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Research Article

A STUDY ON SUBLINGUAL VERSUS VAGINAL MISOPROSTAL FOR CERVICAL PRIMING IN I TRIMESTER MTP

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ABSTRACT
One of the most preventable tragedies for a womankind is the problem of unwanted pregnancy and unsafe abortion. Pre procedure cervical priming is recommended to ripen the cervix prior to performing a surgical abortion and may help in facilitating the procedure. The drugs which can be used are Misoprostal and injectable PGF2 Alfa. In the present study the effectiveness and acceptability of sublingual and vaginal Misoprostal for cervical priming in I Trimester MTP was compared. The study suggests the sublingual group route is convenient to use avoids vaginal application and comfortable to the patient

INTRODUCTION
Misoprostal is a synthetic prostaglandin analogue structurally related to prostaglandin El. It was developed for the treatment of peptic ulcer. In humans the full acid-inhibiting doses of Misoprostal (800 ug/day) was necessary to heal peptic ulcers. Initially, it was thought that the mucosal protective properties played no role.

What was over looked was that in humans the dose-response for the "cyto-protective actions, such as stimulation of mucus secretion, overlapped with that for acid inhibition. Subsequently, the non-acid inhibiting properties were demonstrated to their full effect when it became clear from larger multicentre studies, including comparative studies with H2-antagonists, that Misoprostal was able to protect against non-steroidal anti-inflammatory (NSAID)-induced ulceration.

This protection is achievable at doses of misoprostal half those requires for ulcer healing, which are only weakly acid inhibitory.

Misoprostol is stabilized as dispersion on hydroxyl-propyl-methyl cellulose and presented in tablet form for oral administration at doses ranging from 100 to 800 ug/day. It binds to PGEI and E2 receptors, though only one of its four stereoisomers responsible for the receptor mediated activity, without hindrance of its receptor binding by the other three inactive isomers (Bauer *et al.,* 1987; Hanson *et al.*, 1988).

The issue of fetal and maternal safety must be well addressed for any new indicated technique. Recent studies comparing intra vaginal misoprostol with intracervical dinoprostone for induction of labor shows that misoprostol shortens the induction-to-delivery interval and reduces the need for oxytocin augmentation Sanchez-Ramos 1997.

In addition, misoprostol is much less expensive than dinoprostone or oxytocin. Although no increase in fetal or maternal morbidity has been observed, induction using high doses of misoprostol are associated with uteriner hyperactivity (Sanchez-Rainos *et al.,* 1993).

Decreasing the does of misoprostol from 50 to 25 ug decreased the incidence of tachysystole from 34-37% to 8-17% (Sanchez-Ranios *et al.,* 1993). Even using the lower misoprostol dose, hyper stimulation syndrome and uterine rupture may occur.

As in the past 40 years, the introduction of each new oxytoxic agents, whatever the route of administration, ranging from intramuscular, intravenous, sublingual, intranasal spray, intra amniotic, extra amniotic, vaginal and oral has subsequently been followed by reports of rupture of the uterus. It would seem that misoprostol is no exception to former preparations.

Uterine rupture has been reported in women with (Sciscione *et al.*, 1998) or without previous uterine scar (Bennett, 1996).

Different dosage regimen ranging from 25 ug every 3-6 hrs to 50 ug every 4 h had been used. Some of the uterine ruptures occurred many hours after the last misoprostol dose was administered.

MATERIALS AND METHODS

The study has been conducted in KBNIMS, Gulbarga in women opting for I Trimester MTP. Counseling and details about the method of study were explained to the participants. Informed and written consent were obtained from the participants. Thorough preoperative evaluation was done which includes detailed history, physical examination and routine investigations.

Inclusion Criteria:

1. Age above 18 years
2. Having single intrauterine pregnancy not exceeding 12 weeks as per dates and USG.
3. Patients giving informed consent.

Exclusion Criteria:

1. Patients with Hb% <8gms
2. Patients with active infection
3. Patients not giving consent

The patients and attendants were explained about the procedure and informed consent was obtained. Base line investigations were carried out. The patients were divided into two groups of 50 each.

Group A:

The patients were given 400 ug of sublingual misoprostol 3 hours prior to MVA.

Group B:

400 ug of misoprostol was placed in the posterior fornix 3 hours prior to MVA.

After 3 hours manual vaccum aspiration was done under aseptic precautions. In apprehensive patients paracervical block was given. The cervix was held with a non traumatic valsellum and plastic karmans cannula of increasing size is inserted into the cervix. The correct size of the cannula passed through the cervical os with no resistance and introduced into the uterus. A hand operated double valve vaccum created syringe (50ml) was attached to the cannula. The cannula was given rotator and to and fro movements and aspiration of the products of conception is done. The products of conception are filtered and the amount of blood loss is measured. The patients are discharged on the next day if all parameters are normal and no complications observed.

The two groups are assessed for efficacy on the basis of various parameters like.

1. Primary Outcome measures

Degree of dilatation achieved

2. Secondary outcomes:

i. Duration of procedure
ii. Intra operative blood less
iii. Side effects
iv. Pain score

1. Cervical Dilatation: Measured with maximum size of plastic cannula passed through the cervical os without any resistance.
2. Intraoperative Blood Loss: Measured after sieving away the products of conception.
3. Duration of the procedure.
4. Intra Operative Pain Score: Based on a nominal scale of 0-10. 0-3 mild, 4-6 moderte, 7-10 severe requiring injectable analgesics.
5. Before surgical evacuation the patients were asked about the side effects like abdominal pain: Graded from 0-3, 0 – No pain, I – mind pain, 2 – moderate pain that did not require analgesic, 3 nausea vomiting, shivering and Vaginal bleeding ; Ranging from 0-3

0 – No bleeding, 1 – Minimal spotting
2 – Bleeding like menstrual flow, 3 – severe bleeding.

RESULTS AND DISCUSSION

The mean age in the sublingual group is 26.84 and in the vaginal group is 27.8. There is no significant difference with respect to age, as given in Table 1.

Table 1: Age Distribution

Age in Years	Sublingual	Vaginal
< 20	1	2
21-30	41	37
31-40	8	11
Mean	26.84	27.8
SD	4.2	4.98
P'value	0.300 Not significant	

Table: 2 BMI

BMI	Subligual	Vaginal
<20	15	14
21-25	32	33
>25	3	3
Mean	20.94	21.44
SD	2.08	2.52
P'value	0.275 Not significant	

The mean BMI in the sublingual group was 20.94 and in the vaginal group the mean BMI was 21.44 There was no significant difference with respect to BMI, as mentioned in table 2.

Table 3: Obstetric Code

Obst .Code	Sublingual	Vaginal
G2 P1 L1	16	11
G3P2 L2	30	33
Others	4	6

Among the sublingual group G2P1L1 was 16, G3, P2 L2 was 30 and Others 4. Among the vaginal group G1 P1 L1 was 11, G3 P2 L2 was 33 and others were 6, as shown in table 3.

Table 4: Obstetric History

Obstetric History	Sublingual	Vaginal
F TND	39	37
LSCS	11	11
Nil	0	2

Among the sublingual group 39 had previous FTND and 11 had previous 1 or 2 LSCS. Among the vaginal group 37 had previous FTND and 11 had previous LSCS, as mentioned in Table 4.

Table 5: Gestational Age

Gestational Age	Sublingual	Vaginal
Mean	8.14	8.06
SD	1.51	1.47
'p' value	0.790 Not significant	

For the sublingual group the mean GA was 8.14. vaginal group GA was 8.06. There was no significant difference with respect to GA (Gestational age), as see in Table 5.

Table 6: Hemoglobin

Hb	Sublingual	Vaginal
Mean	9.97	9.98
SD	0.64	0.69
'p' value	0.976 Not significant	

For the sublingual group the mean Hb was 9.97%, Vaginal group the mean Hb% was 9.98, there was no significant difference with respect to t he Hb% level, as noticed in Table 6.

Table 7: Cervical Dilatation

Dilatation	Sublingual	Vaginal
Mean	9	7.68
SD	0.64	0.62
'p' value	<0.001 significant	

The mean cervical dilatation in the sublingual group was 9mm. The mean cervical dilation in the vaginal group was 7.68 mm. the mean cervical dilation was higher in the sublingual group, as mentioned in Table 7.

Table 8: Duration of Procedure

Duration of Procedure	Sublingual	Vaginal
Mean	7.74	10.44
SD	0.92	1.47
'p' value	<0.001 significant	

The mean duration of procedure in the sublingual group was 7.76 min. The mean duration of procedure in the vaginal group was 10.44 min. The duration of procedure was lower as the sublingual compared to vaginal group, as show in Table 8.

Table 9: Blood Loss

Blood Loss	Sublingual	Vaginal
Mean	16.66	19.3
SD	2.34	2.12
'p' value	<0.001 significant	

The mean intraoperative blood loss in the sublingual group was 16.66 ml compared to 19.3ml in the vaginal group, as seen in Table 9.

Table 10: Pain Score

Pain Score	Sublingual	Vaginal
Mean	1.94	2.88
SD	0.94	0.77
'p' value	<0.001 significant	

The pain score in the sublingual group was 1.94 compared to 2.88 in the vaginal group. The pain score was less in the sublingual group compared to vaginal group, as given in Table 10.

Table 11: Side Effects

Side Effects	Vaginal	Sublingual
Mean	0.84	1.52
SD	0.58	0.91
'p' value	<0.001 significant	

The side effects like nausea, vomiting, fever, diarrhea, shivering was 1.52 in the sublingual groups. In the vaginal group it was 0.84. The incidence of side effects was more in the sublingual group, as mentioned in Table 11.

Table 12: Vaginal Bleeding

Vaginal Bleeding	Vaginal	Sublingual
Mean	0.84	1.34
SD	0.68	0.66
'p' value	<0.001 significant	

The vaginal bleeding in the sublingual group was 1.34 and in the vaginal group was 0.84 which is higher in the sublingual group, as given in Table 12.

First trimester abortion by surgical methods has been widely used in modern obstetrics. Vacuum aspiration is a commonly used method for first trimester abortion and is one of the most common surgical procedures performed worldwide. Cervical dilation is the most critical step in vaccum aspiration as most cervical and uterine injuries are due to forceful dilataion of cervix.

Adequate dilation decrease pain and duration of surgery and increases operation ease. Previously, laminaria tent, gemeprost and PGE2&1 have been used for cervical ripening. These days misoprostol, athetic PGE1 analog, has become popular for its effectiveness and for its her advantages like less cervical injuries, minimal intraoperative blood loss reduced requirement of general anesthetics and availability in titrated dosage forms.

It can be given by oral, intravaginal, sublingual or rectal route. The present study observed that the cervical dilation with misoprostol was favorable among the sublingual group compared to the vaginal group. The observed difference can be attributed the different absorption kinetics and subsequent more systemic availability with the sublingual routes. The duration of procedure was less in the sublingual group. This can be explained on the basis of the more cervical ripening and dilatation achieved in this group.

In the present study, subjects in sublingual group experienced more preoperative side effects as compared to vaginal group, the most common being the pain. Other side effects like bleeding, nausea and shivering were also seen slightly more frequently in sublingual group. This increased frequency of side effects may be explained by the higher bioavailability of sublingual misoprostol. None of the subjects in the present study experienced fever, diarrhea or vomiting. But, the difference of side effects in both the groups was not significant.

Following conclusions are drawn from the present study:

1. There was no significant difference between the sublingual and vaginal group with respect to age, parity, gestational age and previous aesthetic history.
2. The sublingual group had significant cervical dilatation, less time duration of surgery and lower pain score.
3. Intra operative blood loss was less in sublingual group.
4. Side effects like abdominal pain, nausea, vomiting, shivering was more in sublingual group.
5. The sublingual group route is convenient to use and avoids vaginal application and comfortable to the patients.

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