Vaginal Misoprostol prior to IUCD Insertion in Patients with Previous Cesarean Section, Does it Reduce Difficulty and Pain? (RCT)

Thesis

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List of Abbreviations

Abbr.	Full-term
ACOG	: American College for Obstetricians and Gynecologists
D & C	: Dilatation and curettage
FDA	: Food and Drug Administration
GTP	: Guanosine-5'-triphosphate
IUCD	: Intrauterine contraceptive device
LNG	: Levonorgestrel
MPA	: Metabolite misoprostol acid
NSAIDs	: Non-steroidal anti-inflammatory drugs
PGE	: Prostaglandin
SPSS	: Statistical package for social science

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Abstract

Introduction: The copper intrauterine devices (IUCDs) are safe, cost-effective in the long term and equally effective compared with tubal sterilization. **Aim of the work:** The aim of the work is to evaluate the efficacy of the vaginal misoprostol to decrease pain intensity and facilitate IUCD insertion in women who delivered only by cesarean section. **Patients and Methods:** A double blinded placebo controlled randomized clinical trial. Settings: The study was conducted at Ain Shams University Maternity hospital. Population of the study: 140 women candidate for IUCD insertion were involved in the study. Half of them received 400 microgram of misoprostol (Misotac®) vaginally and the other half received the placebo. **Result:** Using of misoprostol at a dose of 400 microgram administered vaginally 4-hours prior to IUCD insertion in women who delivered by cesarean section had no effect on the easiness of insertion and did not reduce the incidence of pain during the procedure. **Conclusion:** The study concluded that using of misoprostol at a dose of 400 microgram administered vaginally 4-hours prior to IUCD insertion in women who delivered by cesarean section had no effect on the easiness of insertion and did not reduce the incidence of pain during the procedure. **Recommendations:** Upon the results of the study, the following can be recommended: Further studies on a larger scale are needed to explore this issue. No routine use of misoprostol prior to IUCD insertion.

Key words: copper intrauterine devices (IUCDs), misoprostol, sterilization, vaginal

Introduction

The copper intrauterine contraceptive device (IUCD) is a highly effective contraceptive method, also the ideal method for young, nulliparous women ***(Guttmacher Institute Facts on Induced Abortion, 2010).***

The copper intrauterine devices (IUCDs) are safe, cost-effective in the long term and equally effective compared with tubal sterilization ***(Grimes et al., 2007; Grimes and Mishell, 2008).***

In addition, the levonorgestrel (LNG)-releasing IUCDs (Mirena) provides non-contraceptive benefits, such as treatment for menorrhagia, dysmenorrhea and anemia ***(Hurskainen et al., 2004; Milsom, 2007).***

However, a disadvantage in nulliparous women is that the insertion of an IUCD through a narrow cervix may be technically difficult and painful ***(Farmer and Webb, 2003).***

Failed insertion, complications and side effects are significantly more common among women who have no previous vaginal delivery. The fear of painful insertion may make women to hesitate to use an IUCD ***(Sääv et al., 2007).***

Reported complications related to IUCD insertion are: 8.8% insertion failure, 0.2% cervical perforation, 0.2% syncope and 5.8% expulsion ***(Farmer and Webb, 2003).***

Insertion failures and cervical problems seem to occur more often among women who have never delivered vaginally ***(Farmer and Webb, 2003; Li et al., 2005).***

By trans-vaginal ultrasound the cervix of women with a previous elective cesarean section may resemble the cervix of nulliparous women ***(Kwee et al., 2004).***

In an attempt to facilitate IUCD insertion for nulliparous women, use of misoprostol has been promoted by several sources ***(Hatcher et al., 2007; Association of Reproductive Health Professionals, 2008).***

Misoprostol is an inexpensive prostaglandin E1-analogue, which is associated with few side effects ***(Goldberg, 2007; Wing and Gaffney, 2006).***

Misoprostol commercially widely available and used to decrease the ulcerogenic effects of non-steroidal anti-inflammatory drugs (NSAIDs). Misoprostol is available in oral tablets and the dose used therapeutically is 400-800 microgram daily. PG analogues are used for cervical dilatation prior to surgical abortion in order to avoid damage to the cervix and to decrease the bleeding ***(Ngai et al., 1995, 1999; Lawrie et al., 1996).***

Misoprostol has also been shown to be a highly effective method for termination of first and second trimester pregnancy

(WHO 1987; Ngai et al., 2000) as well as for labour induction and post-partum haemorrhage ***(Bugalho et al., 2001; Villar et al., 2002; Hofmeyr et al., 2005).***

The effect of misoprostol is dependent of the route of administration, oral administration of misoprostol is highly effective in terminating early pregnancy if the duration of amenorrhea is less than 50 days. Thereafter, clinical data indicate that oral misoprostol is less effective ***(McKinley et al., 1993).*** However, if misoprostol (tablets for oral use) is administrated vaginally the efficacy is increased and side effects decreased ***(El-Refaey et al., 1995).*** A possible reason for the more pronounced effect of vaginal misoprostol could be a slower uptake and metabolism and a more prolonged elevated plasma concentration compared with the oral route that allows development of uterine contractions ***(Fiala et al., 2007; Fiala et al., 2005).***

Although vaginal misoprostol has been shown to be more effective and with less side effects, oral administration is preferred by many women ***(Ngai et al., 2000).***

A possible alternative is to administer misoprostol sublingually ***(Aronsson et al., 2004),*** at sublingual administration tablets is allowed to melt under the tongue and has usually melted and disappeared after 10-20 minutes ***(Tang et al., 2002; Aronsson et al., 2004),*** in case the tablets by mistake is swallowed too early the effect will be at least that following oral administration.

Pharmacokinetics studies as well as studies on uterine contractility in pregnant women indicate that the sublingual administration of misoprostol results in a more rapid elevation of plasma levels compared with vaginal administration, a longer duration of elevated plasma concentration of the active misoprostol free acid compared with oral administration and development of uterine contractility similar to vaginal treatment ***(Tang et al., 2002; Aronsson et al., 2004).***

Sublingual administration of misoprostol has shown to be more effective also for cervical priming compared with oral administration ***(Aronsson et al., 2004)*** and equally effective as vaginal administration ***(Hamoda et al., 2004; Tang et al., 2004).***

Priming with misoprostol prior to hysteroscopy and dilatation and curettage (D&C) in premenopausal women resulted in an increased cervical dilatation and a lower rate of cervical laceration ***(Crane and Healey, 2006; Preutthipan and Herabutya, 2006).***

Misoprostol has been shown to be effective for cervical priming prior to IUCD insertion would reduce failure rates, complications and pain during insertion in non-pregnant women of fertile age especially in nulliparous with a narrow cervical canal ***(Sääv et al., 2007).***

Aim of the Work

The aim of the work is to evaluate the efficacy of the vaginal misoprostol to decrease pain intensity and facilitate IUCD insertion in women who delivered only by cesarean section.