



ORIGINAL RESEARCH PAPER

Gynaecology

A PROSPECTIVE STUDY FOR THE EFFECT OF VAGINAL pH ON DINOPROSTONE GEL FOR CERVICAL RIPENING / LABOR INDUCTION

KEY WORDS:

Prof. Dr. Arasi Srivathsan

MD OG., Professor of Obstetrics & Gynecologist Institute of Social Obstetrics and Kasturba Gandhi hospital for women and children, Madras Medical College

Dr. Prasanna*

MD DGO., Assistant Professor of Obstetrics and Gynaecology Institute of Obstetrics and Gynaecology, Madras Medical College *Corresponding Author

Chennai Induction of labor is the artificial initiation of labor before its spontaneous onset by means of various interventions. Now a days, about 10-30% obstetric cases required induction due to various indications. There are many surgical and medical methods available for induction of labor/cervical ripening. Of these cervical ripening using Prostaglandin Gel intracervically is most common practice in modern times. Cervical ripening is a process in which cervix becomes soft and distensible to allow labor and delivery. In pregnancy nearing term many factors induces enzymatic changes for e.g. collagenase in cervix resulting in breakdown of collagen fibers and rearrangements of extracellular matrix that cause cervical ripening. The complex interaction among many cytokines brings profound changes in proteoglycans in the cervix that ultimately cause cervical ripening. Many studies were conducted on the safety and efficacy of various prostaglandin E2 preparations. But only few studies were done on the factors that affect the clinical efficacy of these vaginally administered PGE2 preparations. Generally vagina maintains a acidic pH of 3.8-4. The lactobacillus bacteria present in vagina plays an important role in maintaining acidic vaginal PH by producing lactic acid from glycogen store in vaginal cells. The acidity of vagina may be responsible for variable release of PGE2 gel in the vagina and responsible for variable clinical response among patients. Prostaglandin E2 gel is an organic acid which has low solubility in aqueous solution with low pH. The aim of this study is to evaluate whether vaginal PH has any effect on Dinoprostone gel used for cervical ripening in labor induction.

AIMS AND OBJECTIVES

Recently vaginal PH has been studied to be an important factor which influences the release of Dinoprostone gel used for cervical ripening in labor induction. But the results were inconclusive. Many researches were conducted on the efficacy of vaginal PH in the controlled release PGE2 vaginal insert and PGE2 gel for cervical ripening/labor induction in which overall vaginal PH seemed to influence the PGE2 release. However, the effect of vaginal PH on PGE2 gel in cervical ripening for labor induction has not been well studied till now. The aim of the study is to see

The influence of vaginal PH on the efficacy of PGE2 gel which we commonly use for cervical ripening in labor induction. So it might improve patient selection and we can predict those cases which might go into failed induction with PGE2.

To study the changes in vaginal pH because of various factors e.g. age of the patient, gestational age, parity, draining per vagina etc.

MATERIALS AND METHODS

This prospective observational study was conducted on patients who were undergoing induction of labor with Dinoprostone (PGE2) gel at The Institute of social obstetrics, Government Kasturba Gandhi Hospital, Madras Medical College, Triplicane, Chennai, and Tamil Nadu during the academic year 2016-17. The study was done in 100 patients for duration of 1 year after Institutional Ethical committee clearance. The study was conducted in singleton pregnancy beyond 36 weeks of gestational age who were undergoing PGE2 Gel induction for various medical and obstetrical reasons with an unfavorable cervical Bishop score of ≤5, Singleton pregnancy with vertex presentation with no

contraindication to vaginal delivery and assuring normal fetal heart rate. Patients with known hypersensitivity to prostaglandins, Placenta praevia, suspected chorioamnionitis, parity of >3, previous cesarean delivery or a history of uterine surgery, previous attempted Induction of labor for this pregnancy and cephalopelvic disproportion were excluded.

Before performing any other examination the subjects underwent speculum examination, vaginal PH value was assessed by PH Indicator paper (INDIKROM PAPERS, Thermo Fisher Scientific India Pvt. Ltd. Mumbai, India. After assessing Bishop's score, PGE2 gel was kept intracervically. After 6 hours Bishop's score was assessed and depending on the score either PGE2 gel was repeated maximum of 3 doses or labor was augmented if cervix becomes favorable as per labor ward protocol in our hospital. The time from induction to active phase of labor was assessed and recorded. The analysis was done by statistical package SPSS version 17. The significance of association among each was calculated using chi-square test.

RESULTS

The study undertaken here is an observational study conducted at Government Institute of social obstetrics and Kasturba Gandhi Hospital for women and children Total number of patient analyzed: 100 The patients were made into 2 groups, one group with higher vaginal pH i.e.>4.5 and the other with lower vaginal pH i.e. <4.5.

1. Age distribution of Vaginal PH in the study group:-

VAGINAL PH	Frequency	Percent
<4.5	67	67.0
>4.5	33	33.0
Total	100	100.0

2. Age distribution of study group:-

Age group	Frequency	Percent
18-20 years	22	22.0
21-24 years	33	33.0
25-28 years	26	26.0
29-32 years	14	14.0
33-36 years	5	5.0
Total	100	100.0

3. Parity distribution:-

PARITY	Frequency	Percent
Primi gravidae	66	66
Multi gravidae	34	34
Total	100	100.0

4. Assessment of Bishops score after 6 hour:-

Following PGE2 gel induction for cervical ripening digital examination is done to assess the change in status of the cervix from pre induction Bishops score-

CHANGE IN BISOHPS SCORE AFTER 6 hour	Frequency	Percent
No	44	44.0
Yes	56	56.0
Total	100	100.0

5. Incidence of vaginal delivery in the study group:

GEL TO VAGINAL DELIVERY INTERVAL	Frequency	Percent
Vaginal	49	49.0
Cesarean	51	51.0
Total	100	100.0

6. Gel induction to vaginal delivery interval:-

Here we measure how many patients deliver vaginally within 12 hour of gel induction.

GEL TO VAGINAL DELIVERY INTERVAL	Frequency	Percent
<12 hrs	32	65.3
>12 hrs	17	34.7
Total	49	100.0

Descriptives							
	Statistic						
	Mean	95% Confidence Interval for Mean		Median	Std. Deviation	Minimum	Maximum
		Lower Bound	Upper Bound				
AGE	24.61	23.74	25.48	24.00	4.37	18.00	36.00

VAGINAL PH		age group					Total
		18-20 years	21-24 years	25-28 years	29-32 years	33-36 years	
<4.5	Count	15	19	14	7	2	57
	% within VAGINAL PH	26.3%	33.3%	24.6%	12.3%	3.5%	100.0%
>4.5	Count	7	14	12	7	3	43
	% within VAGINAL PH	16.3%	32.6%	27.9%	16.3%	7.0%	100.0%
Total	Count	22	33	26	14	5	100
	% within VAGINAL PH	22.0%	33.0%	26.0%	14.0%	5.0%	100.0%

Chi-Square=2.102 p= 0.717 (no association)

Crosstab				
VAGINAL PH		PARITY		Total
		Primi	Multi	
<4.5	Count	41	16	57
	% within VAGINAL PH	71.9%	28.1%	100.0%
>4.5	Count	25	18	43
	% within VAGINAL PH	58.1%	41.9%	100.0%
Total	Count	66	34	100
	% within VAGINAL PH	66.0%	34.0%	100.0%

Chi-Square=2.077 p= 0.150 (no association)

Crosstab				
VAGINAL PH		CHANGE IN BISOHPS SCORE AFTER 6 hrs		Total
		No	Yes	
<4.5	Count	37	20	57
	% within VAGINAL PH	64.9%	35.1%	100.0%
>4.5	Count	7	36	43
	% within VAGINAL PH	16.3%	83.7%	100.0%
Total	Count	44	56	100
	% within VAGINAL PH	44.0%	56.0%	100.0%

Chi-Square=23.527** p<0.0001 (association)

Crosstab				
VAGINAL PH		GEL TO VAGINAL DELIVERY INTERVAL		Total
		<12 hrs	>12 hrs	
<4.5	Count	9	9	18
	% within VAGINAL PH	50.0%	50.0%	100.0%
>4.5	Count	24	7	31
	% within VAGINAL PH	77.4%	22.6%	100.0%
Total	Count	32	33	16
	% within VAGINAL PH	65.3%	67.3%	32.7%

Chi-Square=3.893* p= 0.048 (association)

Crosstab				
VAGINAL PH		outcome		Total
		Vaginal	Cesarean	
<4.5	Count	18	39	57
	% within VAGINAL PH	31.6%	68.4%	100.0%
>4.5	Count	31	12	43
	% within VAGINAL PH	72.1%	27.9%	100.0%
Total	Count	49	51	100
	% within VAGINAL PH	49.0%	51.0%	100.0%

Chi-Square=16.099** p<0.0001 (association)

VAGINAL PH		Draining P.V		Total
		Yes	No	
<4.5	Count	20	37	57
	% within VAGINAL PH	35.1%	64.9%	100.0%
>4.5	Count	30	13	43
	% within VAGINAL PH	69.5%	30.2%	100.0%
Total	Count	50	50	100
	% within VAGINAL PH	50.0%	50.0%	100.0%

Chi Square=11.7911** p=0.0001 (association)

SUMMARY

In the present study, we have found out that vaginal pH play a **very important role in predicting** success of PGE2 gel induction. 60% of the study populations were in the age group of 21 to 28 **year**.

33% pregnant women had vaginal pH >4.5. 66% women were primigravidae, while the remaining 34% multigravidae.

In the study, we have not seen much influence of age and parity to the level of vaginal pH.

Among 32 cases of draining P.V. vaginal pH >4.5 is seen in 20 cases, i.e. 62.5%.

Among 100 cases of PGE2 gel induction, 83.7% cases show positive

Bishops score changes after 6 hour of induction in pregnant women with higher vaginal pH of >4.5. If vaginal pH is >4.5, it was found that the time interval between gel to delivery is reduced to <12 hours in 77% of cases.

CONCLUSION

The findings of the present study showed that vaginal pH can be an important predictor for success of PGE2 gel induction. It has been observed that if vaginal pH is high there is better chance of positive Bishops score change, higher chance of vaginal delivery interval and also reduced time to enter into active phase of labour and shorter delivery interval more so in multipara.

Higher vaginal pH has more chance of responding fast to single gel induction and higher chance of vaginal deliveries than caesarean section. So, we can see that assessing vaginal pH before induction can be an useful parameter in predicting the outcome of labour in pregnant women who are undergoing labour induction with PGE2 gel. However further research with a well designed pharmacological study with bigger study population is necessary to study the role of vaginal pH in absorption and overall efficacy of Dinoprostone gel which in future could increase the efficacy and reduce unwanted outcomes.