



Research Paper

medical science

comparative study of oral & vaginal Misoprostol in the management of missed abortions of late first trimester and early second trimester.

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ABSTRACT

This study is carried at Government General Hospital, Kurnool. The aim of the study is to compare the efficacy and safety of oral and vaginal misoprostol administration for termination of missed abortions of late first trimester and early second trimester pregnancies.

KEYWORDS

misoprostol, missed abortion, I-A interval

Introduction

Missed abortion is a commonly encountered problem in day to day obstetrics. It needs to be managed without delay to alleviate psychological upset in the mother for having dead fetus in the uterus and to prevent life threatening complications, though rare, like- disseminated intravascular coagulation.

The term missed abortion is used when fetus/embryo has died but is retained in the uterus for a variable period of time.

Death of the fetus/embryo brings natural fall in progesterone level. Therefore it is logical to use misoprostol in cases of missed abortion.

Misoprostol has been used to effect evacuation of uterus through vaginal and oral routes in recent years. As varied results were observed with different routes of administration a comparative study is done using vaginal and oral misoprostol in the present study.

Materials and Methods:

The present study was carried out in the

Department of Obstetrics and Gynaecology, Government General Hospital, Kurnool.

100 patients of missed abortion were selected for the study. Detailed history is elicited. An initial ultrasonogram was done in all cases to confirm missed abortion. 50 cases were given oral misoprostol and 50 cases vaginal misoprostol.

A randomized prospective comparative study was studied between the two groups of patients. The details are recorded in the proforma and case sheet. Informed consent was taken from all the patients.

Inclusion criteria.

Pregnant women with gestational age 8-14 weeks.

Both primigravidae and multigravidae,

Haemoglobin more than 8mg/dl.

Exclusion criteria:

Patients with complications associated with pregnancy like cardiovascular diseases, unexplained vaginal bleeding, Prior LSCS, ectopic pregnancy, PID, cervicitis, vaginitis.

The patients are randomly assigned to one of the two groups of route of administration.

Group 1 (vaginal misoprostol)

One tablet of 200micrograms misoprostol is placed in the vagina. The dose was repeated every 4th hour for a maximum of 6 doses. The patient is watched for any symptoms and signs of vaginal bleeding. The dose was continued until one of the following outcomes was observed.

- 1.The patient has expelled the products of conception.
2. The patient has excessive bleeding per vaginam.

Ultrasonography was done to confirm completion of abortion.

Group II :

Protocol for administration of the drug and monitoring are similar to group (I) except for the route which is oral instead of vaginal.

In all cases, the women underwent surgical evacuation 19 hours after the initiation of the treatment if the abortion was not complete, or if the women experienced heavy bleeding at any time during the study period.

Criteria for successful induction:

The maximum time period considered in this study is 4 hours after the last dose i.e., 6th dose and a total of 19 hours after induction. The response is categorized into 3 groups.

Complete abortion : the induction is successful.

Incomplete abortion : abortion with retained products, where there is a need for surgical intervention.

No response / only cervical priming: After the above period, there is no abortion and only cervical priming is observed. In these cases, surgical evacuation is carried out.

Observation and analysis:

Total number of cases studied was 100, randomly allocated to the two different groups. Misoprostol was given to 50 women through vaginal route and 50 women through oral route. The outcome in the two routes of administration is compared with reference to response (complete abortion rate), induction-abortion interval and side effects.

For testing the equality of means between the two groups, students 't' test is carried out for those characteristics of continuous nature. In all the cases, the p-value is noted.

1. Response – number of complete abortions:

a. The response in terms of the number of complete abortions out of the 50 cases in each group is as follows:

Group I 72%(36/50)
Group II 12% (6/50)

b. For group II(O), the response is significantly lower than that in the group I(V). The p-value between group II(O) & group I(V) is $0.000 < 0.005$ indicating that the difference is statistically significant.

c. the patients in the No response group are also benefited. No response indicates no expulsion of products.

2. Indication for intervention

	n	Incomplete abortion	No response	Excessive bleeding
Group I(V)	50	8	6	0
Group II(O)	50	16	28	2
total	100	24	34	2

3. Distribution of induction-abortion interval:**Observations:**

Mean I-A intervals for the two groups are

Group I(V) : 12:24 hrs.
Group II(O): 17:58 hr

The difference between the two groups is statistically significant.

p-value for I-A Interval is 0.0042 is significant.

4. I-A interval variation with parity:

	PI	P2	P3	P4	P-value
Group I(V)	11.30	13.79	11.26	14.70	0.2856
Group (O)	16.50	17.50	17.00	18.50	0.5786
total	13.9	15.64	14.13	16.60	

The variation with parity is not statistically significant within each of the two groups as p-value is > 0.05 .

5. Response variation with parity

In both groups, the response is falling with

Increasing parity.

Primis responded better than multigravidae with response declining with increasing parity. This difference is mainly in group II(O).

6. The response variation with gestational age:

- G.A. 8-10 weeks - 29.72%(11/37)
- G.A. 10-12 weeks - 38.22%(13/34)
- G.A. 12-14 weeks - 62.06%(18/29)

P – value for the two groups is 0.0005 is statistically significant.

Complete abortion rate is increasing with gestational age in each group.

Discussion:

The efficacy of misoprostol in the termination of late first trimester and early second trimester has been studied. A maximum of 1200 micrograms has been administered in 6 divided doses of 200 micrograms each 4th hourly through vaginal and oral routes. The results are discussed with reference to

Complete abortion rate (efficacy)
Induction-abortion interval
Side effects.

Rationale for the regimen chosen :

Side effects: the maximum dose of 2400microgm in 3 divided doses of 800microgm each given at an interval of 24 hrs. Significant side effects are nausea, diarrhoea, fever chills, vomiting and in some cases longer period of bleeding. In order to have minimum side effects, a 200microgm dose is considered in this study.

b. abortion rate variation with doses: the studies showed that maximum outcome was observed after the first dose, i.e. within 24 hours and the outcome after 2nd and 3rd doses is low.

2. comparison with other studies:

a. efficacy: for the total dose of 1200microgm in 6 divided doses of 200microgm each at an interval of 3 hours the outcome is

Vaginal route : 71%(36/50)

Oral route : 12%(6/50)

The efficacy is very low in oral route.

In the study of Koopersmith 1996 and Bugalho 1996 the efficacy is 50% and 46%. the outcome in the present study is better than above studies.

Comparison of induction – abortion intervals:

In the studies of Esteve 1999, carbonell 2000, valazco 2000, I-A interval is 8,7,4,6,8 respectively. In the present study I-A interval by vaginal route is 12.24hrs. the mean intervals are slightly higher. But the difference is not significant and the results are comparable.

c. Comparison of side effects :

2 women in group II(O) had excessive bleeding and surgical evacuation was performed. 4 women in group II(O) complained of nausea. 3 women in group I(V) and 2 women in group II(O) complained of pain abdomen.

3. comparison between the two routes of administration:

Group	Complete abortion rate	I-A interval
Group I(V)	72%	12.24+ _ 4.25hrs
Group II(O)	12%	17.58+ _ 1.07hrs

Misoprostol is absorbed through the vaginal mucosa in vaginal administration. It is closer to the site of action. The response in oral group is low since the drug has first pass effect through liver. In most of the studies, vaginal route has been used. Also, in the present study, the side effects are minimal in the two routes of administration.

Summary:

The present study was conducted in the Department of Obstetrics and Gynaecology,

Government General Hospital, Kurnool.

100 patients of missed abortion with gestational age 8-14 weeks were selected for the study. The patients were randomly assigned to one of the two groups of the route of administration. To group I, 200microgm misoprostol was kept in the posterior fornix of vagina and to group II, 200microgm misoprostol given by oral route.

The following observations were obtained.

- ☒ Complete abortion rate in vaginal group is 72% and in oral route is 12%. The difference between the two groups is statistically significant. (p-value is 0.0005 i.p., is < 0.05).
- ☒ The induction abortion interval is 12.24 hours with the vaginal route, whereas in oral route it is 17.58 hours. The difference in I-A interval between the two groups is statistically significant (p-value is 0.0042, i.e., p is < 0.05).
- ☒ The response to misoprostol in terms of complete abortion rate was better in the gestational age group of 12-14 weeks in both routes.
- ☒ The I-A interval for the 12-14 week gestational age group was slightly more than that for the 8-10 and 10-12 week

GA groups, but the difference was not significant.

- ☒ There was no significant difference in response in I-A interval between the two groups in relation to parity. (P-value is >0.05).
- ☒ The response in terms of complete abortion rate is more in primigravida than in multigravida.
- ☒ No complications occurred except in 2 cases of group II(O), where there was excessive bleeding per vaginum, requiring immediate evacuation.
- ☒ No significant side effects were observed in any of the groups even with the maximum dose, with the only exception in 4 cases in group II(O), where there was a complaint of nausea after first dose which subsided with anti-emetics. So the maximum dose of 1200microgm in six divided doses is safe and effective.

Conclusion

Termination of missed abortion by using vaginal misoprostol is safe and far superior to oral misoprostol in terms of blood loss, completeness of abortion, shorter duration with less morbidity to the patient. The oral misoprostol, many a times required additional invasive surgical curettage for completion of the abortion.