Original Research Article

# Induction of labour in live singleton pregnancy: A comparative study between dinoprostone and oxytocin at a tertiary care hospital in Bihar

**Sushma Shikha[1], Kumar Devashish[2*], Seema[3]**

*[1]Senior Resident, Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Bihar, India*

*[2]Tutor, Department of Pharmacology, Darbhanga Medical College and Hospital, Bihar, India*

*[3]Associate professor, Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Bihar, India*

**Received: 02-09-2021 / Revised: 10-10-2021 / Accepted: 10-11-2021**

## Abstract

**Introduction**: Post-term pregnancy is defined as gestation beyond 42 weeks from the first day of the last menstrual period. Previous studies have shown that as the gestational age advances beyond the expected delivery date, the risk of adverse maternal and fetal outcomes increases, including deterioration in coexisting maternal medical conditions, fetal distress, and fetal death. **Materials and methods:** An interventional study was planned by the Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Laheriasri, Bihar. The study duration comprised of 6 months that is from January 2021 to June 2021. Women with viable singleton pregnanciesin late term gestation (41st week that was confirmed by crown-rump length measurement) who visited the hospital during the duration of data collection were recruited in the study after obtaining duly signed informed consent forms. **Results:** A total of 92 women with late-term pregnancy (LTP) were recruited into the study. They were divided randomly in group A and B, thus, each group comprised of 46 women. Based on bishop's score, both groups were divided in subgroups A1, A2 and B1, B2. However, for women with a Bishop's score between 4–6, there was no significant difference in the rate of cesarean delivery between subgroup B2 and A2 (P>0.05). **Conclusion**: Based on the study findings, the researcher conclude that in set up where dinoprostone is unavailable, oxytocin may be considered, rather than a cesarean section, for women with a Bishop's score of 4–6.

**Keywords:** Induction Of Labour, Singleton Pregnancy Dinoprostone, Oxytocin



## Introduction

Post-term pregnancy has an incidence of 5.49% of all pregnancies in the US [1]. Post-term pregnancy is defined as gestation beyond 42 weeks from the first day of the last menstrual period [2]. Previous studies have shown that as the gestational age advances beyond the expected delivery date, the risk of adverse maternal and fetal outcomes increases, including deterioration in coexisting maternal medical conditions, fetal distress, and fetal death [3]. Therefore, clinicians have reached a consensus that pregnant women should be induced for labor at 41 weeks through to 41 weeks, a period designated as late-term pregnancy (LTP) [4].

There are several strategies for the induction of labor (IOL), and pharmacologic agents, including oxytocin and prostaglandins, are most commonly used in clinical practice [5]. Compared with oxytocin, the prostaglandin E2 agent, dinoprostone, has been regarded as more effective for the induction of labor of LTPs with a non-dilated cervix [6,7]. The World Health Organization (WHO) recommends that oxytocin alone is indicated if prostaglandins are not available [8]. Unfortunately, due to the high cost of dinoprostone [9, 10], and instability of pharmacy-prepared dinoprostone gel [10], oxytocin remains in use for IOL at medical centers in developing and rural areas [11].During labor, the readiness of the uterine cervix for IOL can be assessed by several methods, including the use of the Bishop's score. A recently reported cohort study that recruited LTPs with a Bishop's score of between 4–6 showed that when compared with vaginal dinoprostone, intravenous oxytocin resulted in fewer cesarean deliveries and was more effective in IOL [12]. However, this previous study was limited by the small number of cases of LTP studied, which included 90 cases for each group with either dinoprostone or oxytocin [12]. Also, cases with a Bishop's score of <3 was not included in this previous study [12].Because of the remaining controversies associated with the management of LTPs, particularly in developing and rural areas, this study aimed to compare dinoprostone and oxytocin for elective IOL in LTPs and the rate of cesarean section in ten centers in South China. Two subgroups were studied that included LTPs with a Bishop's score of between 0–3 and between 4–6. The secondary outcomes evaluated were the occurrence of maternal and fetal complications.

## Materials and methods

An interventional study was planned by the Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Laheriasri, Bihar. The study duration comprised of 6 months that is from January 2021 to June 2021 . Women with viable singleton pregnanciesin late term gestation (41st week that was confirmed by crown-rump length measurement) who visited the hospital during the duration of data collection were recruited in the study after obtaining duly signed informed consent forms. Other inclusion criteria were a cervical Bishop's score of <6, normal fetal heart electric monitoring, cephalic presentation, and intact membranes without spontaneous uterine contractions. The study exclusion criteria were an estimated birth weight <4,000 g, and the presence of contraindications for prostaglandin treatment. Ethical clearance was obtained from the Institutional Ethics Committee.

### Intervention done

Before IOL, bishop's score was assessed by all pregnant women [13], followed by surveillance of maternal contractions and fetal heart rate.

*Correspondence
**Dr. Kumar Devashish**
Tutor, Department of Pharmacology, Darbhanga Medical College and Hospital, Bihar, India
**E-mail:** mail2drdev@gmail.com

Women who underwent IOL were divided in 2 groups, A and B. Patients in group A were given intravenous oxytocin, and those in group B were given vaginal dinoprostone. In group A, oxytocin was administrated intravenously, starting at 2 mU/min, and then doubled every 30 min to a maximum of 32 mU/min, or until four contractions occurred within 10 minutes, which was regarded as active labor.In group B, a 10 mg dinoprostone suppository was placed in the posterior fornix for up to 12 hours, according to the manufacturer's recommendations. Based on bishop's score, A and B were subdivided in groups A1, A2, B1 and B2. Patients with score of 0-3 were allocated in A1 or B1 and rest in A2 or B2.

**Assessment of outcome**

A failure in initiation was defined as a non-contraction pattern in the dinoprostone group or after an 18-hour oxytocin infusion in the oxytocin group. Fetal distress or failure to progress during labor, defined as no cervical dilatation within an interval for four hours at the active phase, or without fetal descent in a three-hour interval at the second stage, resulted in cesarean section. Cesarean delivery rate was considered to be the primary outcome.

Secondary outcomes included postpartum hemorrhage, with blood loss estimated as previously described [14]. Briefly, blood loss volume in ml was measured during 24 h after delivery, the hemoglobin level in g/dL was measured, and any required transfusion blood volume in ml was recorded, with 1,500 ml of blood loss defined as postpartum hemorrhage [14]. Uterine hyperstimulation was defined as more than five contractions in 10 minutes, averaged over 30 minutes [15]. The time interval from induction to vaginal delivery, duration of the stages of labor, neonatal birth weight, and the Apgar scores at 1 minute and 5 minutes were evaluated.

**Statistical analysis**

Data were analyzed using SPSS version 20 software. Categorical data was analyzed with the chi-squared $\chi^2$ test and the unpaired t-test was done for continuous data. P<0.05 was considered to indicate a statistically significant difference.

**Results**

A total of 92 women with late-term pregnancy (LTP) were recruited into the study. They were divided randomly in group A and B, thus, each group comprised of 46 women. Based on bishop's score, both groups were divided in subgroups A1, A2 and B1, B2. In this way each subgroups had 23 patients each. Background details of the participants patients has been shown in table 1.All the participants had similar indications for cesarean section, as fetal distress accounted for most cases, following by failure to progress, and failure to initiate IOL. Comparison of the cesarean delivery rates between the subgroups showed that for LTPs with a Bishop's score between 0–3, subgroup B1 with dinoprostone showed fewer cesarean deliveries than subgroup A1 given oxytocin (P<0.05) (Table 2). However, for women with a Bishop's score between 4–6, there was no significant difference in the rate of cesarean delivery between subgroup B2 and A2 (P>0.05). The findings for the effects of the intervention given on the time intervals in each subgroup showed that for LTPs with a Bishop's score 0–3, there were no differences in the time intervals for labor in each subgroup, including the interval between induction to labor, the latent stage, the active phase, and the second stage of labor, between subgroups A1 and B1 (P>0.05) (Table 3). However, for LTPs with a Bishop's score between 4–6, both the interval between induction to labor and the duration of the active phase were significantly reduced in subgroup B2 who were given dinoprostone (P<0.05) (Table 3).For LTPs with a Bishop's score between 0–3, subgroup B1 given dinoprostone showed reduced rates of postpartum hemorrhage but an increased hyperstimulation rate (P<0.05). However, there was no difference in these incidences between subgroups with a Bishop's score between 4–6 (Table 4). No differences in neonatal birth weight and Apgar scores at 1 minute and 5 minutes were observed between the groups (Table 5).

**Table 1: Background characteristic of the study participants from all the 4 subgroups**

| Characteristics | Group A | | Group B | |
|---|---|---|---|---|
| | A1 | A2 | B1 | B2 |
| Maternal age (years) | 25.5 ± 5.7 | 27.5 ± 4.9 | 26.7 ± 5.4 | 25.2 ± 6.2 |
| BMI (kg/m$^2$) | 25.8 ± 3.5 | 26.2 ± 4.2 | 26.9 ± 4.6 | 27.8 ± 3.2 |
| Gestational age (weeks) | 40.7 ± 0.4 | 41.2 ± 1.1 | 40.1 ± 0.5 | 41.0 ± 0.7 |
| Nulliparity (n) | 67.3% | 73.5% | 83.4% | 78.3% |

**Table 2: LTP with cesarean delivery among the study groups**

| Bishop's score | Group A | Group B | P value |
|---|---|---|---|
| 0-3 | 8.9% | 3.5% | < 0.05 |
| 4-6 | 7.5% | 6.4% | > 0.05 |

**Table 3: Various time interval (in hours) for each group and subgroup**

| | Group A | Group B | P value |
|---|---|---|---|
| **Bishop's score of 0-3** | **A1** | **B1** | |
| Induction to labor interval | 12.1 ± 11.3 | 10.2 ± 8.3 | > 0.05 |
| Duration of latent phase | 4.2 ± 2.3 | 3.8 ± 2.2 | > 0.05 |
| Duration of active phase | 1.5 ± 1.1 | 1.9 ± 1.2 | > 0.05 |
| Duration of second phase | 0.7 ± 0.2 | 0.6 ± 0.3 | > 0.05 |
| **Bishop's score of 4-6** | **A2** | **B2** | |
| Induction to labor interval | 11.7 ± 9.8 | 8.9 ± 7.8 | < 0.05 |
| Duration of latent phase | 3.8 ± 3.2 | 3.2 ± 2.0 | > 0.05 |
| Duration of active phase | 2.5 ± 2.4 | 1.7 ± 1.1 | < 0.05 |
| Duration of second phase | 0.5 ± 0.3 | 0.3 ± 0.1 | > 0.05 |

**Table 4: Emergence of maternal complications among study participants of various subgroups**

| | Group A | Group B | P value |
|---|---|---|---|
| **Bishop's score 0-3** | **A1** | **B1** | |
| Postpartum hemorrhage | 4 | 2 | < 0.05 |
| Hyper stimulation of uterus | 0 | 2 | < 0.05 |
| **Bishop's score 4-6** | **A2** | **B2** | |
| Postpartum hemorrhage | 4 | 3 | > 0.05 |
| Hyper stimulation of uterus | 1 | 2 | > 0.05 |

**Table 5: Emergence of fetal complications among study participants of various subgroups**

| | Group A | Group B | P value |
|---|---|---|---|
| **Bishop's score 0-3** | **A1** | **B1** | |
| Birth weight (kg) | 3.2 ± 0.8 | 3.5 ± 0.4 | > 0.05 |
| 1 min APGAR <7 | 2 | 8 | > 0.05 |
| 5 min APGAR <7 | 0 | 2 | > 0.05 |
| **Bishop's score 4-6** | **A2** | **B2** | |
| Birth weight (kg) | 3.4 ± 0.3 | 3.5 ± 0.6 | > 0.05 |
| 1 min APGAR <7 | 3 | 10 | > 0.05 |
| 5 min APGAR <7 | 0 | 1 | > 0.05 |

**Discussion**

In the current study, women were recruited with LTP with unfavorable or non-ripened cervix. Women underwent IOL with either oxytocin or dinoprostone. After stratifying the women into two groups using Bishop's scores, we compared cesarean delivery rates as the primary outcome and maternal and fetal complications as the secondary outcomes.The findings showed that approximately 10% of LTPs ondinoprostone for IOL underwent cesarean sections, which is lower than the previously reported range of 10.5–38.6% [16, 17]. In many of the previous trials, prostaglandins had been shown to be more effective in IOL than oxytocin [11]. Oxytocin also reduced the rate of unsuccessful vaginal delivery when compared with expectant management [11]. The findings from the present study showed that the subgroup with a Bishop's score of 4–6 showed no superiority for dinoprostone over oxytocin, which is a finding supported by previous studies [18-20].Also, the design of the present study differed from previous studies on LTPs, as a subgroup was analyzed that had Bishop's scores of between 0–3, in which dinoprostone was more effective than oxytocin. The different mechanisms of action might explain these varied effects of dinoprostoneand oxytocin in LTPs as determined by the different Bishop's scores. Both oxytocin and dinoprostone can bind to specific receptors in the myometrium to initiate or enhance uterine contraction [21, 22].

When the maternal and fetal complications were considered, both oxytocin and dinoprostone were safe for IOL of LTPs with a Bishop's score of 4–6. However, for women with a Bishop's score of between 0–3, dinoprostone reduced postpartum hemorrhage and significantly shortened the time intervals, which was also a finding in the group with a Bishop's score of 4–6. Therefore, despite insufficient positive cases to confirm the effect of overstimulation of dinoprostone, caution should still be recommended for the use of this vaginal prostaglandin reagent with control of the dose.

**Conclusion**

This study was conducted to compare dinoprostone and oxytocin based on their action in elective induction of labor (IOL) in late-term pregnancies (LTPs) and the rate of cesarean section. For LTPs with a Bishop's score of 0–3, dinoprostone was superior to oxytocin for IOL with a lower rate of cesarean delivery, but both agents had a similar outcome for women with a Bishop's score of 4–6. Based on the study findings, the researcher conclude that in set up where dinoprostone is unavailable, oxytocin may be considered, rather than a cesarean section, for women with a Bishop's score of 4–6.

**References**


1. Martin JA, Hamilton BE, Osterman JE, et al. Births: Final data for 2013. Natl Vital Stat Rep. 2015; 64(1):1–65.
2. American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin No. 146: Management of late-term and postterm pregnancies. Obstet Gynecol. 2014; 124(2 Pt 1):390–96.
3. Galal M, Symonds I, Murray H, et al. Postterm pregnancy. Facts Views Vis Obgyn. 2012; 4(3):175–87.
4. Spong CY. Defining "term" pregnancy: Recommendations from the Defining "Term" Pregnancy Workgroup. JAMA. 2013; 309(23):2445–46.
5. Saccone G, Berghella V. Induction of labor at full term in uncomplicated singleton gestations: A systematic review and meta-analysis of randomized controlled trials. Am J Obstet Gynecol. 2015; 213(5):629–36.
6. Sanchez-Ramos L. Dinoprostone vaginal insert for cervical ripening and labor induction: A meta-analysis. Obstet Gynecol. 2001; 98(3):519–20.
7. Reinhard J, Rosler R et al. Prostaglandin E2 labour induction with intravaginal (Minprostin) versus intracervical (Prepidil) administration at term: Randomized study of maternal and neonatal outcome and patient's perception using the Osgood semantic differential scales. Biomed Res Int. 2014; 68:2919.
8. World Health Organisation (WHO) Recommendations for Induction of Labour. Geneva: 2011. Available from: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/9789241501156/en/ last Accessed: 30-10-2021
9. Kho EM, Sadler L, McCowan L. Induction of labour: A comparison between controlled-release dinoprostone vaginal pessary (Cervidil) and dinoprostone intravaginal gel (Prostin E2) Aust N Z J ObstetGynaecol. 2008; 48(5):473–77.
10. Barrilleaux PS, Bofill JA, Terrone DA, et al. Cervical ripening and induction of labor with misoprostol, dinoprostone gel, and a Foley catheter: A randomized trial of 3 techniques. Am J Obstet Gynecol. 2002; 186(6):1124–29.
11. Alfirevic Z, Kelly AJ, Dowswell T. Intravenous oxytocin alone for cervical ripening and induction of labour. Cochrane Database Syst Rev. 2009; (4):CD003246.
12. Koc O, Duran B, Ozdemirci S, et al. Oxytocin versus sustained-release dinoprostone vaginal pessary for labor induction of unfavorable cervix with Bishop score ≥4 and ≤6: A randomized controlled trial. J ObstetGynaecol Res. 2013; 39(4):790–98.
13. Newman RB, Goldenberg RL, Iams JD, et al. Preterm prediction study: Comparison of the cervical score and Bishop score for prediction of spontaneous preterm delivery. Obstet Gynecol. 2008; 112(3):508–15.
14. Wei Y, Cao Y, Yu Y, Wang Z. Evaluation of a modified "Triple-P" procedure in women with morbidly adherent placenta after previous caesarean section. Arch Gynecol Obstet. 2017;296(4):737–43.
15. Macones GA, Hankins GD, Spong CY, et al. The 2008 National Institute of Child Health and Human Development workshop report on electronic fetal monitoring: Update on definitions, interpretation, and research guidelines. Obstet Gynecol. 2008;112(3):661–66.
16. Antonazzo P, Laoreti A, Personeni C, et al. Vaginal dinoprostone versus intravenous oxytocin for labor induction in patients not responsive to a first dose of dinoprostone: A randomized prospective study. Reprod Sci. 2016;23(6):779–84.
17. Gungorduk K, Asicioglu O, Besimoglu B, et al. Labor induction in term premature rupture of membranes: Comparison between oxytocin and dinoprostone followed 6 hours later by oxytocin. Am J Obstet Gynecol. 2012;206(1):60e1–8.
18. Akay NO, Hizli D, Yilmaz SS, et al. Comparison of low-dose oxytocin and dinoprostone for labor induction in postterm pregnancies: A randomized controlled prospective study. GynecolObstet Invest. 2012; 73(3):242–47.
19. Kunt C, Kanat-Pektas M, Gungor AN, et al. Randomized trial of vaginal prostaglandin E2 versus oxytocin for labor induction in term premature rupture of membranes. Taiwan J Obstet Gynecol. 2010; 49(1):57–61.
20. Tan PC, Daud SA, Omar SZ. Concurrent dinoprostone and oxytocin for labor induction in term premature rupture of

membranes: A randomized controlled trial. Obstet Gynecol. 2009;113(5):1059–65.
21. Kim SH, Bennett PR, Terzidou V. Advances in the role of oxytocin receptors in human parturition. Mol Cell Endocrinol. 2017;449:56–63.
22. Kishore AH, Liang H, Kanchwala M, et al. Prostaglandin dehydrogenase is a target for successful induction of cervical ripening. Proc Natl AcadSci USA. 2021;114(31):E6427–36.

**Conflict of Interest:Nil**
**Source of support:None**