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Comparative study of Oral and Vaginal Misoprostol in the Induction of First and Second Trimester induced abortions

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ABSTRACT

Background: Misoprostol is a PGE1 analogue is used to terminate pregnancies with great success. It is administered by various routes, oral, vaginal and rectal. **Aims and Objectives:** To evaluate the efficacy and side effects of oral and vaginal misoprostol in first and second trimester induced abortions. **Materials and Methods:** Our study included a total of 80 women, 40 each in first and second trimester. Patients in each trimester were divided into two groups of 20 and were given misoprostol by oral and vaginal route. Outcomes like complete abortion and side effects were observed. The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc.). **Results:** Success rate of abortion In first trimester was 94 % and 86 % in oral and vaginal group respectively. In second trimester, the success rate was 94 % and 82 % in oral and vaginal group respectively. **Conclusion:** Oral and vaginal routes of misoprostol administration have similar efficacy and patient satisfaction level for first and second trimester induced abortions. Hence, oral route may serve as an alternative to vaginal misoprostol.

Key Words: Abortion, Misoprostol, Oral, Vaginal.

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 (about 26 million legally and 20 million illegally)[1-3]. In 1971, MTP was legalized in India[4].

Broadly there are 2 methods for abortions, medical and surgical, of which the former method is safer.

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Different types of protocols are in use for pregnancy termination, like surgical techniques (D and E) and medical methods like intra-amniotic prostaglandin (PG) F2 α instillation, PGE2 vaginal suppositories, PGE2 and high-dose oxytocin. But all these methods require patients to be hospitalized hospitalization, exposure to surgical trauma and possibility of anaesthetic complications [5,6].Later In the years 2002 and 2003, an amendment was made to the MTP Act sanctioning the obstetrician-gynecologists that they can give a combination of drugs mifepristone and misoprost in a clinical set up after 6 to 7 weeks of pregnancy. Now a days doctors are preferring oral mifepristone with misoprostol administered vaginally [7].Misoprostol is a PGE1 analogue, with a chemical formulae, C22H38O5 or (±) -methyl (13E)-11, 16dihydroxy-16 methyl-9-oxo-prost-13-eonate. 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 and 200 µg tablets. Various routes of

adminstration include oral, vaginal and rectal. The advantages of this drug is it is cost effective, and has few side effects [8,9]. Even though vaginal route of administration was proved to be effective, the fact that it requires repeated vaginal examinations, causing inconvenience to the patient makes it unacceptable. The advantages of oral route of administration are its ease of administration and lesser chances of infection.[10] We carried out our study to evaluate the efficacy and side effects of oral and vaginal misoprostol in first and second trimester induced abortions, so that to determine whether oral route can be an alternative to vaginal administration.

Materials and Methods

This is a prospective randomized trial carried out in the department of Obstetrics and Gynecology. The study was carried out from January 2015 to December 2015. Our study included 80 women were selected for first and second trimester induced abortions. Patients were divided into two groups and each patient was assorted to one of the groups by random number tables.

The patients reported to the department for termination of pregnancy were screened for inclusion in the study. After explaining the patients about the study and obtaining approval from the Institutional ethics committee, a written informed consent was obtained from the patients. A detailed history about duration of amenorrhea, gravidity, parity, any previous spontaneous or induced abortions and medical diseases was recorded. Then 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. Sonography was done if required. Routine investigations such as hemogram, BT, CT, blood sugar, urine examination, VDRL, sickling test, serum creatinine and HIV were carried out in all the included patients.

Inclusion Criteria

1. Patients of age 18 years and above
2. Patients who came with request of an elective termination of pregnancy well within the MTP Act.
3. Patients having an intrauterine pregnancy of less than or equal to 49 days for first trimester abortion and 14–20 weeks according to LMP for second trimester abortion, and also documented by ultrasonography.
4. Patients who are ready to undergo required follow up and surgical management if required.

Exclusion criteria

1. Patients with respiratory tract disease, organic heart disease, diabetes mellitus, renal disease, Patients with pelvic pathology, uterine anomalies and hemorrhagic disorders,
2. Patients with allergy to prostaglandins,
3. Conditions which contraindicates the use of mifepristone like chronic corticosteroid administration and or adrenal disease,
4. Conditions which contraindicates 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 done,
6. Patients with Hemoglobin less than 10 g/dl and those with known clotting defects or who are receiving anticoagulation therapy

First Trimester Abortions

40 patients with pregnancy up to 49 days were selected and were divided into two groups of 20 each).

1. **Group 1:** 200 mg mifepristone orally and misoprostol administration by oral route (Four tablets 200 mcg each) after 48 hours.
2. **Group 2:** 200 mg mifepristone orally and and misoprostol administration by vaginal route (Four tablets 200 mcg each) after 48 hours.

Patients were followed up on 2nd, 14th day and after 6 weeks and were also told to return if they had any complaints. On 14th day, vaginal sonography was carried out to observe for any retained products of conception, if any termination was done by surgical method. Drug-related adverse effects and patient satisfaction were also recorded.

Second trimester abortions

40 women with 14–20 weeks pregnancy were divided into two groups:

1. **Group 1:** 200 mg mifepristone orally and admitted after 48 hours. A first dose of 400 mcg of oral misoprostol followed by 200 mcg of oral misoprostol every 6 hourly until fetal expulsion or maximum 6 doses.
2. **Group 2:** 200 mg mifepristone orally and admitted after 48 hours. 400 mcg intravaginal misoprostol every 6 hourly until fetal expulsion or maximum 6 doses. Then oxytocin, 20 U in 500 mL of lactated Ringer solution at 125 mL/hour, was given to all patients until

delivery of the placenta. Patients were followed up on 14th and 42th day or in between for any complaints.

Parameters

The outcomes measured were

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

The patients were kept under observation and the outcome was considered as successful if a complete abortion without surgical intervention was achieved. Then the patients were discharged and followed up regularly. They were given a questionnaire with inquiries regarding satisfaction level and effects. The obtained data was analyzed 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.

Results

In the first trimester, the effectiveness 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 2 weeks and were given misoprostol 400 mcg and had complete abortion at 1 week follow up. In the second trimester, the effectiveness was found to be 95 % in oral group and 85 % in vaginal group. One patient in oral group and three in vaginal group had retained products of conception, and after explaining them and obtaining consent, surgical intervention was carried out in order to obtain complete abortion.

The demographic findings were comparable in both trimesters and both the groups (Table 1).

Table 1: Demographic Parameters

		First Trimester		Second Trimester	
		Oral	Vaginal	Oral	Vaginal
Mean Age (Years)		27.14±4.32	29.01±4.04	24.52±5.01	23.21±4.02
Socio-economic status	**Lower**	0	1	2	5
	Middle	8	6	12	10
	Upper	12	13	6	5
Background	**Urban**	18	17	8	7
	Rural	2	3	12	13
Mean period of gestation (weeks)		6.02±0.51	5.72±0.54	17.26±2.05	17.34±2.01

The various reasons for which the abortion has to be carried out are listed in Table 2

Table 2: Reasons of abortion

Group	Reasons	Route of Administration		P Value
		Oral	Vaginal	
First Trimester	Failure of contraception	20 (100 %)	20 (100 %)	0.171
Second Trimester	Congenital malformation	17 (85%)	14 (70%)	
	Limiting number of Children	3 (15%)	2 (10%)	
	Premature rupture of membranes with no liquor	0	3 (15 %)	
	Failure of contraception	0	1 (5%)	

Various side effects were noticed after taking the drugs by both the routes (Table 3)

Table 3: Drug-related adverse effects

Group	Route	Altered Taste N(%)	Nausea N(%)	Vomiting N (%)	Diarrhea N (%)	Fever N (%)
First Trimester	Oral	3 (15 %)	5 (25 %)	0	0	0
	Vaginal	0	4 (20 %)	0	0	1 (5 %)
	P Value	0.037*	0.528	-	-	0.312
Second Trimester	Oral	3 (15 %)	6 (30 %)	6 (30 %)	1 (5 %)	0
	Vaginal	0	1 (5 %)	2 (10 %)	0	1 (5 %)
	P Value	0.037*	0.010*	0.081	0.312	0.312

*=Statistically Significant

The data obtained regarding patient satisfaction and comfort were obtained from the filled questionnaires (Table 4 and 5, Graph 1)

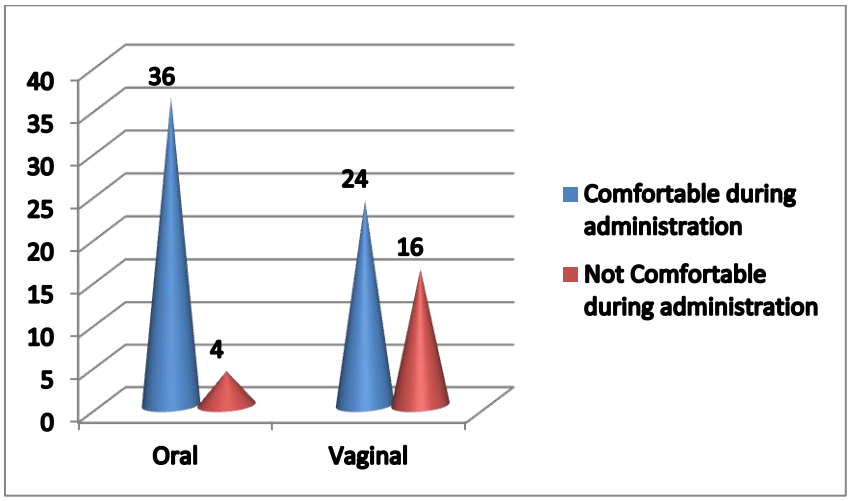
Table 4: Patient satisfaction levels

Group	Satisfaction level	Route		P Value
		Oral N (%)	Vaginal N (%)	
First Trimester	Satisfied	20 (100 %)	17 (85 %)	0.146
	Unsatisfied	0	3 (15 %)	
Second Trimester	Satisfied	19 (95 %)	18 (90 %)	0.294
	Unsatisfied	1 (5 %)	2 (10 %)	

Table 5: Subjective assessments of patients comfort to the route of administration

Characteristic	Oral	Vaginal
Comfortable during administration	36 (90%)	24 (60%)
Not Comfortable during administration	4 (10%)	16 (40%)

Graph 1: Subjective assessments of patients comfort to the route of administration



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. Prostaglandin analogs like misoprostol are being commonly used [1,3].

In our study, we randomly assigned 80 women, 40 each of first and second trimester 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 [11]. 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[6,12].Few other studies have shown results in contrast to ours, vaginal route of misoprostol administration being more effective than other routes[13,14].

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[6]. 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.

We could not find any statistically significant difference in induction time between the groups. Our findings are in accordance with Ellis et al [15].

Conclusion

Oral and vaginal routes of misoprostol was found to have similar effectiveness for first and second trimester induced 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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