

Comparison Between Sublingual and Vaginal Route of Misoprostol in the Management of 1st Trimester Abortions

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Abstract:

Introduction:

The termination of pregnancy before the period of viability is termed as abortion. Statistical estimates have shown that worldwide approximately 40-60 million abortions occur per year. In the year 1971, MTP was legalised in India. Now a days doctors are preferring oral Mifepristone with Misoprostol administered vaginally. Misoprostol is a PGE1 analogue. The advantages of oral route of administration are its ease of administration and lesser chances of infection. The aim of the study is to evaluate the efficacy and side effects of oral and vaginal Misoprostol in first trimester abortions.

Methodology:

The study was a prospective, open labeled, randomised trial, carried out in Kamineni Institute of Medical Sciences, Narketpally from January 2018 to July 2018. 40 patients with pregnancy up to 49 days were selected and were divided into two groups of 20 people each. The first group was given 200mg Mifepristone and 800 mcg of Misoprostol by sublingual route. The second group was given 200 mg of Mifepristone orally and 800mcg of Misoprostol by vaginal route. The efficacy, the induction interval, adverse effects, and the patient's acceptability for route of administration were the measured outcomes in this study.

Results:

Success rate of abortion was 94% in sublingual group and 86% in vaginal group.

Conclusion:

Oral and vaginal routes of misoprostol were found to have similar effectiveness for first trimester abortions. Due to its high acceptability and more comfort to the patients, oral Misoprostol can be used as an alternative route to vaginal route of administration.

Introduction:

The termination of pregnancy before the period of viability is termed as abortion. Statistical estimates have shown that worldwide approximately 40-60 million

abortions occur each year. In the year 1971, MTP was legalised in India¹. Broadly there are two methods for abortions, medical and surgical, of which the former method is safer. Different types of

protocols are in use for pregnancy termination such as: surgical techniques (Dilatation & Evacuation) and Medical methods such as Intra-amniotic prostaglandin PGF2 α instillation, PGE2 vaginal suppositories, PGE2 and high-dose oxytocin. But all these methods require longer patient hospitalization, exposure to surgical trauma and possibility of anaesthetic complications.^{2,3} Later, an amendment was made to the MTP Act sanctioning the Obstetrician-Gynecologists that they can give a combination of drugs Mifepristone and Misoprostol in a clinical set up after 6 to 7 weeks of pregnancy. Now-a-days doctors are preferring oral Mifepristone with Misoprostol administered vaginally.⁴ Misoprostol is a PGE1 analogue. It was originally used to treat peptic ulcers, but was found to have uterotonic effect and hence was used for pregnancy termination with great success. It is available as 100 μ g and 200 μ g tablets. Various routes of administration include oral, vaginal and rectal. The advantages of this drug is it is cost effective, and has fewer side effects.^{5,6} The advantages of oral route of administration are its ease of administration and lesser chances of infection.

This study was done to evaluate the efficacy and side effects of oral and vaginal Misoprostol in first trimester abortions, to determine whether oral route can be an alternative to vaginal administration.

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Aim and Objective:

To evaluate the efficacy and side effects of oral and vaginal Misoprostol in first trimester abortions.

Materials & Methods:

Our study included a total of 40 women in first trimester. Patients were divided into 2 groups of 20 and were given Misoprostol by oral and vaginal route. Outcomes and side effects were observed. This is a prospective randomised trial carried out in Kamineni Institute of Medical Sciences, Narketpally. The study was carried out from January 2018 to July 2018. Our study included selected 40 women with first trimester abortions. After explaining the patients about the study, a written informed consent was obtained from the patients. A detailed history about duration of amenorrhea, parity, any previous spontaneous or induced abortions and medical diseases was recorded. General and systemic examination was carried out. Vaginal examination was done for all the women in order to evaluate the duration of pregnancy and also to rule out the presence of any pelvic pathology. The gestational age was determined by menstrual history and vaginal examination. Ultrasonography and other routine investigations such as hemogram, bleeding time (BT), clotting time (CT), blood sugars, urine examination, and HIV were carried out in all the included patients. 40 patients with pregnancy up to 49 days were selected and were divided into two groups of 20 each.

Group 1 was given 200 mg Mifepristone orally and Misoprostol administration by oral route (Four tablets 200 mcg each) after 48 hours.

Group 2 was given 200 mg Mifepristone orally and Misoprostol administration by vaginal route (Four tablets 200 mcg each) after 48 hours.

Vaginal Sonography was carried out after 24 hours of expulsion to observe for any retained products of conception. Patients were asked to come again after 2 weeks and were also told to return if they had any complaints. The patients were kept under observation and the outcome was considered successful if a complete abortion without surgical intervention was achieved. After confirming that there were no retained products of conception, patients were discharged. The obtained data was analysed using the Statistical Package for Social Science (version 10.0 for Windows, SPSS). The observations were reported as mean and standard deviation. Success rate and side effects were analyzed by their percentage and compared by Chi square test.

Inclusion Criteria:

1. Patients of age 18 years and above
2. Patients having an intrauterine pregnancy of less than or equal to 49 days and also documented by ultrasonography
3. Patients who had given consent and were willing for required follow up and surgical management if necessary.

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 anaemia, 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.

Parameters:

The outcomes measured were:

- A. The efficacy, as judged by complete abortion
- B. The induction interval (duration between initial Misoprostol dose and till expulsion of products of conception)
- C. Drug-related adverse effects
- D. Patient's acceptability for route of administration.

Results:

Success rate of abortion was 94% in oral group and 86% in vaginal group. The effectiveness of the route of administration was assessed by complete abortion and was found to be 95% in oral group and 90% in vaginal group. One patient in oral group and two in vaginal group had retained products of conception after 48 hours, and were given oral Misoprostol 200 mcg BD for 3 days.

Discussion:

Medical methods of abortion is gaining popularity nowadays as it is simple, effective, comfortable to the patient and carries few complications than the surgical methods.⁷ Prostaglandin analogues like Misoprostol are being commonly used.⁸ In our study, we randomly assigned 40 women, 20 each into 2 groups. Each group was given Misoprostol by either oral or vaginal route. Retrospective studies about the safety of medical abortion showed a reduction in the serious infection rates and suggested that oral route has about similar efficacy and can substitute the vaginal route of administration.^{8,9} We also found similar results and the difference between both routes was not statistically significant. Our results are in agreement with Middleton et al and Fjerstad et al.¹⁰

Few other studies have shown results in contrast to ours, vaginal route of Misoprostol administration being more effective than other routes. Among the adverse effects of drugs, nausea was the most frequently reported one and was more in oral route and the difference was statistically significant. Altered taste sensation was more in oral route and the difference was also statistically significant. Our results are in agreement with Middleton et al. The oral route of administration has high satisfaction rate and patients were very comfortable. Hence we suggest that oral route can be used as an alternative for women who feel uncomfortable with vaginal insertion of Misoprostol.

Conclusion:

Oral and vaginal routes of misoprostol were found to have similar effectiveness for first trimester abortions. Due to its high acceptability and more comfort to the patients, oral Misoprostol can be used as an alternative route to vaginal route of administration.

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