



COMPARISON OF SAFETY AND EFFICACY OF INTRACERVICAL DINOPROSTONE GEL AND EXTRA-AMNIOTIC FOLEY'S CATHETER FOR INDUCTION OF LABOUR

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ABSTRACT **BACKGROUND:** The uterus remains quiescent throughout 9 months and begins to act on its own when full term is approached. Almost 50% women deliver in the duration of one week before and after the calculated EDD; and induction of labour is needed in about 20% of women: to increase the success of labour induction, to reduce the duration and complications of labour and to diminish the rate of caesarean sections. Cervical ripening is needed before induction of labour. There are many methods for induction of labour; however till date, none of them can be claimed to be the best. **AIM OF PRESENT STUDY:** To compare the safety and efficacy of Dinoprostone gel versus intracervical foley's catheter for ripening of cervix and induction of labour. **MATERIAL AND METHODS:** Comparative prospective study was conducted on 400 full term uncomplicated primigravida women needing induction of labour between January 2019 to June 2020 in department of obstetrics & gynecology at GMC Kota in Rajasthan. Group A: 200 women induced with Dinoprostone gel and Group B: 200 women induced with extra-amniotic Foley's catheter. Baseline characteristics like maternal age, gestational age, indication for induction were comparable in both the groups. **RESULT:** The mean induction to delivery interval was shorter in group A (12.69 ± 3.64 hours) as compared to Group B (18.17 ± 3.17 hours) and this difference was statistically highly significant ($P = 0.0001$). There was no significant difference observed in mode of delivery, labour progress at 18 hours, indication for caesarean section, maternal side effects, mean birth weight, Apgar score at 5 mins, number of NICU admissions between the two groups. **CONCLUSION:** The number of vaginal deliveries were similar in both the groups but mean induction to delivery interval was significantly shorter with Dinoprostone gel. However, the maternal and fetal outcomes were better in Foley's catheter group although the difference was not statistically significant.

KEYWORDS : Induction of labour, Dinoprostone gel, Foley's catheter, Postdated primigravida

INTRODUCTION:

Labour is a process by which a fetus of viable age is expelled from the uterus through vagina. It may be spontaneous or induced. Labour is considered normal if vaginal delivery of a singleton pregnancy at term with vertex presentation is spontaneous in onset without undue prolongation and with minimal aids and no maternal & fetal complications.[1]

Induction of labour is indicated when it is thought that delivering the baby will be safer for the baby and / or the mother, than for the baby to remain in utero. Cervical ripening is closely related to the success of vaginal delivery. [2]

Cervical ripening refers to the process of preparing the cervix for induction of labour by promoting effacement and dilatation as measured by Bishop's score.[3] The success of induction depends on gestational age, preinduction score, sensitivity of uterus, cervical ripening and presence of fetal fibronectin in vaginal swab. [4] Induction of labour is done for obstetric indications like post-dated pregnancy, PROM, PPROM, pre-eclampsia, eclampsia, IUGR, Rh isoimmunisation, oligohydraminos, chorioamnionitis, Abruptio placenta, IUFD and for medical indications like chronic nephritis, Hypertension, Diabetes. [5]

Since ancient times, there are many **methods used for IOL**. They are categorised as **pharmacological methods** like oxytocin, prostaglandins, progesterone receptor antagonists, Relaxin, Hyaluronic acid, oestrogen and **non-pharmacological methods** like extra-amniotic saline Infusion (EASI); mechanical methods like foley's catheter, osmotic dilators and surgical methods i.e. sweeping of membranes and amniotomy.[4]

The uncountable number of studies available in the literature signify that as yet the search for an ideal method of induction is going on.

This study compares the pharmacological method i.e. Dinoprostone gel with mechanical method of induction i.e. extra-amniotic foley's catheter.

Dinoprostone gel (PGE2) has oxytocic effect on pregnant uterus. It causes change in myometrial cell membrane permeability and

alteration of membrane bound calcium. Dinoprostone gel also sensitises the myometrium to oxytocin and acts mainly on cervix due to its collagenolytic property and increases submucosal water content of cervix. [6,7]

Transcervical Foley's catheter causes cervical ripening with the release of interleukins (IL-6, IL-8), matrix metalloproteinase (MMP-8) and hyaluronic acid synthetase. Foley's catheter ripens the cervix by applying pressure on the internal os of cervix; thereby stretching the lower uterine segment and increasing local prostaglandin secretion and stimulates uterine contractions. [6,7]

AIMS AND OBJECTIVES:

To compare the safety and efficacy of Dinoprostone gel and intracervical Foley's catheter for inducing labour.

MATERIAL AND METHODS:

This comparative prospective randomised study was conducted on 400 patients admitted for IOL at our tertiary care institution in Rajasthan between Jan 2019 to June 2020. The study was approved by ethical committee of institution. Randomisation done on basis of odd and even serial number.

Group A: 200 patients induced with Dinoprostone gel (odd number)
Group B: 200 patients induced with Foley's catheter (even number)

INCLUSION CRITERIA:

- Singleton pregnancy
- Cephalic presentation
- Full term & post-dated pregnancy
- Modified Bishop's score ≤ 5

EXCLUSION CRITERIA:

- Ruptured membranes
- Active genital infections
- Maternal medical illness
- Obstetric contraindication for vaginal delivery

INDICATION FOR INDUCTION:

- Full term pregnancy with poor Bishop's score.

- Post-dated pregnancy (within 7 days)
- Mild hypertensive disease in pregnancy (38 completed weeks)

All women participating in the study were subjected to:

- Written informed consent
- Detailed history: present pregnancy, menstrual, obstetric, personal, past medical, surgical and drug allergy history
- Thorough general physical examination
- Meticulous systemic examination
- Obstetric examination: Per abdominal, Per vaginal and assess modified Bishop's score.

All women were administered Cap Amoxicillin 500 mg TDS for prophylaxis against sepsis and asked to void urine before the procedure and placing the patient in dorsal position at edge of labour table with knees flexed.

In Group A: Dinoprostone gel 0.5 mg in 2.5 ml prefilled syringe was brought to room temp. and instilled intra-cervically and patient asked to remain recumbent for 30 mins. Dinoprostone Gel instillation was repeated after 6 hours if effective uterine contractions were not achieved.

In Group B: No.16 Foley's catheter introduced through the cervix and inflated with 50 ml of NS and pulled back so that the balloon rests on internal os. Proximal end of catheter taped to the thigh to provide constant, moderate tension to balloon. Modified Bishop's score reassessed after 18 hrs or after expulsion of foley's catheter or rupture of membranes (whichever occurred first).

A partogram was maintained for assessing the progress of labour and fetal wellbeing.

The primary outcome measures the modified Bishop's score at the end of 18 hours. Secondary outcome was the induction to delivery interval, mode of delivery, indication of CS, maternal complications, Apgar score at 5 min, number of NICU admissions.

Statistical analysis: The groups were compared by using chi square test and unpaired student T test. Statistical significance were defined as $p < 0.05$

Failed induction: if Bishop score did not increase >6 even after 18hrs of induction.[4]

Tachysystole: >5 contractions in 10 min. averaged over 30 min window[4]

Hyperstimulation: tachysystole + fetal distress[4]

RESULTS:

Table 1: Demographic details

	Group A	Group B	P value
Mean age (years)	25 ± 4.52	25.41 ± 4.63	0.3654
Residence	Rural 125 (62.5%)	140 (70%)	0.9999
	Urban 75 (37.5%)	60 (30%)	
ANC booking	Booked 90 (45%)	64 (32%)	0.9999
	Unbooked 110 (55%)	136 (68%)	
Mean gestational age	39.58 ± 1.04	39.66 ± 0.98	0.4488

Table 2: Indications for induction of Labour (IOL) and Cesarean section (CS)

Indication for IOL			
	Group A	Group B	P value
Mild HDP with 38 weeks completed	60 (30%)	40 (20%)	0.9999
Post-dated pregnancy	110 (55%)	116 (58%)	
Term pregnancy with poor Bishop score	30 (15%)	44 (22%)	
Indication for CS			
Fetal distress	36 (18%)	25(12.5%)	0.6647
Failed induction of labour	26 (13%)	34 (17%)	
Non progress of labour	18 (9%)	36 (18%)	

Table 3: Progress of labour at different intervals and mode of delivery

Vaginal delivery at different intervals			
	Group A	Group B	P value
6 hr	20 (10%)	8 (4%)	0.9999
6-12 hrs	40 (20%)	19 (9.5%)	
12-18 hrs	35 (17.5%)	38 (19%)	
>18 hrs	25 (12.5%)	40 (20%)	

Labour progress at 18 hrs			
	Group A	Group B	P value
Vaginal delivery within 18 hrs	95 (47.5%)	65 (32.5%)	0.8188
Bishop score ≥ 8	25 (12.5%)	40 (20%)	
CS for Bishop score <8 , failure to progress, fetal distress	80 (40%)	95(47.5%)	0.9149
Mode of delivery			
Vaginal delivery	120 (60%)	105 (52.5%)	0.9999
Cesarean section	80 (40%)	95 (47.5%)	
Mean induction to delivery interval (Hours)			
	12.69 ± 3.64	18.17 ± 3.17	0.0001

Table 4: Maternal and Neonatal outcome

Maternal complications			
	Group A	Group B	P value
Tachysystole	0 (0%)	0 (0%)	0.5751
Hyperstimulation	4 (2%)	0 (0%)	
Fever	1 (0.5%)	1 (0.5%)	
Vomiting	5 (2.5%)	0 (0%)	
Diarrhoea	2 (1%)	0 (0%)	
PPH-Traumatic	9 (4.5%)	12 (6%)	
PPH-Atonic	12 (6%)	8 (4%)	
Neonatal outcome			
Mean birth weight	3.01 ± 0.26	3.1 ± 0.90	0.9273
Apgar score at 5 min	≤ 7 20 (10%)	15 (7.5%)	0.9999
	>7 180 (90%)	185 (92.5%)	
NICU admission	56 (28%)	40 (20%)	0.8378
Indication for NICU admission			
Meconium aspiration syndrome	18 (9%)	10 (5%)	0.5751
Birth asphyxia	8 (4%)	5 (2.5%)	
Neonatal jaundice	30 (15%)	25 (12.5%)	

DISCUSSION:

The present study was conducted on primigravidae with unfavourable cervix at full term, comparing the result of safety & efficacy of induction of labour by Dinoprostone gel (group A) and intracervical Foley's catheter (group B).

Studies available on comparison of these two methods of IOL have taken primigravidae^[9,10,11] and others have included primigravida as well as multigravida^[8,12].

1. The demographic profile (maternal age, urban/rural residence, status of ANC booking, gestational age at induction) was similar in both groups of present study.

In the present study mean maternal age was 25.00 ± 4.52 yrs and 25.41 ± 4.63 yrs in the group A and B respectively. Age distribution was similar in the study by **Rajeshwari A et al**^[11]; maternal age was higher in the two groups (28.61 ± 4.11 yrs & 29.10 ± 3.74 yrs respectively) in study done by **Warade S et al**^[8] and maternal age was lesser than present study in other studies^[9,10,12].

Mean gestational age 39.58 ± 1.04 weeks in group A & 39.66 ± 0.98 weeks in group B in the present study, similar to the study by **Hemlata and Joshi G**^[10]; However slightly lesser mean gestational age 38.43 ± 1.29 weeks in Dinoprostone group & 38.48 ± 1.35 weeks in Foley's group was reported by **Kanade A et al**^[9].

2. Preinduction modified bishop score taken as unfavourable was ≤ 5 in present study. Similar to other studies^[9,12]. However, the score taken as unfavourable was ≤ 4 ^[8,10] & ≤ 3 ^[11] by other authors.

3. In the present study, the most common indication for IOL was postdatism (55% and 58% in group A and B respectively) followed by mild hypertension with gestational age ≥ 38 week (30%, 20% in both groups respectively). Similarly, **Warade S et al**^[8] report postdatism as the most common indication for IOL (50% in Dinoprostone group and 54.54% in foley's group respectively) followed by pre-eclampsia. Other studies quoted pre -eclampsia as more common indication followed by postdatism^[9,11].

4. In the present study the number of vaginal deliveries was higher in

Dinoprostone group (60%) as compared to Foley's catheter group (52.5%). Although, this difference was not statistically significant. Other studies also quote greater rate of vaginal delivery in Dinoprostone group but their difference was found to be statistically significant^[8,9,10,12,13]. In contrast to these reports, **Rajeshwari A et al**¹¹ reported greater number of vaginal deliveries in Foley's catheter group.

5. The rate of CS was 40% in Dinoprostone group & 47.5% in Foley's catheter group in the present study (difference not statistically significant); similar to studies by other authors^[8,9,11]. However, statistically significant difference was reported by **Hemlata and Joshi G**¹⁰ and **Mathuriya G et al**¹².

6. In present study, most common indication for CS was fetal distress in Dinoprostone group and failed induction of labour in Foley's group as is also reported by other authors^[11,12]. However, fetal distress was found to be equally common in both the study groups by few authors^[8,10].

7. Mean induction to delivery interval was significantly lesser in Dinoprostone group. In the present study ($p < 0.0001$), similar to the studies by other authors^[10,11,12] and their difference was also statistically significant ($p \leq 0.01$, $p < 0.05$, $p < 0.010$ respectively).

8. Maternal complications encountered during the study were PPH (21 cases in group A & 20 cases in group B); vomiting, uterine hyperstimulation & diarrhoea (5,4 and 2 cases of each respectively in group A); fever (1 case each in both groups). Similarly, PPH was reported in both the groups in few cases^[8]; hyperstimulation in Dinoprostone group^[8,11]; higher rate of complications was reported by **Mathuria G et al**¹⁰ (fever, nausea, vomiting & UTI in 12% cases of Dinoprostone group and 6% cases of Foley's group respectively).

9. The difference in fetal outcome was not statistically significant in the two study groups with respect to birth weight, Apgar score < 7 at 5 min and NICU admission in the present study. However, the number of NICU admission was greater in Dinoprostone group. These findings correlate with other studies^[8,9,10,11,12].

CONCLUSION:

Time taken for cervical ripening as well as mean induction to delivery interval were significantly shorter with Dinoprostone gel. However, maternal and fetal outcomes like uterine hyperstimulation, PPH, Apgar score ≤ 7 and number of NICU admissions were less in Foley's catheter group; although this difference was not statistically significant. It is concluded that Dinoprostone gel is more efficient than Foley's catheter for IOL but in low resource settings as well as absolute or relative contraindication to Dinoprostone gel. Foley's catheter is simple to use, low cost, alternative with potential of reversibility & lesser chances of uterine hyperstimulation and fetal distress.

REFERENCES:

- Shirish N Daftry, Sudip Chakravarti, Muralidhar V Pai, Pralhad Kushtagi (2017). Holland & Brews manual of obstetrics 4th edition. IMT Manesar
- Managing complication in pregnancy and childbirth; a guide for midwives and doctors. Geneva, world health organisation 2000. Available at: <http://www.who.int/reproductivehealth/publications/maternal-perinatal-health/9241545879/en/index.html>
- Tofatter Kf, Bowers D, Standby RN, Gall A, Killam AP. Preinduction cervical ripening with prostaglandin E2 gel. *Am J Obstet Gynecol* 1985;153:268-71
- DC Dutta, Hirralal Konar (2019). DC Dutta's textbook of obstetrics 9th edition
- Ian Donald, Renu Misra (2016). Ian Donald's Practical obstetric problems 7th edition
- F.Gary Cunningham, Kenneth J. Leveno, Steven L. Bloom, Jodi S. Dashe, Barbara L. Hoffman, Brian M. Casey, Catherine Y. Spong March 22, (2018). William textbook of obstetrics, 25th edition New York: Mc Graw Hill
- Sheila Balakrishnan (2020). Textbook of obstetrics 3rd edition Hyderabad
- Warade S, Pahwa A, Dhongade S (2019). Comparative study in a rural tertiary Hospital in Maharashtra between Foley Catheter and Dinoprostone gel for cervical ripening and induction of labour in term patients with unfavourable cervix (Bishop's score < 4). *Global journal for research analysis*, volume-8, Issue-12, Print ISSN No. 2277-8160. doi:10.36106/gira
- Kanada A, Jain M (2019). A comparative study of intracervical foley's catheter and PGE2 gel for induction of labour at term. *International Journal of Reproduction, Contraception, obstetrics and gynecology*. 8(9):3689-3693 doi: <http://dx.doi.org/10.18203/2320-1770.ijrcog20193799>
- Hemlata and Joshi G (2019). Comparison of efficacy and safety of intracervical Foley's catheter balloon with intracervical Prostaglandins E2 gel (Dinoprostone) for induction of labour. *International journal of advanced research (IJAR)* 7(3),1443-1451. doi: URL: <http://dx.doi.org/10.21474/IJAR/8779>
- Rajeshwari A, Sivaranjani P (2017). A comparative study of intracervical Foley's catheter and PGE2 gel for preinduction cervical ripening. *Journal of medical science and clinical research* 5(8),26303-26307. doi:<http://dx.doi.org/10.18535/jmscr/v5i8.53>
- Mathuriya G, Kushwaha S, Pradhan S (2017). Comparative study of induction of labour with dinoprostone gel versus mechanical dilatation in unfavourable cervix (Low Bishop score) *International Journal of Reproduction, contraception, obstetrics & gynecology*. 6 (10), 4363- 4366 doi:<http://dx.doi.org/10.18203/2320-1770.ijrcog20174405>
- Devarajan A, Sangeeranai M, Viswanathan S (2014). Induction of labour by Foley's catheter vs Prostaglandin E2 gel. *International Journal of Modern Research and Reviews*. Volume 2, Issue 9, pp301-303