

# Dinoprostone Intravaginal Slow-release Insert for Labor Induction with and without Saline Vaginal Wash: A Randomized Controlled Trial

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## ABSTRACT

**Aim:** To study the outcome of intravaginal dinoprostone insert for induction of labor with and without a saline vaginal wash.

**Materials and methods:** A randomized controlled trial was conducted from October 2019 to June 2021 in the Department of Obstetrics and Gynaecology of a tertiary care center located in Puducherry, India. The total study population was 164. Participants were allocated into group I ( $n = 82$ ) and group II ( $n = 82$ ) based on computer-generated random numbers. A 20 mL of 0.9% NaCl wash was given intravaginally prior to insertion of dinoprostone for group I and no wash was given for group II. Duration of dinoprostone kept intravaginally, time from insertion to active stage, and full cervical dilatation was noted. The software used was statistical package for social sciences (SPSS) software, version 17.

**Results:** Group I patients were found to attain the active stage of labor in 10 hours compared to group II patients who attained the active stage of labor in 14 hours. The difference between the mean duration of dinoprostone kept intravaginally, insertion to the active stage and full cervical dilatation were statistically significant.

**Conclusion:** Thus, the labor duration for patients who underwent vaginal wash was less when compared to those who did not undergo vaginal washing. Vaginal pH has been shown to alter with vaginal washing. Vaginal washing before intravaginal dinoprostone insertion may increase the vaginal pH, and change the prostaglandin E<sub>2</sub> (PGE<sub>2</sub>) vaginal insert bioavailability leading to shorter labor duration.

**Clinical significance:** For pregnant women with planned labor induction, vaginal douching can be easily performed before intravaginal dinoprostone insertion and can provide safe and rapid labor.

**Keywords:** Dinoprostone, Prostaglandin, Vaginal pH, Vaginal washing.

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## INTRODUCTION

Induction of labor is defined as an intervention intended to artificially initiate uterine contractions resulting in progressive effacement and dilatation of the cervix.<sup>1</sup> It is considered an essential and common practice in modern obstetrics. One of the most important prerequisites for labor induction is cervical ripening.<sup>2</sup> It is a physiological process that occurs throughout the later weeks of pregnancy. The nature of the cervix is therefore crucial in determining whether induction of labor or delivery is likely to be successful. Common methods of labor induction are membrane sweeping, amniotomy, oxytocin infusion, and prostaglandins (PG). Prostaglandin and its analogs such as dinoprostone slow-release inserts are among the pharmacological agents used in labor induction. The need for controlled and sustained release of PG was introduced to alleviate the risks and complications associated with the gel and tablet formulations. The 10-mg PGE<sub>2</sub> insert releases at the rate of 0.3 mg/hour over 24 hours.<sup>3</sup> It is a single insert pessary and alleviates the need for multiple induction agents. One of the most important complications associated with PG is uterine hyperstimulation. Vaginal inserts can be removed easily in the event of uterine hyperstimulation.<sup>4</sup> The average pH of the vagina is maintained in the range of 3.8–4.8. The degree of ionization and absorption of a drug are modified due to vaginal pH changes resulting in varied clinical responses. Vaginal pH is shown to be altered with vaginal washing. Studies have shown that vaginal washing before dinoprostone insertion may increase the vaginal pH and affect the PGE<sub>2</sub> vaginal insert bioavailability.<sup>5</sup>

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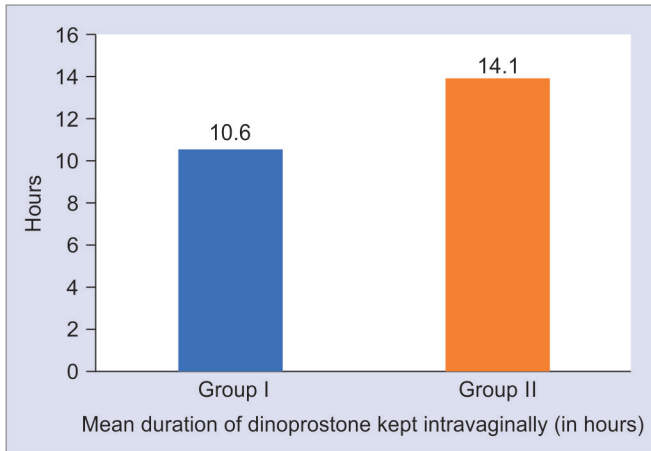
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This study is aimed to evaluate the outcome of vaginal washing prior to dinoprostone pessary insertion. The objective of the study is to assess the interval between induction and onset of active labor, induction and delivery interval, mode of delivery and the maternal side effects in dinoprostone pessary induced patients with vaginal washing and without vaginal washing. The study is the first of its kind among South Indian population.

## MATERIALS AND METHODS

This was a randomized controlled trial conducted in the labor room of a tertiary care center in Puducherry from February 2020 to January 2021 after obtaining institutional ethical clearance. A total of 164 antenatal women with singleton pregnancies above



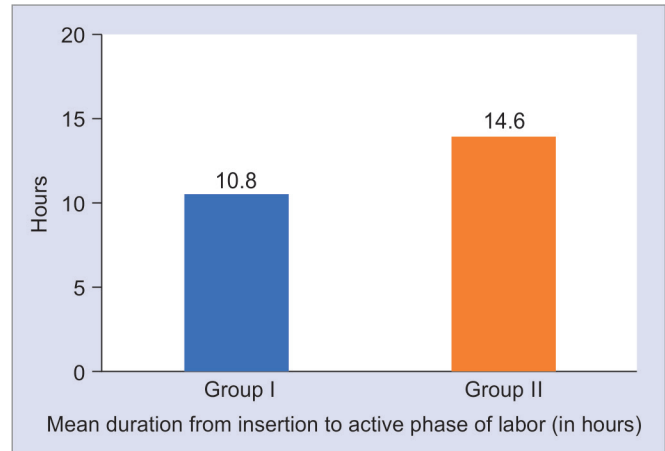
**Fig. 1:** Mean duration of dinoprostone kept intravaginally among the group I participants was  $10.6 \pm 3.1$  hours and group II participants was  $14.1 \pm 4.9$  hours. There was a statistical significance between the two groups with  $p = 0.000$

18 years of age, gestational age between 37 and 42 weeks, vertex presentation, adequate pelvis, and Bishop's score less than 6 admitted for induction of labor using intravaginal dinoprostone pessary were the inclusion criteria. There were divided into group I ( $n = 82$ ) and group II ( $n = 82$ ) based on computer generated random numbers with an allocation ratio of 1:1. After obtaining informed consent, group I women underwent vaginal washing with 20 cc of 0.9% NaCl prior to induction and group II did not undergo vaginal washing. Blinding was not done due to obvious nature of the study. With the onset of active labor, the routine hospital protocol was followed. Primary outcomes were duration of dinoprostone kept intravaginally (hours), duration to active phase of labor (hours), duration to total cervical dilatation (hours). Secondary outcomes were mode of delivery, indication of cesarean section, perinatal outcome, maternal complications. Qualitative variables were reported as proportions and percentages. Quantitative variables were reported as mean and standard deviation. Student *t*-test has been used to find the significance of study parameters on continuous scale between two groups on metric parameters. Statistical significance was taken as  $p < 0.05$ . The statistical software used for data analysis was SPSS software, version 17.

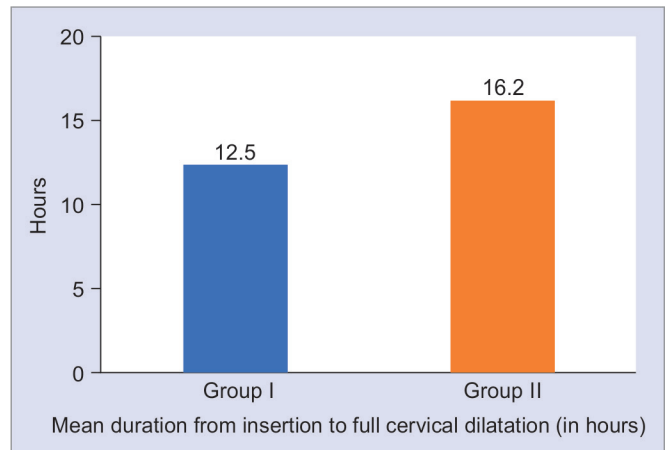
## RESULTS

The mean age of participants in group I was  $26.0 \pm 3.4$  years and group II was  $26.3 \pm 3.3$  years. The mean gestational age was similar in both the groups ( $38.6 \pm 1.0$  weeks). The mean body mass index (BMI) ( $\text{kg}/\text{m}^2$ ) in group I was  $27.8 \pm 4.2$  and in group II was  $28.3 \pm 4.8$ . The sociodemographic parameters are comparably similar in both the groups (Table 1). Group I had 42.7% of primiparous patients and group II had 45.1% of primiparous patients. Majority of the patients in group I and II had no miscarriages.

The mean duration of dinoprostone kept intravaginally among the group I participants was  $10.6 \pm 3.1$  hours and among Group II participants was  $14.1 \pm 4.9$  hours (Table 2). There was a statistical significance between the two groups for mean duration of dinoprostone kept intravaginally with  $p = 0.000$  as shown in Figure 1. The mean duration from insertion to the active phase of labor was found to be  $10.8 \pm 4.9$  hours among group I participants



**Fig. 2:** Mean duration from insertion to the active phase of labor which was  $10.8 \pm 4.9$  hours in group I and  $14.6 \pm 11.5$  hours in group II. The difference between the two groups was statistically significant with  $p = 0.014$



**Fig. 3:** Mean duration from insertion to full cervical dilatation in groups I and II participants was  $12.5 \pm 6.5$  hours and  $16.2 \pm 14.8$  hours, respectively. Statistical significance was noted between the two groups ( $p = 0.040$ )

and  $14.6 \pm 11.5$  hours among group II participants. The difference between the two groups for mean duration from insertion to the active phase of labor was statistically significant with  $p = 0.014$  as shown in Figure 2. Figure 3 shows the mean duration from insertion to full cervical dilatation in groups I and II participants which was  $12.5 \pm 6.5$  hours and  $16.2 \pm 14.8$  hours, respectively. Statistical significance was noted between the groups ( $p = 0.040$ ). In group I, 40.8% delivered vaginally and 9.2% by cesarean and in group II, 19.5% patients delivered vaginally and 30.5% by cesarean. Statistical significance is present between the two groups ( $p = 0.000$ ). The various indications of cesarean delivery were failed induction, fetal distress, cephalopelvic disproportion (CPD), meconium-stained liquor, arrest of dilatation, maternal request, and abruption. In both groups, the most common indication for cesarean was fetal distress seen in 22 patients (33.3%). There was no significance between the groups for indication of cesarean delivery ( $p = 0.084$ ). Out of 164 patients, 11 patients developed maternal complications, 3 patients developed atonic postpartum hemorrhage (PPH) in each

**Table 1:** Mean demographic parameters

	Group I (n = 82) Mean ± SD	Group II (n = 82) Mean ± SD	p-value
Age (years)	26.0 ± 3.4	26.3 ± 3.3	0.591
Gestational age (weeks)	38.6 ± 1.0	38.6 ± 1.0	0.826
BMI (kg/m <sup>2</sup> )	27.8 ± 4.2	28.3 ± 4.8	0.471
	n (%)		
Parity			
Primigravida	70 (42.7)	74 (45.1)	0.339
Multigravida	12 (7.3)	8 (4.9)	
Number of miscarriages			
0	76 (46.3)	75 (45.7)	
1	5 (3.0)	3 (1.8)	
2	1 (0.6)	4 (2.4)	0.316

Mean demographic details which are comparably similar in both groups

**Table 2:** Primary outcomes of the study

	Group I (n = 82) Mean ± SD	Group II (n = 82) Mean ± SD	p-value
Mean duration of dinoprostone kept intravaginally	10.6 ± 3.1	14.1 ± 4.9	0.000
Mean duration from insertion to active phase of labor	10.8 ± 4.9	14.6 ± 11.5	0.014
Mean duration from insertion to full cervical dilatation	12.5 ± 6.5	16.2 ± 14.8	0.040

Duration of dinoprostone was kept *in situ*, mean duration from insertion to the active phase of labor and full cervical dilatation was decreased in group I compared to group II

of the groups (1.8%). Uterine hyperstimulation was seen in three patients (1.8%) in group I and 1 patient (0.6%) in group II. One patient (0.6%) in group II had a perineal tear. The  $p = 0.571$ . The mean birth weight of newborns in both the groups was 2.9 kg. The mean Appearance, Cry, Grimace, Activity, Respiration (APGAR) score at 5 minutes in both groups was 9/10. One baby born to group I mother required neonatal intensive care unit (NICU) admission for 24 hours.

## DISCUSSION

This randomized controlled trial evaluated the outcome of vaginal washing and no vaginal washing on antenatal women undergoing labor induction with intravaginal dinoprostone pessary. Abide et al. performed vaginal washing in patients induced with dinoprostone controlled-release insert and concluded that duration to active labor was decreased resulting in more number of vaginal deliveries.<sup>5</sup> Şahin B et al.<sup>6</sup> showed that when vaginal washing was done prior to induction with dinoprostone pessary, duration to active labor was shortened and concluded that this may augment the bioavailability of dinoprostone by increasing the vaginal humidity and pH. Shabir NA et al.<sup>7</sup> also showed that the patients who underwent vaginal washing prior to dinoprostone pessary induction had shorter labor duration and better perinatal outcomes.<sup>8</sup> The normal acidic pH of the vagina slows the action of intravaginal dinoprostone. Vaginal douching with NaCl solution increases the efficiency of dinoprostone in the vagina by diluting the normal vaginal discharge and mechanical removal of lactobacilli colonization. This change to a well absorbable environmental following alteration of vaginal pH may change the absorption and metabolism of drugs applied intravaginally and decrease labor duration. Vaginal washing increases the concentration of the PGE<sub>2</sub> in the systemic circulation thus

increasing the chances of uterine hyperstimulation. The present study showed that three patients had uterine hyperstimulation in group I compared to one patient in group II. There were a greater number of failed inductions in group II compared to group I. The duration needed to reach the active phase of labor from the time of onset of dinoprostone insertion in the vaginal wash group was less than that of the control group and hence many patients in group II failed induction. An objective measurement of the vaginal pH was not made during the study. In future research, pH assessment can be performed before and after vaginal douching to detect optimal pH for dinoprostone efficacy in labor induction.

## CONCLUSION

It can be concluded that vaginal washing was associated with significantly decreased duration of the dinoprostone pessary kept intravaginally, decreased duration from insertion to active phase of labor and total cervical dilatation. Vaginal washing augments the bioavailability of dinoprostone by increasing the vaginal pH resulting in a shortened labor duration. It is a very easy process and may be useful for obstetricians who induce patients using dinoprostone intravaginal insert to get a better outcome.

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