



Evaluation of Intravaginal Misoprostol for Cervical Priming in First Trimester (Pregnancy Termination)

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Abstract

Women often resort to surgical abortion because they lack information on contraception or fear the side effects of medical methods of abortions. A safe medical or combined medical and surgical method is the need of hour and would save many lives. An effective cervical priming agent would aid surgical abortions or would be effective alone.

Objective: *To compare various dosage, regime and safety of intravaginal misoprostol (posterior fornix) prior to surgical evacuation for cervical priming in first trimester.*

Materials & methods: *It was a prospective study which consisted of 75 patients divided into 3 groups, 25 patients each, with control group of 75 patients who did not have cervical priming .Both groups underwent surgical evacuation.*

Group 1: 200 microgram of misoprostol inserted, 6 hours prior to procedure.

Group 2: 200 microgram of misoprostol inserted, 12 hours prior to procedure.

Group3: 400microgram of misoprostol inserted, 12 hours prior to procedure.

Results: *Successful priming defined as passage of no.10 Hegar's dilator without resistance was noted in 96% in group 3 compared to 88% in group 2 and 60% in group 1.Success rate was significant in 8-12 weeks period of gestation. Only 4% needed operative dilation in group 3 compared to 16% in group 2 and 36% in group 1. Nausea, vomiting and abdominal cramps were noted in 12% in group 1, 4% in group 2 and none in group 3. Blood loss was less in group 3 compared to other groups.*

Conclusion: *Misoprostol has proved to be a safe , cost effective, easily acceptable cervical priming agent in the first trimester termination of pregnancy in the dose of 400micrograms vaginally 12hours prior to surgical evacuation .*

Keywords: *Misoprostol, abortion, cervical priming, vacuum aspiration.*

INTRODUCTION

Unintended pregnancy and abortion are important public health issues worldwide. RCH programme has recommended safe abortion as an important aspect for improving adolescent health care¹

In India 6 million abortions termination of pregnancy occur each year accounting for an abortion rate of 3.3/1000 woman of reproductive age. These statistics do not reflect the large number of illegal abortions that take place in the teenage group or outside marriage. Hence RCH recommended 'safe abortions' as part of adolescent health care..Peak age group for women undergoing legal terminations in India is 25-29 years².According to (Indian Council for Medical Research)³ data , majority of abortion seekers were married women (93.7%) with one or more living children (92.4%).⁴

It is generally felt that it should be the right of each woman to take a decision about her pregnancy based on correct information. A safe medical method would be save many lives. women often resort to abortion because they lack information on contraception or fear the side effects of contraceptives^{5,6}. A safe medical or combined medical and surgical method is the need of hour and would save many lives⁷. The availability of acceptable safe, effective methods for termination of pregnancy will be of immense value for women and the medical profession.^{8,9,10}

During the first trimester , when 90% or more of abortions are performed in most countries , vaccum aspiration and early medical induction are the safest procedures, but dilation and curettage is still common in some parts of the world.^{3,11}

Aiming at this, a comparative study was conducted by using 3 groups of intravaginal misoprostol [15 methyl analogue of PG-E₁] as preoperative cervical ripening agent .

MATERIALS AND METHODS

It was a prospective study which consisted of 75 patients divided into 3 groups of 25 patients each. There was a control group of 75 patients who did not have cervical priming .Both groups underwent surgical evacuation.

75 patients requesting termination of pregnancy with duration of pregnancy between 6-12 weeks were selected randomly for this study.

Misoprostol was inserted into posterior fornix of vagina, prior to surgical evacuation.

Group 1: (25 patients in whom) 200 microgram, 6 hours prior to evacuation.

Group 2: (25 patients in whom) 200 microgram, 12 hours prior to evacuation.

Group3: (25 patients in whom) 400microgram, 12 hours prior to evacuation.

PATIENT SELECTION AND EVALUATION

History: Menstrual history, past , personal history, marital status.

General physical condition, cardiovascular and respiratory syatems were evaluated. patients with present cardiovascular disease , hepatic disease and epilepsy were exluded from the study . A speculum examination was done to note the condition of cervix and vagina. bimanual pelvic examinaton was done to confirm pregnancy , to note the uterine size to rule out any cervical pathology.

The following lab investigations were done.

1. Haemoglobin and PCV
2. Blood group and rh typing
3. HIV
4. HBs Ag
5. VDRL

(gestational age 6-12 weeks when they came requesting a termination of pregnancy)

All the patients were given injection tetanus vaccine 0.5 ml I.M. and informed written consent for the procedure was taken.

Timing of preoperative treatment

Misoprostol tablets were inserted in the vagina 6 or 12 hours prior to the procedure. In patients who were not willing for admission, misoprostol was given for self insertion vaginally. Patients were asked to review 6-12 hours after insertion or when spotting P/V or pain abdomen started.

In admitted patients, once the tablets were placed in the posterior fornix, the patients were kept under observation for the effects like nausea vomiting, abdominal pain, diarrhoea and bleeding. After the time interval of misoprostol administration curettage/ vacuum aspiration was done under I.V. sedation or general anaesthesia. When the whole sac was found to be expelled check curettage or ultrasound was done to ensure complete evacuation.

- a) Preoperatively the factors taken into consideration were the degree of spontaneous cervical dilation and amount of further dilation required.

- b) Intra operative bleeding and location of the products of conception was taken into consideration.
- c) The degree of dilation was assessed in millimeters with Hegars dilator.
- d) Any other complications like abdominal pain requiring analgesia, any diarrhoea, any excessive bleeding P/V were also noted.
- e) Spontaneous cervical dilation of 10 mm (Hegars 10) was regarded as successful outcome of misoprostol cervical priming.

Aims and Objectives

1. To determine the efficacy of misoprostol [PG- E1] prior to surgical evacuation of first trimester pregnancy and its action of effective cervical priming.
2. To compare and evaluate the efficacy and safety of misoprostol, its effective dose and time interval, when applied intravaginally for pre-operative cervical ripening prior to surgical evacuation .
3. To evaluate the side effects of misoprostol when used in different dosage and time intervals.

Results and Discussion

Results of the study conducted on 75 patients at various dosage intervals, using misoprostol as the cervical priming agent are discussed as follows:

1. Successful priming: Passage of number 10 Hegar's dilator without resistance.
2. Percent of cases requiring operative dilation.

3. Side effects.

Success rate:

1. Overall success was highly significant in group 3 where 96% as compared to group 2- 88% and group 1 - 60%
2. Failure cases belonged mostly to gestational age 6-8weeks.

In this study success rate was significant in advanced gestational age [8-12 weeks] as compared to [less than 8 weeks] gestation in the respective study groups. This correlates with studies showing increased efficacy of misoprostol in advanced gestation, this is as a result of increased receptors with the growing uterus and advancing gestational age. This also forms the basis for use of low doses of misoprostol at term for induction of labour.

In a large multicentric clinical trial performed by the WHO task force on prostaglandins for fertility regulation, 1000 patients 8-12 weeks pregnant were randomly treated with either 1 mg of 15 methyl PGF₂= methylester as a vaginal suppository or a placebo suppository. Vacuum aspiration was undertaken 3-12 hours following insertion. The results showed that sufficient cervical dilation could be achieved with a prostaglandin suppository which permitted easier vacuum aspiration with less intraoperative bleeding and fewer short term complications.

In a study conducted by Bugalho et al using intravaginal misoprostol 200microgram 1 tablet 6 hours prior to the procedure for cervical priming the success rate was found to be 70%⁹.

In the present study 15 methyl analogue of prostaglandin E₁ . Misoprostol was chosen to determine if pretreatment would produce sufficient cervical dilation to facilitate subsequent termination of pregnancy by vacuum aspiration or curettage. In the control group without pretreatment serial dilation was required from no 3 Hegars dilator .This study conducted has shown that all three groups of regimens of pretreatment were sufficient to achieve maximal dilation .The study group comprising of 2 tablets 12 hours prior to the procedure showed us the best results .

Average spontaneous dilation and process of expulsion:

This study conducted showed that in the group 3 prior to procedure average spontaneous dilation was 13.96mm. This is significantly more as compared to other 2 groups. Only 4%of the patients in the above mentioned study group needed operative dilation as opposed to 16% in group 2 and 36% in group 1.

It is also noteworthy in the study that in group 3 prior to the procedure 20% of the patients had complete expulsion of products as compared to none in group 2 and group 1. In group 3 the products were already separated and could be easily removed with ovum forceps, check curettage only being needed to ensure completeness of evacuation.

Blood loss was comparatively less in the study group 1 compared to the other two groups.

Efficacy in previous caesarean section cases

In our study there were 5 previous caesarean cases. We found no complications in them with misoprostol cervical priming .

Side effects

Gastrointestinal effects like nausea, vomiting and abdominal cramping were found in 12% in group3, 4% in group2 and none in group1

Distribution According To Parity

	Number	Percentage
Primi	2	2.66%
Multi	61	81.33%
Grand Multi	12	16%

Efficacy of Treatment

	Group1	Group2	Group3
10 mm Or More Spontaneous Dilation	15	22	24
Success %	60%	88%	96%
Failure %	40%	12%	4%

Number of Patients Who Needed Operative Dilation**Average Dilation**

Group	Average Dilation (MM)
1	9.62
2	11.36
3	13.96

	Number	%
Group1	9	36%
Group2	4	16%
Group3	1	4%

Blood Loss

	Group1	Group2	Group3
Minimum	23	21(84%)	21(84%)
Moderate	2	4(16%)	4(16%)
Severe	0	0	0

Number Of Patients With Spontaneous Expulsion

	Completely Expelled	Incomplete Expulsion	Not Expelled
Group1	0	3	22(88%)
Group2	0	5	20(80%)
Group3	5(20%)	10	10(40%)

Distribution According To Gestational Age

	Group1	Group2	Group3
<8 Weeks	7(28%)	4(16%)	3(12%)
8-12 Weeks	18(72%)	21(84%)	22(88%)

Outcome of Cervical Priming In 3 Groups (<8 Weeks)

	Group1	Group2	Group3
Success	4(57.14%)	2(50%)	2(66.66%)
Failure	3(42.86%)	2(50%)	1(33.34%)

Outcome Of Cervical Priming In 3 Groups (8-12weeks)

	Group1	Group2	Group3
Success	12(66.66%)	21(100%)	21(95.46%)
Failure	6(33.34%)	0(0%)	1(4.54%)

Incidence of Side effects In 3 Groups

	Group1	Group2	Group3
Nausea	0(0%)	1(4%)	3(12%)
Vomitting	0	0	1(4%)
Diarrohea	0	0	0
Abd. Cramps	1(4%)	1(4%)	3(12%)

Conclusion

In this study misoprostol has proved to be a very effective cervical priming agent in the first trimester termination of pregnancy. It was found to be safe, cost effective as well as easily acceptable. Due to the ease of administration it was found to improve the effectiveness of-MTP

and decrease the common complications associated with the procedure. It has a very few adverse effects .The safety , efficacy profile , low cost and stability at room temperature make misoprostol an attractive agent for patients and providers .

Women with early pregnancies can opt for medical or surgical methods as soon as pregnancy is diagnosed. First trimester vacuum aspiration is impressively safe and effective when performed by experienced providers using good surgical technique ^{14, 15}.

Cornerstones of good practice include accurate dating, gentle dilation, meticulous evacuation and diligent follow up ¹⁶. In our study we aimed at evaluation of misoprostol in various dosage, regimes as cervical priming agent following which meticulous evacuation could be achieved.

It can be recommended as a safe, very effective and well tolerated agent for cervical priming in first trimester pregnancy termination, in the dose of 400micrograms vaginally 12hours prior to surgical evacuation .

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