ORIGINAL RESEARCH PAPER

Obstetrics & Gynaecology

COMPARISON OF VAGINAL MISOPROSTOL VERSUS SUBLINGUAL MISOPROSTOL IN FIRST TRIMESTER MEDICAL TERMINATION OF PREGNANCY

KEY WORDS: Misoprostol, MTP, first trimester sublingual, vaginal

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ABSTRACT

Medical termination of pregnancy for various indications was legalized in India in 1971. The NHM guidelines issued in the MMA handbook in 2016 recommends mifepristone 200mg and misoprostol 800 g for medical termination of pregnancy before 49 days from the last menstrual period. Misoprostol can be administered by oral, buccal, sublingual or vaginal route, with each route having its own advantages and disadvantages. We have conducted this study on 200 women desiring MTP to compare efficacy of vaginal and sublingual routes of administration of misoprostol. Our study concluded that sublingual misoprostol was more effective for early first trimester MTP compared to vaginal misoprostol.

INTRODUCTION

Abortion is defined as spontaneous fetal loss before the age of fetal viability [1]. The rate of abortion is roughly 10–20% among known pregnant women, while rates among all fertilized zygotes are around 30–50% [2]. In the year 1971, MTP was legalized in India [3]. Broadly there are two methods for abortions, medical and surgical, of which the former method is safer. Different protocols are used for pregnancy termination such as: surgical techniques (Dilatation & Evacuation) and medical methods such as Intra-amniotic prostaglandin PGF2 instillation, PGE2 vaginal suppositories, PGE2 and highdose oxytocin.

But all these methods require longer patient hospitalization, exposure to surgical trauma and possibility of anesthetic complications [4,5] Later, an amendment was made to the MTP Act sanctioning the Obstetrician and Gynecologists that they can give a combination of drugs Mifepristone and Misoprostol in a clinical set up after 6 to 7 weeks of pregnancy [6].

The National Health Mission recommends combination of Mifepristone and misoprostol for pregnancy termination up to 7 weeks of gestation from the first day of last menstrual period in a woman with regular cycles. Mifepristone is an antiprogestin, which blocks the progesterone receptors in the endometrium, causing the necrosis of uterine lining and detachment of implanted embryo. It causes cervical softening and an increased production of prostaglandins, causing uterine contractions. A small percentage of women (3%) may expel products of conception (POC) with Mifepristone alone. Misoprostol is a synthetic prostaglandin E1 analogue. It binds to the myometrial cells, causing strong uterine contractions, cervical softening and dilatation. This leads to the expulsion of POC from the uterus. Misoprostol has an advantage over other prostaglandins as it is well absorbed from different routes of administration, is economical, and stable at room temperatures in comparison to PGF2alpha derivatives [7].

Misoprostol can be administered by various routes including sublingual, buccal, vaginal or oral. Each method has its own advantage and disadvantage.

Numerous studies have discussed the different routes and dosing of misoprostol [8]. The systemic bioavailability of vaginal misoprostol has been observed to be three times higher than that of oral misoprostol [9]. Some problems, however, have been identified with vaginal misoprostol tablets, such as inconsistent absorption, incomplete absorption (even several hours after administration), and discomfort during vaginal administration in some women [10]. As the core of the tablet is non-medicated, this does not affect its efficacy. Moistening the tablet before vaginal administration does not improve efficacy (ACOG, 2009) [7].

This study was conducted to compare the efficacy of vaginal misoprostol with sublingual misoprostol in first trimester medical termination of pregnancy.

AIMS AND OBJECTIVES

To compare the efficacy of vaginal misoprostol with sublingual misoprostol in first trimester medical termination of pregnancy before seven weeks period of gestation.

MATERIALS AND METHODS

This study was conducted in the department of obstetrics and gynecology in 2 centres-1. Zonal hospital in Shimla, Himachal Pradesh and KNSHM&C, IGMC from 1st January, 2023 to 30th April, 2023. A total of 200 women who fulfilled the inclusion and exclusion criteria were enrolled in the study. These women were randomly divided into two groups. Both groups received Tab Mifepristone 200 mg on day 1. On day 3, women in group A received 800 g vaginally and women in group B received 800 g misoprostol sublingually. Women in both groups were assessed after two weeks for completion of the MTP process.

Both groups were compared based on completion the process of MTP on day-14. Failure of the method was defined as need for surgical evaluation for retained products on day-14 or severe bleeding.

Inclusion criteria-

1. More than 18 years of age, 2. Pregnancy with period of gestation <49 days (7weeks) from last menstrual period and confirmed by ultrasound, 3. Women who gave informed consent for MTP and study participation

Exclusion criteria-

1. Patients with respiratory tract disease, organic heart disease, diabetes mellitus, renal disease, and patients with pelvic pathology, uterine anomalies and hemorrhagic disorders. 2. Patients with allergy to prostaglandins. 3. Conditions which contraindicate the use of Mifepristone like chronic corticosteroid administration and/or adrenal disease. 4. Conditions which contraindicate the use of Misoprostol like glaucoma, mitral stenosis, sickle cell anemia, poorly controlled seizure disorders. 5. If any attempt of intervention in the present pregnancy was already done. 6. Patients with known clotting defects or who are receiving anticoagulation therapy.

RESULTS

Age of women in both groups ranged from 18-45years with mean age of 34.3yrs in group A and mean age of 33.6 years in

group B. Period of gestation was also comparable for both groups. Mean gestational age was 45 days (6weeks and 3 days) in group A and 43 days in group B (6weeks and 1 day).

87% women in group A had complete abortion on day 14 which was confirmed sonographically as compared to group B in which 93% women had complete abortion. 4 women in group A required surgical evacuation before day-14 due to heavy bleeding. In group B 2 woman required surgical evacuation before day-14. 9 women in group A and 5 women in group B required surgical evacuation for failed medical method of termination of pregnancy.

Table 1: Outcome Of The Study

Outcome	Group A (%)	Group B (%)
Complete abortion	87	93
Surgical evacuation before 14 days	4	2
Surgical evacuation after 14 days	9	5

Based on above table it is evident that sublingual misoprostol is more effective for early first trimester MTP as compared to vaginal misoprostol.

Side effects in both the groups were mild and limited to nausea, altered taste and fever and affected very few women in both groups which were not of much significance.

DISCUSSION

Medical methods of abortion are gaining popularity nowadays as it is simple, effective, comfortable to the patient and carries few complications than the surgical methods [11]. Prostaglandin analogues like Misoprostol are being commonly used [12]. Several studies have investigated the best regimen for medical management of first trimester abortion including dose (either single or repeated), route and timing of follow-up. Vaginal administration of misoprostol is associated with slower absorption, lower peak plasma levels, greater drug exposure and effect on the cervix, and a lower rate of gastrointestinal side effects [13,14]. The main disadvantages of vaginal misoprostol are the possible effects of vaginal pH and vaginal bleeding on drug bioavailability.

Some advantages of sublingual route are shorter interval of time from administration to evacuation, higher patient satisfaction, higher rate of complete abortion, easier method for the patient requiring no speculum and finally it is a completely outpatient option, but because the greater success rate more pain and bleeding was felt by patient. A pharmacological study also showed that sublingual misoprostol gave the shortest time to peak serum concentration and greatest systemic bioavailability [15]. This means that sublingual misoprostol may have the most potent and quickest onset of action compared to the other route of administration.

Our study agrees with previous studies conducted by Tanha et al, Soghra et al and Ahmed A et al who also demonstrated sublingual route of misoprostol as more effective compared to vaginal route [16,17,18].

CONCLUSION

Based on our study we can say that misoprostol is a safe, convenient, easily available and cheap method of termination of pregnancy which can be given by oral, buccal, sublingual or vaginal methods. Sublingual and vaginal methods are the preferred routes of administration and of these two routes our study shows that sublingual route is more effective than vaginal route.

Further studies are required to assess efficacy of different routes of misoprostol administration in missed abortion, incomplete abortion and second trimester abortion.

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