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# Comparison of Prostaglandin E2 Vaginal Gel versus Intracervical Foley's Catheter Balloon for Induction of Labour

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***Research Article***

***Abstract:*** At times, despite an unripe cervix, induction of labor may be needed. In these cases, a safe and suitable method should be considered for cervical ripening and pregnancy termination. The aim of this study is the comparison of vaginal Dinoprostone Gel (PGE2) with Foley catheter for cervical ripening and induction of labor. This randomized clinical trial was performed on 216 pregnant women. These women were randomly divided into two groups: Dinoprostone (including 98 patients) and Foley catheter (including 118 patients). For the first group, 0.5mg.Dinoprostone vaginal gel was administered every 6 hours up to maximum 2 doses. For the second group, Foley catheter 18 F, inflated with 50 cc of sterile water, was placed through the internal os of the cervix. Data was analyzed and $p < 0.05$ was considered statistically significant. Two groups were similar in the view of demographic characteristics, cesarean indications, maternal and fetal outcomes and neonatal outcomes. Vaginal delivery was significantly higher in Dinoprostone group (89.9 vs. 62.7, $p < 0.01$). The mean of delivery time was significantly shorter in Dinoprostone group ($11.08 \pm 5.6$ vs. $13.6 \pm 16.0$ h, $p < 0.05$). In the cases of pregnancy termination and unripe cervix, two methods of Dinoprostone and Foley catheter were considered suitable, but it seemed that Dinoprostone decreases the delivery time and was needed for the cesarean section.

***Keywords:*** Dinoprostone, Foley catheter, Cervical ripening, Induction of labor.

## Introduction

Labour induction is the artificial initiation of labour prior to its spontaneous onset for the purpose of accomplishing delivery of feto-placental unit[1]. It ia indicated where the benefits to either the mother or the fetus outweighs the benefits of continuing pregnancy[2]. There is little doubt that cervical ripening facilitates labour and ultimately influences the prospects of vaginal delivery[3,4]. Induction of labour when cervix is unripe is associated with maternal complications and high rates of induction failure. Bishop's pelvic scoring system is most commonly used for cervical assessment prior to induction[6]. Cervix is considered unfavorable if the score is less than 6 and cervical ripening is indicated prior to artificial rupture of membranes and oxytocin infusion to reduce the incidence of failed induction and cesarean delivery[7]. Numerous techniques have been used to ripen the unfavorable cervix to achieve the changes necessary for labour[8,9]. Presently pharmacological and mechanical agents are used to modify the cervical status[1]. Prostglandins are most commonly used pharmacological agents for ripening of cervix and PGE2 is the agent of choice for this purpose[10.] A variety of more economical mechanical methods are also used for cervical ripening like intracervical Foley Catheter, bougies and hygroscopic laminaria tents. The use of Foley Catheter to effect cervical ripening was first described by Embrey and Mollison in 1967[12]. Thereafter various balloon catheters have been used to induce cervical ripening[13].

## Material and Methods

This randomized clinical trial was performed on 220 pregnant women admitted to the labor ward for induction of labor. The study was conducted in the Department of Obstetrics, teaching hospital, Krishna Institute of Medical Sciences during a time period of September 2011 to August 2012. The included criteria were gestational age > 37 weeks on the basis of last menstrual period (LMP) or sonography at first trimester, need to pregnancy termination for fetal or maternal indication, unfavorable cervix (Bishop score < 6), gestational diabetes mellitus, singleton pregnancy, reassuring fetal heart rate tracing, cephalic presentation, intact membranes and mild preeclampsia. Women were excluded from the study if any of the following criteria were encountered: hypersensitivity to prostaglandin, temperature > 38 C, previous cesarean delivery or other uterine surgery, placenta previa, chorioamnionitis, vaginal bleeding, fetal distress, need to immediate delivery, macrosomy, and polyhydroamnios. They were randomly divided into two groups: 100 cases in Dinoprostone group (group 1) and 120 cases in Foley catheter group (group 2). At first, the method of the study was completely explained for them; if the written consent was obtained, they were entered the study. For the first group, Dinoprostone gel in prefilled syringe was used. 0.05 mg mi Dinoprostone was placed in

the posterior fornix of the vagina; if needed, same dose was repeated after 6 hours. Vaginal examination was performed every 4 h; if the uterine contractions didn't begin, the patient received another dose. In the presence of spontaneous and frequent contractions (about 40 -50 sec every 3 min), the next dose was not administered. If the effective uterine contractions didn't begin 6 h after the last dose, oxytocin infusion was used. For the second group, 18 F Foley catheters were placed through the cervix in the sterile condition. The balloon was inflated with 50 cc of sterile saline solution and pulled against the internal os of the cervix. In the absence of uterine contractions after 12 h, labor induction was done with oxytocin. At first, oxytocin infusion was used with a dose of 2 mLU/min, as required 2 mLU/min was increased every 20 min in order to effective uterine contraction (at least 3 contractions of 40 - 50 sec every 3 min). The maximum administered dose was 40 mLU/min. If there was inadequate uterine contraction or no progress in the active phase and fetal or maternal indication, cesarean delivery was performed for the patient. From each group, two patients were excluded from further analysis (due to the bad participation) and totally 98 cases in first group and 118 cases in second group completed the study. All data were gathered prospectively with the use of questionnaire. Maternal demographic characteristics (maternal age, gestational age, parity, mode of delivery, first bishop score, neonatal apgar score) were recorded for both groups and then were compared. The indication for the induction and important outcomes of labor were recorded for each patient: the placement time of the Foley catheter or Dinoprostone , the expulsion time of Foley catheter, the amniotomy or spontaneous rupture time of membranes, the initiation time of oxytocin, the time of second stage of labor, and the delivery time. In this study, the main variable was the interval time from the first intervention to the time of delivery. During intervention, the patient was assessed for possible outcomes, uterine tachysystole (defined as $\geq$ 6 contractions every 10 min), and uterine hyperstimulation (continuing contractions more than 2 min). Fetal heart rate tracing was recorded every 15 min.

## Results and Discussion

In this study, a total of 216 pregnant women with indication for pregnancy termination were evaluated. They were randomizedly divided into two groups: 98 cases in Dinoprostone group as first group and 118 cases in Foley catheter group as second group. The studied groups were similar in the view of demographic characteristics including age, gestational age, parity, and Bishop score. The mean and the standard variation of age in Dinoprostone group and Foley catheter was 24.3 ± 4.0 and 24.2 ± 5.0 ($p > 0.1$), respectively. Gestational age, in first group was 39.8 ± 1.4 weeks and in second group was 40 ± 0.9 weeks ($p > 0.1$). Parity, in first group was 1.3 ± 0.63, and in second group was 1.7±1.1 ($p > 0.1$). The Bishop score in Dinoprostone group was 2.7 ± 1.3 and in Foley catheter group was 2.0 ± 1.6 ($p > 0.1$). As it was shown in Table 1, the rate of vaginal delivery in first group was 89.8% and in second group was 62.7%. The rate of vaginal delivery was significantly higher in Dinoprostone group ($p < 0.01$). Table 2 Shows indications of cesarean delivery in the studied groups. Regarding the results of the studied groups shown in Table 3, placental residue occurred in 2% of the first group patients, but no one of the second group were complicated by this outcome ($p > 0.1$). Tachysystole was observed in 2% of the Dinoprostone group patients and no one of the Foley catheter group ($p > 0.1$). 5% of the first group and 6% of the second group were complicated by atony after delivery ($p > 0.1$). The uterine hypertonisity defined as contractions membranes, the initiation time of oxytocin, the time of second stage of labor, and the delivery time. In this study in order to effective uterine contraction (at least 3 contractions of 40 - 50 sec every 3 min). The maximum administered dose was 40 mLU/min. If there was inadequate uterine contraction or no progress in the active phase and fetal or maternal indication, cesarean delivery was performed for the patient. From each group, two patients were excluded from further analysis (due to the bad participation) and totally 98 cases in first group and 118 cases in second group completed the study.

Ideally a cervical ripening agent induce cervical remodeling without stimulating uterine activity, It should be effective, convenient, safe, reversible and inexpensive. Most common indications for induction are postdate pregnancy and hypertension[11,14,15]. The use of Foley's catheter to effect cervical ripening was first described by Embrey and Mollison in 1967[12]. The mechanical action of Foley's balloon is it strips the fetal membranes from the lower uterine segment and starts the process of prostaglandin release which improve consistency and effacement of cervix. The advantages of such mechanical methods of induction are simplicity of use, potential of reversibility, reduction in certain side effects like excessive uterine activity and low cost[16]. Prostaglandins in general, especially PGE2 are extensively used for cervical ripening. They reduce the likelihood of not being delivered in 24 hours and decrease in use of oxytocin for augmentation but with higher rate of uterine stimulation[17]. Multiple studies have been done comparing effectiveness and safety between prostaglandin and Foley's catheter. Sciscione et al[18] compared the two methods and showed that Foleys catheter group had a shorter induction delivery interval.

St Onge and Connors[19] found that both Foleys catheter and PGE2 gel methods led to similar improvement in Bishop's score.

## Conclusion

The results of the present study indicate that vaginal Dinoprostone improves the process of delivery and increases the rate of vaginal delivery in the cases of unripe cervix.

**Table 1:** Mode of delivery

| **Groups** | **Dinoprostone** | **Foleys catheter** | **Total** |
|---|---|---|---|
| Vaginal Delivery | 88(89.8%) | 74(62.7%) | 162(75%) |
| Cesarean Delivery | 10(10.2%) | 44(37.3%) | 54(25%) |
| Total | 98(100%) | 118(100%) | 216(100%) |

**Table 2:** Cesarean indications in the studied groups

| **Groups** | **Dinoprostone** | **Foleys catheter** | **Total** |
|---|---|---|---|
| Fetal distress | 4(4.0%) | 8(6.8%) | 12(5.5%) |
| Non Progress in 1st stage | 1(2.0%) | 5(8.5%) | 6(5.5%) |
| Non Progress in 2nd stage | 0(0.0%) | 5(8.5%) | 5(4.6%) |
| Meconium stained liquor | 2(4.0%) | 7(11.9%) | 9(8.3%) |
| Cord prolapsed | 0(0.0%) | 1(1.7%) | 1(0.0%) |

**Table 3:** Pregnancy outcomes in studied groups

| **Outcomes** | **Dinoprostone** | **Foleys catheter** | **p-value** |
|---|---|---|---|
| Residue | 2(2.0%) | 0(0.0%) | >0.1 |
| Tachysystol | 2(2.0%) | 0(0.0%) | >0.1 |
| Atony | 6(6.0%) | 6(6.0%) | >0.1 |
| Uterine hypertonicity | 2(2.0%) | 0(0.0%) | >0.1 |

**Table 4:** The mean of phases of labour

| | Mean-+SD | | |
|---|---|---|---|
| **Groups** | **Dinoprostone** | **Foleys catheter** | **p-value** |
| Latent phase | 8.5-+5.1 | 10-+6.8 | >0.1 |
| Time of delivery | 11.08-+5.6 | 13.6-+16.9 | <0.05 |

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