

Induction of Labour with Prostaglandin with or Without Vaginal Douching

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Abstract

Objective: To assess the induction of labour with prostaglandin with or without vaginal douching.

Methodology: This randomized controlled trial study was conducted in the department of Obstetrics & Gynecology, Sheikh Khalifa Bin Zayed Al Nahyan Hospital / AK CMH Muzaffarabad Azad Kashmir from October 2019 to May 2020. Pregnant women of age 18-40 years, having single tone pregnancy, at term were included in the study. Vaginal douching was done with 0.9% NaCl serum (20cc) at the time of inserting dinoprostone. In the study group 10 mg PGE2 slow release system was used for vaginal insertion, right after washing the vagina and dinoprostone was inserted without any additional intervention among the women in control group. The standard protocol of the hospital was followed after the onset of active labour.

Results: There was no significant (p-value > 0.05) difference in basic demographic information between vaginal douching group and the control group. The mean duration of dinoprostone kept intravaginally (10.87 ± 6.92 vs. 7.69 ± 4.89 h), time to reach active phase of labour (11.26 ± 7.38h vs 15.32 ± 11.69h) and duration from dinoprostone insertion to total cervical dilatation (17.63 ± 12.24 vs 14.21 ± 7.87h) were noted significantly (p-value <0.05) less in vaginal douching group.

Conclusion: The bioavailability of prostaglandin E2 can be improved by vaginal douching before intravaginal administration of dinoprostone. Vaginal washing before insertion of dinoprostone may improve the entrance of PGE2 into circulation by increasing the vaginal pH.

Keywords: Vaginal douching, Intravaginal dinoprostone, PGE2, Vaginal pH.

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Introduction

Simulated initiation of uterine contractions by intervention for progressive cervix dilatation, effacement, and the birth of the baby is termed as induction of labour. Several causes require labor

induction and about 20% pregnant women will require induction of labor due to these reasons. Many surgical and medical methods are used for induction of labour or cervical ripening. The use of prostaglandins for

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induction of labour has many benefits including an increase in successful vaginal delivery and a decrease in rate of caesarean section, along with lower epidural usage and improved maternal satisfaction.¹

The main cause among approximately half of the women undergoing induction of labour is low Bishop score or unfavorable cervix, and different mechanical and pharmacological techniques are used for this purpose. In pharmacological method, prostaglandins are used for cervical ripening. This method is considered better than the mechanical method because the use of prostaglandin is beneficial for cervical ripening as well as it also stimulates the contractility of myometrium.^{2,3}

Dinoprostone is one of the methods of prostaglandins E2 (PGE2) used for ripening of cervix. Prostaglandin plays a vital role in cervical ripening, uterine contractility and induction of labor. It is produced both locally in cervix and uterus as well as from the membranes of a fetus.⁴

The absorption ability of prostaglandins reduces in aqueous solution and low pH because these are organic acids. In normal conditions, usually the vagina has low pH but some factors like bacterial vaginosis, lower genital tract infections and rupture of membrane can alter the vaginal pH.^{5,6} The outcome of prostaglandin usage is associated with many factors and is not clearly understood, but one of the most important factors is vaginal pH, which can significantly affect the prostaglandin outcome.⁷

The clinical response of the drug has a significant relationship with vaginal acidity level and can affect the release and absorption of the drug in the vagina. Prostaglandins consist on organic acids and their solubility reduces in aqueous solution. A lower level of vaginal pH can also squeeze the solubility process of prostaglandins.⁸

Several self-prescribed preventive measures are in practice among women in different areas of the world. One of the most common such measures is vaginal douching which is usually done with water or other fluids. Vaginal douching may have different effects on vaginal milieu, like changing of microflora from non-pathogenic to pathogenic etc. literature has found an association of various gynecologic and reproductive outcomes with vaginal douching.⁹ The release and absorption of dinoprostone are affected by acidic nature of vaginal surface, affecting the clinical outcome

of the drug. The vaginal douching with water or normal saline alters the vaginal pH level.¹⁰

The vaginal douching before insertion of dinoprostone intravaginally may increase the pH level of vagina, resulting in improvement of PGE2 bioavailability, by which the outcome of induction of labor can be improved considerably. So, this study has been planned to compare the effect of vaginal douching on the induction of labor before insertion of intravaginal dinoprostone.

Methodology

In this randomized controlled trial study all the patients admitted in labour room for induction of labour at term in the department of Obstetrics & Gynecology, Sheikh Khalifa Bin Zayed Al Nahyan Hospital / AK CMH Muzaffrabad Azad Kashmir, were included. The study was conducted in a period of eight months from October 2019 to May 2020. The data collection procedure of this was started after taking approval of the study from hospital ethical review committee. Patients fulfilling our selection criteria were enrolled by nonprobability consecutive sampling method. All the participants selected for study were described about study protocol and informed written consent was taken by the researcher. Confidentiality regarding their medical and non-medical details were maintained. A total of 184 participants were included in the study and were divided randomly into two equal groups of 92 each study and control groups. The sample size was calculated by WHO sample size calculator based on 5% level of significance, 80% power of test, 10.8 population standard deviation, and mean duration of dinoprostone insertion to total cervical dilatation of 13.77 h in study and 18.25 h in control group.¹¹

Pregnant women of age between 18-40 years, having single tone pregnancy, at term (> 38 weeks of gestation), with cephalic presentation and without any contraindication of vaginal delivery were included in the study. Pregnancies with the ruptured membrane, fetal anomaly or fetal demise, emergency delivery indication and history of cesarean delivery were excluded from the study.

Initial cervical assessment of all the patients was made by the same examiner and an initial Bishop score was assigned. Vaginal douching was done with 0.9% NaCl serum (20cc) at the time of inserting dinoprostone, before insertion. In the study group 10 mg PGE2 slow-release system was used for vaginal insertion, right

after washing the vagina and dinoprostone was inserted without any additional intervention among the women in control group. Standard protocol of the hospital was followed after onset of active labour. Duration was recorded between dinoprostone insertion and removal of the agent after confirmed successful induction of labour or hyperstimulation, the successful induction was assessed based on vaginal examination.

The duration between intravaginal dinoprostone administration and active phase of labour (successful labour induction) was recorded as primary outcome of the study. The coordinated uterine contractions along with cervical effacement and more than 5 cm dilatation was considered as active phase of labour. Other outcomes of the study were duration of dinoprostone kept intravaginally, duration till total cervical dilatation from the time of insertion, mode of delivery, failure of labour induction, fetal distress, fetal infection and meconium discharge. All this information along with demographic information was recorded on a predesigned performa.

There was no significant (p -value > 0.05) difference in maternal outcome of both groups. The difference in neonatal outcome was also insignificant (p -value > 0.05) difference based on birth weight and APGAR score at 1 minute. But significantly (p -value < 0.05) higher mean APGAR score was found at 5 minutes (9.2 ± 0.46 vs. 8.73 ± 0.82 , p -value = 0.002) in vaginal douching group. The rate of fetal infection rate was significantly low (1.09% vs. 9.78%, p -value = 0.01) in study group

All the recorded data was entered into SPSS v. 21 for analysis. Qualitative variables with presented in the form of frequency and percentages and quantitative variables based on mean and standard deviation. Chi-square test was applied to compare qualitative data and an independent sample t-test was applied to compare quantitative data between both groups. P -value ≤ 0.05 was taken as significant.

Results

A total of 184 participants divided into two equal groups of 92 each in the study and control group were enrolled for this study. The mean age (25.35 ± 5.42 vs 26.63 ± 4.95 , p -value = 0.096) and gestational age (40.62 ± 1.76 vs. 41.02 ± 1.16 , p -value = 0.07) of study group (vaginal douching group) and control group was similar. There was no significant (p -value > 0.05) difference was observed in pre-induction cervical score ($3.51 \pm$

1.36 vs. 3.22 ± 1.29) and Bishop score (2.16 ± 1.62 vs. 2.58 ± 1.36) between both study and control groups. Similarly, the difference in mean value of vaginal pH was also noted insignificant (p -value > 0.05) between vaginal douching group and control group as elaborated in table I.

Table I: Demographic Characteristics of study groups (n=92)

Characteristics	Study Groups		P-value
	Vaginal Douching Group	Control Group	
Age of participants			
Mean \pm SD	25.35 ± 5.42	26.63 ± 4.95	0.096
Gestational Age			
Mean \pm SD	40.62 ± 1.76	41.02 ± 1.16	0.07
Pre-Induction Cervical Score			
Mean \pm SD	3.51 ± 1.36	3.22 ± 1.29	0.262
Bishop Score			
Mean \pm SD	2.16 ± 1.62	2.58 ± 1.36	0.058
Vaginal pH			
Mean \pm SD	3.56 ± 0.36	3.75 ± 0.92	0.067

The mean duration of dinoprostone kept intravaginally was significantly (p -value < 0.05) higher in control group (10.87 ± 6.92 h) as compared to (7.69 ± 4.89 h) vaginal douching group. The participants in vaginal douching group took significantly (p -value < 0.05) less time (11.26 ± 7.38 h versus 15.32 ± 11.69 h) to reach active phase of labour as compared to control group. Likewise, the mean duration from dinoprostone insertion to total cervical dilatation was significantly (p -value < 0.05) higher in control group (17.63 ± 12.24 h) as compared to vaginal douching group (14.21 ± 7.87 h), indicating a significant impact of vaginal douching on achieving total cervical dilatation. There was no significant (p -value > 0.05) difference in maternal outcome on the basis of mode of delivery, indication of induction of labour and failure of labour between vaginal douching group and control group as given in detail in table II.

The comparison of neonatal outcome showed that there was no significant (p -value > 0.05) difference in birth weight of the baby (3405.03 ± 512.8 vs. 3478.77 ± 482.5 gram, p -value = 0.316) between study group and control group. There was no any significant (p -value > 0.05) difference in APGAR score at 1 minute (8.02 ± 0.64 vs. 7.81 ± 0.96 , p -value = 0.082) between vaginal douching group and control group, but the difference was significant (p -value < 0.05) in mean APGAR score at 5 minutes (9.2 ± 0.46 vs. 8.73 ± 0.82 , p -value = 0.002) indicating a comparatively higher APGAR score

in vaginal douching group as compared to control group.

Table II: Comparison of parameters of dinoprostone and maternal outcome between both groups (n=92)

Characteristics	Study Groups		P-value
	Vaginal Douching	Control Group	
Duration of Dinoprostone kept intravaginally (h)			
Mean ± SD	7.69 ± 4.89	10.87 ± 6.92	0.000 *
Duration from Dinoprostone insertion to active phase of labor (h)			
Mean ± SD	11.26 ± 7.38	15.32 ± 11.69	0.005 *
Duration from insertion of dinoprostone to total cervical dilatation (h)			
Mean ± SD	14.21 ± 7.87	17.63 ± 12.24	0.025 *
Mode of Delivery			
Cesarean Section	15 (16.30%)	26 (28.26%)	0.051
SVD	77 (83.70%)	66 (71.74%)	
Indication for labor induction			
Post term	47 (51.09%)	53 (57.61%)	0.336
Gestational diabetes	7 (7.61%)	10 (10.87%)	
Gestational Hypertension	11 (13.04%)	5 (5.43%)	
Preeclampsia	11 (11.96%)	13 (14.13%)	
Oligohydramnios	15 (16.30%)	11 (11.96%)	
Failure of Labor Induction			
Yes	4 (4.35%)	11 (11.96%)	0.059
No	88 (95.65%)	81 (88.04%)	

* Significant at 5% level of significance

The rate of admission to NICU was similar in both groups having no significant (p-value > 0.05) difference in rate of admission to NICU. According to the results, the fetal infection rate was significantly (p-value < 0.05) associated with vaginal douching showing a considerably low rate of fetal infection (1.09% vs. 9.78%, p-value = 0.01) in a study group in comparison to control group as elaborated in table III.

Discussion

A wide variety of microorganisms is found in the female genital tract, usually it consists on lactobacilli and is known as microflora. This microflora is responsible for healthy state of vagina without causing any infection, and vaginal douching may affect the microflora of normal vagina which might be a risky practice associated with urinary tract infection (UTI). But this remains contradictory and debatable when results from other studies shows preventive role of vaginal douching in the prevention of infection.^{12,13}

Table III: Comparison of neonatal outcome between both groups (n=92)

Characteristics	Study Groups		P-value
	Vaginal Douching	Control Group	
Birth Weight of the baby			
Mean ± SD	3405.03 ± 512.8	3478.77 ± 482.5	0.316
APGAR score at 1 minute			
Mean ± SD	8.02 ± 0.64	7.81 ± 0.96	0.082
APGAR score at 5 minutes			
Mean ± SD	9.2 ± 0.46	8.73 ± 0.82	0.002 *
NICU admission			
Yes	11 (11.96%)	19 (20.65%)	0.11
No	81 (88.04%)	73 (79.35%)	
Fetal Infection			
Yes	1 (1.09%)	9 (9.78%)	0.01 *
No	91 (98.91%)	83 (90.22%)	

* Significant at 5% level of significance

The vaginal microbiota configuration might be affected by vaginal washing. The composition of microbiota of healthy vagina consists of a large number of lactobacilli. Antimicrobial peptides are produced by these lactobacillus species which acidify the vagina by producing lactic acid. The vaginal environment become hostile through this microflora for most of these pathogens. The loss of lactobacilli gives a chance to other anaerobes overgrowth which leads to bacterial vaginosis. Bacterial vaginosis increases the risk of HIV and other infections and transmission.^{14,15}

Prostaglandin E2 is considered as one of the successful agents used for the induction of labour. PGE2 is an agent used for local administration through vaginal tablets, vaginal gels and endocervical gels. It is also available in the form of slow release dinoprostone vaginal insert form. There is wide disparity in efficacy of PGE2 used for cervical ripening and induction of labour. One of the important factors which can affect the clinical efficacy of PGE2 is the vaginal pH. The normal environment of vagina is acidic with mean value of pH level of 4.09±0.52 at 37-42 weeks gestation. This pH level can affect the bioavailability of virginally inserted PGE2.¹⁶

The efficacy of vaginally administered prostaglandin E2 could be affected by vaginal pH level through several ways like the variation in release of drug based upon delivery vehicle used, or alteration in absorption level and metabolism by changing the prostaglandin activity in cervico-vaginal environment. Vaginal pH has a significant relationship with the release and absorption of PGE2 through vaginal insertion, and a higher level of vaginal pH has been found associated with increase prostaglandin release.¹⁷ Similarly it has been observed

that dinoprostone release can be affected by vaginal pH and a decline in release and absorption of PGE2 has been observed with lower level of vaginal pH.¹⁸

Vaginal douching may reduce the density of normal vaginal flora, which may turn the vaginal pH to alkaline. In this study, it was assumed that alkaline pH can enhance the efficacy of PGE2 by increasing the bioavailability of PGE2, so normal saline solution was used to wash the vagina just prior to insertion of dinoprostone vaginally. The vaginal douching before insertion of dinoprostone has shown better results as compared to control group and according to the results mean duration of dinoprostone kept intravaginally was significantly (p -value < 0.05) higher in control group (10.87 vs. 7.69 h). The vaginal douching group took significantly (p -value < 0.05) less time (11.26 versus 15.32 h) to reach active phase of labor. The mean duration from dinoprostone insertion to total cervical dilatation was significantly (p -value < 0.05) higher in control group (17.63 vs. 14.21 h), indicating a significant impact of vaginal douching on achieving total cervical dilatation. There was no significant (p -value > 0.05) difference in maternal outcome based on mode of delivery, indication for induction of labor and failure of labor between vaginal douching group and control group. These results are parallel to previous studies which also favor the vaginal douching at the time of dinoprostone insertion, showing a significantly shorter duration from the beginning of dinoprostone insertion vaginally to the active phase of labor and duration from intravaginal insertion of dinoprostone to total cervical dilatation in study group (vaginal douching group) as compared to control group.^{19,20}

In this present study it was noted that there was no significant (p -value > 0.05) difference in maternal outcome based on the mode of delivery and failure of labour between vaginal douching group and control group. But results of a previous study showed that maternal outcome was different in cases having significantly higher rate of chorioamnionitis and cesarean section among cases group as compared to control group. However, the neonatal outcome was similar in both groups supporting the results of this present study.^{21,22}

According to the results of this present study the comparison of neonatal outcome showed that there was no significant (p -value > 0.05) difference in birth weight of the baby, APGAR score at 1 minute between both groups, but the difference was significant (p -value

< 0.05) in mean APGAR score at 5 minutes indicating a comparatively higher APGAR score in vaginal douching group as compared to control group. The rate of admission in NICU was similar (p -value > 0.05) in both groups. But the fetal infection rate was found to be significantly (p -value < 0.05) associated with vaginal douching showing a considerably low rate of fetal infection (1.09% vs. 9.78%, p -value = 0.01) in a vaginal douching group.

These results were in agreement with previous studies showing that the vaginal douching has a significant impact on first stage of labour due to pharmacodynamics and pharmacokinetic changes due to vaginal washing by decreasing the mean duration of first stage of labour in vaginal douching group as compared to control group. This decrease in duration of labor may have other benefits for fetal outcome like lower rate of infection and passage of meconium which results as the decrease in admission rate to NICU.²³

Conclusion

According to the results of this present study the bioavailability of prostaglandin E2 can be improved by vaginal douching prior to intravaginal administration of dinoprostone. The duration of Dinoprostone kept intravaginally, duration from Dinoprostone insertion to active phase of labour and duration from insertion of dinoprostone to total cervical dilatation were found significantly lower in vaginal douching group as compared to control group. Vaginal washing before insertion of dinoprostone may improve the absorption of PGE2 into circulation by increasing the vaginal pH. This method can be used easily by obstetrician to get better outcome for induction of labour.

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