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Safety and efficacy of vaginal misoprostol alone for first trimester termination of pregnancy

Running title: Vaginal misoprostol

[1]Dr.Gauri shinde, [2]Dr.Manisha Ladded, [3]Dr. Vaishnavi shivade, [4]Dr.Dhruva Patil
[1]Assistant professor, [2]Associate professor, [3]3yr Resident, [4]2 nd yr Resident
Department of obstetrics & gynaecology, Krishna Institute of Medical Sciences, Karad, Maharashtra, India

ABSTRACT

Background: *Termination of pregnancy is one of the most common procedures in gynaecological practice. The present study was conducted to assess safety and efficacy of vaginal misoprostol alone for first trimester termination of pregnancy.*

Materials & Methods: *The present study was conducted on 72 pregnant women. Patients were randomized into two groups. Group I patients received misoprostol with 3 drops of water per tablet and group II patients received misoprostol only. Patients were examined and the bleeding patterns were checked on day 43.*

Results: *There were failure of 3 cases in group I and 1 in group II, live pregnancy was 1 in group I and 0 in group II, complete abortion was 33 in group I and 35 in group II. The difference was non- significant (P> 0.05). Side effects in group I was nausea in 32 and I group II in 28, diarrhea 10 in group I and 11 in group II, dizziness 15 in group I and 17 in group II, fainting 4 in group I and 2 in group II, pain 27 in group I and 22 in group II, dizziness 30 in group I and 31 in group II, breast tenderness 14 in group I and 10 in group II and fatigue 12 in group I and 8 in group II. The difference was non- significant (P> 0.05).*

Conclusion: *Authors found that vaginal misoprostol is safe and efficacious in first trimester termination of pregnancy. Addition of water does not provide additional advantage.*

Key words: *Abortion, Misoprostol, Pregnancy*

Introduction

Termination of pregnancy is one of the most common procedures in gynaecological practice. Vacuum aspiration has been used for first trimester termination of pregnancy. With the introduction of a cervical priming agent, the complications were significantly reduced.[1] Although complications are uncommon, vacuum aspiration has been shown to be associated with uterine perforation, cervical injuries and excessive hemorrhage. The overall complication rate varies between 4 and 10%. In the absence of complications, there is little evidence to suggest that surgical abortion has an adverse effect on future fertility.

However, mifepristone is costly and is unavailable in many settings. In the United States, although the drug is approved for marketing, the Food and Drug Administration has imposed restrictions on its distribution that substantially limit both patients' and providers' access to it. For women who cannot obtain mifepristone, use of misoprostol alone, which is inexpensive and is widely used for various obstetric and gastrointestinal indications, can serve as an important alternative option.[2]

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Misoprostol is a synthetic prostaglandin E1 analogue that was initially used for the treatment of gastric ulcer. We have shown that it is a safe and effective cervical priming agent prior to vacuum aspirations in first trimester abortion. It is also an effective abortifacient when given in repeated doses in second trimester abortion. The results of misoprostol alone in first trimester medical abortion were disappointing.[3] Misoprostol administration in pregnancy induces cervical softening and dilation and uterine contractions at all gestational ages, thereby facilitating uterine evacuation. The potency of misoprostol's effect, however, varies with gestational age, as well as with route of administration, dose, dosing interval, and cumulative dose.[4] The present study was conducted to assess safety and efficacy of vaginal misoprostol alone for first trimester termination of pregnancy.

Materials & Methods

The present study was conducted in the department of Gynecology. It comprised of 72 pregnant women. Patients with ≤9 weeks of gestation were included. Patients with history or evidence of disorders that represent a contraindication to the use of misoprostol (mitral stenosis, glaucoma, sickle cell anemia, diastolic pressure >100 mm Hg, bronchial asthma were excluded. All patients were informed regarding the study and written consent was obtained. Ethical approval was obtained from institutional ethical committee prior to the study.

General information such as name, age, etc. was recorded. Patients were randomized into two groups. Group I patients received misoprostol with 3 drops of water per tablet and group II patients received misoprostol only. On day 1, women in group I received vaginal misoprostol 800 μg with 3 drops of water added onto each tablet; women in group II received vaginal misoprostol 800 μg without water. They stayed in the day ward for a 4 h clinical observation period (hourly recordings of blood pressure and pulse rate). On days 3 and 5, vaginal misoprostol was inserted and the observations were repeated. They were followed up again on days 15 and 43. Transvaginal ultrasound scan was performed in all women on day 15. Patients were examined and the bleeding patterns were checked on day 43. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

Results

Table I Distribution of patients

Groups	**Group I (Misoprostol and water)**	**Group II (Misoprostol alone)**
Number	36	36

Table I shows that group I patients received misoprostol with 3 drops of water per tablet and group II patients received misoprostol only.

Table II Outcome of abortion in both groups

Parameters	**Group I**	**Group II**	P value
Completer abortion	33	35	0.92
Gestation <7 weeks	25/26	26/26	0.85
7-9 weeks	8/10	9/10	0.97
Live pregnancy	1	0	0.07
Missed abortion	2	1	0.06
Overall failure	3	1	0.08

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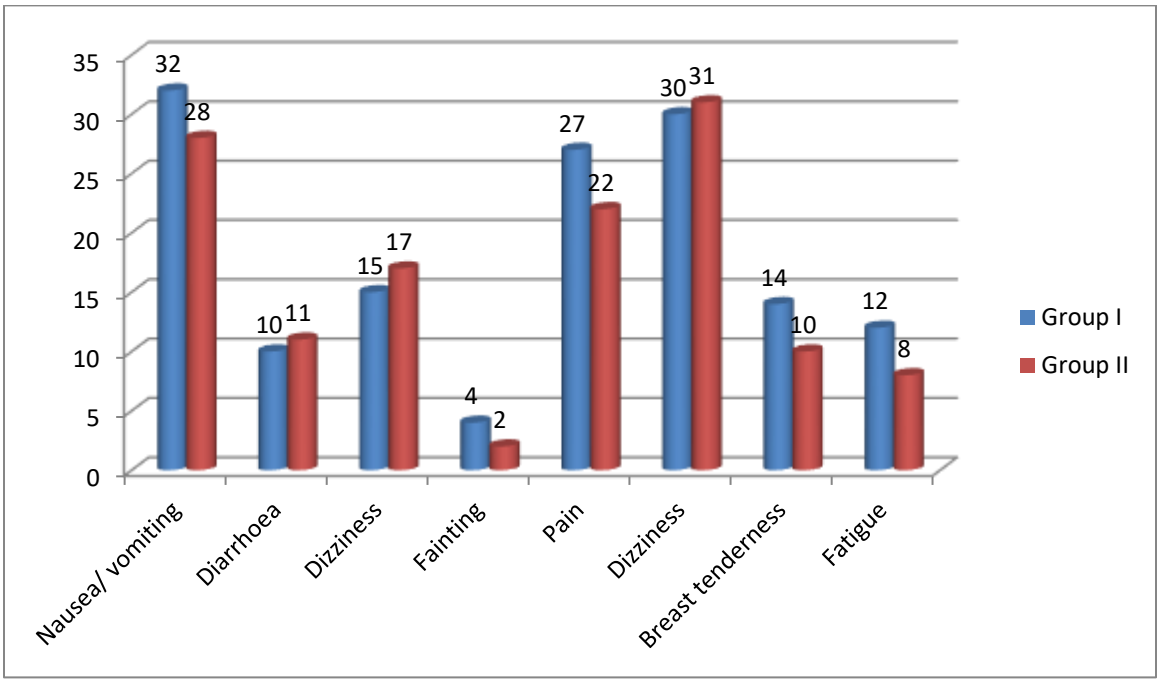
Table II shows that there were failure of 3 cases in group I and 1 in group II, live pregnancy was 1 in group I and 0 in group II, complete abortion was 33 in group I and 35 in group II. The difference was non- significant (P> 0.05).

Table III Side-effects during treatment

Parameters	**Group I**	**Group II**	P value
Nausea/ vomiting	32	28	0.14
Diarrhoea	10	11	0.98
Dizziness	15	17	0.81
Fainting	4	2	0.05
Pain	27	22	0.15
Dizziness	30	31	0.91
Breast tenderness	14	10	0.15
Fatigue	12	8	0.12

Table III, graph I shows that side effects in group I was nausea in 32 and I group II in 28, diarrhea 10 in group I and 11 in group II, dizziness 15 in group I and 17 in group II, fainting 4 in group I and 2 in group II, pain 27 in group I and 22 in group II, dizziness 30 in group I and 31 in group II, breast tenderness 14 in group I and 10 in group II and fatigue 12 in group I and 8 in group II. The difference was non- significant (P> 0.05).

Graph I Side-effects during treatment



Discussion

Over the past two decades, the health evidence technologies and human rights rationale for providing safe, comprehensive abortion care have evolved greatly.[5] Despite these advances, an estimated 22 million

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abortions continue to be performed unsafely each year resulting in the death of an estimated 47,000 women and disabilities for an additional 5 million women.[6]

Medical methods of abortion have been proved to be safe and effective. The most effective regimens rely on the antiprogestin, mifepristone, which binds to progesterone receptors resulting in necrosis and detachment of placenta.[7] It also softens the cervix and causes mild uterine contractions. It sensitizes the uterus to the action of prostaglandin which is given 1–2 days later, like synthetic prostaglandin E1 analogue, misoprostol, which binds to myometrial cells causing strong myometrial contractions and causes cervical softening and dilatation. This leads to expulsion of fetus from the uterus.[8] The present study was conducted to assess safety and efficacy of vaginal misoprostol alone for first trimester termination of pregnancy.

In present study, group I patients received misoprostol with 3 drops of water per tablet and group II patients received misoprostol only. Carbonell et al[9] in their study investigated the efficacy of misoprostol and water versus misoprostol alone for first trimester medical abortion in women at ≤ 9 weeks of gestation. Eighty women were randomly assigned to group 1 (water added to misoprostol) and group 2 (misoprostol alone). Vaginal misoprostol 800 μg was given on days 1, 3 and 5. If the woman did not require vacuum aspiration during the period up to the return of first menstruation after medical abortion, the outcome was classified as complete abortion. The incidence of side-effects and the acceptability were assessed through a standardized questionnaire during and after the abortion. The complete abortion rate appeared higher when water was added but the difference did not reach statistical significance. Gastro-intestinal side-effects were common but well tolerated in both groups. Overall, 40% of the women preferred a surgical method in the future because of the high failure rate. With an overall complete abortion rate of 85%, it is probably not a clinically acceptable method even if the addition of water can improve the results. We conclude that the addition of water onto misoprostol tablets does not improve its efficacy in first trimester medical abortion. Misoprostol alone is not recommended for medical abortion (up to 9 weeks of pregnancy) because of the high failure rate and low acceptability.

We found that there were failure of 3 cases in group I and 1 in group II, live pregnancy was 1 in group I and 0 in group II, complete abortion was 33 in group I and 35 in group II. Side effects such as nausea, diarrhea, dizziness, fainting, pain, dizziness, breast tenderness and fatigue were seen in both groups. Blanchard et al[10] found efficacy of vaginal misoprostol alone for first trimester medical abortion varies widely, from 47 to 94% The latter group used three doses of 800 μg every 48 h in women with pregnancy length <70 days. He modified the administrative procedure by adding 3 drops of water with misoprostol. The complete abortion rate in his study was 92%, which was comparable to that obtained from using mifepristone together with misoprostol.

Conclusion

Authors found that vaginal misoprostol is safe and efficacious in first trimester termination of pregnancy. Addition of water does not provide additional advantage.

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