DOI: 10.7860/JCDR/2024/69877.19446

Original Article

Obstetrics and Gynaecology Section

Efficacy of Foley Catheter Bulb with Intracervical Dinoprostone Gel versus Dinoprostone Gel alone for Cervical Ripening and Induction of Labour: An Observational Study

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ABSTRACT

Introduction: One of the most common obstetrical interventions is the induction of labour. Cervical ripening drugs are typically used before conventional methods of induction since they are linked to an increased risk of protracted labour, chorioamnionitis, and Caesarean Sections (CS) during labour induction when an unfavourable cervix is present. The two major techniques for cervical ripening are mechanical interventions, such as the insertion of balloon catheters, and the application of pharmacologic agents, such as prostaglandins. It is widely accepted that the induction of labour, which ultimately leads to vaginal delivery, is largely dependent on the condition of the uterus' cervix.

Aim: To compare the efficacy of a combination of Foley bulb catheter and intracervical Dinoprostone and intracervical Dinoprostone alone for the induction of labour.

Materials and Methods: A prospective observational study was performed over 150 pregnant mothers from May 2018 to April 2019. in the labour room of North Bengal Medical College and Hospital, a tertiary care institution in Darjeeling, West Bengal, India. The pregnant women were divided into two groups: intracervical Dinoprostone gel alone (Group-1) and a combination of intracervical Foley catheter and intracervical Dinoprostone gel (Group-2) with n=75 patients in each group. Group-1 received intracervical Dinoprostone gel 0.5 mg, which was repeated every 6 hours, a maximum of three doses, or until she went into active labour, whichever occurred earlier. In Group-2, a 16 F Foley catheter was inserted into the cervix, inflated, and a single dose of intracervical Dinoprostone gel 0.5 mg was given alongside it. Participant demographic characteristics, medical and pregnancy history, indication for labour induction, labour course, and outcomes were collected. The collected data were analysed with the mean and standard deviation for numerical variables and counts and percentages for categorical variables. Odds ratio was calculated where deemed relevant.

Results: The induction to delivery time was considered the primary outcome and was shorter in Group-2 by 28 minutes (p=0.342). Among the secondary outcomes, the duration of the latent phase of labour was shorter in Group-2 by 57 minutes, and the proportion of patients delivering within 12 hours was also higher (28%) but statistically insignificant (p>0.05). The rates of CS were unaffected by the mode of induction. None of the two methods were found to be inferior to the other in respect to neonatal outcomes or complications of labour like chorioamnionitis and postpartum haemorrhage.

Conclusion: The combination of Foley catheter with intracervical Dinoprostone gel did not prove to be more efficient than intracervical Dinoprostone alone for labour induction in the current study.

Keywords: Mechanical intervention, Outcome, Parturition, Prostaglandin

INTRODUCTION

Induction of labour is a common obstetric procedure. The favourability of the cervix has a significant impact on the outcome of inducing labour, which eventually strives to achieve vaginal birth [1]. Over the past few decades, there has been a steady increase in the prevalence of labour induction. Approximately, one in four newborns delivered in wealthy nations are delivered at term after labour induction [2]. According to the World Health Organisation's Global Survey on Maternal and Perinatal Health, which was carried out in 24 countries and comprised around 300,000 observations, 9.6% of births were induced labour [3]. Labour induction in the presence of an unfavourable cervix is associated with an increased likelihood of prolonged labour and an increased incidence of chorioamnionitis and caesarean sections; therefore, it is a routine procedure to employ cervical ripening medications before using traditional induction techniques.

The two major techniques for cervical ripening are mechanical interventions, such as the insertion of balloon catheters, and the application of pharmacologic agents, such as prostaglandins. The mechanical methods are said to have several benefits, including low cost, ease of use, reversibility potential, and a decline in certain side-effects such as increased uterine activity [4]. There is no single, clear best practice with respect to the choice of the agent used for cervical ripening; both mechanical and pharmacologic agents are generally acceptable options.

Two randomised trials found no difference in the induction-to-delivery time [5,6]. Thus, although the best agent and method for the induction of labour remain uncertain, it makes logical sense that a mechanical tool (the Foley bulb) and a chemical agent (synthetic prostaglandin) used in tandem could have a synergistic or additive impact that shortens the induction-to-delivery period and increases the degree of cervical ripening. The common observation of cervical dilatation with the Foley bulb without considerable effacement may potentially be overcome by adding a synthetic prostaglandin [7].

A 2016 network meta-analysis comparing the use of misoprostol (oral, vaginal), dinoprostone, and the balloon catheter for cervical ripening concluded that no method was clearly superior when the rates of failure to achieve vaginal delivery within 24 hours, uterine tachysystole with adverse foetal heart rate changes, and

caesarean delivery were all taken into account [8]. Although there have been studies comparing Misoprostol, Dinoprostone inserts, and transcervical Foley Catheter Bulb separately and Misoprostol combined with transcervical Foley Catheter Bulb [5-8], less is known about the combined usage of intracervical Dinoprostone and transcervical Foley Bulb.

The objective of the present study was to compare the efficacy of a combination of the Foley bulb and intracervical Dinoprostone and intracervical Dinoprostone alone for labour induction. The present authors hypothesised that the use of the Foley bulb plus intracervical Dinoprostone will result in a shorter induction-to-delivery time.

MATERIALS AND METHODS

A prospective observational study was conducted in the Labour Room of North Bengal Medical College and Hospital, a tertiary care institution in Darjeeling, West Bengal, India, for a duration of one year (May 2018 to April 2019). Prior approval for the study protocol was obtained from the Institutional Ethics Committee (Memo no. IEC/2017-18/48 dated 06.01.2018).

Inclusion and Exclusion criteria: After providing written informed consent, the study enrolled pregnant women with a single pregnancy of minimum 34 weeks of development, unbroken membranes, an unfavourable cervix (Bishop Score 6 or below), and an appropriate pelvis. Women who had spontaneous labour, multi-foetal gestation, foetal malpresentation, contraindications to prostaglandin, anomalous foetus, foetal demise, cephalopelvic disproportion, placenta previa, active genital herpes, previous caesarean section, and other previous uterine surgeries (myomectomy, cornual wedge resection) were excluded from the study.

Sample size calculation: The induction-to-delivery interval is considered the primary outcome measure for sample size calculation in the present study. It was estimated that 63 subjects would be required per group to detect a difference of four hours in induction to delivery between groups with 80% power and a 5% probability of a type I error. This calculation assumed a standard deviation of eight hours for this parameter and two-sided testing. Allowing for a 5% allowance for dropouts, the recruitment target was kept at a minimum of 67 subjects per group. {Sample size calculation has been done with nMaster 2.0 (Department of Biostatistics, Christian Medical College, Vellore) software}. After rounding up, a total of (n=150) pregnant women were included in the study.

Study Procedure

Women who wished to participate in the study were inquired regarding last menstrual period, menstrual cycle regularity, medical, surgical, and obstetric history. Their vaginal examination included a pelvic assessment as well as a cervix assessment for consistency, effacement, dilatation, and position of the presenting section. Utilising Cardiotocography (CTG). Ultrasonography was performed to assess liquor status and foetal biometry. The indications considered for induction of labour were postdated pregnancy, Pregnancy-induced Hypertension (PIH), oligohydramnios, and dribbling. Participating women were divided into two groups by simple randomisation using systematic sampling. Group-1 underwent cervical ripening with intracervical Dinoprostone gel alone, whereas Group-2 received a combination of Foley catheter bulb with a single dose of intracervical Dinoprostone gel. Dinoprostone-Cerviprime gel® containing 0.5 mg of Prostaglandin E2 (PGE2) per 3 grams present in a 2.5 mL prefilled syringe. The gel was brought to room temperature before application. The patient was put in a lithotomy position, and the perineum and vagina were cleaned with Betadine® lotion. The gel was inserted intracervically after visualising the cervix with the help of a Sim's speculum, and care was taken to ensure that the membranes were not injured. After the operation, the individual was maintained in a recumbent posture for 30 minutes. The highest amount that might need to be taken in a 24-hour period-1.5 mg in three doses-was advised. Uterine activity and foetal heart rate were constantly recorded beginning 15 to 30 minutes prior to the administration of the gel. The Modified Bishop score [9] was assessed after six hours of the procedure. If the cervix was found to be in a non favourable state, then a second dose of gel was applied.

To insert the catheter under proper aseptic conditions, the patient was placed in the 'lithotomy position,' the cervix was visualised using a Sim's speculum, and the anterior lip of the cervix was held with a Ring forceps. A no. 16 Foley catheter was introduced into the cervix with the aid of an artery forceps, taking care not to damage the amniotic membrane. The catheter bulb was inflated with 30-40 mL of distilled water. The catheter was snugly tugged and fixed to the patient's inner thigh. Unless expelled earlier, the catheter was removed after 12 hours, and the Bishop score was assessed.

Further supervision of labour was at the discretion of the on-duty labour team and included expectant management, amniotomy, or intravenous (i.v.) oxytocin. A partogram was maintained, and the foetal heart was auscultated every 30 minutes in the first stage and every 15 minutes in the second stage by the treating physician. If necessary, i.v. oxytocin was administered according to the conventional procedure, with a starting dose of two milligrams per minute and increments of two milligrams every 20 minutes until consistent uterine contractions occurred. Both groups had similar labour management practices in other areas. Data about the participants, such as their demographics, medical and pregnancy histories, labour and delivery path, and outcomes, were gathered. Any indication suggesting the need for labour induction was recorded.

STATISTICAL ANALYSIS

All the data were summarised by routine descriptive statistics, namely mean and standard deviation for numerical variables and counts and percentages for categorical variables. Odds ratios were calculated where deemed relevant. The categorical variables were analysed using Pearson's Chi-square test, while numerical variables were compared by Student's independent samples t-test. Comparisons were two-tailed, and a p-value <0.05 was considered statistically significant. Microsoft excel was used to record all data, and Statistical Package for Social Sciences (SPSS) for Windows version 26.0 was used for statistical analysis.

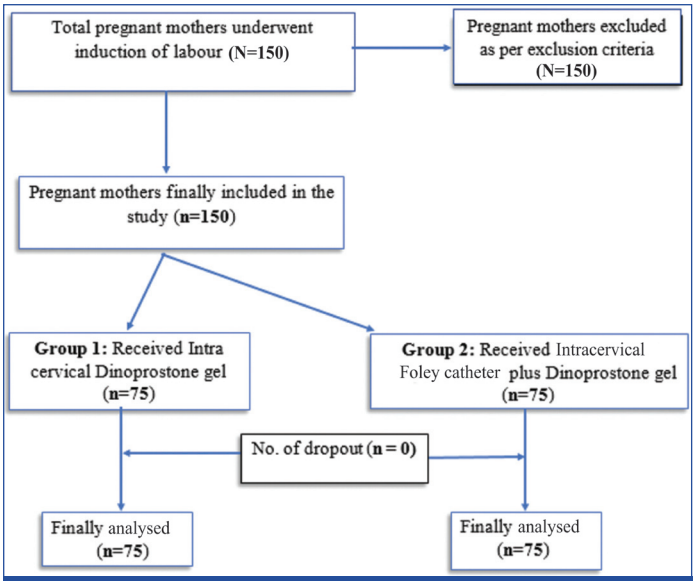
RESULTS

In the present study, 325 pregnant mothers were screened for the induction of labour during the study period, out of which 175 were excluded due to various exclusion criteria. Finally, (N=150) patients were recruited and divided into two study groups with n=75 each. A flowchart on the conduct of the study is shown in [Table/Fig-1].

The maximum number of pregnant mothers was found to belong to the age group of 21 to 25 years, e.g., Group-1, 25 (33.3%), and Group-2, 30 (40%), respectively. The mean age in Group-1 and Group-2 was 25.2±4.6 years and 24.7±4.6 years, respectively, and they were comparable. The majority of the study population belonged to rural areas, 41 (54.6%) and 43 (57.3%) in Group-1 and Group-2, and were nulliparous, 41 (54.7%) and 39 (52%) in Group-1 and Group-2, respectively. It was observed that in the present study, the maximum patients belonged to the gestational age group of 37 to 40 weeks in Group-1, 42 (56%), and Group-2, 48 (64%), respectively. The various indications for the induction of labour among the study population are depicted in [Table/Fig-2].

The most common indications for CS among the recruited pregnant mothers were found to be foetal distress followed by failed induction in the study. Other indications for CS are mentioned in [Table/Fig-3].

It was observed that 28% of women in the combination group (Group-2) delivered by 12 hours compared to 18.7% in the Dinoprostone group alone after the onset of induction (RR 0.667; 95% CI: 0.367-1.210). Among them, n=11 from Group-1 and n=6



[Table/Fig-1]: Flowchart of the study.

Indications for labour induction	Group-1: Dinoprostone (n=75)	Group-2: Dinoprostone plus foley catheter (n=75)	p-value
Post dated	34 (45.3%)	32 (42.7%)	0.892
PIH	20 (26.7%)	19 (25.3%)	
Dribbling	14 (18.7%)	14 (18.7%)	
Oligohydramnios	7 (9.3%)	10 (13.3%)	

[Table/Fig-2]: Indications for induction of labour among the two study groups.
Analysis performed by Chi-square test

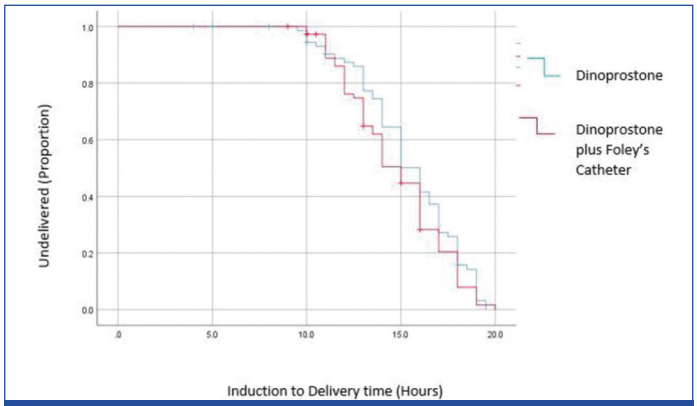
Indications for LUCS n (%)	Group-1: Dinoprostone (n=75)	Group-2: Dinoprostone plus foley (n=75)	Total
Foetal distress	5 (9.33)	7 (9.33)	12
Failed induction	4 (5.33)	4 (5.33)	8
Non progress of labour	1 (1.33)	0	1
Meconium-stained liquor	2 (2.66)	3 (4.0)	5
Total	12 (16)	14 (18.66)	26

[Table/Fig-3]: Various indications of caesarean section in two study groups.
LUCS: Lower uterine caesarean section

mothers from Group-2 were multiparous, respectively [Table/Fig-4]. The relative risks between vaginal mode of delivery between the two study groups were 1.015 with a 95% CI (0.919-1.120) and for CS, it was 0.857 with a 95% CI (0.302-2.401), respectively, which was statistically insignificant (p>0.05). In the present study, there was a mean difference in induction to delivery time of 28 minutes between the two groups [Table/Fig-5].

Outcome parameters	Group-1: Dinoprostone (n=75)	Group-2: Dinoprostone plus foley catheter (n=75)	p-value
Induction to delivery time (hours)	14.87±3.31	14.40±2.74	0.342*
Latent Phase (hours)	9.07±3.48	8.12±2.80	0.069
Proportion of women delivering in 12 hours	14 (18.7%)	21 (28%)	0.177#
Mode of delivery			
Vaginal	63 (84%)	61 (81.3%)	0.666
Caesarean	12 (16%)	14 (18.7%)	
Post-partum haemorrhage	6 (8%)	6 (8%)	1.00
Chorioamnionitis	4 (5.3%)	3 (4%)	0.699
APGAR score at 1 min (≤6)	14 (18.7%)	7 (9.3%)	0.100
APGAR score at 5 min (≤8)	14 (18.7%)	7 (9.3%)	0.100
Neonatal ICU admissions	6 (8%)	4 (5.3%)	0.513

[Table/Fig-4]: Comparison of parameters among the two study groups.
Data expressed as Mean±SD; Analysis performed by independent t-test*, Chi-square test#
APGAR: Appearance, pulse, grimace, activity and respiration; NICU: Neonatal intensive care unit



[Table/Fig-5]: Kaplan-Meier time curve for induction to delivery (Log rank p-value=0.196).

DISCUSSION

The study reveals that the combination group is associated with a shorter induction to delivery time as well as a 55-minute shorter latent phase of labour. The proportion of women delivering by 12 hours from the time of induction was also seen to be higher in the combination group, although the difference was not statistically significant. Caesarean rates and neonatal outcomes were similar in the two groups.

In the present study, the induction to delivery time was considered the primary outcome. The combination group of Foley plus Intracervical Dinoprostone had a shorter induction to delivery time by 28 minutes, which was statistically insignificant. Carbone JF et al., compared vaginal misoprostol against a combination of vaginal misoprostol and Foley catheter and obtained a shorter induction to delivery time in the combination group by almost three hours [7].

Another large randomised controlled trial found a significantly shorter induction to delivery time (almost 6 hours) in the combination of Dinoprostone vaginal insert and Foley catheter compared to Dinoprostone alone. Carbone JF et al., used Misoprostol, and Eser A et al., used PGE2 vaginal insert [7,10]. They concluded that intracervical Dinoprostone gel combined with Foley may not be superior to Foley alone. Eser A et al., recorded a significantly shorter duration of the latent phase of labour with the combination of Vaginal Dinoprostone and Foley catheter (more than six hours) when compared with vaginal Dinoprostone alone [10]. Chowdhary A et al., observed a 45-minute reduction in the latent phase of labour when Foley catheter was combined with intracervical Dinoprostone [11]. In the present study, the latent phase in the combination group was shorter by 55 minutes, although, similar to the other studies, the difference was not statistically significant.

While comparing the proportion of patients delivering by 12 hours from the time of induction, Chowdhary A et al., observed a significantly larger number of women in the combination group (30.8% compared to 9.8% in the Foley alone group) [11]. In another study, 89% of women in the combination group and 75% in the Misoprostol alone group delivered by 24 hours [7]. In comparison, the current study found that 28% in the combination group of Foley and intracervical Dinoprostone delivered in 12 hours compared to 18.7% in the intracervical Dinoprostone alone group. Compared to the study by Chowdhary A et al., the present study included 46.7% of multiparous patients, in contrast to more than 80% nulliparous in that study, which may attribute for the larger proportion of women delivering by 12 hours in both groups [11].

In the present study, the mode of induction did not significantly alter the rates of Caesarean Section (CS) (16% and 18%). The most common indication for Caesarean Section in the present study was

Foetal Distress (12), followed by failed induction (6), meconium-stained liquor (5), and non progress of labour. Chowdhary A et al., recorded pathological CTG as the most common indication for Caesarean Section, followed by meconium-stained liquor and others [11].

While using a mechanical device like Intracervical Foley catheter for labour induction, there is always a potential for infections. In the present study, however, the rates of chorioamnionitis were found to be similar in both groups. Dalui R et al., and McMaster K et al., observed that infectious morbidity was not increased when mechanical methods were used alone [12,13]. However, the risk may increase with repeated administration of Prostaglandins beside the inherent risk of uterine hyperstimulation with repeated doses of prostaglandins. In the present study, the combination group received only a single dose of Dinoprostone, which reduced the potential risk of both of these.

It was observed that the most common indication for the induction of labour in both groups was postdated pregnancies (>40% in both groups). Carbone JF et al., also recorded more than 40% of indications for induction to be postdated pregnancies [7]. Neonatal outcomes, like Appearance, Pulse, Grimace, Activity and Respiration (APGAR) scores at 1 and 5 minutes and subsequent Neonatal Intensive Care Unit (NICU) admissions, were comparable in the two groups, indicating that no method of induction was inferior to the other in terms of neonatal prognosis. Similar results were also observed in other previously published studies by Eser A et al., and Chowdhary A et al., [10,11]. Further planning and execution of randomised controlled trials on more women using combined cervical ripening techniques and comparing them with individual techniques may be explored to fulfill this unmet need.

Limitation(s)

The study sample size was small, and blinding could not be achieved, which may have led to bias in the study. Furthermore, larger studies are required to prove an increased effectiveness of adding a mechanical Foley catheter to intracervical Dinoprostone gel. The study was performed among a selected population in North Bengal, West Bengal, India, and may not accurately on other populations. Management of labour progression and other events were done under the supervision of the on-call labour room duty team, which varied from day to day; and hence could not be expected to be of the same level of performance in all participants.

CONCLUSION(S)

The present study did not find any statistically significant advantage of combining Foley catheter with intracervical Dinoprostone gel when compared with intracervical Dinoprostone gel alone for the induction of labour. However, it appears highly promising that the idea may have an additive or synergistic impact, leading to a larger degree of cervical softening and a shorter induction-to-delivery period.

REFERENCES

[1] Kamlungkuea T, Manonai J, Suriyawongpaisal P, Hansahiranwadee W. Factors predicting successful vaginal delivery following induction of labour in term pregnancy. Int J Womens Health. 2022;19(14):245-55.
[2] Rydahl E, Eriksen L, Juhl M. Effects of induction of labour prior to post-term in low-risk pregnancies: A systematic review. JBI Database of Systematic Reviews and Implementation Reports. 2019;17(2):170-208.
[3] Rayburn WF. Minimizing the risks from elective induction of labour. J Reprod Med. 2007;52:671-76.
[4] Sherman DJ, Frenkel E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavourable cervix with extra amniotic catheter balloon: Clinical experience and review. Obstetrical and Gynecological Survey. 1996;51(10):621-27.
[5] Kashanian M, Akbarian AR, Fekrat M. Cervical ripening and induction of labour with intravaginal misoprostol and Foley catheter cervical traction. Int J Gynaecol Obstet. 2006;92:79-80.
[6] Chung JH, Huang WH, Rumney PJ, Garite TJ, Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter and combination misoprostol-Foley catheter for labour induction. Am J Obstet Gynecol. 2003;189:1031-35.
[7] Carbone JF, Tuuli MG, Fogertey PJ, Roehl KA, Macones GA. Combination of Foley bulb and vaginal misoprostol compared with vaginal misoprostol alone for cervical ripening and labour induction: A randomized controlled trial. Obstet Gynecol. 2013;121(2 Pt 1):247-52. Doi: 10.1097/AOG.0b013e31827e5dca. PMID: 23303106.
[8] Chen W, Xue J, Peprah MK, Wen SW, Walker M, Gao Y, et al. A systematic review and network meta-analysis comparing the use of Foley catheters, misoprostol, and dinoprostone for cervical ripening in the induction of labour. BJOG. 2016;123(3):346-54.
[9] Crane JMG. Factors predicting labour induction success: A critical analysis. Clin Obstet Gynecol. 2006;49(3):573-84.
[10] Eser A, Ozkaya E, Abide CY, Eser T, Eser GY, Abike F, et al. Transcervical Foley balloon catheter and vaginal prostaglandin E2 insert combination vs. Vaginal prostaglandin E2 insert only for induction of labour at term: A randomized clinical trial. Arch Gynecol Obstet. 2019;299(2):451-57.
[11] Chowdhary A, Bagga R, Kalra J, Jain V, Saha SC, Kumar P. Comparison of intracervical Foley catheter used alone or combined with a single dose of dinoprostone gel for cervical ripening: A randomised study. J Obstet Gynaecol. 2019;39(4):461-67.
[12] Dalui R, Suri V, Ray P, Gupta L. Comparison of extraamniotic Foley catheter and intracervical prostaglandin E gel for preinduction cervical ripening. Acta Obstet Gynecol Scand. 2005;84(4):362-67.
[13] McMaster K, Sanchez-Ramos L, Kaunitz AM. Evaluation of a transcervical Foley catheter as a source of infection: A systematic review and meta-analysis. Obstet Gynaecol. 2015;126(3):539-51.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Feb 01, 2024
- Manual Googling: Mar 11, 2024
- iThenticate Software: Apr 01, 2024 (14%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jan 31, 2024**
Date of Peer Review: **Mar 07, 2024**
Date of Acceptance: **Apr 03, 2024**
Date of Publishing: **May 01, 2024**