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# A comparative study of instillation of single dose prostaglandin E2 Gel 0.5mg v/s misoprostol (PG E1) 25mcg for induction of labour

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**Abstract**
Induction of labour using prostaglandins is a common practice nowadays. This study aims to evaluate the effect of single application of intracervical PGE2 gel 0.5 mg and tablet misoprostol PGE1 per vaginally 25 mcg and evaluates maternal mortality and morbidity and outcome after application. Induction helps to decrease the rate of cesarean sections and helps in increasing the vaginal deliveries within 24 hour. This study had shown that the induction of delivery interval was less, rate of cesarean section was less, the rate of complications were higher in the misoprostol group compared to dinoprostone. This shows that the intravaginal misoprostol is a better drug of choice in ripening of the cervix during the IOL compared to Dinoprostone. The use of randomised controlled methodology is the strength of this study. Further research with stronger methodology and adequate sample size helps in generalising the study results.

**Keywords:** PGE1, PGE2, NICU, IOL

## Introduction
The induction of labour is a common practice which is practiced by obstetricians world wide. The induction of labour prevents the chance of cesarean section and helps in achievement of vaginal delivery in circumstances where the prolongation of the labour may be potentially dangerous for either the pregnant woman or baby [1]. The induction of labour involves contractions of the uterus before the spontaneous onset leading to progressive effacement and dilation of the cervix and delivery of the baby [2]. The main aim of the induction of labour is to complete the process of labour with defined time frame in good condition and minimum discomfort and complications to the pregnant women. The indications of induction of labour include fetal and maternal indications at full term. The rate of induction varies from 9.5% to 33.7% of all the pregnancies annually. About 20% of the pregnant women requires medical intervention in the form of induction [3]. The overall rates of induction of labour is increased only during last few decades. Post dated pregnancy, maternal problems including diabetes mellitus, renal disease, hypertension, intrauterine growth retardation, oligohydromnios, premature rupture of membranes, intrauterine death, logistic factors and other medical or obstetric conditions are some of the common indications for induction of labour. The most common indication for induction of labor is post dated pregnancy [4]. The prostaglandin mainly acts through the fibroblast activity and also as chemotactic agents promoting the infiltration of leucocytes and macrophages into the cervical stroma. The cell thus infiltrated is the source of specific degradative enzymes and change in the extracellular matrix associated with ripening [5]. $PGE_2$ has been shown to be successful in increasing the vaginal deliveries within 24 hours with no increase in operative delivery rates [6]. It is the most common prostaglandin used recently. The systematic absorption of the $PGE_2$ results in side effects including nausea, vomiting and initiation of uterine contractions may lead to uterine hyperactivity especially in women with unfavourable cervix and even in the placental absorption [7]. $PGE_1$ is a synthetic analogue of naturally occurring prostaglandin $E_1$ which was originally manufactured for the treatment of peptic ulcer. It is an effective drug for ripening of the cervix and labour induction. It is also cheap, easy to handle and can be stored at room temperature [8]. It is also preferred for short induction delivery interval, easy availability, low maternal and fetal complications and low failure rate are especially useful [9]. This study was taken up to compare the safety and efficacy of $PGE_2$ with intra vaginal $PGE_1$.

## Materials and Methods

A randomised controlled study was undertaken in the department of Obstetrics and Gynaecology, DR DY PATIL Medical College And Hospital, PUNE from July 2017 to September 2019 among indoor pregnant women after 37 completed weeks of gestation. A total of 100 cases constituted the sample size. The Clearance from institutional ethical committee was obtained before the study was started. An informed, bilingual consent was obtained from each patient before the induction of labour. The inclusion and exclusion criteria were as follows,

**Inclusion criteria:** Pregnancy Induced Hypertension, Post term, Foetal anomaly, IUGR, Diabetes Mellitus, Rh incompatibility, Duration of pregnancy – 37 to 42 week's period of gestation, Age – 18-35 years, Single foetus with vertex presentation, Cervical score – 0-3, Primipara and Multipara.

**Exclusion criteria:** Subject who have had previous uterine surgeries, Hypersensitivity to prostaglandins, With favourable cervix (modified bishop's score > or =8), Abnormal lie and presentation, Multiple pregnancy, Non reassuring foetal status, Severe hydrocephalus, Abnormal placentation (placenta previa, vasa previa), Active genital herpes, Cervical cancer, Cephalopelvic disproportion, contracted pelvis or distorted pelvic anatomy, Grand multipara.

A total of 100 patients were randomly allocated Dinoprostone and Misoprostol groups. Group A included pregnant women who were in labour received 25 µg of Misoprostol intravaginally, 6$^{th}$ hourly to a maximum of 4 doses, patients were kept in recumbent position for one hour and Group B included 50 pregnant women who received 0.5 mg of Dinoprostone intracervically 6$^{th}$ hourly to a maximum of 3 doses with or without oxytocin augmentation Bishop score was assessed every 6 hours. If the contractions were not adequate, in active phase of labour oxytocin drip was started with 2.5 U in 500 ml ringer lactate with 2 mU/min and increased in geometric fashion every 30 min till 3 contractions were observed in 10 min period each lasting for 45 – 60 seconds up to a maximum of 40 mU/min. Artificial rupture of the membranes was conducted in active labour to hasten the process of delivery and to note down the colour of liquor.

Labour and delivery parameters including interval from start of induction to delivery, mean number of patients requiring oxytocin augmentation, mode of delivery were compared. Occurrence of fever, gastrointestinal symptoms, hyperstimulation, postpartum haemorrhage were also evaluated.

## Results

**Table 1:** Distribution of the study groups according to age

| Age group | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| Less than 20 years | 6 (12.0) | 4 (8.0) | 10 (10.0) |
| 21 – 25 years | 25 (50.0) | 31 (62.0) | 56 (56.0) |
| 26 – 30 years | 17 (34.0) | 11 (22.0) | 28 (28.0) |
| More than 30 years | 2 (4.0) | 4 (8.0) | 6 (6.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |
| Mean ± SD | 24.3 ± 3.4 | 24.7 ± 3.6 | 24.5 ± 3.5 |
| T value | 0.298 | | |
| p value | 0.586, NS | | |

The mean age of the misoprostol group was 24.3 (± 3.4) years and dinoprostone group was 24.7 years. Majority of the women in both the groups belonged to 21 – 25 years of age group. There was no statistically significant difference between the two groups.

**Table 2:** Distribution of the study groups according to Booking status

| Booking status | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| **Booked** | 34 (68.0) | 34 (68.0) | 68 (68.0) |
| **Unbooked** | 16 (32.0) | 16 (32.0) | 32 (32.0) |
| **Total** | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 0.000 df=1 p value=1.0, NS

About 68% of the pregnant women in both the groups were booked cases and 32% were unbooked cases. There was no statistically significant difference between the two groups.

**Table 3:** Distribution of the study groups according to Gravida status

| Gravida | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| Multi | 17 (34.0) | 20 (40.0) | 37 (37.0) |
| Primi | 33 (66.0) | 30 (60.0) | 63 (63.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 0.386 df=1 p value=0.534, NS

About 66% of the pregnant women in misoprostol group were primigravida and about 60% of the women in dinoprostone group were primigravida. There was no statistically significant difference between the two groups.

**Table 4:** Distribution of the study groups according to Indication for induction

| Indication for induction | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| Gestational hypertension | 6 (12.0) | 7 (14.0) | 13 (26.0) |
| Foetal anomaly | 1 (2.0) | 0 | 1 (1.0) |
| Oligohydromnios | 12 (24.0) | 21 (42.0) | 33 (33.0) |
| Polyhydromnios | 1 (2.0) | 1 (2.0) | 2 (2.0) |
| Post dated pregnancy | 26 (52.0) | 19 (38.0) | 45 (45.0) |
| Severe eclapmsia | 4 (8.0) | 2 (4.0) | 6 (6.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 5.287 df=1 p value=0.382, NS

The main indication of induction of labour in the misoprostol group was post dated pregnancy (52.0%) and in dinoprostone group was oligohydromnios (42.0%). Oligohydrominos (24.0%) was the second indication of induction in misoprostol group and post dated pregnancy was the second indication in dinoprostone group (38.0%).

**Table 5:** Distribution of the study groups according to Bishop score

| Bishop score | Group | | T value | P value, Sig |
|---|---|---|---|---|
| | Misoprostol Mean (± SD) | Dinoprostone Mean (± SD) | | |
| Bishop score at baseline | 2.46 (± 0.79) | 2.54 (± 0.73) | 0.525 | 0.601, NS |
| Bishop score at 6 hours | 5.1 (± 1.84) | 4.42 (± 1.47) | 2.038 | 0.044, Sig |
| Bishop score at 12 hours | 6.76 (± 1.32) | 6.3 (± 1.69) | 1.583 | 0.117, NS |

The mean Bishop score at baseline in misoprostol group was 2.46 (± 0.79) and 2.54 (± 0.73) in dinoprostone group. The mean Bishop score at 6 hours in misoprostol group was 5.1 (± 1.84) and 4.42 (± 1.47) in the dinoprostone group. The mean Bishop score at 12 hours in the misoprostol group was 6.76 (± 1.72) and in dinoprostone group was 6.3 (± 1.69). There was a statistically significant difference in Bishop Scores at 6 hours between the two groups.

**Table 6:** Distribution of the study groups according to number of doses

| No of doses | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| One | 19 (38.0) | 16 (32.0) | 35 (35.0) |
| Two | 23 (46.0) | 23 (46.0) | 46 (46.0) |
| Three | 8 (16.0) | 11 (22.0) | 19 (19.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 0.731 df=2 p value=0.694, NS

In misoprostol group, two doses of the drug was used 46% of the pregnant women and in dinoprostone group also two doses of the drug was used for induction in 46% of the ca

**Table 7:** Distribution of the study groups according to use of oxytocin

| Use of oxytocin | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| No | 18 (36.0) | 12 (24.0) | 30 (30.0) |
| Yes | 32 (64.0) | 38 (76.0) | 70 (70.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 1.714 df=1 p value=0.19, NS

The oxytocin was used in 64% of the pregnant women in misoprostol group and 76% of the dinoprostone group. This difference in use of oxytocin was not statistically significant between the two groups.

**Table 8:** Distribution of the study groups according to induction delivery interval

| Induction delivery interval (Hrs) | Group | | T value | P value, Sig |
|---|---|---|---|---|
| | Misoprostol Mean (± SD) | Dinoprostone Mean (± SD) | | |
| Mean ± SD | 10.68 (± 4.16) | 12.66 (± 4.13) | 2.39 | 0.019, Sig |

The mean (± SD) induction delivery interval was 10.68 hours in misoprostol group and 12.66 hours in dinoprostone group. This difference in induction delivery interval was statistically significant between the two groups.

**Table 9:** Distribution of the study groups according to accelerated delivery

| Accelerated delivery | Group | | T value | P value, Sig |
|---|---|---|---|---|
| | Misoprostol Mean (± SD) | Dinoprostone Mean (± SD) | | |
| Mean ± SD | 3.86 (± 0.83) | 4.02 (± 0.84) | 0.953 | 0.343, NS |

The time of accelerated delivery was 3.86 hours in the misoprostol group and 4.02 hours in the dinoprostone group. There was no statistically significant difference in accelerated delivery of the two groups.

**Table 10:** Distribution of the study groups according to mode of delivery

| Mode of delivery | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| Ventouse | 3 (6.0) | 0 | 3 (3.0) |
| LSCS | 11 (22.0) | 12 (24.0) | 23 (23.0) |
| Kiwi (vaccum) | 1 (2.0) | 1 (2.0) | 2 (2.0) |
| Vaginal delivery | 35 (70.0) | 37 (74.0) | 72 (72.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 3.099 df=3 p value=0.377, NS

About 70% of the misoprostol and 74% of the dinoprostone group were delivered by normal vaginal delivery. The cesarean section was conducted in 22% of the misoprostol and 24% of the dinoprostone groups. This difference in mode of delivery was not statistically significant between the two groups.

**Table 11:** Distribution of the study groups according to outcome of labour

| Outcome of labour | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| Uneventful | 39 (78.0) | 38 (76.0) | 77 (77.0) |
| Fetal distress | 5 (10.0) | 5 (10.0) | 10 (10.0) |
| Meconium stained amniotic fluid | 2 (4.0) | 1 (2.0) | 3 (3.0) |
| Non progression of labour | 4 (8.0) | 6 (12.0) | 10 (10.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 0.746 df=3 p value=0.862, NS

The outcome of the labour was uneventful in 78% of the misoprostol group and 76% of the dinoprostone group. About 10% labour in both the groups experienced fetal distress, 4% in misoprostol group had meconium stained liquor and 12% in the dinoprostone group had non progression of the labour. There was no statistically significant difference in the outcome of the labour between the two groups.

**Table 12:** Distribution of the study groups according to maternal complications

| Maternal complications | Group | | Total n (%) |
|---|---|---|---|
| | Misoprostol n (%) | Dinoprostone n (%) | |
| Nil | 40 (80.0) | 34 (68.0) | 74 (74.0) |
| Diarrhea | 0 | 3 (6.0) | 3 (3.0) |
| Fever | 0 | 4 (8.0) | 4 (4.0) |
| Hyper stimulation | 4 (8.0) | 5 (10.0) | 9 (9.0) |
| PPH | 5 (10.0) | 2 (4.0) | 7 (7.0) |
| Tachysystole | 1 (2.0) | 2 (4.0) | 3 (3.0) |
| Total | 50 (100) | 50 (100) | 100 (100) |

$\chi^2$ Value= 9.217 df=5 p value=0.101, NS

About 80% of the misoprostol group and 68% of the dinoprostone group had no complications as a result of IOL. About 10% in the misoprostol group experienced PPH, 8% had hyper stimulation and 2% had tachysystole. About 6% in the dinoprostone group had diarrhoea, 8% had fever, 4% had PPH and 4% experienced tachysytole.

## Discussion

A randomised controlled study of 100 cases constituted the sample size. The mean age of the misoprostol group was 24.3 (± 3.4) years and dinoprostone group was 24.7 years. Majority of the women in both the groups belonged to 21 – 25 years of age group.

Booking status about 68% of the pregnant women in both the groups were booked cases and 32% were unbooked cases.

Gravida status About 66% of the pregnant women in misoprostol group were primigravida and about 60% of the women in dinoprostone group were primigravida.

Indication for induction the main indication of induction of labour in the misoprostol group was post dated pregnancy (52.0%) and in dinoprostone group was oligohydromnios (42.0%). Oligohydromnios (24.0%) was the second indication of induction in the misoprostol group and post dated pregnancy was the second indication in dinoprostone group (38.0%).

Bishop scores The mean Bishop score at baseline in misoprostol group was 2.46 (± 0.79) and 2.54 (± 0.73) in dinoprostone group. The mean Bishop score at 6 hours in misoprostol group was 5.1 (± 1.84) and 4.42 (± 1.47) in the dinoprostone group. The mean Bishop score at 12 hours in the misoprostol group was 6.76 (± 1.72) and in dinoprostone group was 6.3 (± 1.69).

Number of doses In misoprostol group, two doses of the drug was used 46% of the pregnant women and in dinoprostone group also two doses of the drug was used for induction in 46% of the cases.

Use of oxytocin The oxytocin was used in 64% of the pregnant women in misoprostol group and 76% of the dinoprostone group.

Induction delivery interval The mean (± SD) induction delivery interval was 10.68 hours in misoprostol group and 12.66 hours in dinoprostone group. The mean induction delivery interval was lesser in Dinoprostone group compared to Misoprostol group.

Accelerated delivery The time of accelerated delivery was 3.86 hours in the misoprostol group and 4.02 hours in the dinoprostone group.

Mode of delivery The cesarean section was conducted in 22% of the misoprostol and 24% of the dinoprostone groups.

Outcome of labour The outcome of the labour was uneventful in 78% of the misoprostol group and 76% of the dinoprostone group. About 10% labour in both the groups experienced fetal distress, 4% in misoprostol group had meconium stained liquor and 12% in the dinoprostone group had non progression of the labour.

Adverse effects About 80% of the misoprostol group and 68% of the dinoprostone group had no complications as a result of induction of labour. About 10% in the misoprostol group experienced PPH, 8% had hyperstimulation and 2% had tachysystole. About 6% in the dinoprostone group had diarrhoea, 8% had fever, 4% had PPH and 4% experienced tachysystole.

## Conclusion

- Failed induction of labour results in prolonged hospitalisation, an increased cesarean delivery rate upto 60% when the bishop score is less than 4 and increased emotional distress to the patients even if the cesarean delivery is immediately performed.
- The prostaglandin mainly acts through the fibroblast activity and also as chemotactic agents promoting the infiltration of leucocytes and macrophages into the cervical stroma.
- The systematic absorption of the $PGE_2$ results in side effects including nausea, vomiting and initiation of uterine contractions may lead to uterine hyperactivity especially in women with unfavourable cervix.
- $PGE_1$ is a synthetic analogue of naturally occurring prostaglandin $E_1$ which was originally manufactured for the treatment of peptic ulcer.
- The studies comparing the efficacy and safety of single dose $PGE_1$ and $PGE_2$ are poor in this part of the country.
- A randomised controlled study was undertaken in the department of Obstetrics and Gynaecology, DR DY Patil Medical College And Hospital, PUNE among the pregnant women after 37 completed weeks of gestation. A total of 100 cases constituted the sample size.
- The mean age of the misoprostol group was 24.3 (± 3.4) years and dinoprostone group was 24.7 years.
- About 68% of the pregnant women in both the groups were booked cases and 32% were unbooked cases.
- About 66% of the pregnant women in misoprostol group were primigravida and about 60% of the women in dinoprostone group were primigravida.
- The main indication of the induction of labour in the misoprostol group was post dated pregnancy (52.0%) and in dinoprostone group was oligohydromnios (42.0%). Oligohydromnios (24.0%) was the second indication of induction in the misoprostol group and post dated pregnancy was the second indication in dinoprostone group (38.0%).
- The mean Bishop score at baseline in misoprostol group was 2.48 (± 0.84) and 2.54 (± 0.73) in dinoprostone group. The mean Bishop score at 6 hours in misoprostol group was 4.72 (± 2.3) and 1.6 (± 2.7) in the dinoprostone group. The mean Bishop score at 12 hours in the misoprostol group was 3.98 (± 3.13) and in dinoprostone group was 5.32 (± 2.53).
- In misoprostol group, two doses of the drug was used 46% of the pregnant women and in dinoprostone group also two doses of the drug was used for induction in 46% of the cases.
- The oxytocin was used in 64% of the pregnant women in misoprostol group and 76% of the dinoprostone group.
- The mean (± SD) induction delivery interval was 10.68 hours in misoprostol group and 12.66 hours in dinoprostone group.
- The time of accelerated delivery was 3.86 hours in the

misoprostol group and 4.02 hours in the dinoprostone group.

- The cesarean section was conducted in 22% of the misoprostol and 24% of the dinoprostone groups.
- About 10% labour in both the groups experienced fetal distress, 4% in misoprostol group had meconium stained liquor and 12% in the dinoprostone group had non progression of the labour.
- About 80% of the misoprostol group and 68% of the dinoprostone group had no complications as a result of induction of the labour. About 10% in the misoprostol group experienced PPH, 8% had hyperstimulation and 2% had tachysystole. About 6% in the dinoprostone group had diarrhoea, 8% had fever, 4% had PPH and 4% had tachysystole.

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