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**Original Research Article**

# Induction of labour using transcervical Foley's catheter with extra amniotic saline infusion versus intracervical prostaglandin E2 gel at term gestation: a comparative study

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## ABSTRACT

**Background:** The intentional commencement of cervical ripening and uterine contraction for the purpose of achieving delivery prior to the onset of spontaneous parturition is known as induction of labour. When the benefits to the mother or the foetus surpass the benefits of extending the pregnancy, it is indicated. The purpose of this study was to assess the efficacy of a transcervical foley's catheter with extra amniotic saline infusion against intra cervical prostaglandin E2 gel for inducing labour in term pregnant women.
**Methods:** From January 2020 to June 2021, a comparative study was undertaken at R.L. Jalappa Hospital and Research Centre. The study enrolled a total of 72 individuals. After obtaining informed consent from the patients who were admitted, and meeting the inclusion criteria, detailed history was collected, baseline investigations were done. After clinical examination of the patient, by using the simple lottery method, patients were divided into group A (Extra amniotic saline infusion group with Foley's catheter) and group B (Dinoprostone (PGE2 gel) group).
**Results:** Prolonged gestational age, hypertensive disorders in pregnancy, and oligohydramnios were the most frequent causes for induction in the EASI group, accounting for 38.89%, 38.89%, and 22.22%, respectively. The dinoprostone group has 36.11%, 33.33%, and 25%, respectively. After induction, the majority of patients in the EASI group had a modified Bishop's score of 2.
**Conclusions:** Our research found that PGE2 and EASI were equally effective in inducing labour.

**Keywords:** Extra amniotic saline infusion, Prostaglandin E2, Dinoprostone, Induction of labour, Bishop's score

## INTRODUCTION

Induction of labour is the intentional initiation of cervical ripening and uterine contractions with the goal of achieving delivery before the onset of spontaneous parturition. In medical or obstetric problems of pregnancy, cervical ripening and labour induction are frequently required. Patients with hypertensive disorders of pregnancy, a prolonged period of gestation, intraamniotic infection, foetal danger, and maternal medical issues such as diabetes mellitus and chronic renal sickness are all candidates for induction of labour.[1]

The ratio of progesterone to oestrogen, prostaglandin synthesis, and the condition of the cervical collagen matrix all play a role in the induction of labour success. Non-pharmacological therapies for cervical softening and labour induction include sexual intercourse, breast stimulation, medicinal herbs, homeopathic treatments, purgatives, enemas, acupuncture, and membrane stripping. Laminaria, extra amniotic Foley balloon catheter and extra

amniotic sodium chloride infusion using Foley catheter are mechanical procedures for inducing labor.[2] The act of inducing labour is linked to the dangers like prolonged labour, a high Caesarean rate, a high rate of epidural analgesia, and a low APGAR score at one minute and five minutes.[3] In nulliparous women, it also increased the rate of operative vaginal delivery techniques. It also lowered the rate of spontaneous births, increased the rate of caesarean sections, and caused shoulder dystocia in many women.

### *Aims and objectives*

To compare the efficacy and safety of extra amniotic saline infusion using trans cervical foley's catheter versus administration of intracervical dinoprostone (prostaglandin E2) for induction of labour.

To assess fetomaternal outcome in subjects with extra amniotic saline infusion using trans cervical foley's catheter, compared to intracervical prostaglandin E2 for induction of labour.

## METHODS

A comparative study was conducted at R.L. Jalappa Hospital and research center, Tamaka, Kolar, attached to Sri Devaraj Urs Medical College from January 2020 to June 2021

A total of 72 cases (36 in transcervical foley and 36 in cervical E2 gel group) were estimated based on the induction delivery interval between two groups (transcervical foley's and dinoprostone) as 6.9±1.9 hours and 5.2± 2.3hours respectively from the study by Sunil kumar et al.[4] Considering these values at 1.7% alpha error and 80% power a sample size of 32 in each group was obtained from Open Epi software.

### *Inclusion criteria*

Singleton pregnancy with a cephalic presentation who were between 37-42 weeks of gestation visiting labour room at R.L. Jalappa Hospital. Intact membranes, Bishop score<6, Reactive Non-Stress test.

### *Exclusion criteria*

Patients with previous caesarean section/scarred, UD, contraindications of labour induction were excluded from the study.

After obtaining informed consent from the patients who were admitted, they were included under the study once they met the inclusion criteria. A detailed history, baseline and clinical examination of the patient was done and by using the simple lottery method, patients will be divided into group A (Extra amniotic saline infusion group with Foley's catheter) and group B (Dinoprostone (PGE2 gel) group).

### *Group A: Extra amniotic saline infusion group with Foley's catheter*

All women have undergone a per speculum examination. Cervix was prepared with betadine solution. The prophylactic antibiotic was given to all patients before half an hour to the procedure. Foley's catheter of size 16-18F in primigravida and 18-20F in multigravida was passed through the cervical canal past the internal OS. Foley's balloon was inflated with 30-40ml sterile water. The catheter was gently withdrawn until it rests at the level of the internal OS. With moderate traction on the catheter, 200 ml of isotonic saline was infused through the catheter into the extra amniotic space. With the same traction, the catheter was taped into the inner aspect of the thigh. The catheter was blocked by putting a knot on the catheter before taping it. Catheter was left in place for 24 hrs.[5]

Pulse rate, blood pressure, uterine activity, fetal heart rate, respiratory rate, bleeding P/V was monitored regularly. The catheter was removed after 24hrs. Per vaginal examination was done when the catheter fell out or after removal at 24 hrs to assess Bishop score. Catheter was assessed every 6 hrs whether it falls out/ removed after 24 hrs to assess Bishop's score. When the favourable cervix, i.e., the cervix is 4cm dilated, artificial rupture of membranes (ARM) was done, and Oxytocin augmentation was done as per the protocol of the labour ward. If the cervix was unfavourable, then it was augmented with Misoprostol 25mcg every 4th hrly.

### *Group B - Dinoprostone (PGE2 gel) group*

For subjects assigned to this group, dinoprostone was instilled into the endocervical canal. After 6 hours of instillation, a repeat vaginal examination was done, and the bishop score was reassigned. When no improvement in Bishop's score noted, a repeat dose of dinoprostone (PGE2) was done to a maximum of 3 doses. The time to achieve maximum dosing of Dinoprostone was 24hrs.

Pulse, BP, uterine contractions, fetal heart rate, bleeding P/V was monitored regularly. If Bishop's score was found favourable, oxytocin augmentation was done as per the protocol of the labour ward.

### *Statistical analysis*

Bishop's score, NICU admission, APGAR score, etc., were considered as primary outcome variables. The study group was considered as a primary explanatory variable. For categorical data, descriptive analysis was performed using frequency and%age. Data was also represented using appropriate diagrams like bar diagrams.

All Quantitative variables were checked for normal distribution within each category of an explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- Wilk test was also conducted to assess normal distribution. Shapiro Wilk test

p- value of >0.05 was considered as a normal distribution. Categorical outcomes were compared between study groups using the Chi-square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used). P value < 0.05 was considered statistically significant. Data were analysed by using SPSS software, V.22.6.

## RESULTS

A total of 72 people took part in the trial, with 36 in the EASI group and 36 in the Dinoprostone group.

**Table 1: Comparison of maternal age between study group (N=72).**

| Maternal age (years) | Study group | |
|---|---|---|
| | EASI (N=36) | Dinoprostone (N=36) |
| **19-20** | 0 (0%) | 35 (97.22%) |
| **21-25** | 34 (94.44%) | 1 (2.78%) |
| **26-30** | 2 (5.56%) | 0 (0%) |

Majority of the patients were 21-25 years maternal age in EASI group i.e.,34 (94.44%) and 19-20 years maternal age in dinoprostone group 35 (97.22%) as showed in (Table 1).

**Table 2: Comparison of parity between study groups (N=72).**

| Parity | Study group | | Chi-square | P-value |
|---|---|---|---|---|
| | EASI (N=36) | Dinoprostone (N=36) | | |
| **Primi gravida** | 17 (47.22%) | 22 (61.11%) | 1.399 | 0.237 |
| **Multi gravida** | 19 (52.78%) | 14 (38.89%) | | |

Primigravida were more in the dinoprostone group 22 (61.11%) whereas multigravida were more in EASI group with 19 (52.78%). The difference in Parity between study groups was statistically not significant (P-value 0.237). (Table 2).

**Table 3: Comparison of gestational age between study group (N=72).**

| Gestational age | Study group | | Chi-square | P-value |
|---|---|---|---|---|
| | EASI (N=36) | Dinoprostone (N=36) | | |
| **37w - 38+6 days** | 7 (19.44%) | 9 (25%) | 0.740 | 0.864 |
| **39 w - 39+6 days** | 14 (38.89%) | 13 (36.11%) | | |
| **40 w - 40 + 6 days** | 9 (25%) | 10 (27.78%) | | |
| **41 w - 41+6 days** | 6 (16.67%) | 4 (11.11%) | | |

Majority were 39 to 39+6 days of gestational age in both the study groups with total of 14 (38.89%) and 13 (36.11%) respectively and was statistically not significant (P-value 0.864). (Table 3).

**Table 4: Comparison of indication of induction between study group (N=72).**

| Indication of induction | Study group | |
|---|---|---|
| | EASI (N=36) | Dinoprostone (N=36) |
| **Post dated** | 14 (38.89%) | 13 (36.11%) |
| **Preeclampsia** | 14 (38.89%) | 12 (33.33%) |
| **Oligohydramnios** | 8 (22.22%) | 9 (25%) |
| **Rh negative pregnancy** | 0 (0%) | 2 (5.56%) |

Post-dated indication of induction was majorly reported in both the study groups as 38.89% (14/36) and 36.11% (13/36) in EASI and Dinoprostone groups, respectively.

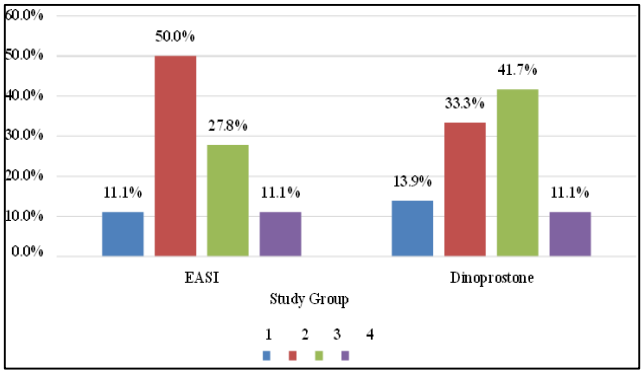


**Figure 1: Comparison of pre-induction modified bishop's score between study group (N=72).**

Pre induction modified Bishop's score was of score 3 was 10 (27.78%) in the EASI group and 15 (41.67%) in the dinoprostone group which was major in both the groups and was statistically not significant (P-value 0.510). (Figure 1).

**Table 5: Descriptive analysis of the number of doses in the dinoprostone group (N=36).**

| Number of doses | Frequency | Percentages |
|---|---|---|
| **1** | 13 | 36.11% |
| **2** | 17 | 47.22% |
| **3** | 6 | 16.67% |

Majority of the patients required 2 doses in dinoprostone induced group with total of 17 (47.22%). (Table 5).

Induction to active stage interval was 4 to 6 hours in the majority as 15(41.67%) in the EASI group and it was 7 to 9 hours in the dinoprostone group as a majority with 15(41.67%) and was statistically not significant (P-value 0.115). (Table 6).

**Table 6: Comparison of induction to active stage interval between study group (N=72).**

| Induction to active stage interval | Study group | | Chi-square | P-value |
|---|---|---|---|---|
| | EASI (N=36) | Dinoprostone (N=36) | | |
| **4 to 6 hours** | 15 (41.67%) | 7 (19.44%) | 4.329 | 0.115 |
| **7 to 9 hours** | 12 (33.33%) | 15 (41.67%) | | |
| **10 to 12 hours** | 9 (25%) | 14 (38.89%) | | |

Majority of the patients required 16-20 hrs of induction to the delivery in both the groups with 14 (38.89%) and 17 (47.22%) respectively and it was not statistically significant (P value>0.05). (Table 7).

**Table 7: Comparison of induction to the delivery interval between study group (N=72).**

| Induction to delivery interval | Study group | | Chi-square | P-value |
|---|---|---|---|---|
| | EASI (N=36) | Dinoprostone (N=36) | | |
| **5 to 10 hours** | 8 (22.22%) | 4 (11.11%) | 1.824 | 0.610 |
| **11 to 15 hours** | 12 (33.33%) | 12 (33.33%) | | |
| **16 to 20 hours** | 14 (38.89%) | 17 (47.22%) | | |
| **21 to 25 hours** | 2 (5.56%) | 3 (8.33%) | | |

Vaginal delivery was done majorly in both the groups as 17 (47.22%), 21 (58.33%) in EASI group and dinoprostone group respectively and the difference in the mode of delivery between study groups was statistically not significant (P-value 0.610). (Figure 2).

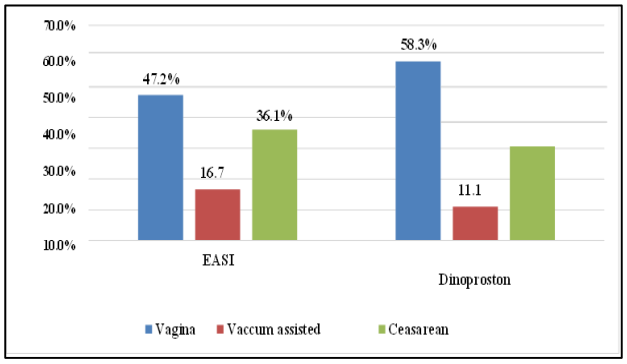


**Figure 2: Comparison of mode of delivery between study group (n=72).**

Fetal distress was more in both the groups EASI and dinoprostone as an indication for C section with 53.85% and 54.55%, respectively. And the difference in indication for the C section between study groups was statistically not significant (P-value 0.946). (Table 8).

**Table 8: Comparison of indication for C section between study group (N=24).**

| Indication for C section | Study group | | Chi-square | P-value |
|---|---|---|---|---|
| | EASI (N=36) | Dinoprostone (N=11) | | |
| **Fetal distress** | 7 (53.85%) | 6 (54.55%) | 0.111 | 0.946 |
| **Failed induction** | 3 (23.08%) | 2 (18.18%) | | |
| **Non-progression of labour** | 3 (23.08%) | 3 (27.27%) | | |

Oxytocin augmentation requirement was present in only 22 (61.11%) in the EASI group and very less people in 2 (5.56%) in the dinoprostone group. The difference in Oxytocin augmentation requirement between study groups was statistically significant (P value<0.001). (Figure 3).

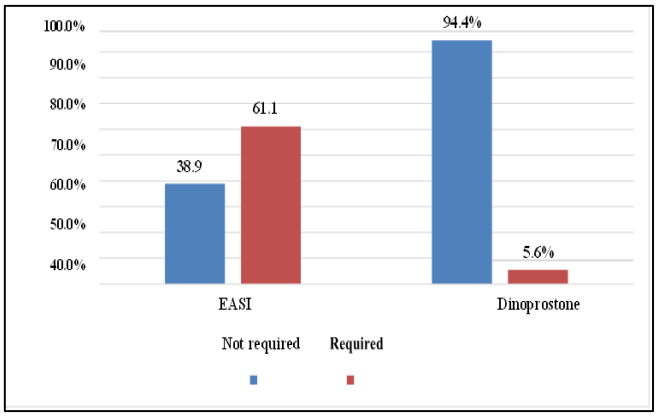


**Figure 3: Comparison of oxytocin augmentation requirement between study group (N=72).**

No maternal adverse effects present in both the groups. Reassuring FHR was present in all participants in both study groups.

***Summary of neonatal outcome***

Meconium-stained liquor was present in less proportion in both groups as 1 (2.78%) in the EASI group and 3(8.33%) in the dinoprostone group. The difference in liquor status between study groups was statistically not significant (P-value 0.614). APGAR score was >or=7 at 1 minute in both the groups was 100%. APGAR score was >/=9 at 5 minutes in 100% EASI group, whereas it was in 97.22% in the dinoprostone group. NICU admission was reported in 5 (13.88%) in the EASI group, and it was 7 (19.44%) in the dinoprostone group. The difference in NICU admission between study groups was statistically not significant (P-value 0.326). Respiratory distress was noted as a major cause for NICU admission in both groups as 4(80%) in

EASI groups and 4 (80%) 85.71% in the dinoprostone group.

## DISCUSSION

The purpose of this study was to assess the effectiveness of a transcervical Foley catheter to extra amniotic saline infusion and intra cervical prostaglandin E2.

In this study where 72 people were enrolled, 50% of each group belonged to EASI and 50% to dinoprostone, respectively. Prajakta Goswami et al., conducted a randomized prospective trial on 200 pregnant women, with 50% of them belonging to the EASI and PGE2 groups, which matches our findings.[7] The majority of people in the EASI group were between the ages of 21 and 25, whereas the dinoprostone group included 97.22% of those between the ages of 19 and 20.

**Table 9: Comparison of mean of age between various studies.**

| Study | Population | Mean of age | |
|---|---|---|---|
| **Present study** | 72 | EASI 19-20 (0%) | Dinoprostone 19-20 (97.22%) |
| | | 21-25 (94.44%) | 21-25 (2.78%) |
| | | 26-30 (5.56%) | 26-30 (0%) |
| **Rodrigues SV et al.[9]** | 82 | EASI | Dinoprostone |
| | | <19 (31.71%) | <19 (36.59%) |
| | | 21-25 (51.22%) | 21-25 (48.78%) |
| | | 26-30 (17.07%) | 26-30 (12.20%) |
| | | >=31 (0%) | >=31 (2.44%) |

In the current study, the majority of the patients in the EASI group (52.78%) were multigravida, whereas the dinoprostone group (61.11%) was the primigravida. Sunil Kumar et al.4 found that the majority of individuals in the EASI group were multigravida (34%) and primigravida (38%) in the PEG2 group, which is similar to our findings. Another research by Prajakta Goswami et al. found that the majority of individuals in the EASI and PGE2 groups were primigravida, with 66% and 70% respectively, which contradicted our findings.[7]

The majority of individuals in the EASI and dinoprostone groups had a gestational age of 39 W-39+6 Days, with 38.89% and 36.11%, respectively, in the current research. Rodrigues SV et al. conducted a randomized controlled experiment on 82 women, finding that 51.22% and 58.54% of the pregnant women in the dinoprostone gel and extra-amniotic saline infusion groups, respectively, had gestational ages of 41 and 42 weeks.[9] Our findings were similar to those of Prajakta Goswami et al., Rodrigues et al.[7,9]

The most frequent causes for induction in the EASI group were postdate, preeclampsia, and oligohydramnios, accounting for 38.89%, 38.89%, and 22.22%, respectively. With 36.11%, 33.33%, and 25% in the dinoprostone group, respectively. Postdates, mild pre-eclampsia, oligohydramnios, and gestational hypertension were the most frequent causes for induction of labour in the EASI group (64%, 8%, 6%, and 10%, respectively), whereas, in the PEG2 group, it was 50%, 16%, 6%, and 10%, respectively.

PIH, IUGR, and post-dated pregnancy - frequent indications for labour induction in the Prajakta Goswami, et al. study, with 43%, 32%, and 13% in the EASI group, and 46%, 26%, and 10% in the PEG2 group, respectively.[7] Sunil Kumar et al. found that post-dated pregnancy was the most prevalent reason for induction. Prajakta Goswami et al. as well as our research.[4,7]

The majority of individuals in the EASI group had a modified Bishop's score of 2 after induction, with 50%, followed by a score of 3 with 27.78%. The majority of individuals in the dinoprostone group had a post-induction modified Bishop's score of 3 with 41.67%, followed by a score of 2 with 33.33%. In prospective research of 80 women, Dhananjaya BS. et al. found that the majority of the study population in the EASI group had a post-induction modified Bishop's score of 2 (45%) while the majority of the individuals in the dinoprostone group had a post-induction modified Bishop's score of 3 (35%).[10] Dhananjaya BS et al., Rodrigues, et al. and our study showed similar results.[9,10]

In this study, the majority of individuals in the dinoprostone group got two doses (47.22%), followed by one dosage (36.11%). Patsy Varghese et al. conducted a study on 106 women in which the majority of the subjects received two doses of PGE1, with 47.2% receiving two doses, 32.1% receiving one dosage, and 20.8% receiving three doses, respectively.[11]

In the current study, the majority of cases (41.67% in the EASI group) had an induction to active stage interval of 4 to 6 hours, whereas the dinoprostone group had an induction to active stage interval of 7-9 hours.

Vijayalakshmi V et al. conducted a prospective randomized control study on 200 pregnant women, finding that the majority of women with extra amniotic saline infusion induction established an active stage of labour in

6 hours, while the active stage of labour in PGE2 gel established in 6-12 hours, which is similar to our findings.[12]

The majority of patients in the EASI and dinoprostone groups (38.89% and 47.22%, respectively) identified the induction to the delivery interval as 16-20 hours in the current study. The induction to the delivery interval in the Extra-amniotic saline infusion group showed 14.02 (hours), whereas it was 17.70 (hours) in the dinoprostone group, according to Rodrigues SV et al. research. Another study by Vijayalakshmi V et al. found that the majority of women with extra amniotic saline infusion induction delivered within 12 hours as compared to PGE2 gel, which matches our findings.[9,12]

Vaginal birth was found as the most common mode of delivery in the EASI and dinoprostone groups, with 47.22% and 58.33%, respectively, followed by caesarean section with 36.11% and 30.56%. The majority of the subjects in the Rachel Alexander A. et al. study had a spontaneous method of birth with 68.09% and 62.26%, respectively, followed by caesarean section with 19.15% and 30.19%.[8] Sunil Kumar et al. found that the majority of women in the EASI and PEG2 groups delivered vaginally, with 66% and 64% respectively.[4] In another research by Vijayalakshmi V et al., the majority of individuals in the EASI and PEG2 groups (76% and 67%, respectively) had vaginal deliveries.[12] Kumar S et al. and Vijayalakshmi V et al. both found that vaginal birth was the most prevalent route of delivery.[4,12]

Fetal distress failed induction and non-progression of labour were found as indications for the C section in the current study, with 53.85%, 23.08%, and 23.08%, respectively, in the EASI group. In the case of the dinoprostone group, it was found in 54.55%, 18.18%, and 27.27%.

Oxytocin augmentation was seen in 61.11% of EASI individuals and 5.56% of dinoprostone subjects in this study. The majority of individuals in the EASI group (86.79%) required oxytocin augmentation in Rachel Alexander A. et al. research. PGE2 needed oxytocin augmentation in 42.55% of cases.[8] Another research by Farah Ziyauddin et al. found that 26% of PGE2 group participants needed oxytocin augmentation.[13]

Meconium-stained liquor was found in 2.78% of the study population in the EASI group and 8.33% in the dinoprostone group in the current research. Meconium staining was seen in 4% of participants in the EASI group and 18% in the PGE2 group in prospective and comparative research of 200 women done by Aruna Kumari et al.[14] Meconium staining was seen in 9.43% of the EASI group and 8.51% of the PGE2 group in Rachel Alexander A. et al. research.[8] Aruna Kumari et al., A Meconium staining was higher in the PGE2 group than in the EASI group, according to Rachel Alexander A. et al. and our investigation.[8,14] In this study, all subjects in the dinoprostone group had an APGAR score of >=9 at 5 minutes, whereas the EASI group had an APGAR score of 97.22%. In research with 70 participants, Farah Ziyauddin et al. found that 51.43% of the patients in the PGE2 group had an APGAR score of 9 at 5 minutes.[13]

NICU admission was recorded in 13.88% of the EASI group and 19.44% of the dinoprostone group in the current research. NICU admission was needed by 22.64% in the EASI group and 8.51% in the PGE2 group in the Rachel Alexander A. et al. research.[8]

### *Limitations*

One of the study's primary limitations is the small sample size. The study might include detailed maternal and foetal outcomes.

## CONCLUSION

Our research found that PGE2 and EASI were equally effective in inducing labour. Foley's catheter with EASI is superior than the PGE2 technique of induction in highly unfavourable cervices, especially in locations with limited resources.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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