International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Agarwal N et al. Int J Reprod Contracept Obstet Gynecol. 2025 Nov;14(11):3793-3798
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20253520

Original Research Article

Comparison of the efficacy and safety of sublingual misoprostol (PGE1) versus intracervical dinoprostone (PGE2) for induction of labour: a prospective study

Neha Agarwal, Priyanka Raghav*, Saroj Singh, Anu Pathak

Department of Obstetrics and Gynecology, S. N. Medical College, Agra, Uttar Pradesh, India

Received: 22 June 2025
Revised: 01 October 2025
Accepted: 04 October 2025

***Correspondence:**
Dr. Priyanka Raghav,
E-mail: priyankaraghav124@gmail.com

ABSTRACT

Background: Induction of labour is indicated when the benefits of induction to either mother or fetus outweigh those of pregnancy continuation. Various mechanical methods include use of extra amniotic saline infusion, artificial rupture of membranes, balloon tipped catheter, natural and synthetic laminaria or stretch sweep method. Pharmacological methods are mainly using prostaglandins either Dinoprostone (PGE2) or Misoprostol (PGE1). This study aimed to compare the efficacy and safety of sublingual Misoprostol (PGE1) versus intracervical Dinoprostone (PGE2) for induction of labour and to compare maternal and perinatal outcome in both groups.
Methods: In this study, 250 antenatal women with 35 weeks or more period of gestation with a single live fetus, cephalic presentation were included for induction of labour.125 women received 25mcg misoprostol sublingually (group A) and 125 women received 0.5mg of dinoprostone intracervically (group B).
Results: There was shorter induction to active phase interval (7.68±3.39 vs 11.42±5.43 hours), induction to delivery intervals (11.46±3.46 vs 16.23±5.61 hours) and less requirement of oxytocin augmentation (25.6% vs 73.6%) in misoprostol group than dinoprostone group. Mode of delivery, maternal and neonatal complications were similar in both groups.
Conclusions: Use of sublingual misoprostol in lower dose is a safe and cost-effective method for induction of labour.

Keywords: Dinoprostone gel, Induction of labour, Misoprostol, Prostaglandins

INTRODUCTION

Induction of labour is defined as iatrogenic stimulation of uterine contractions to accomplish delivery prior to the onset of spontaneous labour, aimed at delivery by vaginal route.[1,2] Induction of labour is indicated when the benefits of induction to either mother or fetus outweigh those of pregnancy continuation.[3] The most important decision to be made when considering induction of labour is whether or not the induction is justified. Adopting safe and effective methods of labour induction at appropriate gestation age can greatly decrease maternal and fetal complications and morbidity.

Mechanical methods include use of extra amniotic saline infusion, artificial rupture of membranes, balloon tipped catheter, natural and synthetic laminaria, membrane sweep also called as Hamilton maneuver or stretch sweep method.

Pharmacological methods are mainly using prostaglandins either Dinoprostone (PGE2) or Misoprostol (PGE1). Dinoprostone (PGE2) is most commonly used prostaglandin to achieve cervical ripening and induction of labour. It has been approved by the Food and Drug Administration (FDA), U.S. for cervical ripening and induction of labour in women at or near term by

intracervical administration. PGE2 induces collagenases, metalloproteinases and elastin activity thus causing separation of collagen bundles and cervical ripening[4]. Dinoprostone is costlier and requires refrigeration for storage, as it is unstable at room temperature.[5]

Misoprostol (PGE1) is approved by FDA for reducing the risk of non-steroidal anti-inflammatory drug induced gastric ulcers. Misoprostol is being increasingly used as an "off the label" drug in market, for induction of labour.[6] Misoprostol is safe, reliable, inexpensive, and easily available drug that can be given by various routes for induction of labour. It can be stored at room temperature and is easy to handle.

The objective of this study was to assess the efficacy and safety of sublingual misoprostol (PGE1) and compare it with intracervical dinoprostone(PGE2) gel for induction of labour.

METHODS

Total 250 antenatal women with 35 weeks or more period of gestation with indication of induction of labour were randomly selected from antenatal outpatient department and labour room in the Department of Obstetrics and Gynaecology, S.N. Medical College, Agra from March 2021 to December2021.

Inclusion criteria

Inclusion criteria were singleton pregnancy with vertex presentation, parity five or less, clinically adequate pelvis, Modified Bishop's score six or less, reassuring fetal heart rate tracing, pregnancy with hypertension, gestational diabetes mellitus, prolonged pregnancies, fetal growth retardation (FGR) requiring induction of labour, premature rupture of membranes.

Exclusion criteria

Patients with parity more than five, multiple pregnancies, previous uterine scar, fetal distress (FHS <100 or >160), estimated fetal weight on scan greater than 4 Kg, amniotic fluid index less than 5 cm, non-reassuring admission Non Stress Test (NST), foetal malformations, any obstretic contraindication for induction of labour (antepartum haemorrhage, cephalopelvic disproportion, contracted pelvis or unexplained vaginal bleeding), those with history of bronchial asthma, glaucoma, serious cardio vascular disorders, renal diseases or allergy to prostaglandins were excluded from study.

All subjects equally divided into two equal halves. One half of 125 antenatal women who had received 25 µg misoprostol tablet which was placed sublingually under the guidance treated as group A while other half of 125 antenatal women who had received 0.5 mg dinoprostone gel in the cervical canal treated as group B.

A detailed written informed consent was obtained from the participant and her relatives. The following were addressed in consent form: indication for induction, drug to be administered with its dosage, mode of administration, side effects of drugs, risk associated with the administration of these drugs, and if complication arise alternative mode of termination were discussed. All selected women were subjected to detailed history taking, and complete General and Obstetrics examination and routine investigations. Vaginal examination was done under strict aseptic precautions. All selected women underwent Non-Stress Test (NST) at the time of admission to assess the fetal wellbeing and USG for fetal wellbeing, fetal growth parameters and AFI. Modified Bishop's scoring was performed in all the women before induction.

Patient in misoprostol group received 25 µg misoprostol tablet which was given sublingually and the patient instructed, not to chew or swallow, but to keep underneath the tongue for about 4-8 minutes till completely dissolved under supervision. A maximum of 4 doses which were repeated every 4 hourly. Repeat doses were given if cervical dilatation is less than 4cm and if adequate uterine contractions (3 or more in10 minutes lasting more than 40 seconds) were not present.

The patient was made to lie in supine position. Using speculum cervix was visualized and cleaned of excess mucus. Dinoprostone gel, removed from refrigerator in direct connection with catheter (after assembling all parts), was inserted into cervix, under aseptic precaution. To insert the gel, the cap of barrel (in which the gel is filled) was removed and applied at its end to serve as plunger extension. The catheter was filled with gel by gently pushing the plunger assembly to expel the air from catheter prior to administration to the patient. Using sterile technique, the catheter was introduced into the cervical canal and the entire content in the barrel was pushed into cervix. After complete gel has been inserted, the entire assembly is removed. Patient was instructed to remain in left lateral position for atleast 30 minutes. Fetal heart and uterine activity were monitored accordingly. After 6 hrs of giving gel, repeat dose was given if cervical dilatation was less than 4cm and if adequate uterine contractions (3 or more in 10 minutes lasting more than 40 seconds) were not present. A maximum of two doses were given.

In both groups, all the patients were observed for uterine contractions which were monitored in the form of frequency, intensity and duration by palpating uterus per abdomen, continuous electronic fetal monitoring was done, progress of labour was assessed by Partogram, maternal vitals like blood pressure, pulse rate, respiratory rate were monitored every 30 minutes from the time of induction, per vaginal examination was done after six hours following drug administration or earlier, if the patient complained of leaking per vaginum or excessive uterine contractions.

The following parameters were studied. The primary outcomes included the success of induction, defined as the onset of the active phase of labour (cervical dilatation 4 cm or more) within 24 hours of the first dose of the inducing agent, the time taken from induction to onset of the active phase (IAP interval), and the induction to delivery interval (IDI interval). The secondary outcomes included maternal and fetal parameters. Maternal outcomes comprised the vaginal delivery rate, the need for oxytocin augmentation, and maternal complications such as uterine hyperstimulation, hypersystole, and other side effects. Fetal outcomes included fetal distress, Apgar score at 1 minute and 5 minutes, and NICU admission.

Statistical analysis

Continuous data was represented in terms of means and standard deviation and the categorical data was represented in the form of frequencies and percentages. The Chi-square (χ^2) test was used to find the significance of study parameters on categorical scale between variable groups. Independent t test was used to identify whether there is significant difference among Misoprostol and Dinoprostone group. Numerical data between two groups were compared using the student t-test. Graphical representation of the data was done using Microsoft Excel and Microsoft Word. Statistical Software SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyse the data. Appropriate tests of significance were used based on the type of data. P-value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

RESULTS

A total of 250 subjects randomly selected for study. Majority of women belonged to the age group 21-25 years, class IV socio-economic status according to revised B.G. Prasad classification in both the groups. The youngest case is of 18 years and oldest case is of 36 years. 58.4% in Group A (Misoprostol group) and 67.2% in group B (Dinoprostone group) were nulliparous. There was no significant difference in mean age and mean Bishop Score at the time of admission (Table 1).

Table 1: Comparison of demographic variables in Group A and Group B.

	Group A (Misoprostol)	Group B (Dinoprostone)	p value
Age in years	25.06±3.96	25.36±3.66	0.5295
Socio-economic status (class IV) (%)	83.20	80.00	0.8108
Period of gestation (weeks)	39.9±42.07	39.77±2.23	0.5383
Parity (P0) (%)	58.40	67.20	0.4641
Modified Bishop score at admission	3.16±1.60	3.2±1.51	0.8397

Table 2 showed that the post-dated pregnancy was the most common indication of induction of labour in both groups but observed more in group B (56.80%) as compared to group A (56%) followed by pre-eclampsia which was found in 24.8% and 26.4% in group A and B respectively.

Table 2: Indication of induction of labour.

Indication	Group A (Misoprostol), N (%)	Group B (Dinoprostone), N (%)	p value
Post-dated pregnancy	70 (56)	71 (56.8)	0.876
Pregnancy induced hypertension	31 (24.8)	33 (26.4)	
Fetal growth restriction	11 (8.8)	1 1 (8.8)	
Premature rupture of membranes	10 (8)	6 (4.8)	
Gestational diabetes mellitus	3 (2.4)	4 (3.2)	
Total	125	125	

Labour was considered established if patient had 3 or more uterine contractions in 10 minutes and dilatation of cervix is 4cm or more. The mean induction to active phase interval was 7.68±3.39 hours in group A and 11.42±5.43 hours in group B, p-value <0.0001 that was statistically significant. In group A, 68.8% cases attained active phase of labour within 8 hours which is much higher than group B in which only 19.8% cases attained active phase in 8 hours (Table 3).

The mean induction to delivery interval was 11.46±3.46 hours in group A and 16.23±5.61 hours in group B, p-value <0.0001 that was statistically significant. In group A, 70 % cases delivered within 8 hours which is much higher than group B in which only 21% cases delivered in 8 hours (Table 4). Maternal side effects were more in group A as compared to group B but there was no significant difference seen (p-value=0.7997). Uterine hypertonus is when one contraction lasted more than 2 minutes and

uterine tachysystole is defined as more than five contractions per 10 minutes (Table 5).

Table 3: Induction to active phase interval.

IAP (hours)	Group A (Misoprostol) N (%)	Group B (Dinoprostone) (%)	P Pvalue
<4	6 (4.8)	1 (0.8)	
4-8	80 (64)	23 (18.4)	
8-12	33 (26.4)	74 (59.2)	
12-24	4 (3.2)	17 (13.6)	<0.0001
> 24	2 (1.6)	10 (8)	
Total	125	125	
Mean±SD	7.68 ± 3.39	11.42 ± 5.43	

Table 4: Induction to delivery interval.

IDI (hours)	Group A (Misoprostol) N (%)	Group B (Dinoprostone) (%)	P value
8	3 (2.75)	1 (1.03)	
8-12	70 (64.22)	21 (21.43)	
12-16	25 (22.94)	34 (34.69)	
16-20	8 (7.35)	22 (22.45)	<0.0001
20-24	2 (1.84)	10 (10.20)	
>24	1 (0.9)	10 (10.20)	
Total	109	98	
Mean±SD	11.46±3.46	16.23±5.61	

Table 5: Maternal side effects during therapy.

Side effects	Group A (Misoprostol) N (%)	Group B (Dinoprostone) N (%)
Uterine tachysystole	2 (1 .6)	0
Uterine hypertonus	1 (0.8)	1 (0.8)
Nausea	3 (2.4)	1 (0.8)
Vomiting	3 (2.4)	2 (1 .6)
Diarrhoea	1 (0.8)	0
Shivering	1 (0.8)	0
Pyrexia	2 (1 .6)	0
Bronchospasm	1 (0.8)	0

Neonatal APGAR score at 1 and 5 minute were found similar in both groups. Few neonatal complications were noted in both the groups. Fetal distress was noted in 8.8% in group A and 6.4% in group B. Although the number is more in group A but the difference is not significant because in present study misoprostol is given in low dose via sublingual route at optimum 4 hourly interval so has less direct effect thus causing less fetal distress (Table 6).

The mode of delivery was most commonly vaginal in both the groups (87.2% in group A and 78.4% in group B). Mode of delivery was not found to be associated with subjects treated with PGE1 and PGE2. Caesarean section was done in few cases (12.8% and 21.6%) in group A and B; respectively (Table 7).

Table 6: Neonatal complications.

Neonatal complications	Group A (Misoprostol) N (%)	Group B (Dinoprostone) N (%)	P value
Hyper-bilirubinemia	2 (1 .6)	1 (0.8)	
Septicemia	1 (0.8)	1 (0.8)	
IUFD	0	0	<0.0001
Neonatal mortality	0	0	
Total	3 (2.4)	2 (1 .6)	

Table 7: Outcomes.

	Group A (Misoprostol), N (%)	Group B (Dinoprostone) N (%)	P value
Induction to Active phase Interval (lAP) in hours	7.68±3.39	11.42±5.43	<0.0001
Success of induction	98.40%	92.00%	0.0384
Induction to Delivery Interval (lDl) in hours	11.46±3.46	16.23±5.61	<0.0001
Vaginal delivery rate	109 (87.20)	98 (78.40)	0.0938
Oxytocin augmentation	32 (25.60)	92 (73.60)	<0.0001

DISCUSSION

An ideal inducing agent is one which is effective, non-invasive, economical and safe to the mother and fetus.[7] It must achieve labour in shortest possible time, with lower incidence of failure, to achieve vaginal delivery without increasing perinatal morbidity.[8] No ideal method is known yet but prostaglandins are one of the most effective means of achieving cervical ripening and induction of labour. FIGO has given his recommendation for the use of intravaginal Misoprostol (25µg 4 hourly for maximum six dosages) for induction of labor at term.[9] Therefore, Misoprostol can be such an agent with the advantages of

cost and convenience, despite of the fact that it is not FDA-labelled for this purpose. Praveen et al done comparative studies of sublingual, oral and vaginal misoprostol for cervical ripening and reported that administration of misoprostol by the sublingual route is better than the oral and vaginal routes for cervical ripening.[10] Therefore in this study we compared sublingual misoprostol with intracervical dinoprostone gel for induction of labor.

Patients receiving sublingual administration of misoprostol have shorter induction to active phase, induction to delivery time intervals and also require less oxytocin for augmentation than the patients in which intra cervical dinoprostone gel was administered. Similar to present study Yadav et al, Panchal et al reported shorter IAP and IDI in Misoprostol group than in Dinoprostone group.[6,10]

Similar to present study Yadav et al, Panchal et al reported higher rate of tachysystole in women receiving misoprostol than receiving dinoprostone. APGAR score at 1 and 5 minute as well as neonatal complications were statistically similar in both the groups. Yadav et al and Panchal et al also reported the same.[6,10]

Table 8: Comparison with other studies.

	Present study		Panchal et al		Yadav et al	
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
Sample size	125	125	100	100	50	50
Pre-induction Bishop score	3.26±	3.2±	3.32	3.45	2.84±	3.30±
	1 .6	1.51			3.39	1 .87
IAP (hours)	7.51±	11 .01±	1 1 .8	14.5	1.71±	5.47±
	2.76	4.8			1 .23	3.31
IDI (hours)	11 .72±	16.31±	1 1.97	16.2	5.39+	10.8±7
	3.79	5.45			2.97	0.33
Vaginal Delivery Rate (%)	87.2	76	81	76	88	74
Caesarean Section Rate (%)	12.8	24	19	24	6	10
Oxytocin augmentation (%)	25.6	73.6	34	67	22	66

The limitation of the study was small sample size and short duration of the study.

CONCLUSION

Sublingual misoprostol is demonstrated to be a viable alternative technique of labor induction since it is efficacious, easily administered, not expensive, stable at room temperature, needs no refrigeration with a longer shelf-life than dinoprostone gel. It allows the better patient acceptability although uterine hyper stimulation and meconium staining is the main concern with misoprostol use, close maternal-foetal monitorization and timely intervention measures would prevent devastating adverse effects during labor induction and increase tolerability of the drug by both the mother and foetus. So, by present study, it was concluded that Low dose sublingual misoprostol is more effective than Dinoprostone gel for labour induction without compromising safety. It has an advantage of decreasing the need of additional measures to achieve vaginal delivery, lower cost, ease of administration and patient acceptability.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of S.N. Medical College, Agra, Uttar Pradesh, India

REFERENCES

1. Cunningham FG, Leveno KJ, Bloom SL, Spong CY, Dashe JS, Hoffman B, et al. Labour induction. In: Williams Obstetrics. 24th ed. New York: Mc Grew Hill; 2014:523-4.
2. Arias F, Dftary SN, Bhide AG. Arias' practical guide to high risk pregnancy and delivery. In: Abnormal labour and delivery. 3rd ed. Amsterdem: Elsevier; 2008:373-90.
3. Weeks AD, Navaratnam K, Alfirevic Z. Simplifying oral misoprostol protocols for the induction of labour. BJOG. 2017;124(11):1642-5.
4. Bakker R, Pierce S, Myers D. The role of prostaglandins E1 and E2, dinoprostone, and misoprostol in cervical ripening and the induction of labor: A mechanistic approach. Arch Gynecol Obstet. 2017;296(2):167-79.
5. Chitrakar NS. Comparison of misoprostol versus dinoprostone for pre-induction cervical ripening at-term. J Nepal Health Res Counc. 2012;10:10-5.
6. Yadav S, Chandwaskar N. Comparative study of misoprostol sublingually and dinoprostone gel intracervically for cervical ripening and induction of labour. Int. J Reprod Contracept Obstet Gynecol. 2017;6(8):3624-7
7. Acharya R, Chaudhari P, Choudhary A, Sharma A, Jain S. Mifepristone as cervical ripening agent for

labor induction in women with previous one caesarean section. Int J Med Res Rev. 2016;4(4):624-9.
8. Veena B, Rajinish S, Leeberk RI, George EC. Sublingual misoprostol (PGE1) versus intracervical dinoprostone (PGE2) gel for induction of labour: A randomized control trial. J Obstet Gynecol India 2016;66(Suppl1):122-8.
9. Weeks A, Faúndes A. Misoprostol in obstetrics and gynecology. Int J Gynecol Obstet. 2007;99(2):S156-9.
10. Parveen S, Khateeb ZA, Mufti SM, Shah MA, Tandon VR, Hakak S, et al. Comparison of sublingual, vaginal, and oral misoprostol in cervical ripening for first trimester abortion. Ind J Pharmacol. 2011;43(2):172-5.
11. Panchal PH, Sheth MH, Shah SR, Mehta AV. Comparative study of misoprostol sublingually and dinoprostone gel intracervically for cervical ripening and induction of labor. IJSR 2019;8(11).

Cite this article as: Agarwal N, Raghav P, Singh S, Pathak A. Comparison of the efficacy and safety of sublingual misoprostol (PGE1) versus intracervical dinoprostone (PGE2) for induction of labour: a prospective study. Int J Reprod Contracept Obstet Gynecol 2025;14:3793-8.