration needed for complete evacuation and for decrease the complications of surgical abortion .

Aim of the Study

This study was designed to investigate whether the insertion of a weighted fluid filled trans-cervical Foley's catheter in women undergoing midtrimester termination of pregnancy for various reasons; may further improve the effectiveness of vaginal misoprostol in terminating their pregnancies.

Second Trimester Abortion

Missed abortion is death of foetus in utero before 24 weeks of gestation but uterus fails to expel products of conception (*Eng and Guan, 1997*). Regarding congenitally abnormal foetus mostly termination of pregnancy is done for neural tube defects i.e. anencephaly.

Second trimester medical abortion for fetal structural anomalies may have advantages over surgical abortion as it is operator independent and the intact fetus may be preferable for fetopathological examination (*Kaasen et al., 2006*). There are many medical methods for planned termination of pregnancy in the second trimester of pregnancy. Medical abortion, however, also has several limitations including the need for the hospitalization, the need for surgical removal of the retained products of the placenta when indicated and the emotional impact of the process of labor and delivery on women who choose to end a pregnancy (*Kelly et al., 2010*).

Medical abortion in the first trimester of pregnancy is considered successful if complete expulsion of the conceptus occurs without the need for surgical intervention. Beyond the first trimester, definitions differ but generally consider expulsion of the fetus separate from management of the placenta (*Christin-Maitre et al., 2000*).

Up to 9 weeks of gestation the overall rate of complete abortion can be up to 98% with only 2% needing a surgical intervention (**Ashok et al., 2002**). At 13–21 weeks of gestation the rate of successful abortion has been reported to be as high as 92%, with only 8% needing a surgical intervention (**Ashok et al., 2004**).

Uterine responsiveness to conventional methods of induction of labour increases as pregnancy approaches term. But second trimester TOP has always been a difficult task. TOP in second trimester is associated with three to five times' higher risk of maternal morbidity and mortality than termination during first trimester (**Ansa Islam et al., 2006**).

The success of induction depends on the state of the cervix before commencement with the most favourable outcomes occurring in cervixes which are soft and effaced (**Pennell et al., 2009**).

Approximately half of the deaths and two-thirds of the major complications of abortion occur when the procedure is performed after the 13th week (**Lalithkumar et al., 2007; Gómez and Wing, 2009**).

Moreover, most fetal abnormalities and associated indications for abortion are not identifiable until the 16th or even the 20th week of pregnancy.

Medical abortion

Physiologic actions of drugs inducing abortion:

Implantation of a fertilized ovum (embryo) involves complex interactions with the endometrium. The embryo becomes attached to the endometrial epithelium and invades the endometrial stroma on day 6 to 10 after ovulation. These events depend on progesterone, which modifies the transcription of many genes involved in the implantation process (Fig. 1).

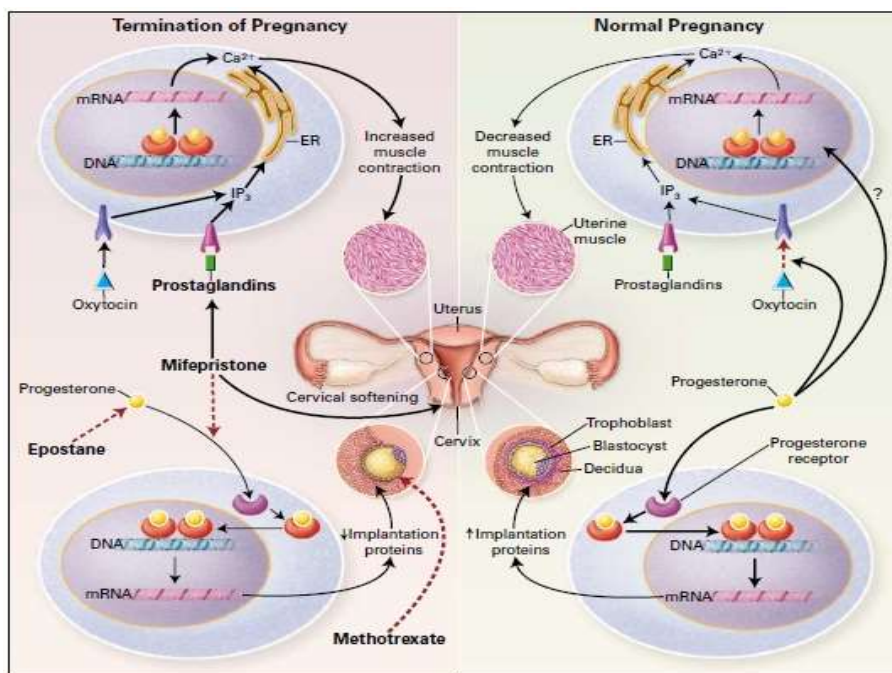


Figure (1): Physiology of Pregnancy and Site of Action of Drugs Used to Terminate Pregnancy.

Progesterone also inhibits myometrial contractions (*Chwalisz and Garfield, 1997*). The drugs used to terminate pregnancy act by inhibiting the synthesis of progesterone, inducing myometrial contractions, antagonizing the action of progesterone, or inhibiting the development of the trophoblast.

1. Inhibition of Progesterone Synthesis:

Modified steroidal molecules, such as (2 *a*,4 *a*,5 *a*,17 *b*)-4,5-epoxy-17-hydroxy-4,17-dimethyl-3-oxoandrostane-2 carbonitrile (epostane) and other competitive inhibitors of ovarian and placental 3 *b* -hydroxysteroid dehydrogenase, such as trilostane, inhibit the synthesis of progesterone from its precursor, pregnenolone (*Creange et al., 1981*).

The action of epostane in reducing progesterone synthesis and terminating pregnancy is prevented by the administration of progesterone (*Creange et al., 1981*).

2. Induction of Myometrial Contractions:

Prostaglandins and oxytocin stimulate uterine contraction by binding to specific receptors on the myometrial- cell surface. This action results in increased calcium production by the endoplasmic reticulum and, consequently, in uterine contraction (*Izumi, et al., 1994*).