

Medical Versus Surgical Abortion In The First Trimester Regarding The Amount Of Blood Loss(Randomized Controlled Trial)

Thesis

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By

AHMED NASR ABD EL SALAM

Resident of Obstetrics and Gynecology (2009)

(M.B.B,CH)

Suez general hospital

Under Supervision of
Prof. Dr. Khaled Saïd Mohamed

Professor of Obstetrics and Gynecology

Faculty of Medicine – Ain Shams University

Prof.Dr. Ahmed Hussein Salama

Professor of Obstetrics and Gynecology

Faculty of Medicine – Ain Shams University

Faculty of Medicine

Ain shams university

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List of Contents

Protocol.....	1
Introduction	17
Aim of the Work	19
Review of Literature	20
Material and Method	42
Results	55
Discussion	64
Summary	70
Conclusion and Recommendations	72
References	74
Arabic summary	—

List of Figures

Figure (1):	Traction on cervix.....	31
Figure (2):	Karmen cannula	34
Figure (3):	Rotation of the suction curette	35
Figure (4):	Distribution of parity	55
Figure (5):	Comparison of age	56
Figure (6):	Comparison of gestational age.....	56
Figure (7):	Comparison of previous cs	57
Figure (8):	Evacuation rate	60
Figure (9):	Complication rate.....	61
Figure (10):	Abdominal cramping	62
Figure (11):	Satisfaction in both groups	63

List of Tables

Table (1):	contraindications of medical abortion	28, 29
Table (2):	The randomization of cases	45
Table (3):	The clinical data of patients	58
Table (4):	The level of hemoglobin decrease	59
Table (5):	Comparison of evacuation rate.....	60
Table (6):	Complication rate in both groups	61
Table (7):	Abdominal cramping during the procedures	62
Table (8):	Satisfaction in both groups	63

INTRODUCTION

Miscarriage or spontaneous abortion is the spontaneous end of a pregnancy at a stage where the embryo or fetus is incapable of surviving, generally defined in humans at prior to 20 weeks of gestation; miscarriage is the most common complication of early pregnancy **(Petrozza., 2009)**.

Very early miscarriages which occur before the sixth week LMP (Last Menstrual Period) are medically termed early pregnancy loss or chemical pregnancy. However, miscarriages that occur after the sixth week LMP are medically termed clinical spontaneous abortion **(Wang.,2004)**.

Early pregnancy failure also known as blighted ovum, early fetal death or missed abortion complicates 15-20% of all pregnancies **(Kovavisarach and Jamnansiri ., 2005)**.

Uterine curettage has been traditionally used as the surgical method of treatment. It is associated with 4% to 10% rate of hemorrhage, infection, uterine adhesions,

Introduction

impaired fertility, cervical trauma, uterine perforation and anesthesia errors (**Muffley et al., 2002**).

Some studies reported lower success rate of misoprostol (**Szymanska et al., 2003**). On the other hand there are different reports about the complication of this drug (**Kovavisarach and Jamnasiri., 2005**).

AIM OF THE WORK

The aim of the study is to compare between medical evacuation using Misoprostol (administered vaginally) and the standard surgical evacuation in first trimester missed abortion regarding the success rate of treatment and complications rate as assessed during, immediately and after one week of treatment.

MEDICAL ABORTION

Medical abortion has become an alternative method for first trimester pregnancy terminations with the availability of mifepristone (progesterone receptor agonist) and misoprostol (prostaglandin) (**Wedisinghe and Elsandabesee,. 2010**).

Misoprostol for abortion:

Misoprostol is a synthetic prostaglandin E₁ analogue that is commonly used for medical abortion. It can be given orally, vaginally, rectally and sublingually. A pharmacokinetic study has shown that sublingual misoprostol has the shortest onset of action, the highest peak concentration and the greatest bioavailability among the four routes of administration. Earlier clinical trials have shown that vaginal misoprostol is superior to oral misoprostol when combined with mifepristone for early first trimester medical abortion. Recent studies on the clinical efficacy of sublingual misoprostol have demonstrated that it is as effective as vaginal misoprostol. Further studies are required to determine the optimal dose and route of administration of misoprostol that can

Review of Literature

give the highest complete abortion rate and least side effects **(Oi Shan., 2006)**.

In a study on 141 women seeking abortion with pregnancy less than 70 days, they took up three doses of 800 micro g misoprostol every 48 hours vaginally complete abortion occurred in 93.6% **(Carbonell et al., 2000)**.

Oral misoprostol was tried in early complicated pregnancy such as blighted ovum and missed abortion with repeated doses of 200 micro g till a maximum dose of 1200 micro g was given, complete or partial abortion took place within 7 ± 5 hours in 92.5% of patients with minor side effects. This study demonstrated that the use of oral misoprostol is an easy procedure for terminating early complicated pregnancy **(Haberal ., 2005)**.

To compare the pharmacokinetics of vaginal and oral administration of Misoprostol, 20 women were studied, 10 were pregnant and another 10 non pregnant, all received 400 micro g of Misoprostol either orally or as a tablets placed high in the posterior fornix. It was found that the systemic bioavailability of vaginal administered Misoprostol was three times higher than that of orally administered. With the vaginal route, peak plasma levels were reached more slowly and slightly lower but were

Review of Literature

sustained up to 4 hours, suggesting that vaginally administered Misoprostol could be dosed at longer intervals than orally administered (**Zieman et al., 2001**).

The per rectal route also has the same advantage as the vaginal route in terms of decreasing the adverse effects as vomiting, diarrhea, and shivering as there is no gastric absorption. However, the advantage of rectal route over the vaginal route is that it can be used in cases of vaginal bleeding which might affect the feasibility of its use and absorption (**Obrien et al., 2003**).

Jain et al., (2001) completed a randomized trial with 800 micro g Misoprostol given 48 hours after 24 hours treatment with Tamoxifen or placebo. The vaginal Misoprostol dose was repeated every 24 h for 8 days if abortion did not occur. Although complete abortion rates were similar with or without Tamoxifen (93% and 91%, respectively) both groups showed high incidence of vomiting, diarrhea, fever and chills. Majority of participates (125 of 150) started that they were satisfied with the method.

It has been pursued that relatively high success rates have been reported with multiple dosing, but the most effective regimen and the best method of

Review of Literature

administration remain to be determined. The administration of 800 micro g Misoprostol daily for 3 days has been reported to very effective late in the first trimester (**Kamal et al., 2005**).

Adverse effects of Misoprostol:

Bleeding for 2 weeks after vaginal Misoprostol for missed abortion is common. Heavy bleeding is usually limited to a few days after treatment. Clinically important changes in hemoglobin after Misoprostol use are rare. Though uncommon, delayed episodes of prolonged or heavy bleeding requiring surgical evacuation can occur following medical management of missed abortion. **(Davis,2000)**

Diarrhea is the major adverse reaction that has been reported consistently with Misoprostol but it is usually mild and self-limiting. Nausea and vomiting may also occur and will resolve in 2 to 6 hours. Some women found an unpleasant taste when it is taken sublingually or buccally. A sense of numbness over the mouth and throat has also been reported when it is taken sublingually **(Henriques et al., 2007)**.

The most common side effects are shivering and pyrexia, which are dose-related. Systematic review of randomized comparisons between Misoprostol 600 micro g versus 400 micro g for the prevention of post partum hemorrhage found the rate of fever 38 °C to be 17% for

Review of Literature

600 micro g versus 8% for 400 micro g (**Gülmezoglu et al., 2007**).

The toxic dose of Misoprostol is unknown. A recent case report has identified a woman who died of multi-organ failure following an overdose of Misoprostol (60 tablets over 2 days) (**Henriques et al., 2007**).

In some studies, oral ingestion of Misoprostol increased the incidence of diarrhea. However, these findings are not consistent for doses of 400 micro g and lower (**Ramin et al., 2002**).

Chills were reported in 32% – 57% of women receiving Misoprostol (**Derman et al., 2004**).

Another concern about the use of Misoprostol is the risk of uterine rupture, especially in women with a previous uterine scar. Reports of uterine rupture are rare in first trimester medical abortion, but the risk seems to increase with gestation (**Kim et al., 2003**).

Infection is not common after medical abortion by Misoprostol. The incidence has been reported to be only 0.92% (**Shannon., 2004**). Nevertheless, the recent reports on fatal infection with *Clostridium Sordellii* after using vaginal Misoprostol for abortion has led to concerns over

Review of Literature

the use of this method. However, after extensive investigation there is still no consensus as to the mechanism of infection in these cases (**Fischer., 2005**).

Exposure to Misoprostol in early pregnancy has been associated with multiple congenital defects. However, mutagenicity studies of Misoprostol have been negative and Misoprostol has not been shown to be embryotoxic, fetotoxic or teratogenic (**Pastuszek et al., 2001**). These malformations, therefore may be due to a disturbed blood supply to the developing embryo during Misoprostol-induced contractions.

It is estimated that absolute risk of malformations after exposure to Misoprostol is relatively low, in the order of 1% among exposed fetuses. In population registers, the incidence of abnormalities does not seem high (**Tang., 2007**).

A wide range of defects is possible depending on the time of exposure to Misoprostol. Central nervous system and limb defects are the most commonly reported anomalies. Mobius syndrome, which is characterized by congenital facial paralysis with or without limb defects, has been associated with Misoprostol exposure (**Orioli and Castilla., 2000**). Other abnormalities like transverse limb