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# Comparative Study of Induction of Labour with Misoprostol versus Foley's Balloon Catheter with Extra Amniotic Saline Infusion in Unfavourable Cervix

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**Abstract**
**Background:** *Induction of labour by use of artificial means improves the obstetric outcome in complicated cases. This observational study compares the effect of prostaglandin $E_1$ ($PGE_1$) and extra amniotic saline infusion (EASI) for pre-labour ripening of unfavourable uterine cervix.*
**Materials and Methods**: *This prospective observational study was conducted in the Department of Obstetrics and Gynaecology, Government TD Medical College, Alappuzha, Kerala. Data were collected from 232 antenatal women with gestational age ≥37 weeks and who satisfied the inclusion and exclusion criteria were included in this study. 232 patients were divided into two groups. Group-1 contains 179 patients received intravaginal $PGE_1$ (tablet Misoprostol 25 µg or 50 µg) inserted in the posterior vaginal fornix under all aseptic precautions. Group-2 contains 53 patients who were induced with extra amniotic saline infusion (EASI). The main outcome variables were the number of subjects with favourable Bishop's score, mode of delivery, maternal complications and neonatal outcomes.*
**Results:** *Majority of the patients in both groups were under the age of 21-30 years. There was significant difference in age, parity and gestation age of both groups. In our study we found only 2 cases of postpartum haemorrhage among the entire sample. We also found significant difference in oxytocin augmentation between both groups. The occurrence of hyper stimulation was higher in $PGE_1$ group. We found no significant difference in the occurrence of hyper stimulation and maternal pyrexia among two groups. There was significant difference in the neonatal outcomes of both groups.*
**Conclusions:** *$PGE_1$ and EASI have similar efficacy in induction of labour, but in very unfavourable cervices Foley's catheter with EASI is better than other methods of induction especially in areas with limited resources.*
**Keywords:** *$PGE_1$, EASI, labour induction, oxytocin, Bishop score.*

## Introduction

In majority of women labour induction starts spontaneously and results in vaginal delivery at or near term. Labour induction when performed in a woman with an unripe cervix, often results in prolonged and difficult labour. Failed inductions may lead to caesarean delivery.[1] Therefore induction of cervical ripening is critical to successful induction of labour in a pregnant woman whose cervix has not gone through the ripening process which will reduce the risk of maternal or neonatal morbidity and mortality. [2] Induction of labour can be defined as the artificial initiation of labour before its spontaneous onset, for the purpose of delivery of the fetoplacental unit.[3,4]

Oxytocin and prostaglandins are the pharmacologic agents most frequently used for induction of labour.[5] Although oxytocin infusion is widely accepted as a safe and effective labour induction method, its success is highly dependent on the condition of the cervix at the beginning of induction. Hence cervical ripening agents often are applied in women with unfavourable cervices before an oxytocin infusion is initiated.[6]

The various pharmacological and mechanical (non-pharmacological) methods are available for cervical ripening of unfavourable cervix. Mechanical device dilates the cervix by accessing the fetal membrane and pharmacological preparation cause connective tissue softening, cervical effacement and uterine activity.[7,8] Despite the multiplicity of techniques, there is no universally accepted idea, thus the ideal method of labour induction remains elusive.[9]

Prostaglandins are extensively used in clinical practice since 1960s for induction of labour and cervical ripening. Prostaglandins including a variety of classes, doses and routes of administration, have been widely studied as alternatives to oxytocin.[10-11] Induction of labour with prostaglandins offers the advantage of promoting both cervical ripening and myometrial contractility. A drawback of PGEs is their ability to induce excessive uterine contractility which can increase perinatal morbidity. The commonly used prostaglandins are misoprostol ($PGE_1$) and dinoprostone ($PGE_2$). $PGE_1$ has replaced the use of $PGE_2$due to its lower cost, higher stability and probably higher efficacy.[12]

Mechanical dilation methods comprise of trans-cervical Foley catheter alone and trans-cervical Foley catheter with extra amniotic saline infusion (EASI) for enhanced endogenous prostaglandin secretion. Cervical ripening with extra amniotic balloon catheters possess the advantages of simplicity, low cost, reversibility and lack of severe side effects; however ripening with extra amniotic balloons subsequently requires oxytocin augmentation in many cases and is associated with significant rate of dysfunctional labour and caesarean section. The balloon catheter with EASI probably has a place as a cervical ripener, especially when prostaglandins are contra indicated or when uterine hyper stimulation should be avoided such as in cases of fetal IUGR or placental insufficiency. EASI is of low cost, effective and relatively less frequent occurrence of major complications. Studies shows this method can be safely used in patients with previous caesarean section for cervical ripening and labour induction. Different studies conducted so far shows that EASI is as effective as prostaglandins, safe and much cheaper than prostaglandins.

## Aim

The present study was undertaken with the aim to compare the effect of $PGE_1$ and EASI for prelabour ripening of unfavourable uterine cervix in pregnant women. This study also compares the effects of $PGE_1$ and EASI on maternal complications and neonatal outcomes.

## Materials and Methods

This study was an observation study conducted at the Department of Obstetrics and Gynaecology (OB&G), Government TD Medical College, Alappuzha. The study protocol was approved by the Regional Committee for Medical Research Ethics. The period of study was for one year.

Information was collected from 232 pregnant women who were selected for induction of labour at MCH Alappuzha (OI unit). All the participants were informed about this research and written consents were obtained from each participant.

**Inclusion criteria**

Women admitted to the Department of OB&G who met the following inclusion criteria were selected for the study.

- Bishop's score <6
- Unscarred uterus
- Singleton pregnancy
- Cephalic presentation
- Intact membranes
- No contraindication for vaginal delivery

**Exclusion criteria**

Pregnant women with the following conditions were excluded from our study

- Previous scar on uterus i.e., previous LSCS, previous myomectomy etc.
- Patients in active labour i.e. more than 3 cm dilatation and or having more uterine contraction lasting for more than 30 seconds in ten minutes of observation.
- Ruptured membranes
- Hyper sensitivity to prostaglandins
- Any serious maternal disease or fetal condition

General and systemic examination (cardiovascular system and respiratory system) was also performed. All biochemical investigations including blood and urine examinations were done. Baseline parameters were noted. Pre-induction counselling was done. Patients were explained about the need for induction as well as use of the drugs, their safety and adverse effects.

Bishop's score was noted prior to induction (at zero hour). Detailed pelvic examination was done to judge the condition of cervix according to Bishop's score and adequacy of pelvis. An admission fetal non-stress test (NST) was carried out to examine fetal wellbeing. The patients with reactive NST were taken for the study. When NST was reactive, patient was induced with either of the two drugs. All pregnant women with Bishop Score < 6 were randomly allotted for induction of labour either with PGE1 or patients whose Bishop Score < 3 was induced with EASI.

**Dosage/procedure**

All the 232 patients were provided either with intravaginal $PGE_1$. They were divided into two groups. Group-1 consisted of 179 patients who received 25 µg or 50 µg of $PGE_1$. Group II comprised of 53 patients who were induced with Foley's catheter with EASI.

The dosages of $PGE_1$ used were 50µg (fourth hourly) or 25 µg (3 hourly to a maximum of 250 µg). $PGE_1$was instilled to the posterior vaginal fornix and ARM was done in active phase of labour.

In Foley's catheter with EASI method of induction, with all aseptic precautions, No.18 Foley's catheter was introduced extra amniotically after visualizing cervix with speculum and clearing with povidone iodine. 50m1distilled water was used to inflate the bulb. Bulb was pulled and 200m1 lukewarm saline was injected extra amniotically one ml per minute. Foley's catheter removed after 24hrs and oxytocin drip was started after removal or spontaneous expulsion of the bulb. For this group Ampicillin 2gm intravenous injection at 6th hourly and Metrogyl 500mg intravenous injection at 8th hourly were given.

Vital parameters of all patients were recorded and per abdomen examination was done one hourly for uterine activity, tachysystole or hyperstimulation. Fetal heart rate was monitored. All patients in $PGE_1$ group were reassessed after 3 and 4 hours for 25 and 50 µg respectively. Repeat the doses if required. Reassessment was also done to note improvement in Bishop's score and progression to active phase.

Important anthropometric details were recorded from the patients using a standard questionnaire. To avoid inter observer and instrumental bias; all measurements were taken by the same measuring instrument/scale and by same person.

**Statistical analysis**

The descriptive statistics of the study population was calculated. Chi Square test was carried out to study the association of different methods of labour induction and pregnancy outcomes.

**Results**

In the sample of 232 women, 77.15 % (Group I) were induced with 25 µg/50 µg of $PGE_1$.and remaining 22.85 % women (Group II) were induced using Foley's catheter with EASI.

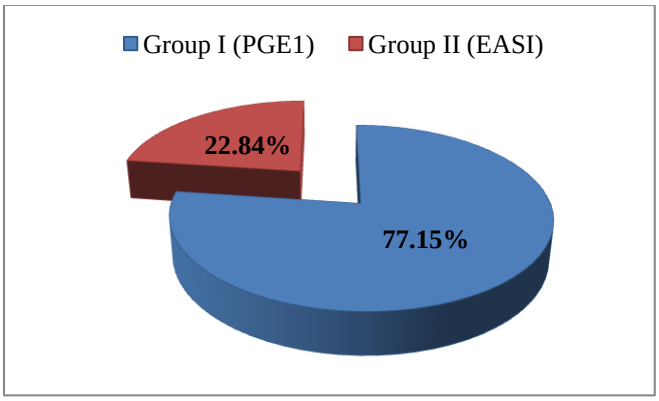


**Fig 1.** Distribution of women according to method of induction

The maternal demographic profile of the women participated in this study is portrayed in table 1. Both groups were comparable with respect to maternal age, parity and mean gestational age at the time of induction. In group I maximum patients belonged to the age group of 21- 30 years and minimum number was found in the age group between 31 – 40 years. Similar distribution was found in group II. We found significant difference between the age, parity and gestation age of two groups.

**Table 1.** Comparison of Demographic Variables in $PGE_1$ and EASI Groups

| Indicators | | $PGE_1$ % | EASI % | P value |
|---|---|---|---|---|
| Age (years) | <=20 | 14.53 | 24.53 | 0.000*** |
| | 21-30 | 81.01 | 71.70 | |
| | 31-40 | 4.47 | 3.77 | |
| Parity | Primi | 66.48 | 96.23 | 0.000*** |
| | First | 28.49 | 3.77 | |
| | Second | 5.03 | 0.00 | |
| Gestational age | Pre term | 7.26 | 18.87 | 0.000*** |
| | Term | 92.74 | 81.13 | |

***significant at 1%

We found significant difference in the oxytocin augmentation between group I and group II. Table 2 depicts the oxytocin augmentation in group I and group II along with p value.

**Table 2:** Comparison of oxytocin augmentation in $PGE_1$ and EASI groups

| Pitocin | $PGE_1$ (%) | EASI(%) | P value |
|---|---|---|---|
| yes | 38.55 | 86.79 | 0.000*** |
| No | 61.45 | 13.21 | |

***significant at 1%

In table 3, mode of delivery is presented. 81.56 % and 62.26 % women underwent spontaneous delivery in group I and group II respectively. Caesarean and instrumental delivery was found higher in group II. Our study found significant difference in the mode of delivery among group I and group II (p value 0.000).

**Table 3:** Comparison of mode of delivery in $PGE_1$ and EASI groups

| Mode of delivery | $PGE_1$ (%) | EASI (%) | P value |
|---|---|---|---|
| Spontaneous | 81.56 | 62.26 | 0.000*** |
| Caesarean section | 12.85 | 30.19 | |
| Instrumental (forceps or ventouse) | 5.59 | 7.55 | |

***significant at 1%

Table 4 depicts the maternal complications of group I and group II. In our study, we found only 2 cases of Postpartum Haemorrhage (PPH) among the entire sample and it was in patients who were induced with 25µg of $PGE_1$ group. Hyper stimulation and maternal pyrexia were the two maternal complications measured in our study. Hyper stimulation was found more in group I whereas cases of maternal pyrexia were almost similar in group I and II. We found no significant difference in the occurrence of hyper stimulation and maternal pyrexia among $PGE_1$ and EASI groups.

**Table 4.**Comparison of maternal complications in $PGE_1$ and EASI groups

| Maternal complications | | $PGE_1$ (%) | EASI (%) | P value |
|---|---|---|---|---|
| Hyper stimulation | Yes | 6.15 | 1.89 | 0.219 |
| | No | 93.85 | 98.11 | |
| Maternal pyrexia | Yes | 3.35 | 3.77 | 0.883 |
| | No | 96.65 | 96.23 | |

Apgar score of all new born babies was noted at zero minute and after five minutes of birth. Apgar

scores are presented in table 5 and 6. All the babies born in $PGE_1$ group had a higher Apgar score (7-10). At zero minute, 3.77% babies had zero Apgar score for group II whereas it was only 1.68% in $PGE_1$ group.

**Table 5** APGAR scores of $PGE_1$ and EASI groups at zero minute

| Time | APGAR score | $PGE_1$ (%) | EASI (%) |
|---|---|---|---|
| At zero minute | 0 | 1.68 | 3.77 |
| | 4 | 0.00 | 1.89 |
| | 6 | 0.00 | 0.00 |
| | 7 | 4.47 | 1.89 |
| | 8 | 5.03 | 3.77 |
| | 9 | 88.83 | 88.68 |

**Table 6** APGAR scores of $PGE_1$ and EASI groups after five minutes

| Time | APGAR score | $PGE_1$ (%) | EASI (%) |
|---|---|---|---|
| After 5 minutes | 0 | 1.68 | 3.77 |
| | 4 | 0.56 | 0.00 |
| | 6 | 0.00 | 1.89 |
| | 8 | 0.56 | 0.00 |
| | 9 | 97.21 | 94.34 |

In table 7, the neonatal outcomes are presented. Meconium staining fresh still births (FSB) and NICU admission was higher in group II. There was significant difference between two groups with regard to neonatal outcomes.

**Table 7.** Comparison of neonatal outcome in PGE1 and EASI groups

| Neonatal outcomes | $PGE_1$ (%) | EASI(%) | P value |
|---|---|---|---|
| Meconium staining | 36.36 | 38.46 | 0.000*** |
| Fresh still births | 9.09 | 7.69 | |
| NICU admission | 54.55 | 53.85 | |

***significant at 1%

## Discussions

Labour induction is one of the most commonly performed obstetric procedures in patients undergoing inpatients cervical ripening. Recently, induction of labour by use of prostaglandins is very common due to the rise of maternal or fetal reasons[13].Induction of labour with prostaglandins offers the advantage of promoting both cervical ripening and myometrial contractility. A drawback of prostaglandin is their ability to induce excessive uterine contractility which can increase perinatal morbidity.[14] Prostaglandins are highly efficacious cervical ripening agents used to shorten induction to delivery intervals, improve induction success, and reduce morbidities associated with prolonged labour induction. According to Mohamed and Jayaguru extra amniotic saline infusion for induction of labour is a cost effective method worthy of wider use.[15] EASI is successful in inducing labour in antepartum fetal deaths after 20 weeks of gestation. This method has been shown to be safe and well tolerated by the women and should be considered in areas with limited resources.[16]

A sample of 232 pregnant women was taken in this study. Out of the total samples, 179 cases were induced with $PGE_1$ (group I) and rest 53 were induced with EASI (group II). The mean induction delivery interval in $PGE_1$ was 12.56 hrs and in the EASI group was 27.6 hrs. The baseline characteristics taken in the study were age, parity and gestational age. Among the three baseline characteristics we found significant difference in age parity and gestational age among two groups.

$PGE_1$ is associated with less oxytocin augmentation and lesser caesarean section operations for failed induction Bartha et al.[17] (2000). Our study also indicates that $PGE_1$ was linked with less need of oxytocin augmentation. Caesarean section was lesser in group I. Many studies reported that hyperstimulation were found more in patients who were induced with $PGE_1$. It may be due to the reason there is less risk of hyperstimulation with lower dose of misoprostol but at the same time reducing the effectiveness of labour induction. Our study also found that hyperstimulation was higher in patients induced with $PGE_1$. Regarding neonatal outcomes, perinatal results evaluated by means of Apgar score, FSB, meconium stain and admission to intensive care unit were comparable between two groups with similar perinatal outcome. It has been found that there was significant difference in neonatal outcomes in both the groups.

**Conclusions**

Our study investigated the comparison between $PGE_1$ and EASI in labour induction. Association of $PGE_1$ and EASIwith maternal complications and neonatal outcomes were estimated using Chi-square test. In this study it was proven that there was significant difference in age, parity and gestational age of $PGE_1$ and EASI groups. The mean induction delivery interval in $PGE_1$ was 12.56 hrs and in the EASI group was 27.6 hrs. Our study proved that $PGE_1$has more cases of hyper-stimulation when compared to EASI group. Being a small-scale study, we used small sample size. Therefore we recommend further studies involving large samples comparable to those done in developed countries. Precise use of induction agents with careful selection of patients can be a useful method to reduce the perinatal morbidity and mortality.

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