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Original Research Article

Comparative study of efficiency of vaginal versus oral misoprostol along with mifepristone for first trimester medical termination of pregnancy

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ABSTRACT

Background: Authors estimate that 15.6 million abortions (14.1 million-17.3 million) occurred in India in 2015. Incomplete abortion is a known disadvantage of medical method of abortion reported in 0.2-3% of cases. Though Misoprostol can be used with different routes including oral, sublingual and vaginal, few evidences are available in drug effectiveness as well as its related side effects when used through different routes and more so in India. The present study is aimed to compare the efficacy of misoprostol in first trimester abortion when taken vaginally as compared to orally. Thus, whichever route results in lower rates of incomplete abortions, can be employed in our health set up, minimizing the complications of failed first trimester MTP.

Methods: An experimental study was conducted on 74 women seeking termination of pregnancy within 9 weeks of amenorrhea during the period of 9 months in a tertiary care institute. Tablet mifepristone 200 mg was given to all participants. After 48 hours, 37 women were given 800 mcg tablet of Misoprostol for oral consumption while other 37 women were given 800 mcg Misoprostol for self-administering vaginally. Abortion status and complications were checked.

Results: The complete abortion rates in vaginal group and oral group were 97.3% and 86.49 % respectively. Satisfaction was more in case of vaginal misoprostol, while side effects were similar in both groups.

Conclusions: Mifepristone with vaginal misoprostol was more effective as compared to oral misoprostol for first trimester abortion.

Keywords: Medical abortion, Mifepristone, Misoprostol, Oral, Vaginal

INTRODUCTION

Medical abortion is defined as voluntary termination of unwanted pregnancy before 20 weeks of pregnancy (before viability). An "abortus" is a foetus or embryo removed or expelled from the uterus during the first half of gestation - 20 weeks or less, or in the absence of accurate dating criteria, born weighing <500 g.¹

Abortion was made legal in India by the Medical Termination of Pregnancy (MTP) Act, which was enacted by Indian Parliament in the year 1971. The Act permits abortion, if the continuance of the pregnancy would

involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health or there is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.²

Since then the act has been amended in the years 1975 and 2002. The ultimate aims of these amendments are: to eliminate abortions by untrained persons and in unsafe and unhygienic conditions, so as to reduce the maternal mortality and morbidity as well as female foeticide.^{3,4} It is estimated that 46 million pregnancies are terminated voluntarily each year, 27 million carried under safe

condition and 19 million falling into the category of 'unsafe' abortion. As per recent data, abortion rate in India is 47 per 1000 women aged 15-49 years. Unsafe abortion (2002) remains one of the leading causes of maternal death in most of developing countries.⁵

Unsafe abortions account to 13% of the maternal deaths worldwide of which 19% occurs in South East Asia.⁶

Infection rate associated with Misoprostol was significantly lower than that with alternative traditional methods. If given in sufficient frequency, alone can abort a high proportion of pregnancies. Provision of safe abortion to the full extent of the law is an important component of reproductive health services. Ideally, any method of medical abortion should have an overall efficacy comparable to that of surgical method, i.e. a rate of complete abortion of more than 95% and an ongoing pregnancy rate of less than 1%.⁷

Progesterone is fundamentally important for sustaining a pregnancy in first trimester. Withdrawal of progesterone support results in expulsion of embryo by a prostaglandin mediated mechanism. Medical abortion using mifepristone and misoprostol are safe, highly effective and well accepted by women who wish to avoid invasive procedure. Millions of women worldwide have safely terminated their pregnancies with medication i.e. mifepristone or RU 4868. Present study was carried out to know efficiency of oral versus vaginal misoprostol along with mifepristone for first trimester abortion.

METHODS

It was an experimental study which was conducted in an Obstetric department of a tertiary care center in a Gandhinagar city of Gujarat state, India from March 2017 to December 2017.

Women with Intrauterine pregnancy up to 9 weeks which were confirmed by transvaginal sonography and who were willing to participate in the study were enrolled. Women with confirmed ectopic pregnancy, adnexal mass, hemoglobin <8 gm%, bleeding disorders, any systemic disease which might affect drug metabolism, Allergy to mifepristone or misoprostol or other prostaglandins and with chronic adrenal failure or systemic steroid therapy were excluded from the study.

A total of 74 participants (37 in each group) were enrolled through following method. After checking the eligibility of the participants through transvaginal sonography, randomizations were done. It was done by tossing the coin. Coin tossing was done for odd number of the participants. If head came, participant was allocated to group A (who were given mifepristone with oral misoprostol) and if tail came then participant was allocated to group B (who were given mifepristone with vaginal Misoprostol). The even numbers of the participant were enrolled in the opposite group of the

previous one. This process was done until there were 37 participants in both groups.

After getting ethical approval from the institutional ethical committee, the study was started. Participant's eligibility was confirmed through gestational age by transvaginal sonography. Participants were provided Information sheet in the vernacular language and those who agree to participate in the study were enrolled after signing the Informed consent form. After doing randomization, following procedure was done. Participants from the both groups were asked thorough history and full clinical, as well as obstetric examination, was done. Hemoglobin, blood group, and TVS were performed in all participants in both groups. On day 1, tablet mifepristone (200 mg) was given orally and injection Anti D (50 mcg) was given to Rh negative woman in both groups. On day 3 (After 48 hours), tablet misoprostol 800mcg orally after food were given to Group A while tablet misoprostol 800mcg were given to Group B participants for self-administering it intravaginally. All Patients were asked to note the time of time of abortion and side effects. On day 7, all Patients from both groups were called for follow up. On that day clinical examination, as well as transvaginal ultrasound, was done. Patients were asked for any side effects. Patient's demography, their convenience, and satisfaction were also noted.

Success rate of abortion was defined as complete expulsion of products of conception. Failure was defined as partial or no expulsion of products of conception. Failure cases were treated with suction evacuation. Side effects like nausea, vomiting, abdominal pain requiring analgesics, fever, diarrhea, shivering, and headache were asked on the follow-up of the participants. Patient satisfaction and convenience were also asked.

Statistical analysis

Data were entered and analyzed through Epi Info 7. Continuous variables were presented as mean with standard deviation and categorical variables were expressed with percentages. Chi-square/fisher test and t-test were applied accordingly. A p-value less than 0.05 were considered as statistically significant.

RESULTS

Table 1 shows socio-demographic details of the both groups undergoing the study. Age, education, socioeconomic class and gestational weeks at the time of abortion were matched before the starting of the study.

As shown in Table 2, complete abortion was seen among 86.49% of the women who were given mifepristone with oral misoprostol while complete abortion was seen among 97.3% of participants who were given mifepristone with vaginal misoprostol.

Table 1: Socio-demographic characteristics of study participants (n=74).

	Group A mifepristone with oral misoprostol (n=37)	Group B mifepristone with vaginal misoprostol (n=37)	p-value
Age	29.11 ± 5.52	28.11 ± 4.81	0.481
Education			
Illiterate	02 (05.41%)	01(02.70%)	
Primary	09 (24.32%)	05 (13.51%)	
Secondary	07 (18.92%)	06 (16.22%)	
Higher secondary	16 (43.24%)	19 (51.35%)	
Graduate and above	03 (08.11%)	06 (16.22%)	
Socioeconomic class			
Lower class	05 (13.51%)	03 (08.11%)	0.711
Middle class	32 (86.49%)	34 (91.89%)	
Gestational week			
4 weeks	04 (10.82%)	07 (18.92%)	
5 weeks	22 (59.46%)	06 (16.21%)	
6 weeks	05 (13.51%)	21 (56.76%)	
7 weeks	05 (13.51%)	03 (08.11%)	
8 weeks	01 (02.70%)	00 (00.00%)	

Table 2: Status of abortion after treatment (n=74).

	Group A mifepristone with oral misoprostol (n=37)	Group B mifepristone with vaginal misoprostol (n=37)	p-value
Complete	32 (86.49%)	36 (97.30%)	0.199
Incomplete	05 (13.51%)	01 (02.70%)	

Table 3: Side effects after and during the MTP procedure (n=74).

	Group A mifepristone with oral misoprostol (n=37)	Group B mifepristone with vaginal misoprostol (n=37)	p-value
Nausea	20 (54.05%)	21 (56.76%)	
Vomiting	09 (24.32%)	15 (40.54%)	0.214
Abdominal pain	19 (51.35%)	23 (62.16%)	0.482
Fever	04 (10.81%)	01 (02.70%)	0.358
Headache	05 (13.51%)	10 (27.02%)	0.247
Diarrhea	06 (16.22%)	09 (24.32%)	0.564
Shivering	02 (05.40%)	01 (02.70%)	1.000

Table 4: Attitude towards MTP procedures (n=74).

	Group A mifepristone with oral misoprostol (n=37)	Group B mifepristone with vaginal misoprostol (n=37)	p-value
Convenient treatment	29 (78.38%)	31 (83.78%)	0.786
Satisfied with the treatment	32 (86.49%)	36 (97.30%)	0.199
Repeat procedure in future if needed	31 (83.78%)	33 (89.19%)	0.736

Table 3 shows side effects among both groups. Nausea and abdominal pain are two common side effects observed in the both groups but neither of them are statistically significant. Other side effects are vomiting, headache, fever, diarrhea and shivering. Table 4 shows general attitude of the patients. Around 78% women believe that oral misoprostol is convenient while 83.78% of women believed that vaginal misoprostol along with

mifepristone is convenient. Around 86.49% women were satisfied with oral misoprostol while 97% of the women were satisfied with vaginal misoprostol.

DISCUSSION

The present study was conducted to compare two regimens vaginal misoprostol + mifepristone with oral

misoprostol + mifepristone in the women going in first trimester. In a study by Jyothi S et al in Manipal, rate of complete abortion was 96.7% and 86.2% among women who had been given vaginal and oral misoprostol respectively along with mifepristone.⁹ In an another study, El Refaey et al, found that 95% aborted with the vaginally administered misoprostol and 87% aborted with oral misoprostol, which are also similar to our results.¹⁰ But the study done in Mumbai by Sahu RR et al founded that the complete abortion rate with mifepristone followed by oral misoprostol was 91.4%, which was comparable to that with mifepristone followed by vaginal

and sublingual misoprostol (90%).¹¹ This study showed oral misoprostol is slightly better than vaginal misoprostol. Nausea, vomiting, abdominal pain are the common side effects in our study. Nausea was present in 54.05% of the women who were given oral misoprostol with mifepristone while it was present in 56.76% of the women who were given vaginal misoprostol. El Refaey et al, reported that the incidence of gastrointestinal side effects was higher when misoprostol was given orally than when it was administered vaginally.¹⁰ Similar, results were found with Jyothi S et al.⁹

Table 5: Comparison of rates of complete abortion between oral misoprostol versus vaginal misoprostol regimes in various studies.

Sr. no.	Author	Mifepristone with oral misoprostol (rate of complete abortion)	Mifepristone with vaginal Misoprostol (rate of complete abortion)
1	El Refaey et al ¹⁰	87%	95%
2	Jyothi S et al ⁹	86.2%	96.7%
3	Sahu RR et al ¹¹	91.4%	90%
4	Present study	86.49%	97.3%

Satisfaction among women was more in case of vaginal misoprostol (97.3%) because it causes complete abortion comparatively more than oral misoprostol and 89.19% of the women agreed to repeat the same procedure with mifepristone and vaginal misoprostol if they wanted to undergo abortion in the future.

CONCLUSION

Present study concluded that mifepristone followed by vaginal misoprostol is more effective in inducing abortion in first trimester than oral misoprostol. Small sample size is the limitation of the study but this study can act as a good base for the further research.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Bhaskar A, Kaushik R, Kumar A. A prospective comparative study of oral and vaginal misoprostol after pre-treatment with single dose of mifepristone for second trimester abortion. *Int J Reprod Contracept Obstet Gynecol.* 2017;7(1):272-6.
- Government of India, The Medical Termination of Pregnancy Act, No. 34; 1971.
- Government of India, Medical Termination of Pregnancy Rules and Regulations, Vide GSR 2543; 1975.
- Government of India. The Medical Termination of Pregnancy Act, 1971 (Act No. 34 of 1971), and MTP Rules and Regulations, 2003 (GSR No. 485(E)). New Delhi: Gazette of India; 2003.
- World health organization. Unsafe abortion global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000. 4th edition WHO; 2004.
- Singh S, Shekhar C, Acharya R, Moore AM, Stillman M, Pradhan MR, et al. The incidence of abortion and unintended pregnancy in India, 2015. *The Lancet Global Health.* 2018;6(1):e111-20.
- Patel U, Chauhan K, Singhi S, Kanani M. Second trimester abortion-mifepristone and misoprostol or misoprostol alone? *Int J Reprod Contracept Obstet Gynecol.* 2016;2(3):315-9.
- Patel BS. Early pregnancy termination with oral mifepristone and vaginal misoprostol. *Paripex-Indian J Res.* 2018;6(8).
- Shetty J MNV. Medical abortion by mifepristone with oral versus vaginal misoprostol. *J Obstet Gynecol India.* 2006;56(6):529-31.
- El-Rafaey H, Rajasekar D, Abdalla M. Induction of abortion with mifepristone (RU 486) and oral or vaginal misoprostol. *N Engl J Med.* 1995;332:983-7.
- Sahu RR, Soni AA, Raut VS. Randomized control study of oral versus vaginal and sublingual misoprostol with mifepristone for first-trimester MTP. *Indian J Clin Pract.* 2013;24(7):668-73.

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