Section: Obstetrics and Gynaecology

Original Research Article

# COMPARISON OF INDUCTION OF LABOUR WITH DINOPROSTONE GEL VERSUS MECHANICAL DILATATION IN UNFAVOURABLE CERVIX

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## ABSTRACT

**Background:** Induction of labor becomes mandatory when there is a risk of continuation of pregnancy either to the mother or fetus. The purpose of cervical ripening and induction of labor is to achieve vaginal delivery and avoid operative delivery by cesarean section. **Materials and Methods:** Out of 180 pregnant women (gestation after 37 weeks) were studied. 90 pregnant women (group I) received dinoprostone gel intracervically, and 90 pregnant women (group II) were administered catheter No. 18 through the canal with visualization of cervical OS. The balloon was filled with 50 ml of sterile water, and the catheter was tapped on the inner thigh to maintain traction. **Result:** The baseline characteristics in gravidity, comparison of labor profile, maternal outcome, and maternal and neonatal complications had significant p-values ($p < 0.001$). **Conclusion:** It is proved that group I dinoprostone gel had more rapid cervical ripening, shortening induction to vaginal delivery interval within 24 hours. Hence, the dinoprostone gel technique is more ideal than mechanical dilatation in an unfavorable cervix.

## INTRODUCTION

Induction of labor is defined as the initiation of uterine contraction before spontaneous onset of labor. For the majority of women, labor starts spontaneously and results in vaginal delivery at or near term.[1] However, induction of labor is mandatory when there is a risk of continuation of pregnancy either to the mother or to the fetus. The purpose of cervical ripening and induction of labor is to achieve vaginal delivery and to avoid operative delivery by cesarean section. A successful labor induction must result in adequate uterine contractions and progressive dilation of the cervix.[2] It should also result in vaginal delivery with minimum discomfort and no risk for both mother and fetus.

There are two means of cervical ripening prior to labor induction: pharmacological methods and non-pharmacological methods. Pharmacological methods consist of prostaglandins, and they are capable of stimulating uterine contractions, resulting in favorable vaginal labor. Prostaglandins can be administered by various routes: vaginal, oral, and intracervical.[3] The non-pharmacological methods are natural and mechanical. Natural methods consist of intercourse, breast stimulation, membrane stripping, and amniotomy and the mechanical methods are balloon devices and hygroscopic dilators.[4] Hence, an attempt is made to compare induction labor with Dinoprosten gel versus mechanical dilatation in an unfavorable cervix, and results are evaluated.

## MATERIALS AND METHODS

180 pregnant women admitted at Khaja Banda Nawaz University, Faculty of Medicine Kalaburgi, Karnataka-585102, were studied.

**Inclusion Criteria:** Gestation age after 37 weeks irrespective of parity, singleton, cephalic presentation, intact membranes, and unfavorable cervix (Bishop score < 6). The patients gave their consent in writing for studies that were selected for study.

**Exclusion Criteria:** Fetal malpresentation, rupture of membranes, multifetal gestation, abnormal fetal heart rates, fetal demise, previous cesarean delivery, or other uterine surgery (myomectomy, Cornual wedge resection) and anomalous fetuses were excluded from the study.

**Method:** Out of 180 pregnant women, 90 are grouped as Group I (dinoprostone group), who received 2 mg of dinoprostone gel intracervically. Group II women were 90 administered with a Foley's


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catheter No. 18, which was inserted through the cervical canal with visualization of the cervical OS during examination with a speculum. Once past the internal OS, the balloon was filled with 50 ml of sterile water, and the catheter was tapped to an inner thigh to maintain traction. The position and traction of the balloon were checked once or twice on each hour, and the catheter remained in place until the balloon was expelled spontaneously.

All the women were monitored clinically for the progress of labor and fetal well-being. The program was maintained in all cases. When the Bishop score attained a value of equal to or more than 7, the membranes were ruptured artificially, or in cases of preterm rupture, oxytocin was administered if necessary. If Bishops' score remains unfavorable, equal to or less than 5, after 18 hours of treatment in any group, there in those patients was further individualized.

The primary outcome measure was the induction-to-delivery interval; the secondary outcome was the incidence of instrumental delivery (including cesarean section). Uterine hyperstimulation with or without abnormalities in fetal heart, staining of amniotic fluid with meconium, requirement for augmentation with oxytocin, and occurrence of postpartum bleeding. The neonatal outcome recorded was where the Apgar score was 5 minutes after birth, a necessary admission to the neonatal intensive care unit.

The duration of the study was from October 2024 to March 2025.

**Statistical Analysis:** Baseline characteristics, labor profile, material outcomes, maternal complications, and neonatal outcomes were compared with p-value. The statistical analysis was carried out using SPSS software.

## RESULTS

**Table 1:** Comparative study of baseline characteristics –

- Maternal age 23.50 (± 2.40) in Group I, 24.2 (± 4.18) in group II, and p < 0.892 (p-value is insignificant).
- Gravidity G1: 47 (52.2%) in group I, 38 (42.2%) in group II, p value is significant (p < 0.003).
- G2: 28 (31.1%) in group I, 31 (34.4%) in group II, and p value is highly significant (p<0.005).
- G3: 13 (14.4%) in group I, 11 (12.2%) in group II, and p value is highly significant (p<0.004).
- G4: 1 (1.1%) in group I, 9 (10%) in group II, and p value is highly significant (p < 0.001).

**Table 2:** Comparative study of labor profile –

- Initial Bishop Score: 2.22 (± 0.72) in group I, 2.32 (± 0.78) in group II, and p-value is insignificant.
- Bishop score: >6 hour induction 8.30 (± 2.10) in group I, 7.62 (± 1.70) in group II, and p < 0.001 (p value is highly significant)
- Duration from initiation of induction to active phase of labor in hours: 4.54 (± 2.8) in group I, 7.42 (± 3.2) in group II, and p < 0.001 (p value is highly significant).
- Duration from cervix ripening to delivery: 5.75 (± 2.56) in group I, 6.82 (± 4.30) in group II, and (p value is highly significant) p < 0.004

**Table 3:** Comparative study of maternal outcomes –

1. Mode of delivery:
2. Cesarean section: 8 (8.88%) in group I, 27 (30%) in group II, and p < 0.001 (p value is highly significant).
3. Assisted vaginal delivery 4 (4.4%) in group I, 6 (6.6%) in group II, and p value is highly significant.
4. Vaginal delivery: 80 (88.8%) in group I, 67 (74.4%) in group II, and p value is highly significant.

B) Mode of delivery

- Non-Reassuring FHS: 4 (4.4%) in group I, 5 (5.5%) in group II.
- Failed induction: 4 (4.4%) in group I, 20 (22.2%) in group II

**Table 4: Comparative study of maternal complications**

- Meconium stained amniotic fluid: 5 (5.5%) in group I, 7 (7.7%) in group II, and p value is highly significant (p < 0.001).
- Fever during delivery: 2 (2.2%) in group I, 1 (1.1%) in group II, and p value is highly significant (p < 0.001).
- Hyperstimulation: 4 (4.4%) in group I, 2 (2.2%) in group II, and p value is highly significant (p < 0.001).
- Nausea, vomiting: 9 (10%) in group I, 1 (1.1%) in group II p value is highly significant (p<0.001).
- UTI: 1 (1.1%) in group I, 3 (3.3%) in group II and p value is highly significant (p<0.001).

**Table 5: Comparison of Neonatal Outcomes**

- Apgar score ≤ 4 at minute: 1 (1.1%) in group I, 2 (2.2%) in group II
- Apgar Score ≤7 at 5 minutes: 11 (22.2%) in group I, 14 (15.5%) in group II
- Admission to NICU: 9 (10%) in group I, 14 (15.5%) in group II.

**Table 1: Comparative study of Base line characteristics** **Total No of patients: 180**

| Base line | Group I (90) | Group II (90) | p value |
|---|---|---|---|
| Maternal age | 23.50 (± 2.40) | 24.2 (± 4.18) | p>0.892 |
| Gravidity G1 | 47 (52.2%) | 38 (42.2%) | P<0.003 |
| G2 | 28 (31.1%) | 31 (34.4%) | P<0.005 |
| G3 | 13 (14.4%) | 11 (12.2%) | P<0.004 |
| G4 | 1 (1.11%) | 9 (10%) | P<0.001 |

(p<0.005 p values are highly significant)


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**Table 2: Comparative study of labour profile**

| Labour profile | Group I (90) | Group II (90) | p value |
|---|---|---|---|
| Initial Bishop score | 2.22 (±0.72) | 2.32 (± 0.78) | p>0.37 |
| Bishop Score > 6hours after Induction | 8.30 (± 2.10) | 7.62 (± 1.70) | P<0.001 |
| Duration from initiation to active phase of labour (in hrs) | 4.54 (± 2.8) | 7.42 (± 3.2) | P<0.001 |
| Duration in from cervix ripening to delivery | 5.75 (± 2.56) | 6.82 (± 4.30) | P<0.004 |

(HS=p value is highly significant)

**Table 3: Comparative study of Maternal Outcome**

| (A) Mode of delivery | Group I (90) | Group II (90) | p value |
|---|---|---|---|
| Caesarean section | 8 (8.8%) | 27 (30%) | P<0.001 |
| Assisted vaginal delivery | 4 (4.4%) | 6 (6.6%) | P<0.004 |
| Vaginal delivery | 80 (88.8%) | 67 (74.4%) | P<0.001 |
| **(B) Mode of delivery** | **Group I (90)** | **Group II (90)** | **p value** |
| Non-reassuring FHS patterns | 4 (4.4%) | 5 (5.5%) | |
| Failed Induction of labour | 4 (4.4%) | 20 (22.2%) | P<0.001 HS |

**Table 4: Comparative study of maternal complications**

| Maternal complications | Group I (90) | Group II (90) | p value |
|---|---|---|---|
| Meconiumstained amniotic fluid | 5 (5.5%) | 7 (7.7%) | P<0.001 |
| Fever during delivery | 2 (2.2%) | 1 (1.1%) | P<0.001 |
| Hyper stimulation | 4 (4.4%) | 2 (2.2%) | P<0.001 |
| Nausea, Vomiting | 9 (10%) | 1 (1.1%) | P<0.001 |
| UTI | 1 (1.1%) | 3 (3.3%) | P<0.001 |

**Table 5: Comparison of Neonatal outcomes**

| Neonatal outcomes | Group I (90) | Group II (90) |
|---|---|---|
| Apgar score ≤ 4 at minute | 1 (1.1%) | 2 (2.2%) |
| Apgar score ≤ 7 at 5 minutes | 11 (12.2%) | 14 (15.5%) |
| Admission to NICU | 9 (10%) | 14 (15.5%) |

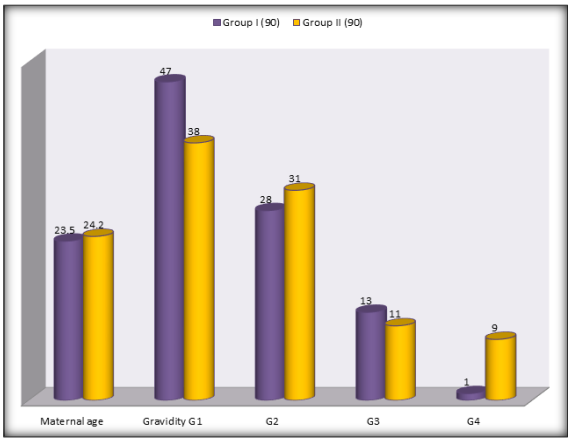


**Table 1: Comparative study of Base line characteristics**

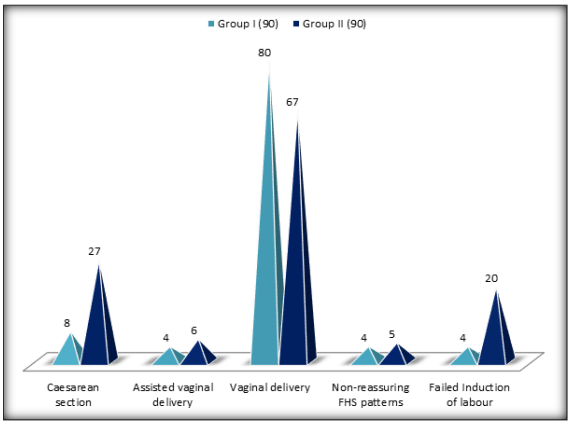


**Table 3: Comparative study of Maternal Outcome**

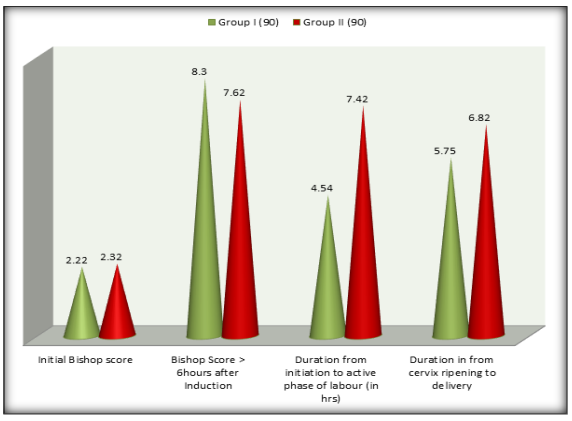


**Table 2: Comparative study of labour profile**

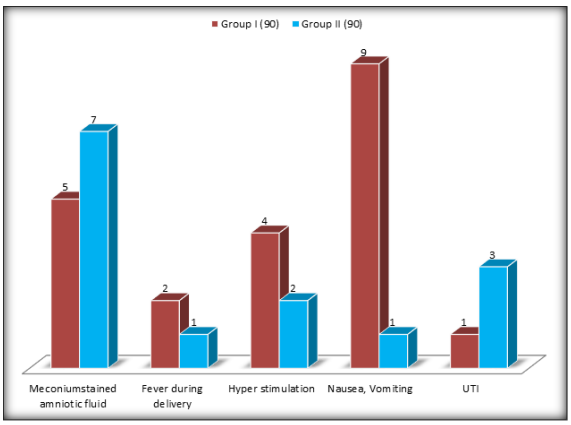


**Table 4: Comparative study of maternal complications**



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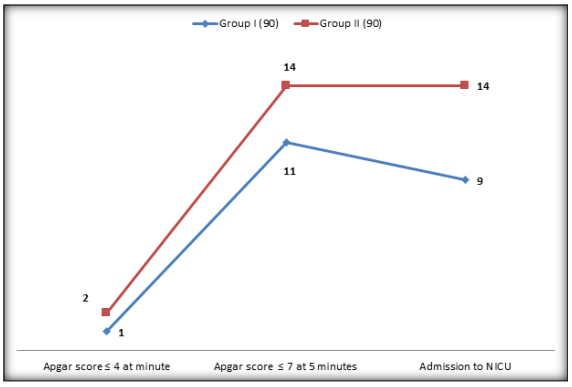


**Table 5: Comparison of Neonatal outcomes**

## DISCUSSION

Present a comparative study of the induction of labor with dinoprostone gel versus mechanical dilatation in an unfavorable cervix. The groups of pregnant women were administered. Dinoprostone gel was introduced cervically, and in group II pregnant women, a Foley's catheter was introduced through the cervix to the extra-amniotic space using a sterile technique. In the baseline studies, the gravidity G1, G2, G3, and G4 were compared in both groups, and the p-value was highly significant ($p < 0.001$) (Table 1). Comparative study of labor profile Bishop score > 6 hours, duration from initiation of induction to active phase of labor (in hours), and duration from cervix ripening to delivery has a significant p-value ($p < 0.001$) (Table 2). In the comparative study of maternal outcomes in the cesarean section group, I had 8 and 27 in group II. In assisted vaginal delivery, 4 patients in group I and 6 in group II had significant p-values ($p < 0.001$). Vaginal delivery had 80 in group I and 67 in group II. In the study of indications for cesarean section. In non-reassuring FHS pattern 4 in group I, 5 were in group II. Failed induction of labor: 4 in group I, 20 in group II, and p-value was highly significant ($p < 0.001$) (Table 3). In the comparative study of maternal complications, meconium-stained amniotic fluid was found in 5 in group I and 7 in group II. Fever during delivery: 2 in group I, 1 in group II. In hyperstimulation studies, 4 were in group I and 2 in group II. Nausea and vomiting patients were 9 in group I and 1 in group II. UTI was observed 1 in group I, 3 in group II, and the p-value was highly significant ($p < 0.001$) in every parameter (Table 4). In the comparison of neonatal outcomes. Apgar score ≤4 at minute 1: 1 in group I, 2 in group II; Apgar ≤7 at 5 minutes: 11 in group I, 14 in group II. Admission in NICU 9 in group I, 14 in group II (Table 5) These findings are more or less in agreement with previous studies.[5,6,7]

Pregnant women treated with dinoprostone as a slow-release vaginal insert were effective methods for successful induction of labor when compared with manual technique induction labor.[8] It is also reported that the cesarean section rate decreased only in multiparous women who benefited more from the dinoprostone slow-released vaginal insert, and multiparity was an indicator for successful vaginal delivery in women treated with dinoprostone gel in 24 hours.

Although Foley's catheter is a cheap and easily available but underutilized method for cervical ripening with hardly any neonatal or maternal risks.[9] It is reported that Foley's catheter takes more time in the induction-to-delivery interval compared to prostaglandin.[10]

It is also reported that, in a study comparing PGE2 insert versus Foley's catheter for labor induction, no significant difference was noted in the mode of delivery or induction delivery interval between the two groups. However, PGE2 insert was associated with more cases of tachysystole and the requirement of a second method of cervical ripening.[11] Hence, the pathophysiology of the uterus and CVS profile of pregnant women must be taken into observation during the study of PGE2 insert patients because tachysystole may cause adverse complications to both the fetus and mother. Hence, the dosage of dinoprostone gel and the body mass index of the mother must be correlated before administration.

## CONCLUSION

In the present comparative study of induction of labor with dinoprostone gel versus mechanical dilatation in an unfavorable cervix (low Bishop's score). It is observed that Dinoprostone gel was more rapid in cervical ripening, shortening the induction to vaginal delivery interval, and increasing the number of vaginal deliveries within 24 hours. Such a study must be carried out in a large number of patients in a high-tech obstetrics and gynecology hospital to confirm the significant results of the present study because the factors and exact mechanism that cause contraction of the uterus during delivery are still unclear.

**Limitation of study:** Owing to remote location of research centre, small number of patients, lack of latest techniques we have limited finding and results.

- This research work was approved by the ethical committee of Khaja Banda Nawaz University, Faculty of Medicine Kalaburgi, Karnataka-585102.
- No Conflict of Interest.
- Self-Funding

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