



## COMPARATIVE STUDY OF LOW DOSE VAGINAL MISOPROSTOL AND DINOPROSTONE GEL FOR INDUCTION OF LABOR

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### ABSTRACT

**BACKGROUND:** The study aims at comparing the low dose of vaginal misoprostol and dinoprostone gel for the induction of labor.

**METHODS:** The study was conducted on 200 pregnancy females, randomized into two groups, each group having 100 women. First group received misoprostol per vaginally and second group received dinoprostone gel. The time interval from induction to delivery, mode of delivery, labor and fetal complications were recorded.

**RESULTS:** The induction to delivery interval was significantly less in misoprostol group as compared to dinoprostone group (14.21 vs 16.35 hours;  $p < 0.01$ ). Therefore, early labor and early delivery is seen with misoprostol as compared to dinoprostone.

**CONCLUSIONS:** As shown in this study, the time intervals from induction to delivery interval were significantly shorter and the requirement of oxytocin was less for augmentation of the labor with misoprostol than dinoprostone gel with no difference in maternal and neonatal complication rate.

**KEYWORDS :** Dinoprostone gel, Labor induction, Misoprostol, Labor Analgesia

### INTRODUCTION:

Induction of labor at term with an intention of achieving a vaginal delivery is a common accepted obstetric intervention when continuation of pregnancy is deleterious to mother or fetus or both. Induction of labor is an intervention that artificially stimulates uterine contractions leading to progressive dilation and effacement of cervix and expulsion of fetus prior to onset of spontaneous labor by medical and/or surgical method.<sup>(1)</sup> To be successful, induction of labor must fulfill three aims. First, it should result in labor namely adequate uterine contractions and progressive dilatation of cervix. Second, this labor should result in vaginal delivery. Third, in viable pregnancies, these aims must be achieved with minimum discomfort and risk to both mother and fetus. The drugs commonly available for the purpose of induction are misoprostol, dinoprostone and oxytocin.<sup>(2)</sup>

Prostaglandins alter the extracellular ground substance of the cervix, ripen the cervix and increase the activity of collagenase in the cervix.<sup>(3)</sup> Dinoprostone (PGE<sub>2</sub>) is the drug of choice and is accepted for labor induction at term. Although safe and effective, it is expensive and required refrigeration for storage. Misoprostol (PGE<sub>1</sub>) is a synthetic prostaglandin, also rapidly absorbed through alimentary canal. It is effective, inexpensive, can be stored at room temperature and no need of needle or syringe for administration.<sup>(4,5)</sup> The present study was undertaken to compare safety and efficacy of intra vaginal misoprostol with dinoprostone cervical gel for cervical ripening and for induction of labor.

### METHODS:

The study is prospective comparison study conducted at Department of Obstetrics and Gynecology, MGM Hospital, Navi Mumbai. Written, valid and informed consent was obtained from all women who participated in the study. All women attending the labor room at term pregnancy (37-42 weeks), with a singleton fetus in cephalic presentation, Amniotic fluid index between 8-18cm, clinically adequate pelvis and reactive fetal heart rate pattern were included in study. Grand multipara with previous caesarean section or other surgical scars on uterus, multifetal gestation, placenta previa, non-reassuring fetal heart rate pattern, thyrotoxicosis, bronchial asthma, heart disease, known hypersensitivity to prostaglandins and patients not consenting to participate were excluded from the study.

Total 200 women were randomized and divided into two groups of 100 each. The first group of 100 women received 25 micrograms of misoprostol intravaginal. The dose was repeated every 6 hours with maximum of 3 doses. Second group received dinoprostone gel 0.5mg intracervical every 6hourly depending on the need. Reassessment was done in both groups after 6 hours to note improvement in Bishop's score and progression to active phase. Amniotomy and oxytocin were added wherever necessary. The course of labor was monitored until delivery with respect to maternal vital signs and fetal heart rate.

The quantitative data will be represented as their mean SD. Categorical and nominal data will be expressed in percentage. The t-test will be used for analyzing quantitative data and categorical data will be analyzed by using chi-square test.

### RESULTS

**Table 1: Comparison of study groups as per Obstetric history**

PARITY	PGE <sub>2</sub>	PGE <sub>1</sub>	TOTAL
PRIMIGRAVIDA	50 (50.0%)	45 (45.0%)	95 (47.5%)
MULTIGRAVIDA	50 (50.0%)	55 (55.0%)	105 (52.5%)
TOTAL	100 (100.0%)	100 (100.0%)	200 (100.0%)

p-value – 0.57

**Table 2: Comparison of mean gestation age among study groups**

Variable	Group	N	Mean	SD	P value
Gestation Age (weeks)	PGE <sub>2</sub>	100	39.37	1.22	0.246
	PGE <sub>1</sub>	100	39.16	1.26	

**Table 3: Mean comparison of Induction to delivery interval**

Variable	Group	N	Mean	SD	P - value
Induction to delivery interval	PGE <sub>2</sub>	100	16.35	4.75	<0.01
	PGE <sub>1</sub>	100	14.21	4.34	

**Table 4: comparison of study groups as per type of delivery**

Delivery	PGE <sub>2</sub>	PGE <sub>1</sub>	TOTAL
Vaginal	50 (50.0%)	63 (63.0%)	113 (56.5%)
Assisted Vaginal	10 (10.0%)	12 (12.0%)	22 (11.0%)
LSCS	40 (40.0%)	25 (25.0%)	65 (32.5%)

Total	100 (100.0%)	100 (100.0%)	200 (100.0%)
p- value 0.07			

**Table 5: Mean Comparison of APGAR score among study groups**

Variable	Group	N	Mean	SD	p- value
Birth Weight	PGE2	100	2.91	0.93	0.39
	PGE1	100	3.07	0.81	
APGAR at 1 minute	PGE2	100	8.28	0.75	0.272
	PGE1	100	8.16	0.79	

**Table 6: comparison of study groups as per maternal complications**

Maternal Complications	PGE2	PGE1	Total
YES	10 (10.0%)	16 (16.0%)	26 (13.0%)
NO	90 (90.0%)	84 (84.0%)	174 (87.0%)
TOTAL	100 (100.0%)	100 (100.0%)	200 (100.0%)
p- value 0.29			

**Table 7: comparison of study groups as per requirement of NICU admission**

NICU Admission	PGE2	PGE1	TOTAL
YES	6 (6.0%)	6 (6.0%)	12 (6.0%)
NO	94 (94.0%)	94 (94.0%)	188 (94.0%)
TOTAL	100 (100.0%)	100 (100.0%)	200 (100.0%)
p- value 1.0			

**Table 8: Comparison of study groups as per requirement of Oxytocin**

OXYTOCIN	PGE2	PGE1	TOTAL
NO	36 (36.0%)	54 (54.0%)	90 (45.0%)
YES	64 (64.0%)	46 (46.0%)	110 (55.0%)
TOTAL	100 (100.0%)	100 (100.0%)	100 (100.0%)
p- value – 0.015			

**DISCUSSION:**

The two-study groups did not significantly differ with respect to baseline characteristics like gravid and gestational age. Most of the subjects in Mean age of the study group was 24.12 with no difference between the study groups (p-0.193). Mean Bishop's score at baseline was comparable between both groups. However, at 6 hours and 12 hours, mean Bishop's score was significantly higher in misoprostol group, showing early ripening of cervix in these patients. Multiple doses were required in 70% cases of dinoprostone group in present study as compared to 55% cases of misoprostol group. The findings of our study were consistent with finding reported by Neiger et al. (6) In present study, Induction to delivery interval was significantly less in misoprostol group as compared to dinoprostone (14.21 vs 16.35 hours; p<0.01). the findings were consistent with findings reported by Kamal P et al. (7)

In present study, the requirement of oxytocin was observed in 64% cases managed by dinoprostone as compared to 46% cases managed by misoprostol (p<0.05). these finding were consistent with findings reported by Alaparathi et al. (8) Caesarean section was required in 40% cases of dinoprostone group as compared 25% cases managed by misoprostol. In the study by Patil et al. (9), caesarean section rate was less in misoprostol group as compared to dinoprostone. Maternal complications were seen in 10% cases managed by dinoprostone as compared to 16% cases managed by misoprostol. The difference was statistically non-significant (p-0.29). most common complication observed in both groups was development of fever (4.5%). Mean birth weight and APGAR score at 1 minute among new borns was comparable among both groups. Fetal complication in the form of Meconium Aspiration syndrome was seen in 4% cases managed by dinoprostone as compared to 7% cases managed by misoprostol. The difference was statistically non-significant (p-0.54). NICU admission rate was 6% in both groups (p-1.0).

The mean overall induction cost in misoprostol group was much less as compared to cerviprime group. As no refrigeration is required for misoprostol, its affordability and availability is more in peripheral areas.

**CONCLUSION**

The results of the present study show that the time intervals from induction-delivery intervals were significantly shorter and the requirement of oxytocin was less for augmentation of the labor with misoprostol than dinoprostone gel with no difference in maternal and neonatal complication rate. Misoprostol is also more cost effective when compared to dinoprostone as it is stable at room temperature and does not need refrigeration. Intravaginal misoprostol is thus an effective agent for induction of labor than intracervical gel as it is easy to use, less expensive, effective and safe to mother and fetus.

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