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"To Compare Efficacy of Vaginal Misoprostol in Termination of First and Second Trimester Missed Abortion Cases"

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Abstract
Objective: *To compare efficacy and complication rates of vaginal misoprostol in termination of first and second trimester missed abortion cases.*
Materials and Methods: *Seventy five women in age group between 18-38 years were recruited for the study. 800 µg of vaginal misoprostol was kept in the posterior fornix for all the women. If the patient did not abort after 24 hours, the similar dose was repeated followed which the patient was treated as failure and surgical evacuation was carried out. The subjects were then followed for completion of abortion, need for suction evacuation, vaginal bleeding and side effects if any.*
Results: *Of 75 women diagnosed with missed abortion, 36 had gestational age ≤ 12 weeks and 38 had gestational age between 12 to 20 weeks. 9 cases having gestational age between 12 to 20 weeks needed suction evacuation in comparison to 3 cases whose period of gestation was ≤ 12 weeks (p=0.073) Similarly, heavy vaginal bleeding was statistically higher when period of gestation was more than 12 weeks.*
Conclusion: *Use of vaginal misoprostol is effective for termination of both first and second trimester missed abortion cases. But, the need of suction evacuation and incidence of heavy vaginal bleeding is higher when gestational age is more than 12 weeks.*
Key-words: *Missed abortion, vaginal misoprostol, vaginal bleeding, first trimester, second trimester.*

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I. Introduction

Missed abortion is defined as unrecognized death of fetus or embryo without expulsion of the products of conception. The various options for such cases include expectant management, surgical evacuation or medical management. Expectant management has unpredictable success rate and waiting period puts women in a state of anxiety with additional need of surgical evacuation in case of incomplete expulsion of products of conception makes the women to suffer more[1]. Surgical evacuation has own drawbacks of infection, bleeding, formation of intrauterine adhesions following the procedure and need for hospitalisation and need for anesthesia which make this procedure less preferred by women these days.

Among various pharmacological agents available to medically manage cases of missed abortion, misoprostol alone has been studied in research and is found to be effective for these cases[2,3]. Another widely used and researched is combination of mifepristone and misoprostol which has equally good results but some studies have shown increased risk of bleeding with mifepristone[4,5] and also mifepristone is a costly drug which will add to unnecessary expenses.

Second trimester missed abortions deserve special importance because of the inherent morbidity and complications associated with them. The ideal method to complete the abortion in these cases is still eluding us. Complications appear to increase with the increment in duration of pregnancy and prolongation of the induction abortion interval.

This study was planned to compare the efficacy and complication rates with use of vaginal misoprostol in first and second trimester missed abortion cases.

II. Materials and Methods

This prospective study was conducted at the Indira Gandhi Medical College, Shimla after approval from institute Ethics Committee. Informed written consent was obtained from all patients. Seventy five women with diagnosis of missed abortion were recruited for the study. The diagnosis of missed abortion was confirmed by ultrasound.

The subjects were admitted to the hospital after diagnosis of missed abortion and detailed history was taken including a history of past medical disorders and surgical procedures. In case of subjects, who were unwilling to get admitted, they were treated as out patients provided there was access to telephone and transportation. Telephone number of the doctor was provided. Detailed general physical examination, systemic examination with special reference to per abdomen and pelvic examination were done as per the proforma. Hemoglobin (Hb%), bleeding time (BT), clotting time (CT), urine albumin and sugar, blood grouping and ultrasound to confirm the diagnosis were done.

After the woman was selected for misoprostol tablet insertion, the subject was placed in dorsal lithotomy position and bimanual examination was done, to confirm the findings. Sim's speculum was introduced and misoprostol tablets [800 µg] moistened with normal saline were inserted in the posterior fornix. The subjects were instructed to remain lying down for 30 minutes after instillation. Her pulse, BP, respiration rate, temperature, uterine activity and other complaints were monitored. Instructions were given to both admitted and out-patients to report back in case of abdominal cramps, pain, bleeding or passage of mass per vaginum. When subjects reported back, per speculum and per vaginum examination were done, to look for expulsion of products of conception. If products of conception were expelled, no check curettage was done at this point of time and women were further observed for four hours for excessive bleeding per vaginum or any other complaint. If the patient did not abort after 24 hours, the dose was repeated in the same manner. In case the patient still didn't abort after total duration of 48 hours, the patient was treated as failure and surgical evacuation was carried out. On discharge, the woman was instructed to report on the 10^{th} day for check ultrasound, Hemoglobin estimation and for signs and symptoms of bleeding, pain, infection or any other complication.

Patients were asked to report earlier in case of any complaints. Complete and successful abortion was considered as one in which there was complete expulsion of the products of conception without the need for surgical intervention within forty eight hours, as proven by ultrasound or if on dilation and aspiration, no curetting were obtained or histopathology revealed no products of conception.

III. Results

Both the groups had comparable demographic profile. Thirty six patients had period of gestation less than equal to 12 weeks (48%) versus 38 patients who had gestational age more than 12 weeks (50.6%). Gestational age was not known in one patient as she conceived in lactational amenorrhoea. Details of number of doses required, insertion to spontaneous expulsion time and need for suction and evacuation is given in Table1. No significant differences were observed in these parameters among both the groups.

Table 1. Comparison of both the groups in terms of no. of doses required, insertion to spontaneous expulsion time and need for suction and evacuation

Characteristics	Group 1 (n=36)	Group 2 (n=38)	p value
No. of doses of misoprostol			
one	32 (88.9%)	36(94.7%)	0.357
two	4(11.1%)	2(5.3%)	
Insertion to spontaneous expulsion time (in hours)			
0-5	4 (13%)	7 (21/9%)	0.747
5-10	16 (51.6%)	18 (56.3%)	
10-15	7 (22.6%)	4 (12.5%)	
15-20	1 (3.2%)	1 (3.1%)	
>20	3 (9.7%)	2 (6.3%)	
Need for suction and evacuation			
No	33 (91.7%)	29 (76.3%)	0.073
Yes	3 (8.3%)	9 (23.7%)	

Table 2 shows change in haemoglobin level which followed the abortion after insertion of vaginal misoprostol. There was no significant change in levels of haemoglobin (Done baseling and repeated 10 days after vaginal insertion of misoprostol) noted among both the groups.

Table 2. Change in Haemoglobin level among both the groups

Characteristics	Group 1 (≤ 12 weeks) (n=36)	Group 2 (12 – 20 weeks) (n=38)	p value
Change in Hb level			
0.0-0.5	25 (69.4%)	17 (44.7%)	0.149
0.5-1.0	7 (19.4%)	11 (29.0%)	
1.0-1.5	4 (11.1%)	6 (15.8%)	
1.5-2.0	0(0%)	2 (5.3%)	
≥2.0	0(0%)	2 (5.3%)	

The incidence of heavy vaginal bleeding was significantly higher when period of gestation was more than 12 weeks (p=0.073). Majority of the women among both the groups did not experience any side effects. Abdominal pain was the most common symptom reported in both the groups. [Table 3]

Table 3. Incidence of complications among both the groups

Characteristics	Group 1 (≤ 12 weeks) (n=36)	Group 2 (12 – 20 weeks) (n=38)	p value
Vaginal Bleeding			
Average	33 (91.7%)	29 (76.3%)	0.073
Heavy	3 (8.3%)	9 (23.7%)	
Side Effects			
Abdominal pain	2 (5.6%)	2 (5.3%)	
Fever	0 (0%)	1 (2.6%)	
Shivering	0 (0%)	2 (2.6%)	
Vomiting	1 (2.8%)	1 (2.6%)	
Nil	33 (91.7%)	32 (84.2%)	

Vaginal misoprostol was successful in 28 cases when period of gestation was >20 weeks in comparison to 36 cases when gestational age was less than equal to 12 weeks. [Table 4]

Table 4. Success/Failure of vaginal misoprostol among both the groups

Outcome	Group 1 (≤ 12 weeks) (n=36)	Group 2 (12 – 20 weeks) (n=38)	p value
Success	33 (91.7%)	28 (80.6%)	0.173
Failure	3 (8.3%)	7 (19.4%)	

IV. Discussion

It was found that single 800 µg dose of vaginal misoprostol is equally effective for termination of first trimester and second trimester abortion cases. The maximum number of patients aborted within 15 to 20 hours of insertion of the tablet irrespective of period of gestation. (51.6% when period of gestation was less than twelve versus 56.3% when period of gestation was between twelve to twenty weeks. This observation was not found to be statistically significant (P=0.747). In cases with period of gestation of twelve weeks or less, there was no need for suction evacuation in 91.7% cases and only in 8.3% cases suction evacuation was required whereas in cases with period of gestation between twelve to twenty weeks 76.3% cases, there was no need for suction & evacuation and in 23.7% cases suction & evacuation was done. This observation was significant (P=0.073). This shows increased need for surgical evacuation as the period of gestation increases. The main reasons for evacuation was excessive vaginal bleeding or retained placenta.

There was no case with period of gestation less than twelve weeks who had hemoglobin level change more than 1.5 g/dl but four (10.6%) cases with POG between 12-20 weeks had hemoglobin level change more than 1.5 g/dl. Although this observation was not found statistically significant (P=0.149) because of the small sample size (n=4) but it can be safely concluded that as the period of gestation increases, there is more blood loss.

Average vaginal bleeding was found in 91.7% cases with period of gestation twelve weeks or less after the insertion of tablet misoprostol. The cases with POG between 12-20 weeks had average vaginal bleeding in 76.3% cases. This means that 8.3% cases had heavy vaginal bleeding in cases with POG less than twelve weeks and in cases with POG between 12-20 weeks, 23.7% cases had heavy vaginal bleeding. This observation is significant statistically (P=0.073). This shows that as the period of gestation increases the incidence of heavy vaginal bleeding increases.

Side effects observed in the present study were mild and self limiting. The commonest side effect observed was abdominal pain in both the groups. No case required analgesic for relieve of pain. No case had major complications viz. uterine rupture, hypersensitivity reaction, infection or septic shock. The studies

conducted by Crenin et al[6], Demetroulis et al[7] and Muffley et al[8] are comparable in term of side effects to the present study. All these studies found the side effects to be mild and self limited. The results of present study were not comparable to the study by Vimala et al[9] who found the side effects to be significantly high. This can be explained by the sublingual route used by them which leads to rapid peak plasma concentrations in the blood and higher incidence of side effects. Various studies have also found that apart from being less efficacious, oral misoprostol has a longer induction to abortion interval when compared to vaginal route and may be associated with greater gastrointestinal side effects like vomiting and diarrhea [10].

Vaginal misoprostol was successful in inducing abortion in 91.7% cases, when the period of gestation was twelve weeks or less and failed to do so in 8.3% of these cases. In cases with period of gestation between twelve to twenty weeks, the drug was successful in 80.6% and failed in 19.4% cases. Even in the cases where complete expulsion was not achieved (fetus was expelled and the placenta was retained), it was easier to do suction evacuation because there was softening of cervix due to the action of misoprostol. Wood & Brain[11] found the success to be 80% (20/25) and Thomas et al[12] had success in 76.7% (43/60) cases.

Thus, we can say that single 800 µg of vaginal misoprostol is equally effective for abortion in both first trimester as well as second trimester missed abortion pregnancies. Though there were increased chances of suction and evacuation and increased chances of vaginal bleeding when period of gestation was more than 12 weeks, vaginal misoprostol was successful in inducing complete abortion in 80% of cases.

V. Conclusion

High efficacy and minimal side effects make vaginal misoprostol an useful alternative for termination of pregnancy in both first and second trimester. Whereas, chances of heavy vaginal bleeding and need for surgical evacuation increases significantly in second trimester in comparison to first trimester.

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