ISSN Print: 2394-7500
ISSN Online: 2394-5869
Impact Factor: 5.2
IJAR 2018; 4(11): 83-86
www.allresearchjournal.com
Received: 11-09-2018
Accepted: 15-10-2018

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Comparison of sublingual and vaginal misoprostol on cervical priming prior to vacuum aspiration in first trimester abortion at tertiary care hospital

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Abstract
Background: world-wide more than 40 million abortions are occurred each year, more than two third of these abortions occur during the first trimester of pregnancy. Vacuum aspiration is the method of choice for the first trimester abortions and is one of the commonly performed surgical procedures. Cervical priming prior to vacuum aspiration facilitates the procedure, decreases the risk of cervical injury and uterine perforation by making the cervix softer and easier to dilate.
Objective: To compare the efficacy and side effects of sublingual and vaginal misoprostol on cervical priming prior to vacuum aspiration in first trimester abortions.
Material & Methods: It was a hospital based prospective randomised trial. A total of 160 pregnant women between 6-13 weeks of gestation who opted for termination of pregnancy either because of failed contraception, USG findings suggestive of missed abortion or blighted ovum were taken into study & divided into sublingual and vaginal group. Single dose of 400micrograms of misoprostol was administered either sublingual or vaginal route 3-4 hours before the procedure.
The outcome measures compared were cervical dilatation before vacuum aspiration, duration of the procedure, intraoperative blood loss and preoperative side effects.
Results: The mean cervical dilatation of subjects in the sublingual group was significantly higher than the vaginal group (6.9 $\pm$ 2.12 mm vs 4.96 $\pm$ 1.4 mm, p= 0-002). The mean duration of the procedure was significantly lower compared to the vaginal group (2.62 $\pm$ 0.84mt Vs 3.17 $\pm$ 0.74mt, p=0.001). The intra operative blood loss was slightly higher in the sublingual group compared to the vaginal group (40.61 $\pm$ 5.1 ml Vs 32.84 $\pm$ 6.04 ml) but the difference was statistically not significant (p=0.68). The preoperative side effects like vomiting, abdominal pain, fever, diarrhoea and rigours were less in the sublingual group compared to vaginal group.
Conclusion: Sublingual misoprostol is more effective with good patient acceptability than vaginal misoprostol for cervical priming prior to vacuum aspiration in first trimester abortions.

Keywords: misoprostol, first trimester abortion, sublingual, vaginal, cervical priming, vacuum aspiration

Introduction
An abortion is termination of pregnancy either spontaneously or intentionally before the foetus reaches the period of viability. More than one third of pregnancies are unplanned and about 20% of them end in induced abortions. Worldwide more than 40 million abortions are occurred each year more than two third of these abortions occur during the first trimester of pregnancy. Unsafe abortion is the cause of significant maternal mortality and morbidity in developing countries and account for up to 20% of maternal deaths [2]. In India despite liberalization of rules for performing medical termination of pregnancy, illegal abortions still contribute significantly to maternal morbidity and mortality. Surgical abortion using vacuum aspiration following dilatation of the cervix is the method of choice for first trimester induced abortion [3]. Cervical dilatation is the most critical step in vacuum aspiration and complications like perforation of the uterus, haemorrhage, cervical incompetence, sepsis etc occurred following forceful cervical dilatation [1].
Cervical priming prior to vacuum aspiration facilitates the procedure, decreases the risk of cervical injury and facilitates the procedure. The pharmacological agents most commonly used for cervical priming are the Prostaglandins and the most important effect of prostaglandins is uterine contraction and cervical ripening [4].

Drugs like PGE_2 gel, gemeprost and laminaria tents were used previously for cervical priming. But nowadays misoprostol (PGE1) has become the most popular drug for cervical ripening before vacuum aspiration. It is initially developed for the treatment of peptic ulcer and is manufactured as tablets of 200mcg and 400mcg [5]. Misoprostol is commonly used for various procedures like termination of pregnancy, induction of labour and prevention of postpartum haemorrhage [6]. It has the advantage of easy bioavailability, ease of administration, lower cost, stability at room temperature, and fewer systemic side effects. Misoprostol can be taken either orally, bucally, sublingually, rectally and vaginally. It is commonly administered vaginally for the induction of labour or cervical priming, but majority of misoprostol is not dissolved even after several hours of vaginal administration. Most women preferred to take the misoprostol either orally or sublingually in order to avoid the uncomfortable vaginal route which needs more privacy.

Sublingual route of misoprostol administration is a new one. It has the quickest onset of action, achieves highest plasma concentration, has highest systemic bioavailability, is most potent and above all has excellent patient compliance [7].

It avoids the first pass metabolism in the liver seen with the oral route and the need of other person to insert for the vaginal route.

Aim is to conduct a study among pregnant women between 6-13 weeks of gestation undergoing first trimester surgical termination of pregnancy.

Objectives

1. To compare the efficacy and acceptability of sublingual and vaginal routes of 400mcg misoprostol on cervical priming prior to vacuum aspiration in first trimester.
2. To know the severity of side effects such as abdominal pain, bleeding per vagina, vomitings, diarrhoea, rigors and fever (experienced by the patient).

Study Design: It is prospective randomized controlled study

Materials and Methods

The study was conducted in the Apollo Medical College and Hospital Chittoor for a period of one year among pregnant women between 6-13 weeks of gestation undergoing first trimester termination of pregnancy.

The study was approved by institutional ethics committee.

Inclusion criteria

1. Pregnant women between 6-13 weeks gestation with failed contraception
2. USG findings suggestive of missed abortion or blighted ovum [8, 9].

Exclusion criteria

1. Women with heart disease
2. Women with history of bronchial asthama
3. Women with known allergy to prostaglandins
4. Women with uterine anomaly
5. Women with haemoglobin < 9 gm/dl

160 pregnant women between 6-13 weeks of gestation who fulfilled the eligibility criteria were taken into study. After informed consent patients were randomized into sublingual and vaginal groups based on a randomization chart. The codes given were 'S' for those receiving sublingual misoprostol and 'V' for those receiving vaginal misoprostol.

The women were admitted either as night or on the morning of the procedure. Detailed history with complete physical and obstetric examination was done. Routine investigations like blood group, haemoglobin estimation, bleeding time, clotting time and urine analysis was done. After clinical examination gestational age of the patient was confirmed by ultrasonography.

The women were given 400 mcg misoprostol either vaginally or sublingually 3-4 hr before the procedure based on the randomization chart.

The baseline pulse rate, blood pressure and temperature recorded. The severity of other side effects associated misoprostol like pain abdomen, fever, vomiting, diarrhoea and rigors were noted.

The procedure was carried out 3-4 hr after after administration of misoprostol by vacuum aspiration under intravenous sedation. The primary outcomes measured were cervical dilatation, duration of the procedure, degree of cervical ripening and intraoperative blood loss.

The dilatation of cervix was measured by passing Hegars dilators ascending order starting from number 6 to number 12 and size of the largest dilator that was passed without any resistance was noted [2]. The time taken for the procedure was measured from the start of dilatation of cervical os to complete evacuation of uterus as suggested by no products of conception coming from the cervix, the intraoperative blood loss was assessed by the cylinder in the suction apparatus, the women were kept in the hospital for observation for 6-8hrs. The women who experienced severe abdominal pain, fever, vomiting, diarrhoea were treated with analgesics, anti-emetics and intravenous fluids.

The women were assessed for the efficacy, acceptability and side effects of vaginal and sublingual route of misoprostol.

Table 1: Demographic Profile

	Vaginal (mean ± 2D)	**Sublingual (mean ± 2D)**	**P Value**
Age	25.18 ± 5.19	27.08 ± 4.19	0.694 (ns)
Gravida	2.84 ± 0.17	3.13 ± 0.18	0.72 (ns)
Parity	2.14 ± 0.12	2.18 ± 0.11	0.8 (ns)
Gestational Age	8.45 ± 1.07	7.99 ± 1.89	0.626 (ns)

Table 2: Clinical profile of the parcipants

S. No	**Vaginal (mean ± 2SD)**	**Subligual (mean ± 2SD)**	**P Value**
1.Respiratory Rate	18.18 ± 1.19	24.18 ± 2.19	0.694 (ns)
2.Systolic BP (mm of hg)	118.29 ± 8.07	120.01 ± 6.10	0.087 (ns)
3.Diastolic BP (mm of hg)	70.05 ± 9.57	75. 81 ± 8.16	0.075 (ns)
4.Pulse Rate	81.45 ± 8.97	89.05 ± 9.57	0.0087 (s)
	Vaginal (mean + 2D)	Sublingual (mean + 2D)	P Value

1. Priming To Abortion Interval	2.39 + 0.19	2.18 + 0.12	0.894 (ns)
2. Cervical Ripening	75 %	78 %	
3. Duration For Cervical Ripening (min)	4.78 ± 1.84	3.61 ± 1.27	0.71 (ns)
4. Duration Of The Procedure	3.17 ± 0.74	2.62 ± 0.84	0.68 (ns)
5. Blood Loss (ml)	40.61 ± 5.1	32.84 ± 6.04	
6. Cervical Dilatation (mm)	4.96 ± 1.84	6.98 ± 2.12	0.002 (s)

Results

Table 1: summarises the characteristics of women recruited into the vaginal and sub lingual groups. There was no significant difference between the age, gravida, parity and gestational age at the time of termination of pregnancy between the two groups.

Table 2 summarises the baseline parameters like blood pressure, respiratory rate and pulse rate between the two groups, the pulse rate was higher in women of sublingual group compared to vaginal group [89.45 ± 8.97 vs 81.05 ± 9.57 P=0.0087] which was statistically significant. The increased pulse rate is due to severe pain and bleeding experienced by the women in sublingual group.

The priming to abortion interval is less in sublingual group [2.39+0.19min vs 2.18+0.12min].

The degree of cervical ripening was more in sublingual group compared to vaginal group [75% vs 78%], but it was statistically not significant.

The duration for cervical ripening was slightly less in sublingual group [3.61±1.27min vs 4.78±1.84] but the blood loss in sublingual group was slightly more compared to women in the vaginal group; [40.61±5.1ml vs 32.84±6.04ml P=0.68]. The mean cervical dilatation in the sublingual group was higher compared to the vaginal group; [6.98±2.12mm vs 4.96±1.84mm; P=0.002] which was statistically significant.

In the present study, the preoperative side effects were more in the sublingual group compared to the vaginal group such as pain [93% vs 76%], bleeding [55% vs 38%], vomiting's [105 vs 7%], and rigors [63% vs 2%]. None of these subjects in the vaginal group experienced diarrhoea and fever was experienced by one woman in each group. But the difference of side effects in both the groups was statistically not significant.

Serious complications requiring further hospital admission was not occurred in both the groups. Out of the total 80 women in vaginal group, the tablet was partially absorbed in 24[30%] women, while the tablet was completely absorbed in 5-10min in all the women of sublingual group.

The women in the sublingual group does not complain any unpleasant taste of the drug and A.

Side Effects	Vaginal		Sublingual	
	No	%	No	%
Bleeding	33	38	42	55
Vomiting	9	10	5	7
Pain	67	76	71	93
Diarrhoea	0	0	3	4
Fever	1	1	1	1
Rigors	2	2	48	63

Discussion

In the present study the subjects in the sublingual group had more cervical ripening and dilatation compared to the vaginal group. This can be explained by the different pharmacokinetic and more systemic bioavailability of misoprostol in the sublingual group than the vaginal group. Similar results were observed in a study by saxena *et al* and parveen *et al* and vimala *et al*. [10].

The duration of the procedure in the sublingual group was less compared to the vaginal group. The observed difference can be attributed to more cervical ripening and dilatation achieved in the sublingual group. Similar findings were reported in a study conducted by saxena *et al* and parveen *et al* and vimala *et al*. and carbonell *et al*. [10, 11].

In the present study the subjects in the sublingual group have more intraoperative blood loss compared to vaginal group but none of them required blood transfusion, which was not significant. Similar results were observed in the study conducted by parveen *et al*. and Tang *et al*.

The incidence of pre operative side effects were more in the sublingual group compared to the vaginal group. Abdominal pain was most common [93%] followed by rigors [63%], bleeding, vomiting and diarrhoea.

The higher bioavailability of misoprostol is mainly responsible for the increased incidence of the preoperative side effects in the sublingual group but statistically no significant difference was found between the two groups. Similar results were found in a study conducted by Parneeth kaur *et al* and Manjeeth kaur *et al*. [2]

Sublingual route of misoprostol is more effective and favourable for cervical priming than oral and vaginal routes in first trimester termination of pregnancy [3]. None of the patients in the present study complained unpleasant taste of misoprostol in the sublingual group.

In a study conducted by Fateen *et al*. sublingual misoprostol was more convenient and as effective as vaginal misoprostol to induce cervical priming with good patient acceptability.

Conclusion

The sublingual route of misoprostol was more convenient and effective than vaginal misoprostol on cervical priming in first trimester abortion. It also as good patient acceptability with decreased operative time. However there was no significant difference in the side effects experienced by the subjects between the sublingual and vaginal group.

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