

## The Comparative Study of Intravaginal Misoprostol and Intracervical Prostaglandin E2 Gel for Induction of Labour

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### Abstract

**Objective:** To study the efficacy, safety, cost effectiveness, intrapartum complications, mode of delivery and neonatal outcome with intravaginal misoprostol and intracervical dinoprostone for induction of labor. **Methods:** 200 antenatal women who were decided for induction of labor were randomly divided into two groups, one group (PGE1) received misoprostol 25mcg intravaginally and another group (PGE2) received dinoprostone 0.5mg intracervically. The efficacy and safety of these methods were analysed and compared in the following parameters: induction delivery interval, mode of delivery, neonatal outcome, fetomaternal complications and cost of the drug. **Results:** Among 200 antenatal women of different age groups and different indications for induction of labor, 100 women of one group receiving PGE1, of which 82% had vaginal delivery compared to 69% of PGE2 group which is statistically significant ( $p = 0.032$ ). C-section rate was 31% in PGE2 group compared to 18% in PGE1 group, which is statistically significant. 64% of PGE1 group had vaginal delivery within 12hrs compared to 37% of PGE2 group which is statistically significant ( $p = 0.0007$ ). PGE1 group had less need for acceleration of labor with oxytocin i.e 42% compared to 81% in PGE2 group. Failed induction with PGE2 is more

statistically significant ( $p = 0.037$ ). Maternal and fetal complications are not significant statistically. **Conclusion:** PGE1 is more efficacious for cervical ripening and labor induction than PGE2 as PGE1 has lesser requirement of oxytocin for labor augmentation, shorter induction delivery interval, more number of vaginal deliveries, less C-section rate, stable at room temperature and cost effective, however uterine contraction abnormalities, fetal heart rate irregularities and MSL should be carefully assessed by close monitoring of labor by intrapartum CTG and partogram.

**Keywords:** PGE1; PGE2.

### Introduction

Induction of labor implies initiation of uterine contractions after viability of fetus with the aim to achieve vaginal delivery. Labor is induced when risk of continuing pregnancy outweighs the risk of delivery. Favourable condition of the cervix is important for the success of labor induction which can be predicted by Bishop's score. Introduction of prostaglandins has revolutionized the concept of cervical ripening. They offer the advantage of promoting cervical ripening with an increase in myometrial contractility [2]. Prostaglandins PGE1 in the form of oral/vaginal tablets and PGE2 in the form of intracervical gel used for induction of labor [1]. In our study safety and efficacy of intravaginal PGE1 and intracervical PGE2 are compared.

### Aims and Objectives

1. To study the efficacy, safety, cost effectiveness and advantages of vaginal

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misoprostol and Intracervical-dinoprostone for induction of labor.

2. To study and compare the intrapartum-complications, mode of delivery and neonatal outcome with intravaginal misoprostol and intracervical dinoprostone.

## Materials and Methods

### Sample Size

200 cases of pregnant women

- *Type of study:* Prospective comparative study
- *Place of study:* Dept of OBG, Niloufer Hospital, Hyderabad.

### Inclusion Criteria

1. Induction for indications like PIH, post dates, Rh -ve @ term
2. Singleton gestation
3. Live fetus
4. Cephalic presentation
5. Pelvis adequate for vaginal delivery
6. Bishop's score <5
7. Intact membranes

### Exclusion Criteria

1. Multiple pregnancy
2. Malpresentation
3. Abnormal fetal heart rate pattern
4. Cephalopelvic disproportion
5. Ruptured membranes
6. Scarred uterus
7. Parity >3
8. History of hypersensitivity to prostaglandins
9. BOH
10. Placenta previa
11. Bishop's score >5

## Methodology

Detailed history and thorough clinical examination was done for those antenatal women admitted for induction of labor. After appropriate investigations and cervical assessment with bishop's score, ultrasound examination for AFI, BPP,

congenital abnormalities and after NST, induction is planned. These women were divided into 2 groups, Group- PGE1(N=100) received misoprostol 25mcg intravaginally and another group- PGE2 (N=100) received dinoprostone 0.5mg intracervically.

## Method of Application of Drug

1. PGE1 tablet – under strict aseptic precautions, 25mcg misoprostol was placed digitally in the posterior fornix of vagina every 4<sup>th</sup>hrly for a maximum of 6 doses.
2. PGE2 gel – under strict aseptic precautions, 0.5mg dinoprostone gel was instilled intracervically. The cervix is exposed with a speculum and catheter was advanced into cervical canal upto the level of internal os. The contents of the syringe were emptied slowly by withdrawing the catheter. This was instilled every 6<sup>th</sup>hrly for a maximum of 3 doses. After drug instillation patient was kept in bed strictly for 30min.
3. Uterine contractions and FHR were carefully monitored. Per vaginal examination was repeated before drug administration or earlier if patient complained of draining p/v or labor pains. The doses were repeated till either the change of bishop's score to >6 or till 3 instillations of PGE2 gel or 6 doses of PGE1. Membranes were ruptured when cervix is fully effaced and dilation is >3cm. Whenever necessary labor was augmented with oxytocin in incremental doses starting with 2mcu/min slowly titrated at an interval of 30min till adequate contractions reached (3-4 regular contractions in 10min each lasting for 40-50sec). Maternal pulse, BP& FHR were monitored every 30min and progress of labor assessed with partogram. Even after receiving last dose of PGE1 or PGE2, if bishop's score is <6 then it was considered as failure and taken for c-section.
4. The efficacy and safety of these methods were analysed and compared in the following parameters:
  - Induction delivery interval, mode of delivery, neonatal outcome, fetomaternal complications and cost of drug.
  - Statistical analysis was done by chi square test.

## Results

It is a prospective comparative study in 200 cases of pregnant women divided 100 in each as Group- PGE1 received misoprostol 25mcg intravaginally and

another group- PGE2 received dinoprostone 0.5mg intracervically .

The number of patients requiring oxytocin for acceleration of labor is 35 in PGE1 group compared to 56 in PGE2 group.

Statistically significant vaginal deliveries more for PGE1 (p = 0.032). C-section rate was 31% in PGE2 group compared to 18% in PGE1 group which is statistically significant.

PGE1 induction to delivery interval <12 hrs is statistically significant.

Failed induction with PGE2 is more with p = 0.037 and chi square = 4.34 which is statistically significant.

P=0.334 chisquare=0.93 not significant. Maternal complications more or less same with PGE1 and PGE2.

Fetal outcome P=0.506 chisquare=0.44 which is not significant.

**Table 1:** Demographic distribution in study

Age intervals	Group- PGE1 N=100 Number of subjects	Group- PGE2 N=100 Number of subjects
<20 yrs	40	43
21-25 yrs	55	50
26-30 yrs	5	7
<b>Parity</b>		
Primi	47	45
Multi	53	55
Total	100	100
<b>Indication</b>		
Prolonged pregnancy	57	56
Pregnancy induced HTN	38	36
IUGR	3	5
Well controlled GDM	2	3

**Table 2:** Comparison of patients delivery and Induction interval

Type of Delivery	Group- PGE1 N=100 Number of subjects	Group- PGE2 N=100 Number of subjects
Vaginally delivered	82	69
c-section	18	31
Total	100	100
<b>Induction delivery interval</b>		
<12 hrs	53	26
12-24 hrs	29	38
>24 hrs	0	5
Total	82	69
Mean time range	11.32 +_ 2.93	15.06+_ 4.06

**Table 3:** Maternal and fetal Outcome in study

Indication for C-section	Group- PGE1 N=100 Number of subjects	Group- PGE2 N=100 Number of subjects
Fetal distress	10	8
Failed induction	8	23
Total	18	31
<b>Maternal Complications</b>		
Tachysystole	6	2
Hyperstimulation	3	3
<b>Neonatal outcome</b>		
Good APGAR >6	87	90
Low APGAR <6	13	10
NICU admissions	4	2

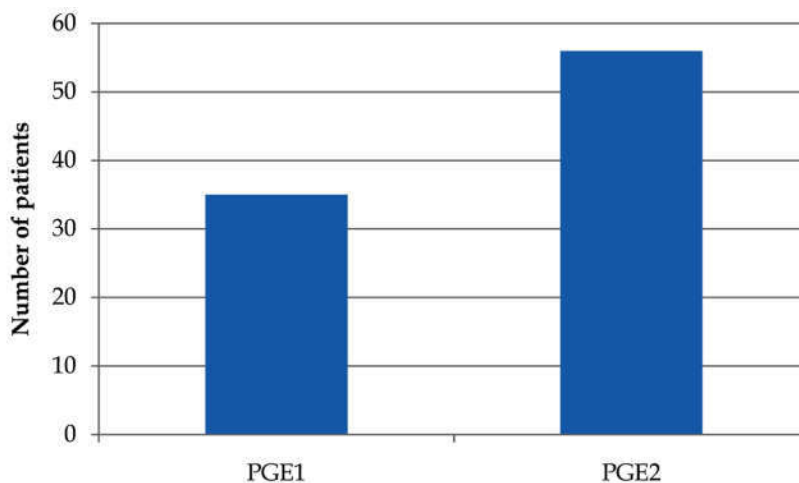


Fig. 1: Need for oxytocin augmentation in groups

## Discussion

Induction of labor is one of the most commonly performed obstetric procedures. The prostaglandins are highly efficacious cervical ripening agents and used to shorten induction - delivery interval, to improve induction success and to reduce morbidities associated with prolonged labor induction. Multiple trials have been studied in the past to show the efficiency of PGE1 over PGE2. In our study, vaginal delivery is considered as success of induction irrespective of time duration of labor. Gupta et al [3] and MB Krishnamurthy et al [4] showed significant vaginal deliveries with PGE1 group compared to PGE2 group which is similar to the present study i.e 82% vs 69%.

Induction delivery interval (in hrs) with PGE1 & PGE2  $11.32 \pm 2.93$ ,  $15.06 \pm 4.06$  respectively which is correlating with SB Chowdary et al [5]; Gupta et al [3]. There is significant induction-delivery interval within 24hrs with PGE1. The Cochrane [6] pregnancy and child birth group reviewed trials comparing misoprostol with placebo, oxytocin and PGE2 for cervical ripening showed that vaginal misoprostol was more effective than dinoprostone for inducing vaginal delivery within 24hrs. The preparation of women who underwent caesarean section for failed induction was lower in PGE1 group than PGE2 group which was similar to the studies of MB Krishnamurthy et al [4] and SB Chowdhary et al [5].

Misoprostol was associated with less need of oxytocin augmentation. The Cochrane [6] review also concluded that oxytocin augmentation was consistently used less often with PGE1. Regarding neonatal outcome, perinatal results are evaluated by

means of low APGAR score, meconium stained liquor and admission to NICU were slightly more with PGE1 than PGE2 and is not significant statistically.

The incidence of tachysystole and hyperstimulation was more with PGE1 than PGE2 i.e 9% vs 5% which was not statistically significant, which is comparable to the studies of Gupta et al [3] and MB Krishnamurthy [4]. Regarding average cost of induction, the mean cost of therapy in the misoprostol group was Rs 11.70 per woman compared to Rs 365.40 in PGE2 group which is statistically significant.

## Summary

The present study consists of comparison of induction of labour with Misoprostol and Dinoprostone gel in 200 patients. 100 patients received 25 mcg intravaginal Misoprostol remaining 100 patients received PGE2 gel 0.5 mg (Dinoprostone) intracervically.

Indications, parity, gestational age were comparable to both groups. Misoprostol induction resulted in more number of vaginal deliveries compared to PGE2 gel (82% compared to 69%) P value 0.032 statistically significant. Misoprostol group had more number of vaginal deliveries within 24hrs (82% compared to 64%) P value 0.0007 statistically significant. Misoprostol group had less need for acceleration of labour with oxytocin compared to PGE2 gel group (42% compared to 81%).

Misoprostol group had lower caesarean section rate compared to PGE2 gel group (18% compared to 31%). Misoprostol group had less induction failure rates compared to PGE2 gel group (8% compared to 23%) P value 0.037. Statistically significant. Misoprostol

group had slightly higher incidence of uterine contractility abnormalities that is tachysystole and hyper stimulation (9% vs 5%). Which is not statistically significant. Misoprostol group had slightly higher incidence of fetal complications i.e 13% vs 10% which is statistically not significant.

NICU admissions were comparatively more with PGE1 than PGE2 which is not statistically significant i.e 4% vs 2%. All mothers and babies were healthy at time of discharge. The average cost of labor induction with Misoprostol is less compared to PGE2 gel group.

### Conclusions

Misoprostol (PGE1) is more efficacious for cervical ripening and labor induction than Dinoprostone (PGE2) as Misoprostol had lesser requirement of oxytocin for labor augmentation, shorter induction delivery interval, more number of vaginal deliveries, less caesarean section rate, stable at room temperature and cost effective. However uterine contraction abnormalities, fetal heart irregularities and meconium staining of liquor should be carefully assessed by close monitoring of labor by intrapartum CTG and partogram.

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