International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622

www.gynaecologyjournal.com
2022; 6(1): 218-220
Received: 11-11-2021
Accepted: 14-12-2021

Dr. Lakshmi Priya Polisetty
Junior Resident, Department of Obstetrics and Gynaecology Shri B.M. Patil Medical College and Research Centre, BLDE Hospital, Karnataka, India

Dr. PB Jaju
Professor, Department of Obstetrics and Gynaecology Shri B.M. Patil Medical College and Research Centre, BLDE Hospital, Karnataka, India

Corresponding Author:
Dr. Lakshmi Priya Polisetty
Junior Resident, Department of Obstetrics and Gynaecology Shri B.M. Patil Medical College and Research Centre, BLDE Hospital, Karnataka, India

Sublingual misoprostol versus intracervical dinoprostone gel for induction of labour: A randomized trial

Dr. Lakshmi Priya Polisetty and Dr. PB Jaju

DOI: https://doi.org/10.33545/gynae.2022.v6.i1d.1139

Abstract
Background: Sublingual misoprostol and intracervical dinoprostone gel are used for induction of labor. The aim of the study was to compare the efficacy and safety profile of sublingual misoprostol (PGE1) versus intracervical dinoprostone gel (PGE2) for induction of labor.
Methods: 84 women with single live fetus as per inclusion and exclusion criteria for induction of labor were recruited for the study. Patients were randomized to receive either 50µg of misoprostol sublingually or dinoprostone gel (0.5mg) intracervically.
Results: There was shorter induction to active phase, induction to delivery time intervals and less requirement of oxytocin augmentation in sublingual misoprostol group than intracervical dinoprostone gel group. Caesarean section rate is more in sublingual misoprostol group than intracervical dinoprostone gel group because of increased fetal distress in sublingual misoprostol group. Incidence of tachysystole was higher in sublingual misoprostol group than intracervical dinoprostone gel group. Perinatal outcome is better in intracervical dinoprostone group because of lesser side effects like tachysystole, fetal distress.
Conclusions: Use of dinoprostone gel is a safe method for induction of labor.

Keywords: Dinoprostone, labor induction, sublingual misoprostol, prostaglandin

Introduction
The ability to induce labour has become one of the most significant tools in the arsenal of an obstetrician. It is done with the goal of attaining vaginal birth anytime the mother's or fetus well-being is jeopardized by continuing the pregnancy. Modern obstetrics techniques have substantially improved the safety and reliability of induction of labour, allowing it to be carried out with more confidence. Timely induction thus reduces the maternal and perinatal morbidity and mortality [1, 2]. Prostaglandin preparations are well known and widely accepted for inducing labor. Dinoprostone which is Prostaglandin E2 analog is approved drug by Food and drug administration (FDA), USA for the induction of labor, and requires refrigeration for its storage [3, 4]. Moreover additional oxytocin augmentation is required in many patients during induction of labor by intracervical dinoprostone. Misoprostol which is a Prostaglandin E1 analog can be administered through vaginal, oral or sublingual routes and can be stored at room temperature [5]. The aim of study was to compare the efficacy and safety of sublingual misoprostol tablet (50µg) versus intracervical dinoprostone gel (0.5mg) for cervical ripening and induction of labor.

Methods
84 pregnant women with single live fetus as per inclusion and exclusion criteria with indication for induction of labor were recruited randomly according to computer generated randomization sequence for the study. Inclusion criterion was Singleton pregnancy, Cephalic presentation, Bishop Score<6, Post maturity, Fetal Growth Restriction, Oligohydramnios Polyhydramnios, Rh isoimmunization, Premature rupture of membranes and IUD. Patients with known case of glaucoma, haemoglobinopathies and hypersensitivity to prostaglandins, previous uterine surgery, presentation other than cephalic, patients with history of asthma, cephalopelvic disproportion and placenta previa were excluded from the study. All subjects were equally divided into two equal halves. 42 pregnant women received 50µg misoprostol tablet which was placed sublingually under the guidance and treated as group A, while other 42 pregnant women received 0.5mg dinoprostone gel intracervically and treated as group B.

All the recruited women were explained about the complete treatment procedure in their own language and consent was taken to participate in the study. Detail history of the patient was recorded with special reference to age, parity, menstrual history and obstetrical history. Gestational age was calculated from the first day of last menstrual cycle and ultrasonography. Taking all aseptic precautions per vaginal examination was done. Pelvis was assessed, cervical status was recorded specially the position, length, consistency was noted along with station of the head the prediction of inducibility can be done by modified bishop score. Patients in group A received 50µg misoprostol tablet which was placed sublingually under the guidance and modified bishops score was assessed after 4 hours. If score was less than 6 repeat sublingual misoprostol 25 µg was put to a maximum of 6 doses every 4th hourly. In group B, under all aseptic measures, Sims vaginal speculum was inserted and cervix was visualized. The catheter of preloaded PGE2 gel (Dinoprostone 0.5 mg) syringe was then introduced under vision into the cervical canal. The catheter was then advanced upto the internal Os and then slightly withdrawan. While slowly withdrawing the catheter, the plunger was slowly pushed to instill the contents into the cervical canal. The patient was asked to remain supine for at least 30 minutes after gel administration after 6 hours patient was assessed for modified bishop's score. After 6hours, if bishop's score was less than 6, repeat intracervical insertion of dinoprostone 0.5mg was done to a maximum of 3 doses every 6th hourly. If the cervix reached 4 cm or more of dilatation oxytocin was started to augment the labour. In both groups all the patients were observed for initiation of contractions by palpating uterus per abdomen, auscultation of fetal heart rate by stethoscope or Doppler. Length and dilatation of cervix, condition of membranes, position of presenting part were noted by pervaginal examination. Pulse rate, respiratory rate, blood pressure were recorded. Side effects like vomiting, diarrhea, nausea, tachycardia, fever, chills, bronchial spasm, tachysystole, hypertonus, fetal heart rate abnormalities and passage of meconium were recorded. Subjects in group A were compared with subjects in group B for induction of labor and to compare the effectiveness, safety and side effects of sublingual misoprostol versus intracervical dinoprostone gel.

Results

84 women were randomly selected for study as per the inclusion and exclusion criteria. Period of gestation, indication for induction, no. of doses for induction were not statistically significant. 28cases had meconium stained liqour in group A whereas only 7 had meconium stained liqour in group B. In group A, 56.0% women were primigravida while 62.0% in group B were primigravida. The age of all women in both the groups were between 18 years to 37 years. There was no significant difference in mean age and mean Bishop Score at admission in both groups. 36% of cases in group A underwent LSCS and 64% had vaginal delivery. 9.5% of cases in group B underwent LSCS and 90.5%% had vaginal delivery. NICU admission rate was higher in group A as compared to group B.

Table 1: Perinatal Outcome

Perinatal Outcome	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
Healthy	6	14.3	38	90.5	41.248	0.0001
NICU Admission, RDS	36	85.7	4	9.5		
Total	42	100.0	42	100.0		
Statistically Significant						

Table 2: Induction to Normal Delivery

Induction To Normal Delivery	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
Vaginal Delivery <= 12hrs	19	45.2	32	76.2	11.380	0.0034
Vaginal Delivery 13+Hrs	8	19.0	7	16.7		
Lscs	15	35.7	3	7.14		
Total	42	100	42	100		
Statistically Significant						

Table 3: Adverse Effects

Adverse Effects	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
Fetal Distress	31	73.9	6	14.4	65.716	0.0001
Shivering, Fever And Uterine Hyperstimulation	10	23.9	0	0		
Statistically Significant						

Table 4: Mode of Delivery

Mode Of Delivery	Sublingual Misoprostol		Dinoprostone		Chi square test	P value
	No. of patients	%	No. of patients	%		
Vaginal Delivery	27	64.3	38	90.5	14.209	0.0026
Lscs In View Of Fetal Distress	15	35.7	4	9.5		
Total	42	100.0	42	100.0		
Statistically Significant						

Induction to active labour interval was short in group A but adverse effects like fever, chills, hyperstimulation of uterus and fetal distress were noted. As adverse effects to mother and fetus are more with sublingual misoprostol group compared to intracervical dinoprostone group and caesarean section rate was increased in group A. we considered dinoprostone gel as better and safe inducing agent compared to 50micrograms sublingual misoprostol.

Postdatism was most common indication for induction of labor in both groups followed by Pre-eclampsia in 6% and 7% in group A and group B respectively. Labor was considered established if patient had 3 or more uterine contractions in 10 minutes and dilatation of cervix was >4 cm. The mean induction delivery interval (IDI) was also shorter in the PGE1 group as compared to PGE2 group (5.39±2.97 hours vs. 10.88±7.33 hours respectively). 94% patients in PGE1 group and 60% patients in PGE2 group delivered the baby within 12 hours in present study ($P < 0.0001$).

Discussion

The ideal agent for induction of labor should be effective, non-invasive, economical, rapid in action and safe to both mother and fetus. None of the methods or agents currently available fulfill all these criteria, but prostaglandins are one of the most effective means of achieving induction of labor providing, good clinical efficacy and patient satisfaction when used. FIGO has given this recommendation for the use of intravaginal Misoprostol (25µg 4 hourly for maximum six dosages) for induction of labor at term [6]. 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 (S/L), 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 [7]. 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, Wing *et al*, McKenna *et al*, Liu *et al*, and Jha *et al*. reported shorter Induction to delivery interval in Misoprostol group than in Dinoprostone group [8-11]. However Zhang *et al*. did not find significant difference in Induction to delivery interval in two groups [12]. Similar to present study Zhang *et al*. reported higher rate of tachysystole in women receiving misoprostol than in those receiving PGE2 gel. In their study, APGAR score at 1 minute and at 5 minute as well as neonatal complications was statistically similar in both the groups. Liu *et al*, Langenegger *et al* and Patil *et al*. also reported the same [10, 13, 14]. They demonstrated that misoprostol was viable alternative technique of labor induction since it is efficacious, easily administered, 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 high dose of misoprostol use. Close maternal-foetal monitoring and timely intervention would prevent devastating adverse effects during labor induction and increase tolerability of the drug by both the mother and foetus.

Conclusion

By the present study, it is concluded that intracervical dinoprostone gel is a more successful agent for induction of labor than 50µg sublingual misoprostol with regard to efficacy, safety and less maternal and fetal side effects.

References

1. Gülmezoglu AM, Crowther CA, Middleton P, Heatley E. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane database of systematic reviews. 2012(6).
2. Stock SJ, Ferguson E, Duffy A, Ford I, Chalmers J, Norman JE. Outcomes of elective induction of labour compared with expectant management: population based study. Bmj. 2012, 344.
3. Witter FR. Prostaglandin E2 preparations for preinduction cervical ripening. Clinical obstetrics and gynecology. 2000;43(3):469-74.
4. Cirier J, Diguisto C, Arlicot C, Denis C, Potin J, Perrotin F. Mechanical methods for cervical ripening in France: an evaluation of professional practices. Gynecologie, obstetrique & fertilite. 2015;43(5):361-6.
5. Tang OS, Gemzell-Danielsson K, Ho PC. Misoprostol: pharmacokinetic profiles, effects on the uterus and side-effects. International Journal of Gynecology & Obstetrics. 2007;99:S160-7.
6. Weeks A, Faúndes A. Misoprostol in obstetrics and gynecology. International Journal of Gynecology & Obstetrics. 2007;99:S156-9.
7. 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. Indian journal of pharmacology. 2011;43(2):172.
8. Wing DA, Rahall A, Jones MM, Goodwin TM, Paul RH. Misoprostol: an effective agent for cervical ripening and labor induction. American journal of obstetrics and gynecology. 1995;172(6):1811-6.
9. McKenna DS, Ester JB, Proffitt M, Waddell KR. Misoprostol outpatient cervical ripening without subsequent induction of labor: a randomized trial. Obstetrics & Gynecology. 2004;104(3):579-84.
10. Liu A, Lv J, Hu Y, Lang J, Ma L, Chen W. Efficacy and safety of intravaginal misoprostol versus intracervical dinoprostone for labor induction at term: A systematic review and meta-analysis. Journal of Obstetrics and Gynaecology Research. 2014;40(4):897-906.
11. Jha N, Sagili H, Jayalakshmi D, Lakshminarayanan S. Comparison of efficacy and safety of sublingual misoprostol with intracervical dinoprostone gel for cervical ripening in prelabour rupture of membranes after 34 weeks of gestation. Archives of gynecology and obstetrics. 2015;291(1):39-44.
12. Zhang Y, Wang J, Yu Y, Xie C, Xiao M, Ren L. Misoprostol versus prostaglandin E2 gel for labor induction in premature rupture of membranes after 34 weeks of pregnancy. International Journal of Gynecology & Obstetrics. 2015;130(3):214-8.
13. Langenegger EJ, Odendaal HJ, Grove D. Oral misoprostol versus intracervical dinoprostone for induction of labor. International Journal of Gynecology & Obstetrics. 2005;88(3):242-8.
14. Patil KP, Swamy MK, Rao RK. Oral misoprostol vs intra-cervical dinoprostone for cervical ripening and labour induction. J Obstet Gynecol India. 2005;55(2):128-31.