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Original Research Article

Efficacy of 25 mcg sublingual versus vaginal misoprostol for induction of labor

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ABSTRACT

Background: Currently, to decrease the incidence of contractility disturbances and neonatal complications, 25 mcg of vaginal misoprostol is recommended for induction of labor. American College of Obstetrics and Gynecology suggested 25 mcg every 4-6 hourly by vaginal route. But till date, there is no consensus either for route or dosage. The present study was to compare the efficacy and suitability of low dose (25 µg) sublingual misoprostol for induction of labor in term pregnancy as compared with the same dose given vaginally.
Methods: This was a hospital based unblinded randomized prospective study conducted in the Department of Obstetrics and Gynecology in collaboration with the Department of Pediatrics, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh from February 2015 to November 2016.The study involved pregnant women attending O.P.D. or admitted in the labor room. Patients were randomly allocated into two groups: Group 1 received 25 mcg of misoprostol sublingually and Group 2 received 25 mcg of misoprostol 4 hourly vaginally to a maximum of 5 doses. Maternal and neonatal outcomes were analysed.
Results: There is no difference between groups for indications for induction of labor, mean induction to the onset of contraction interval and mean interval from the initiation of induction to the delivery. No significant difference in indication for caesarean section and number of doses. No significant differences in neonatal outcomes.
Conclusions: 25µg misoprostol administered by sublingual route is equally efficacious as by vaginal route for induction of labor at term.

Keywords: Efficacy, Induction of labour, Misoprostol, Maternal and perinatal outcome, Pregnancy, Sublingual Misoprostol, Vaginal

INTRODUCTION

Induction of labor is a technique of stimulating uterine contraction prior to the onset of labor to achieve vaginal delivery.

It is an important and common procedure in obstetrics. In developed countries, 25% of deliveries occur after induction.[1] PGE1 analogue, misoprostol, is being used for induction of labor for more than two decades. It was first used in 1992 by Margulies et al who used 50 mcg misoprostol for induction of labor.[2]

More trials were done (Caliskan, Bartusevicius, Nassar and Zahran), but still no consensus has reached regarding route and optimal dosage.[3-6]

Research is being conducted to find the better route and ideal dose.

Currently, to decrease the incidence of contractility disturbances and neonatal complications, 25 mcg of vaginal misoprostol is recommended for induction of labor. Filho et al, Feitosa et al, Siwatch et al, Ayati et al and Jahromi et al compared the 25-mcg misoprostol sublingual with the vaginal route.[7-11] It is associated with decreased incidence of uterine hyperstimulation and neonatal acidosis. ACOG suggested 25 mcg every 4-6 hourly by vaginal route. But till date, there is no consensus either for route or dosage. The present study was to compare the efficacy and suitability of low dose (25 μg) sublingual misoprostol for induction of labor in term pregnancy with live foetus as compared with the same dose given vaginally.

METHODS

The aim of the study was to compare effectiveness and safety of two routes of administration (sublingual and vaginal) and to know the perinatal outcome with both routes. This hospital based unblinded randomized prospective study was conducted in the Department of Obstetrics and Gynecology in collaboration with the Department of Pediatrics, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh from February 2015 to November 2016.

The study involved pregnant women attending Obstetrics and Gynecology O.P.D. or admitted in the labor room of J.N. Medical College.

Inclusion criteria

- Singleton pregnancy
- Gestational age of 37 weeks or greater
- Live fetus,
- Cephalic presentation
- Bishop Score 6 or less
- Baby weight less than 4.

Exclusion criteria

- IUGR
- Uterine scarring
- Contraindications to vaginal delivery
- Genital herpes
- Fetal malformations
- Antepartum hemorrhage
- Any medical disorder such as cardiac disease, glaucoma, convulsive disorder, asthma, severe anemia, severe renal and hepatic failure, clinically suspected chorioamnionitis, known hypersensitivity to prostaglandin
- Any oral pathology and acid peptic disorder.

Ethical clearance was sought from Institutional Ethics Committee of Jawaharlal Nehru Medical College, Aligarh. Patient attending ANC, OPD and labour room of the Department of Obstetrics and Gynecology were subjected to a detailed history of present pregnancy, obstetrical history, past medical and surgical history. A general physical examination and an obstetrical examination were done to ascertain fundal height, lie and presentation of fetus and Bishops score. Gestational Age will be confirmed by LMP or USG measurement at less than 20 weeks or documentation of 30 weeks of fetal heart tones by Doppler USG or passage of 36 weeks since positive urine β-HCG. An informed consent was taken from subjects willing to participate in the study. They were randomly allocated into two groups: Group 1: received 25 mcg of misoprostol sublingually 4 hourly up to a maximum of 5 doses. Group 2: received 25 mcg of misoprostol 4 hourly vaginally to a maximum of 5 doses.

A sample size of approximately 100 in each group was calculated. A vaginal examination was performed to assess the Bishop score followed by administration of 25 mcg of misoprostol, sublingually in group 1 and vaginally in group 2. In sublingual group, the tablet was placed under the tongue. In vaginal group, the tablet was inserted into posterior fornix of the vagina. In both groups, administration of misoprostol was repeated every 4 hours until regular uterine contractions were achieved, or woman had received a total of 5 doses.

Administration of misoprostol was also stopped when there was a need for obstetric intervention. The uterine contraction was monitored by palpation and fetal heart rate was monitored by intermittent auscultation as per labor room protocol. Cardiotocographic tracing was performed according to availability, possibility and at the discretion of attending obstetrician. The uterine activity was clinically assessed every 30 minutes. Once in the active phase, the patient was managed as per protocol of labor room. If the patient remained undelivered after 24 hours of the last dose, then the decision about further management was as per clinical in-charge. If the uterine contractions were inadequate, oxytocin was used for augmentation of labor.

The women were monitored for nausea, vomiting, uterine contraction, uterine hypertonus, hyperstimulation, tachysystole. The progress of labor was recorded using a partograph. Primary outcome was to know the percentage of women going into labor within 24 hours and having a successful induction. Secondary outcomes were to calculate total number of doses of 25 mcg misoprostol required by either route and induction delivery interval, the percentage of women not delivered within 24 hours, rate of uterine contraction abnormalities, side effects/adverse events, percentage of fetal distress (meconium stained liquor or fetal heart abnormality), Apgar score and admission in NICU and its indication. Statistical analysis was done to investigate the difference between two groups by using mean, standard deviation, Chi-square test, Student t-test and paired t-test by SPSS software (version 23.0). Intention to treat analysis was done. A significance level of 5% was adopted. 95% confidence interval (CI 95%) was calculated to assess the

magnitude of the association between outcomes and studied parameters

RESULTS

A total of 234 patients were enrolled in the study who were randomly allocated into two groups to receive either 25µg misoprostol by sublingual route (Group A) or 25µg misoprostol by vaginal route (Group B) 4 hourly up to a maximum of 5 doses

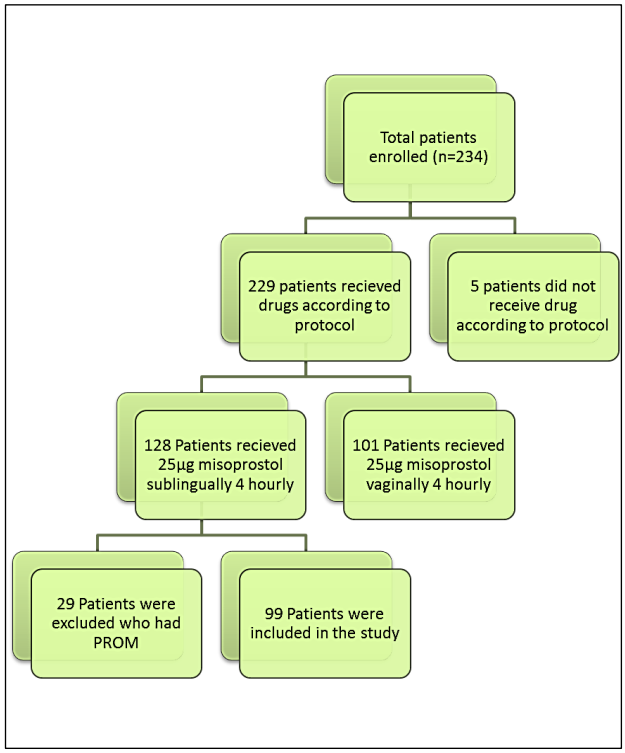

Figure 1: No. of patients in each group included and excluded.

In the present study, the percentage of primigravida was 44.4% in sublingual and 43.6% vaginal group. The percentage of multigravida was 55.6% in sublingual and 56.4% in vaginal group and the difference was not statistically significant (p-value = 0.900). The average parity in the sublingual group was 1.207±.121 and vaginal group was 1.3±0.129 but this difference was not statistically significant (p value=0.652). The mean gestational age in the sublingual group was 39.639±1.233 weeks and in the vaginal group was 39.667±1.394 weeks and the difference were not statistically significant (p-value= 0.880).

In the present study, the two most common indications for induction were post-dated pregnancy and pregnancy induced hypertension. Other indications were cholestasis of pregnancy, gestational diabetes mellitus and oligohydramnios. The maximum number of cases in both the groups had a pre-induction Bishop Score (PIBS) of ≥4 with 80.8% cases in sublingual group and 78.2% cases in vaginal group. The mean PIBS in sublingual group was 4.242±0.858 and in vaginal group was 4.139±1.029 and this was not statistically significant (p= 0.440). In the present study, we have reported the improvement in Bishop Score after 4 hours of administration of the first dose of misoprostol. The mean induction to the onset of contraction interval was 4 hours 22 minutes±3 hours 44 minutes (262.732±224.844 minutes) in sublingual group and 4 hours 32 minutes±4 hours 16 minutes (272.129±256.791minutes) in vaginal group. Statistically, the difference is insignificant (p=0.785). The mean interval from the initiation of induction to the delivery in sublingual group was 13 hours 30 minutes±8 hours 56 min (810.202±536.588 minutes) and in vaginal group was 14 hours 2 minutes±9 hours 1 minutes (842.426±541.406 minutes) and this difference is statistically insignificant (p value= 0.673). 94.6% women in sublingual group and 98.4% women in vaginal group delivered vaginally within 24 hours of induction while 5.4% in sublingual group and 1.6% in vaginal group delivered vaginally after 24 hours of induction. This difference was statistically insignificant (p-value=0.228). In the present study, uterine contraction abnormalities were not found in any of the patients in the sublingual group while tachysystole was found in 1 (1%) of the women in vaginal group. Mainly two maternal complications were found in our study – nausea and vomiting. In sublingual group, nausea was not seen while the incidence of vomiting was only 2%. In vaginal group, the incidence of nausea was 1.9% and that of vomiting was 1.9%. The statistical significance could not be calculated as the values were too small.

Table 1: Demographic profile of two groups.

Characteristics	Group A (25µg sublingual) N=99	Group B (25µg vaginal) N=101	P-value
Mean age (years)	24.242	24.861	0.217
Mean height (cm)	152.253	151.74	0.451
Mean weight (kg)	62.712	63.832	0.169
Average parity	1.207	1.3	0.652
Mean haemoglobin (gm%)	10.145	10.224	0.603
Mean gestational age (weeks)	39.639	39.667	0.880
Primipara	44 (44.4%)	44 (43.6%)	1.0
Multipara	55 (55.6%)	57 (56.4%)	0.631
Booked cases	93 (93.9%)	88 (87.1%)	0.710
Unbooked cases	6 (6.1%)	13 (12.9%)	0.108

The mean neonatal birth weight in the sublingual group was 2957.25± 457.56 grams and in the vaginal group, it was 2885±489.94 grams in our study. Both the groups were comparable and there was no statistical difference between the neonatal weight in both the groups (p-value=0.285). The percentage of new-borns getting admitted in NICU was equal in both the groups. The difference was statistically insignificant (p= 0.977).

Table 2: Maternal outcome.

Outcome	Group A (25µg sublingual)	Group B (25 µg vaginal)	P-value
Indication of induction (n)	99	101	
Post-dated	55 (55.6%)	54 (53.5%)	0.924
PIH	20 (20.2%)	27 (26.7%)	0.307
Cholestasis	19 (19.2%)	13 (12.9%)	0.289
GDM	1 (1%)	4 (4%)	0.180
Oligohydramnios	4 (4%)	3 (3%)	0.705
Mean pre-induction Bishop score	4.242	4.139	0.440
Mean change In BS (4 hours)	4.61	4.35	0.111
Mean induction to onset of contraction interval (minutes)	262.732	272.129	0.785
Mean induction to delivery interval (minutes)	810.202	842.426	0.673
Mean number of doses of Misoprostol	2.525	2.446	0.683
Mode of delivery(n)	99	101	
Vaginal	74 (74.7%)	64 (63.4%)	0.395
Cesarean	25 (25.3%)	37 (36.6%)	0.128
Vaginal deliveries <24 hours	70 (94.6%)	63 (98.4%)	0.544
Vaginal deliveries >24 hours	4 (5.4%)	1 (1.6%)	0.180
Caesarean indications(n)	25	37	
Foetal distress	21 (84%)	27 (72.9%)	0.386
Non-reassuring CTG	2 (8%)	3 (8%)	0.655
Non-progress of labor	0 (0%)	5 (13.5%)	can't be calculated
Failed induction	1 (4%)	1 (2.7%)	1.0
Deep transverse arrest	1 (4%)	1 (2.7%)	1.0
Number of doses	99	101	
1	32 (32.3%)	32 (31.7%)	1.0
2	23 (23.2%)	27 (26.7%)	0.572
3	18 (18.2%)	17 (16.8%)	0.866
4	12 (12.1%)	15 (14.9%)	0.564
5	14 (14.1%)	10 (9.9%)	0.414
Oxytocin requirement	19 (19.2%)	16 (15.8%)	0.612
Meconium stained liquor	18 (18.2%)	11 (10.9%)	0.194
Maternal complications			
Nausea	0 (0%)	2 (1.9%)	can't be calculated
Vomiting	2 (2%)	2 (1.9%)	1.0

Table 3: Neonatal outcome.

Outcome	Group A (25µg sublingual)	Group B (25µg vaginal)	P-value
Mean birth weight	2957.25	2885.36	0.285
APGAR score at 1 minute			
≤7	69 (69.7%)	77 (76.2%)	0.508
>7	30 (30.3%)	24 (23.8%)	0.414
Mean	7.09	6.93	0.282
APGAR score at 5 minutes			
≤7	8 (8.1%)	11 (10.9%)	0.491
>7	91 (91.9%)	90 (89.1%)	0.941
Mean	8.22	8.10	0.257
NICU admission	4 (4%)	4 (4%)	1.0

The various indications for NICU admission were respiratory distress syndrome (RDS), meconium aspiration syndrome (MAS), sepsis and hypoxic ischemic encephalopathy (HIE). In sublingual group, 2% were admitted in NICU for MAS and 1% were admitted each for sepsis and HIE. In vaginal group, 2% were admitted each for RDS and sepsis. RDS was seen in the neonates of the patients who were induced for PIH at 37 weeks

while MAS was seen in patients who were induced for post-dated pregnancy. So, these complications may be due to the problem in mothers and not due to the misoprostol. Five of the neonates admitted expired, in which 3 neonates were of vaginal group and 2 were of sublingual group. The cause of mortality in neonates was sepsis in 60% (n=3), out of which two-third (n=2) mortality occurred in vaginal group and one-third (n=1) in sublingual group. One neonate (20%) expired due to meconium aspiration syndrome in sublingual group. The patient was induced for postdatism. One neonate (20%) expired because of RDS in vaginal group. The patient was induced for PIH.

DISCUSSION

Several studies have been conducted to achieve the ideal dose and route of administration of misoprostol for induction of labor. But there has been no standardization of the best and safest dose and route of administration for labor induction till now. There are only 5 studies which have compared 25 µg Misoprostol by sublingual and vaginal route. Only three out of these five studies followed the 4 hourly schedules as ours. These are Siwatch et al, Ayati et al and Jahromi et al.[9-11] The average parity was found comparable to the study of Ayati et al. Other studies did not calculate average parity. The mean gestational age is almost similar to the study of Ayati et al. The present study is found similar to Ayati et al, where maximum inductions were done for postterm pregnancy.[10] Only a few cases were oligohydramnios and PIH. In Siwatch et al, maximum inductions were done for pregnancy induced hypertension followed by post-dated pregnancy.[9] Jahromi et al have not mentioned the indication for induction but they excluded women with hypertension, diabetes and oligohydramnios from their study.[11]

In Siwatch et al mean PIBS was 3.14±0.838 in sublingual group and 3.04±0.892 in vaginal group which was lower than the present study which could be due to the reason that induction was done at a lower gestational age than ours.[9] In Ayati et al mean PIBS in sublingual group was 3.47±1.68 and 2.72±1.32 in vaginal group which was lower than the present study.[10] In Jahromi et al mean pre-induction Bishop Score was 4.84±1.50 in sublingual and 4.78±1.54 in vaginal group which was more than the present study which could be due to a greater gestational age when the patient was induced.[11] The mean induction to contraction interval is not mentioned in previous studies except that of Filho et al, where it was found to be 17 hours 10 minutes in sublingual group and 14 hours 2 minutes in vaginal group which is higher than the present study.[7] This could be due to the reason that the dose of misoprostol was repeated 6 hourly. Present study is similar to the study of Siwatch et al, the mean induction to delivery interval in sublingual group was 15.25±5.03 hours and in vaginal group was a 16.17±5.96 hours which is almost similar to the present study.[9] In Ayati et al, mean interval from induction to delivery is less than the present study.[10] This may be due to the fact that they have used a maximum of 6 doses instead of 5 doses. The mean induction to delivery interval was much lower in the study of Jahromi et al due to the reason that majority of their patients were already in labor.[11] Present study was found comparable to Siwatch et al reported that 94.3 % in sublingual and 91.8% in vaginal group delivered vaginally within 24 hours.[9] No other studies have divided the percentage of vaginal delivery according to time except Feitosa et al who have mentioned that 81% patients in sublingual group and 79% patients in vaginal group deliver vaginally within 24 hours.[8] The reason could be due to a dosing interval of 6 hours compared to 4 hours in the present study.

In the present study, a higher percentage of women delivered after a single dose of misoprostol, both in sublingual group (32.3%) and vaginal group (31.7%). The differences in the percentage of patients in each dose were not statistically significant in either of the groups (p=0.856). Ayati et al reported that 96% of patients in sublingual group and 100% of patients in vaginal group entered the active labor within 5 doses which is almost similar to the present study.[10] In Ayati et al, percentage of patient delivered after a single dose was 44.6% in sublingual and 50% in vaginal group which was higher than the present study.[10] An additional 6th dose was required in 4.3% women in sublingual group while there was no such case in vaginal group. Jahromi et al did not mention the percentage of women delivering with different doses.[11] They reported that only 4% of women in sublingual group and 7% of women in vaginal group required a 5th dose of misoprostol which is lower than the present study. This could be due to the reason that maximum number of patients included in their study were already in labor. Siwatch et al had not mentioned the percentage of women delivering with different doses, so it could not be compared.[9] It was seen in the present study that mean number of doses required in sublingual group was 2.525±1.416 and in vaginal group was 2.446±1.337 and this was found to be statistically insignificant (p=0.683). Only Siwatch et al had reported mean number of doses of misoprostol used which was found to be 2.05±0.980 in sublingual group and 1.81±0.843 in vaginal group which was found comparable to the present study.[9] It seems that uterine contraction abnormalities are more common with vaginal misoprostol in the present study, but the statistical significance of this difference cannot be calculated as the value was too small. Siwatch et al also reported uterine contraction abnormalities more in vaginal group than in the sublingual group.[9] Ayati et al reported contraction abnormalities in 2.2% in sublingual group and 2% in vaginal group.[10] Jahromi et al reported hyperstimulation in 13% in sublingual group and 7% in vaginal group which are higher than the present study.[11] It may be due to the reason that 52% patients in sublingual and 48% patients in vaginal group included in their study were already in labor. We found the incidence of meconium during induction and labor was more in sublingual group

similar to Siwatch et al and Jahromi et al 25.3% women in sublingual group and 36.6% women in vaginal group underwent cesarean section.[7,11] In the study of Siwatch et al, caesarean section was done in 11.3% in sublingual group and 8.8% in vaginal group.[9] Ayati et al reported caesarean in 14.1 % women in sublingual and 10% women in vaginal group whereas Jahromi et al reported caesarean section in 22% women in sublingual group and 14% women in vaginal group.[10,11] These values are lower than the present study. This could be due to the reason that they have the facility of continuous CTG monitoring for all patients and CTG in the present study could not be done in all patients due to logistic reasons. The most common indication for cesarean was fetal distress in both groups.

Present study was found similar to Siwatch et al who have done maximum cesarean for meconium and fetal and Jahromi et al who have done maximum cesarean for foetal distress.[9,11] Ayati et al did most of the cesarean for failed induction in sublingual group and for fetal distress in vaginal group.[10] The incidence of maternal complications was almost similar in both the groups. Jahromi et al also found the incidence of nausea and vomiting similar in both the groups.[11] Siwatch et al reported only 2 cases of nausea and vomiting in sublingual group and 3 cases in vaginal group.[9] Ayati et al reported incidence of nausea and vomiting as 12% in sublingual and 10% in vaginal group which was higher than the present study.[10] This could be due to the reason that misoprostol was given up to a maximum of 6 doses, while in present study, maximum of 5 doses were given.

Siwatch et al reported the mean neonatal birth weight in sublingual group as 2.68±0.333kg and 2.79±0.389 kg in vaginal group which was lower than the present study.[9] Other studies did not mention the birth weight. The Apgar score at 1 minute in the sublingual group was ≤7 in 69.7% and >7 in 30.3% of the neonates in the present study while in the vaginal group, 76.2% had an Apgar score of ≤7 and it was >7 in 23.8% of the neonates. Jahromi et al reported 14% (sublingual) and 10% (vaginal) have Apgar score of less than 7 at 1 minute.[11] These are much lower than our study because of a lesser number of induction for postdated pregnancy (24% in sublingual and 27% in vaginal) and a lesser number of cesarean section for fetal distress. No other studies have mentioned the Apgar score at 1 minute. The mean Apgar score at 1 minute in sublingual group was 7.09±1.021 and in vaginal group was 6.93±1.079 in the present study. There was no statistical difference in both the groups (p-value = 0.282). Siwatch et al had mean Apgar score of 8.20±0.54 in sublingual group and 8.00±1.396 in vaginal group at 1 minute which was almost comparable to the present study.[9] None of the other studies have mentioned the mean Apgar score, so it could not be compared. The Apgar score at 5 minutes was ≤7 in 8.1% and >7 in 91.9% of the patients in the sublingual group. In the vaginal group, Apgar score was ≤7 in 10.9% and >7 in 89.1% of the patients. Jahromi et al reported 1% (sublingual) and 2% (vaginal) have Apgar score of less than 7 at 5 minutes. These are much lower than the present study because of a lesser number of induction for postdated pregnancy (24% in sublingual and 27% in vaginal) and a lesser number of cesarean section for fetal distress. No other studies have mentioned Apgar score at 5 minutes. The mean Apgar score in sublingual group at 5 minutes was 8.22±0.736 and in vaginal group was 8.10±0.794. The difference was not significant (p-value=0.257). Siwatch et al have reported their mean Apgar score at 5 minutes as 9.11±0.36 in sublingual group and 8.93±0.823 in vaginal group which was almost comparable to the present study. None of the other studies have mentioned the mean Apgar score, so it could be compared. The number of NICU admissions was 4% of the neonates in both sublingual and vaginal groups. Only Jahromi et al had reported about NICU admission, 11% of neonates were in sublingual group and 7 % were in vaginal group.[11] These values were higher as compared to our study. They reported their maximum NICU admissions were due to meconium (8% in sublingual group and 3% in vaginal group) and respiratory distress (3% in sublingual group and 5% in vaginal group). They have not reported any neonatal mortality. None of the other studies have mentioned NICU admissions and therefore, cannot be compared.

The patients in the present study were asked about the preference of route in next pregnancy in which all patients (100%) in sublingual group preferred sublingual route while 65.3% patients in the vaginal group would prefer sublingual route in next pregnancy due to its ease of administration and freedom of mobility after dose administration. The vaginal route was preferred by 34.7% patients in the vaginal group while there was no such patient in the sublingual group. There are certain limitations in the present study. The sample size was small, so the study had the inadequate statistical power to evaluate the efficacy of misoprostol by both routes. This was not a blinded study, so there may have been some bias as the medical staff was aware of the route by which misoprostol was being given.

CONCLUSION

5µg misoprostol administered by sublingual route is equally efficacious as by vaginal route for induction of labor at term.

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