



Effect of Vaginal Ph on the Efficacy of Dinoprostone Gelfor Induction of Labour.

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ABSTRACT:The aim of this study is to study the effect of vaginal pH on efficacy of dinoprostone gel for induction of labour.

Methods :A prospective observational study was conducted on 150 patients at Goa Medical college. Preinduction vaginal pH was checked and compared with respect to age, parity, Bishops score change, time to enter into active labour, induction delivery time, mode of delivery. Overall data was compiled in Microsoft excel. Numeric values expressed as mean \pm SD and Ordinal values expressed as number(%).Chi-square test, student's t test used to calculate the "p" value. The SPSS version 22 used for statistical analysis.Test of significance at $p < 0.05$.

Results: Patients with higher vaginal pH showed favourable outcome following induction. High vaginal pH was associated with favourable bishops score, less time taken to enter labour, less induction-delivery time and higher rates of vaginal deliveries.

Conclusion: Vaginal pH has significant effect on efficacy of dinoprostone gel for induction of labour. Preduction assessment of vaginal pH can serve as useful parameter to predict labour outcome and thereby reduce unnecessary inductions and failed induction rates in a cost effective manner.

KEYWORDS: Vaginal pH, Induction of labour, Dinoprostone gel.

I. INTRODUCTION

Induction of labour is a commonly practiced method to initiate the process of labour in patients in whom the continuation of pregnancy will either pose a threat to the mother or the fetus.

A wide variety of options for methods of induction are available like oxytocin, prostaglandins(E2 and E1),hygroscopic dilators, artificial rupture of membranes etc. of which the most widely used method for induction of labour is application of exogenous PGE.

Prostaglandin (PGE) is a well-established agent that has a primary action in softening the cervix(1) . Prostaglandins likely modify extracellular matrix

structure of cervix to aid ripening(2).PGE2 promotes enzymatic activity eg. collagenase and elastase,and also an alternation in glycosaminoglycans,dermatansulphate and hyaluronic acid levels in the cervix.A relaxation of cervical smooth muscle fascilitates dilatation(3).

A variability in the efficiency of PGE2 has been observed in patients undergoing induction by this method.A large number of factors can be attributed for this variation . Vaginal pH has been shown to be a significant factor affecting the prostaglandin effect (3).

In general, vagina maintains a pH between 3.8-4.8, which is influenced by frequency of coitus, presence of cervical mucus and the amount of vaginal transudate, genital tract infection, rupture of membranes etc. The acidity of the vagina may alter the release of the drug and this could result in variable clinical response. Prostaglandins are organic acids that have diminished solubility in aqueous solution with a low pH (4).

Hence, to know the effect of vaginal pH on the action of prostaglandin E2,this study has been undertaken in Goa Medical College.

By this a large number of unwarranted cesarean sections can be avoided, thus increasing the percentage of normal deliveries in patients undergoing induction of labour.Also it would improve patient selection for PGE2 induction and reduce the incidence of failed induction with PGE2.

II. AIMS & OBJECTIVES:

To evaluate whether vaginal pH has an effect on the efficacy of Dinoprostone gel for induction of labour, with respect to

1. bishops score change over 6 hours
2. time interval from induction to onset of labour
3. time interval from induction to delivery
4. need for Augmentation
5. mode of delivery.
6. maternal age, gestational age, gravidity



III. MATERIALS AND METHODS:

PLACE OF STUDY: study was conducted in GOA MEDICAL COLLEGE in department of Obstetrics and Gynaecology.

DURATION OF STUDY: study had commenced on 1 st January 2021 till the sample size was reached (after the approval from Institutional Ethics Committee)

STUDY DESIGN: Prospective observational study.

SAMPLE SIZE:

TOTAL 150 cases

□ The sample size is as per previously published studies : (6)

$$n = 2(Z\alpha + Z\beta)^2 \sigma^2 / d^2$$

$$= 2(10.49)2.56 / 0.36$$

$$= 2(26.85) / 0.36$$

$$= 53.7 / 0.36$$

$$= 149.16 (\text{rounded up to } 150)$$

Where, n = sample size

$Z\alpha = 1.96$ at 95% confidence interval

$Z\beta = 1.2816$, at 90% power

$$d = x_1 - x_2 = 2.7 - 3.3 = 0.6$$

$$\sigma = \sqrt{\sigma_1^2 + \sigma_2^2} / 2$$

$$= 1.8 * 1.8 + 1.4 * 1.4 / 2 = 1.6$$

STUDY SUBJECTS

□ **INCLUSION CRITERIA:** 1. An unfavourable cervical bishop score of less than 6(3)

2. Singleton pregnancy with vertex presentation.

3. No contraindication to vaginal delivery.

4. Assuring FHR trace.

□ **EXCLUSION CRITERIA:** 1. Known hypersensitivity to Prostaglandins.

2. Placentaprevia

3. Suspected Chorioamnionitis

4. Previous LSCS /history of uterine surgery

5. cephalopelvic disproportion

6. Ruptured membranes.

SAMPLING TECHNIQUE: Purposive sampling

PROCEDURE: Subjects who met the above mentioned criterias were enrolled in this study after giving an informed consent.

Each participant underwent a speculum examination and vaginal pH value was assessed by using pH indicator paper. The indicator paper was placed on lateral vaginal wall, colour change of the

strip was immediately compared with the standard colorimetric scale and findings were recorded.

Patients were divided into 2 groups ; Group 1 included vaginal $\text{pH} \leq 4.5$ and Group 2 included vaginal $\text{pH} > 4.5$ (4).

A vaginal examination was then performed to determine the Bishop's score. Bishop score was assessed: Cervical dilatation, cervical effacement/length, Cervical consistency, Cervical position, Fetal station. Each component was given a score of 0-2 or 0-3. The highest possible score was 13 and less than 6 was unfavourable cervix that needs induction.

After ruling out all contraindications, Dinoprostone gel was applied 0.5mg endocervically, patient instructed to remain recumbent for at least 30 minutes.

After 6 hrs depending on Bishop Score and uterine contraction, either PGE2 gel was repeated (maximum 3 doses) or labour was augmented as per the protocol(5) .

The effect of the gel, noted in terms of change in bishops score over 6 hours, time between induction and onset of active labour, induction delivery interval, mode of delivery.

CONFLICT OF INTEREST: None, NO external funding.

IV. RESULTS:

The present study was conducted in the Department of Obstetrics and Gynecology, Goa Medical College and Hospital, Bambolim. The study included a total of 150 participants who were divided into 2 groups based on the vaginal pH. The study aimed to evaluate the effect of vaginal pH on the efficacy of Dinoprostone gel for induction of labour.

The data collected was analyzed for descriptive data to understand the distribution of participants based on age, gestational age, gravidity and mode of delivery. Table 1 depicts the frequency distribution based on the age of the participants included in the study. It was seen that majority (78%) of the participants belonged to the age group between 20 and 30 years. The mean age in group 1 was 26.02 years and in group 2 it was 27.32 years. No significant difference was noted between the 2 groups.



Table 1: Frequency distribution of participants based on age

Parameter		Frequency	Percent	Sig.
Age	Less than 20 years	6	4	0.052
	20-30 years	117	78	
	31-40 years	27	18	

Table 2 represent the distribution based on the gestational age. The average gestational age in group 1 was 38.35 weeks and in group 2 it was 38.29 weeks. 41.3% of the participants were in the

38.1 to 39 weeks category followed closely by 37 to 38 weeks gestational age category. No significant difference was seen between the groups in terms of the gestational age.

Table 2: Frequency distribution of participants based on Gestational age

Parameter		Frequency	Percent	Sig.
Gestational age	37-38 weeks	56	37.3	0.436
	38.1-39 weeks	62	41.3	
	39.1-40 weeks	26	17.3	
	40.1-41 weeks	6	4	

The participants were also categorized based on the gravidity. The frequency distribution of the same is shown in Table 3. Most of the

participants (61.3%) were in the primigravida category. No significant difference was noted when the gravidity of the two groups was compared.

Table 3: Frequency distribution of participants based on Gravidity

Parameter		Frequency	Percent	Sig.
Gravidity	Primi	92	61.3	0.333
	G2	40	26.7	
	G3	15	10	
	G4	3	2	

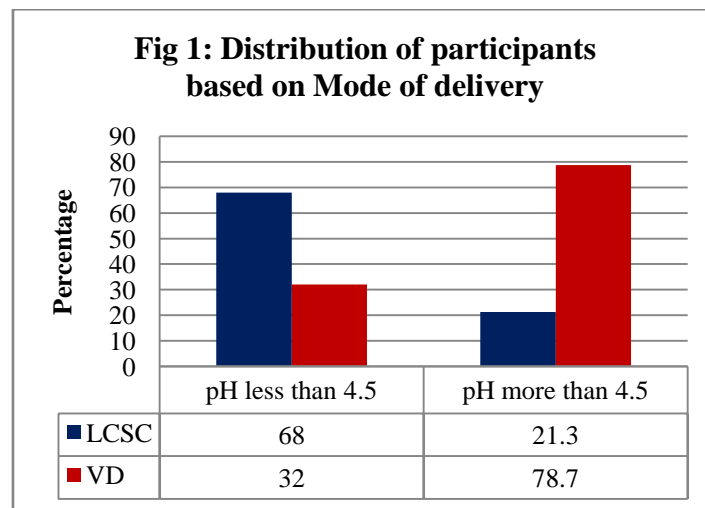
Frequency distribution of the participants based on the mode of delivery among the two groups is tabulated in Table 4 and graphically represented in Fig 1. There were 2 modes of deliveries- LCSC and VD. In the group with pH less than 4.5, a little over half of the participants had undergone LCSC, which was about 68% of the total number of participants in that group. The

remaining which was 32% had undergone VD mode of delivery. The opposite was seen in the group with pH more than 4.5. Majority of the participants 78.7% had undergone VD and only 21.3% had undergone LSCS. A highly significant difference was noted on comparison of the two groups.



Table 4: Frequency distribution of participants based on Mode of delivery among the two groups

Parameter		pH less than 4.5	pH more than 4.5	Sig.
Mode of Delivery	LCSC	51	16	0.000*
		68%	21.3%	
	VD	24	59	
		32%	78.7%	
	Total	75	75	



The comparison of baseline pH, Initial Bishop's score and the Bishop's score change over 6 hours were compared between group 1 and group 2. A highly significant difference was noted between the groups for the baseline pH and Bishop's score change over 6 hours. Baseline pH was higher in group 2 with the mean at 5.59 and rightly so as the group was categorized as pH more

than 4.5. The mean in group 1 was 3.59. Initial Bishop's score in group 1 was 1.31 and in group 2 was 1.20, indicating that group 1 had a slightly higher score compared to group 2. As for the change in score over 6 hours, mean score was 2.43 in group 1 and 4.43 in group 2. These values have been presented in Table 5 and Fig 2.

Table 5: Intergroup comparison of baseline pH, Initial Bishop's Score and Bishop's Score change over 6 hours

Parameter	Groups	Mean	Std. Deviation	Sig.
Baseline pH	pH less than 4.5	3.59	0.50	0.000*
	pH more than 4.5	5.59	0.62	
Initial Bishops score	pH less than 4.5	1.31	1.03	0.493
	pH more than 4.5	1.20	0.87	
Bishops score change over 6 hours	pH less than 4.5	2.43	1.62	0.000*
	pH more than 4.5	4.43	2.28	

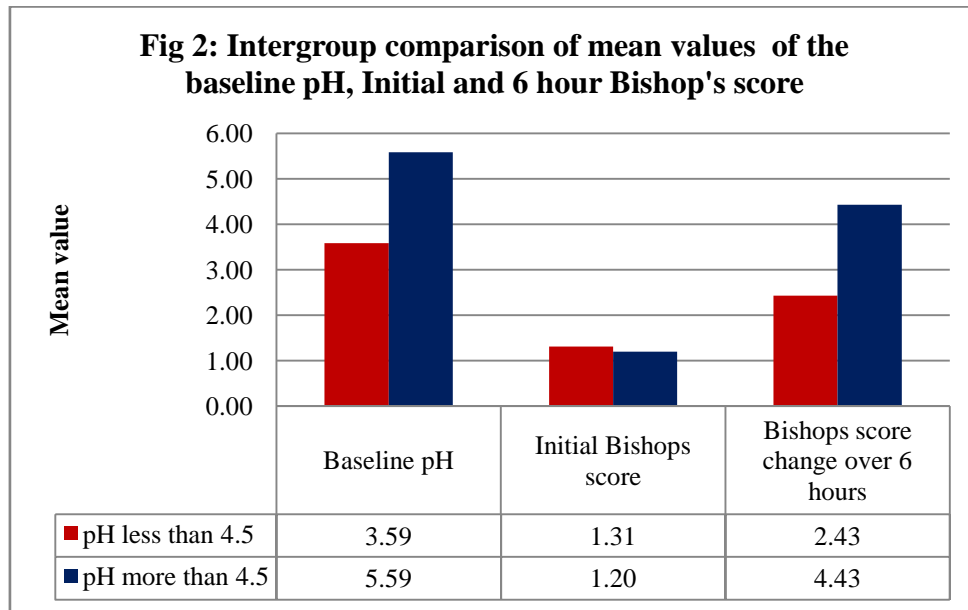


Table 6 and Fig 3 demonstrates the comparison between the two groups based on time of induction to onset of labour, time of induction to delivery and augmentation. A highly significant difference was observed for the time of induction

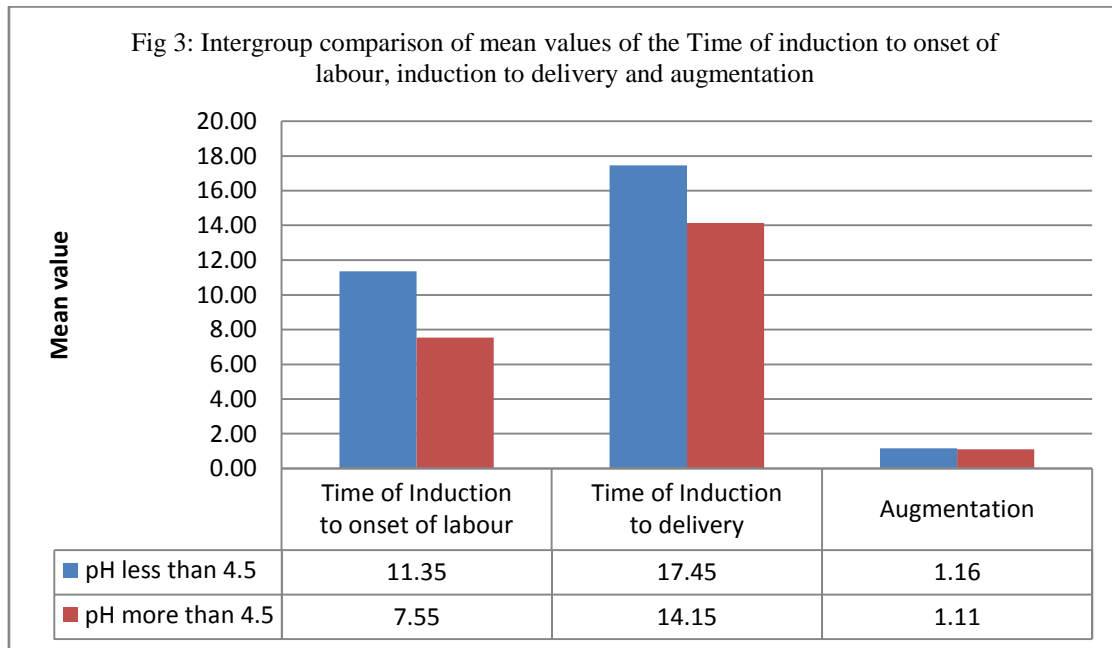
parameter, both onset of labour as well as delivery. Mean was higher in group 1 with time at 11.35 to onset of delivery and 17.45 to delivery. No significant difference was seen with the augmentation.

Table 6: Intergroup comparison based on time of induction to onset of labour, time of induction to delivery and augmentation

Parameter	Groups	Mean	Std. Deviation	Sig.
Time of Induction to onset of labour	pH less than 4.5	11.35	5.67	0.000*
	pH more than 4.5	7.55	2.58	
Time of Induction to delivery	pH less than 4.5	17.45	6.26	0.000*
	pH more than 4.5	14.15	4.22	
Augmentation	pH less than 4.5	1.16	0.37	0.34
	pH more than 4.5	1.11	0.31	



Fig 3: Intergroup comparison of mean values of the Time of induction to onset of labour, induction to delivery and augmentation



Based on the results obtained, it can be seen that there was a shift in the mean value of the Bishop's score when it was initially assessed and when assessed 6 hours later. The group with higher pH had a higher score while on initial assessment, the group with the lower pH had higher scores. As for the time of induction, group 1, which had lower pH had higher mean values for both induction to onset of labour as well as induction to delivery.

V. DISCUSSION

In this prospective observational study, the effect of vaginal pH on the efficacy of dinoprostone gel was investigated in women with unfavourable cervix, undergoing induction of labor.

Observations made in the present study show a statistically significant change in the Bishop's score (BS) over 6 hours, time interval from induction to onset of active labor, induction delivery time and also the mode of delivery.

In our study, it was observed that the vaginal pH is an important factor that influences the efficacy of dinoprostonegel. The overall delivery outcomes were found to be better in group with a high vaginal pH >/-4.5 (i.e group 2) as compared to the group with low pH < 4.5 (i.e group 1).

The baseline characteristics including maternal age (years), gestational age (weeks), gravidity (no), initial BS, baseline vaginal pH were similar in both the study groups in study done by Jayshree et al, as well as in our study.

In our study, no significant difference was noted between the two study groups with regards to

the baseline characteristics, similar observations were made in Jayshree et al.

Kurien MJ et al study observed a significant association between parity and vaginal pH, wherein subjects with high parity have a higher pH, as opposed to our study where no significant association was found.

In one study conducted by Ramsey PS et al showed a statistically significant association between higher vaginal pH and less time to enter active phase of labor and shorter time to delivery, as was observed in our study.

Lyneras et al study found that vaginal Ph influence the PGE2 release rate, with a faster release rate being achieved at a higher vaginal pH. Hence, in our study it was observed that subjects with a higher vaginal pH showed better change in BS.

Basirat et al in their study pointed out that the subjects with a high vaginal pH took comparatively lesser time to enter active phase of labor and was statistically significant, similar observations were made in our study as well. The study also demonstrated that the incidence of cesarean section rates in women with higher vaginal pH was lower, as is seen in the current study.

In the study conducted by Onen et al and Singh et al a statistically significant change was noted in BS over 12 hours and 18 hours respectively, after commencement of induction process, in the group with a high vaginal pH, as observed in our study as well.



In current study, it is observed that, subjects with higher initial vaginal pH exhibited a favourable change in Bishop’s score over 6 hours after induction with PGE2 gel.

In Group 2, with high vaginal pH, time taken to reach active labour was shorter in comparison to Group 1 subjects with low vaginal pH..

The present study shows a significant association between the vaginal pH and induction delivery interval. The time taken from induction to delivery in group 2 was less compared to that in group

In current study, under group 1 32% of subjects underwent vaginal . Whereas in group 2, 78% subjects had higher rates of vaginal delivery .

Study conducted by	Association of vaginal ph and bishops score change over 6hours	Association of vaginal ph and onset of active labour	Association of vaginal ph and delivery interval	Association of vaginal ph and mode of delivery
1.Ramsey et al 2002	B	A	A	A
2. Ramsey et al 2003	B	B	B	B
3.Onen et al	A	B	B	A
4.Singh et al	A	B	B	A
5.Basirat et al	A	A	A	A
6.Jayshree et al	A	A	A	A
7.Sumathy et al	A	-	A	A
8.Aruna et al	A	-	A	A
9.Reena M et al 2018	-	A	A	-
10.Present study	A	A	A	A

A=Significant association B=No significant association

VI. CONCLUSION

Induction of labor is one of the most common interventions in the modern obstetrics with an increased risk of cesarean delivery and its associated complications.

In the present study it was observed that vaginal pH is an important factor that can effect the efficacy of dinoprostone gel in induction of labour. The group with higher vaginal pH >/- 4.5 i.e group 2, showed an overall better outcome like better change in Bishop’s score, less mean time from induction to active labor/ induction to delivery and more number of subjects delivered vaginally.

Thus, we conclude that vaginal pH can be an important predictor for the success of PGE2 gel induction.

Also, knowing the vaginal pH prior to the process of induction can prove beneficial in assessing the outcome of labour.

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