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Comparison of Sublingual and Vaginal Misoprostol in Cervical Ripening for First Trimester Abortion

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Original Research Article

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Abstract: To compare the effectiveness and tolerability of misoprostol as a cervical ripening agent in first trimester abortion through sublingual and vaginal administrations of administration before suction evacuation (SE). It was a hospital based comparative study. A total of 100 randomly selected married women were equally divided in two groups for sublingual (S/L) and vaginal and oral 400 *mc*g of misoprostol single dose administration. The drug was administered 3 hours before SE. Efficacy was assessed on the basis of dilatation achieved, duration of the procedure, intra-operative blood loss. The tolerability was noted on the basis of side effects. Statistical analysis: Mean standard deviation for descriptive analysis and Z test and Chi Square test as test of significance. The cervical dilatation in S/L and vaginal group was comparable. Total duration of the procedure in S/L group was significantly less than vaginal group ($p < .0.05$). The mean intra-operative blood loss was more in vaginal as compared to the S/L group ($p < 0.01$). Abdominal pain and nausea, episodes of chills were more common with the S/L group than vaginal group. Administration of misoprostol by the sublingual administration is better than vaginal administrations for cervical ripening only disadvantage is that sublingual administration has more side effects.

Keywords: Cervical ripening, first trimester abortion, misoprostol, sublingual, vaginal, comparison

INTRODUCTION

Abortion is the termination of pregnancy, either spontaneously or intentionally, before the fetus develops sufficiently to survive ex utero. By convention, abortion is usually defined as pregnancy termination prior to 20 weeks gestation or less than 500 gm birth weight [1]. According to WHO, 80,000 women die annually due to unsafe abortions. Almost one-fifth of worldwide abortions take place in India. Maternal mortality attributable to abortions in India is 12-18% and is mostly contributed by illegal abortions [2].

Various methods e.g. medical and surgical are in use for MTP. Surgical method like suction evacuation is a commonly performed procedure and the method of choice in 1st trimester MTP. Cervical ripening is beneficial prior to suction evacuation (SE). Cervical softening and dilatation prior to surgical termination of pregnancy, reduces the risk of cervical injury, uterine perforation, hemorrhage and incomplete uterine evacuation. It also shortens the suction evacuation procedure. Various methods medical and surgical are in use for the same.

Misoprostol (a prostaglandin E1 analogue) is an important agent used for cervical ripening. It has several potential advantages such as it is stable at room temperature, it is relatively inexpensive and it can be given via several administrations such as oral, vaginal,

sublingual, buccal. These properties make misoprostol an ideal agent for induction of labour, particularly in settings where the use of prostaglandin E2 is not possible owing to lack of availability, facilities for storage, or financial constraints [3]. Vaginal administration is more effective than oral administration. Sublingual administration is a relatively new one. Misoprostol tablet is put under the tongue; it dissolves within 10-15 minutes. We carried out a study of sublingual administration of administration of misoprostol in comparison with vaginal administration for cervical ripening prior to suction evacuation in 1st trimester MTP. We primarily compared degree of cervical dilatation at the end of 3 hours, time duration taken for suction evacuation, intra-operative blood loss and incidence of associated side effects.

MATERIAL AND METHODS

This study was carried out at tertiary care hospital in North Maharashtra region of India. Randomly selected pregnant women up to 12 weeks of gestation who opted for surgical termination of pregnancy and who had given written informed consent were included in the study.

Inclusion criteria

- Age group 18-35 years
- Gestational age less than or equal to 13 weeks, confirmed by a) Last menstrual period, b) Urine pregnancy test, c) Pre-vaginal examination and by all or one of other method along with per vaginal examination, d) Ultrasonography

Exclusion criteria

- Patients with known hypersensitivity to misoprostol
- Patients below 18 and above 35 years
- Patients who had not given written informed consent

Intervention in details

The patients were randomly categorized into two groups by lottery method to receive either sublingual or vaginal misoprostol for cervical ripening prior to suction evacuation in 1st trimester MTP. Out of total sample, 50% study participants were selected for Sublingual misprostol and 50 % for Intravaginal misoprostol. 50 % patients were given 400 mcg of misoprostol sublingually and 50% patients were inserted 400 mcg of misoprostol in the posterior fornix of the vagina.

Pre-operative vital signs – pulse rate, respiratory rate, blood pressure, temperature and side effects like vaginal bleeding, nausea, vomiting, diarrhea, fever >38^0 C, chills and abdominal pain were recorded. After 3 hours of administration of the drug, suction evacuation was performed under intravenous analgesia (short general anaesthesia) or spinal anaesthesia if patient underwent tubectomy at the same sitting.

STATISTICAL ANALYSIS

Mean, standard deviation used for descriptive analysis. Z test and chi square test was used as test of significance.

Ethical considerations

The study was conducted according to the Declaration of Helsinki, the protocol was reviewed and approved by the independent ethics committee. Written informed consent was obtained.

RESULTS

A total of 100 patients who fulfilled the inclusion criteria were included for the study. Out of these, 50 patients received 400 mcg Misoprostol sublingually and 50 patients received 400 mcg Misoprostol vaginally. The participants in both the groups did not differ significantly in their demographic characters.

The mean age of the participants in the sublingual group was 24.46 years (SD=4.272 years) and in vaginal group it was 25.12 years (SD=4.87 years). This difference was not statistically significant. The mean parity in the sublingual group was 1.18 (SD=1.13) and in vaginal group it was 1.52 (SD=1.38) the difference being statistically insignificant. In both the groups majority of the patients were between 22 – 26 years of age. 17 cases (34 %) in the sublingual group and 8 cases (16 %) in the vaginal misoprostol group were primigravida.

Table–1: Comparison of Important Parameters

Parameters	Sublingual (n = 50) (Mean ± SD)	Vaginal (n = 50) (Mean ± SD)	'P' Value	Z value
Mean cervical dilation (mm)	7.91 ± 1.324	7.25 ± 2.09	> 0.05	0.19
Average time required for procedure (min)	8 ± 2.063	8.84 ± 2.015	< 0.05	2.0
Blood loss (ml)	40.92 ± 11.14	50.66 ± 12.133	< 0.01	4.44

The mean cervical dilatation achieved with sublingual misoprostol was 7.91 mm (SD=1.32 mm) and in vaginal group was 7.25 mm (SD=2.09 mm). This difference was not statistically significant (P > 0.05).

The average time required for suction evacuation procedure was 8 minute with standard deviation of 2.06 minutes in sublingual group while it was 8.84 minutes with standard group deviation of 2.0 minutes in vaginal group. This difference was significant at 95% level of significance. (P < 0.05)

The mean blood loss during the procedure in case of sublingual misoprostol was 40.32 ml with standard deviation of 11.14 ml, while it was 50.66 ml with standard deviation of 12.13 ml in case of vaginal group. This difference was statistically significant at 99% level of significance. (P < 0.01)

Table–2: Comparison of Side effects

Side effects	Sublingual n = 50 (n = %)	Vaginal n = 50 (n = %)	'P' Value	Chi-square test
Abdominal pain	15 (30)	5 (10)	< 0.05	$\chi^2 = 6.250$
Nausea	17 (34)	7 (14)	< 0.05	$\chi^2 = 5.482$
Vomiting	4 (8)	3 (6)	> 0.05	$\chi^2 = 0.154$
Chills / Shivering	20 (40)	4 (8)	< 0.01	$\chi^2 = 14.035$
Bleeding	14 (28)	10 (20)	> 0.05	$\chi^2 = 0.877$
Fever	2 (4)	2 (4)	> 0.05	$\chi^2 = 0.000$

The incidence of nausea and abdominal pain was significantly higher in sublingual group as compared to vaginal group (p < 0.05) this significant difference was found at 95% level of significance.

Chills or shivering was a frequent side effect noted in 40% of participants in sublingual group, whereas only 8% of those in vaginal group. This difference was statistically significant at 99% level of significance.

Other side effects observed were fever, diarrhea which was found to be similar in both the groups No complications like uterine perforation, cervical injury or excessive hemorrhage were seen during the present study.

DISCUSSION

Suction evacuation is a commonly performed procedure for termination of pregnancy in the first trimester. Cervical ripening is beneficial prior to suction evacuation. It reduces the risk of cervical injury, uterine perforation, excessive hemorrhage and incomplete evacuation. It also shortens the evacuation procedures. Various methods like osmotic cervical dilators, prostaglandis, antiprogesterone and antimetabolites are used for cervical ripening[4,5].

Misoprostol a prostaglandin E_1 analogue is one of the few drugs whose use has been taken up very enthusiastically by obstetricians as it is the PG of choice as it is cheap and stable at room temperature and available in different dosage forms.

This study was undertaken to compare sublingual and vaginal misoprostol in cervical ripening prior to suction evacuation in 1st trimester MTP. This study observed that total duration of the procedure in S/L group was significantly less than vaginal group (p <.0.05). The mean intra-operative blood loss was more in vaginal as compared to the S/L group, however there was no difference in the mean cervical dilatation.

The results of present study are comparable with two similar studies by Tang O S *et al.* [6] and Vimala N *et al*, [7] The difference in the mean cervical dilatation (in mm) achieved with sublingual and vaginal misoprostol was not statistically significant in our study and that of Tang O S *et al*. [6] But this difference was significant in the study of Vimala N *et al*, [4]. In the study by Vimala N *et al*. [7] the difference in the average time taken for suction evacuation procedure was not statistically significant between the sublingual and vaginal misoprostol groups. But in the present study, this difference was statistically significant. The difference in the mean blood loss between the sublingual and vaginal misoprostol group was not significant in the studies by Tang O S *et al*. and Vimala N *et al*. But in the present study the difference in the mean blood loss in both the groups was statistically significant. Saxena P *et al* .compared sublingual administration with oral as well vaginal administration

of misoprostol and. concluded that Sublingual administration was significantly more effective than oral or vaginal administration of misoprostol for cervical dilatation [8]. Parveen *et al*. compared effectiveness and tolerability of misoprostol as a cervical ripening agent in first trimester abortion through three different administrations of administration before surgical evacuation. They concluded that Administration of misoprostol by the sublingual administration is better than the oral and vaginal administrations for cervical ripening [9].

CONCLUSION

The present study concluded that sublingual administration of misoprostol is better that vaginal administration in terms of time duration required for the procedure. Sublingual administration is also associated with less blood loss compared to vaginal administration. Only disadvantage is that sublingual administration has more side effects. Larger studies on Indian population are recommended.

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