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# Assessment of outcome of induction of labor with intracervical dinoprostone gel with and without foley's catheter balloon

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**Abstract**
**Background:** Induction of labour (IOL) is indicated when continuing a pregnancy is no longer beneficial to the mother or foetus. The present study was conducted to assess and compare outcome of induction of labor with intracervical dinoprostone gel with and without foley's catheter balloon.
**Materials and Methods:** 60 patients at term with various indications for induction of labor were alternatively allocated to either PGE2 gel (Group I, n = 30), PGE2 gel with Foley's catheter (Group II, n = 30) method.
**Results:** The mean age was 28.2 years in group I and 29.1 years in group II, mean parity was 0.27 in group I and 0.14 in group II and mean period of gestation (POG) at IOL was 38.2 weeks in group I and 38.5 weeks in group II. The difference was non- significant ($p$> 0.05).
**Conclusion:** Administering one dose of an intracervical PGE2 gel with Foley was superior to intracervical dinoprostone gel alone for cervical ripening and IOL.

**Keywords:** PGE2 gel, foley, induction of labor

## Introduction
Labor induction - also known as inducing labor - is prompting the uterus to contract during pregnancy before labor begins on its own for a vaginal birth. Induction of labour (IOL) is indicated when continuing a pregnancy is no longer beneficial to the mother or foetus, and stimulating artificial labour pains to deliver the baby is better than continuing the pregnancy in conditions such as pre-eclampsia or foetal growth restriction. Prior to an IOL, cervical ripening by pharmacological or mechanical methods improves the chances of a vaginal delivery [1]. Mechanical methods (laminaria tent, various types of balloon catheters, and extra-amniotic saline infusion) that were initially developed to ripen the cervix are thought to work by physically dilating the cervix and stimulating the release of endogenous prostaglandins [2]. Pharmacologic ripening agents include oxytocin administration and various forms of exogenous prostaglandin administered orally or vaginally. Currently, prostaglandin E2 preparations (Prostin1, Cervidil1, and Propess1) are the preferred choices in many countries. However, the best method of labor induction is unknown [3].
The mechanical methods were observed to be as effective as PGs as the proportion of women with an unfavourable cervix after 12 to 24 hours (h), and the caesarean section (CS) rates were similar with the balloon catheter, misoprostol (PGE1) and dinoprostone (PGE2). Mechanical methods were observed to be more effective than PGs, as ripening with a Foley catheter resulted in a shorter induction delivery interval (IDI), compared to the PGE2 vaginal insert, with a similar CS rate [4]. Combining a Foley with PGs may enhance efficacy and reduce untoward effects, like tachysystole (by reducing the requirement of PGs) and infection (a faster ripening and an earlier expulsion of Foley) [5].

## Need of the study
To determine the optimal method of labor induction, investigators have conducted many clinical trials that have compared the efficacy and safety of the Foley catheter balloon with the dinoprostone insert. However, the results have not led to a consensus. So, the present study was conducted to assess and compare outcome of induction of labor with intracervical dinoprostone gel with and without foley's catheter balloon.

## Materials and Methods

The present study comprised of 60 patients at term with various indications for induction of labor after a written, valid consent. Inclusion criteria was primigravida, ≥37 weeks of gestation, singleton pregnancy, cephalic presentation and Bishops score <4. Exclusion criteria was multiple pregnancy, mal-presentation, absent membranes, APH, medical disease e.g., heart disease, renal disease and IUFD. Objective was to assess induction delivery interval, augmentation, mode of delivery and change in bishop's score in both the group and to compare induction delivery interval, augmentation, mode of delivery and change in bishop's score in both the group.

Patients were alternatively allocated to either PGE2 gel (Group I, n = 30), PGE2 gel with Foley's catheter (Group II, n = 30) method. The Bishop's score was determined earlier. Each patient was questioned in detail and examined thoroughly. Last menstrual period (LMP) was ascertained and correlated clinically. Post induction Bishop's score was assessed after 6 hours of induction preferably by the same person. Followed by at 12 and 18th hour of induction. Demographic profile, gestation age, improvement of Bishop's score, induction-delivery interval, mode of delivery and feto-maternal outcome was noted. Dose repetition of PGE2 gel was considered if post-induction Bishop's score was ≤7 in both the groups. Need of augmentation of labor was assessed and implemented by other methods such as oxytocin administration. Failure of induction was declared if patient failed to go in active phase of labor within 24 h of induction. Student's t test and Chi square test were used to statistically compare the two group. Differences with a P value of <0.05 were considered statistically significant with the confidence limit of 95% (power of test 80%).

## Results

**Table 1:** Demographic characteristics

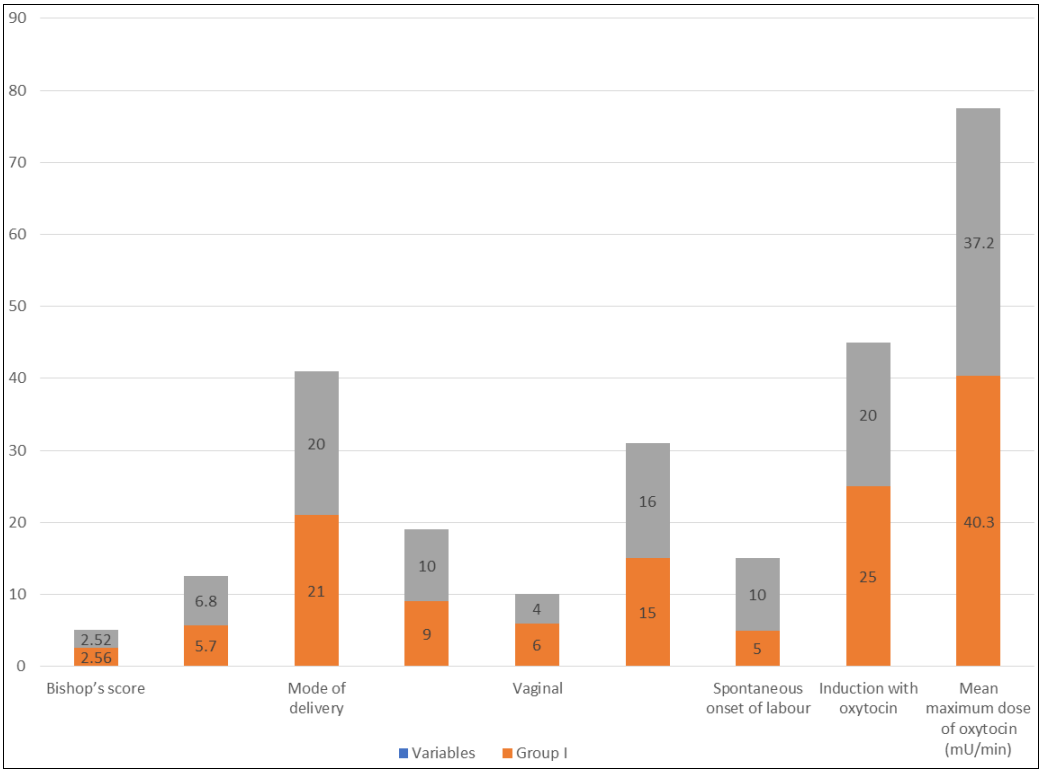
| Baseline | **Group I** (PGE2 gel alone) | **Group II** (PGE2 gel with foleys catheter) | P value |
|---|---|---|---|
| Mean age (years) | 28.2 | 29.1 | 0.13 |
| Mean parity | 0.27 | 0.14 | 0.26 |
| Mean period of gestation (POG) at IOL in weeks | 38.2 | 38.5 | 0.52 |

Table I shows that mean age was 28.2 years in group I and 29.1 years in group II, mean parity was 0.27 in group I and 0.14 in group II and mean period of gestation (POG) at IOL was 38.2 weeks in group I and 38.5 weeks in group II. The difference was non- significant ($p$> 0.05).

**Table 2:** Comparison of parameters

| Parameters | Variables | Group I (PGE2 gel alone) | Group II (PGE2 gel with foleys catheter) | P value |
|---|---|---|---|---|
| Bishop's score | Pre-ripening | 2.56 | 2.52 | 0.94 |
| | Post-ripening | 5.7 | 6.8 | 0.81 |
| Mode of delivery | Vaginal | 21 | 20 | 0.05 |
| | Caesarean | 9 | 10 | |
| Vaginal | Instrumental | 6 | 4 | 0.05 |
| | Spontaneous | 15 | 16 | 0.92 |
| Spontaneous onset of labour | | 5 | 10 | 0.02 |
| Induction with oxytocin | | 25 | 20 | 0.72 |
| Mean maximum dose of oxytocin (mU/min) | | 40.3 | 37.2 | 0.71 |

Table II, graph I shows that mean Bishop's score pre- ripening score in group I and group II was 2.56 and 2.52 and post-ripening score was 5.7 and 6.8. Mode of delivery was vaginal in 21 and 20 and caesarean in 9 and 10 and vaginal was instrumental in 6 and 4 and spontaneous in 15 and 16, spontaneous onset of labour was seen in 5 and 10, induction with oxytocin was seen in 25 and 20. The mean maximum dose of oxytocin (mU/min) was 40.3 and 37.2 in group I and group II respectively. The difference was significant ($p$< 0.05).




**Graph 1:** Comparison of parameters

**Table 3:** Other parameters

| Parameters | Variables | Group I (PGE2 gel alone) | Group II (PGE2 gel with foleys catheter) | P value |
|---|---|---|---|---|
| Cervical ripening time (mins) | | 635.2 | 568.3 | 0.17 |
| Neonatal outcome | APGAR score at 1 min | 8 | 8 | 1 |
| | APGAR score at 5 mins | 9 | 9 | 1 |
| | NICU admission | 2 | 2 | 1 |
| | Neonatal jaundice | 12 | 16 | 0.82 |

Table III shows that Cervical ripening time was 635.2 minutes in group I and 568.3 minutes in group II. APGAR score at 1 minute was 8 in both groups, at 5 minutes was 9, NICU admission was 2 in each group and neonatal jaundice was seen in 12 and 16 in group I and II respectively. The difference was non- significant ($p$> 0.05).

## Discussion

The pharmacological methods used for cervical ripening are prostaglandins (PGs) which soften the cervix, but also initiate contractions and may lead to hyperstimulation [6]. Mechanical methods are intracervical catheters (Foley or double balloon) and hygroscopic dilators which cause release of PGs from foetal membranes and decidua [7, 8, 9]. These do not cause hyperstimulation, but infection may be a concern [10, 11]. The present study was conducted to assess and compare outcome of induction of labor with intracervical dinoprostone gel with and without foley's catheter balloon.

We found that mean age was 28.2 years in group I and 29.1 years in group II, mean parity was 0.27 in group I and 0.14 in group II and mean period of gestation (POG) at IOL was 38.2 weeks in group I and 38.5 weeks in group II. Zhu *et al.* [12] found that eight trials including 1191 women who received the intracervical Foley catheter balloon and 1199 who received the dinoprostone insert were used for this study. There was no significant difference between the 2 groups regarding the induction-to delivery (I-D) interval in a random effect model. The highly significant heterogeneity (I 2=97%) could be explained by the subgroup analysis of the type of Foley catheter and balloon volume. There was no significant difference between the 2 methods regarding the caesarean delivery rate, Apgar score, or side effects, including maternal infection rate, postpartum hemorrhage, and hyperstimulation. No obvious publication bias was found. Conclusions: According to the caesarean delivery rate, the intracervical Foley catheter balloon was as efficient as the dinoprostone insert. A moderate balloon volume (30 mL) and higher dose of dinoprostone (≥6 mg) were related to shorter I-D intervals. Additionally, there was no significant difference between the two methods regarding maternal or neonatal safety.

We found that mean Bishop's score pre- ripening score in group I and group II was 2.56 and 2.52 and post- ripening score was 5.7 and 6.8. Mode of delivery was vaginal in 21 and 20 and caesarean in 9 and 10 and vaginal was instrumental in 6 and 4 and spontaneous in 15 and 16, spontaneous onset of labour was seen in 5 and 10, induction with oxytocin was seen in 25 and 20. The mean maximum dose of oxytocin (mU/min) was 40.3 and 37.2 in group I and group II respectively. Cbowdhary *et al* [13] found that women (n = 110) planned for IOL, ≥37 weeks of gestation and with a Bishop Score of ≤6 were randomised into two groups: intracervical Foley catheter alone or combined with dinoprostone gel (0.5 mg) for 12 hours followed by oxytocin. The primary outcome was the IDI and the others were: change in Bishop Score, caesarean section (CS) requirement, any complications and neonatal outcome. The baseline Bishop was ≤4 in all and >80% were nulliparous. The post-ripening Bishop

was significantly higher (6.67 vs. 5.98; p = .045) and the IDI was significantly lower in the combined group (16 hours and 16 minutes vs. 20 hours 44 minutes, p = .002). The CS rate was similar (29.1 vs. 25.5%; p = .669).

In multiparous women who require cervical maturation, all cervical maturation methods have similar success rates. However, the use of PGE2CR inserts is associated with significantly longer delivery intervals compared to Foley catheters or PGE2 gels [14].

Multiple studies have been done comparing effectiveness and safety between prostaglandin and Foley's catheter. Sciscione *et al* [15] compared the two methods and showed that Foleys catheter group had a shorter induction delivery interval. St Onge and Connors [16] found that both Foleys catheter and PGE2 gel methods led to similar improvement in Bishop's score.

The limitation the study is small sample size. Induction of labour following cervical ripening was done as per obstetrician's convenience. Hence difficult to compare and interpreted induction to delivery interval.

## Conclusion

Pre-induction cervical ripening is a major obstetric challenge because achievement of a vaginal delivery is the greatest factor determining the ability to successfully induce labor in a woman who requires labor induction. Results of present study showed that one dose of an intracervical PGE2 gel with Foley was superior to intracervical dinoprostone gel alone for cervical ripening and IOL

## Conflict of Interest

Not available

## Financial Support

Not available

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