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A Comparative Study To Assess Effect Of Vaginal Ph On Cervical Ripening With Dinoprostone (Pge_2) Gel Between Rural And Urban Primigravida

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ABSTRACT*: OBJECTIVES: To study effect of vaginal pH on cervical ripening with dinoprostone gel in terms of time to active labour,induction delivery time interval, mode of delivery and feto-maternal outcome between rural and urban primigravida.*
METHODS: -In a hospital based comparative study,dinoprostone gel with vaginal pH in patients with modified Bishops score ≤5 in 100 primigravida inserted and outcome noted and statistical analysis done in both group.
RESULTS : - Urban primigravida required lesser time interval in terms of time to active labour, induction delivery time interval and better feto-maternal outcome as compared to rural primigravida.
CONCLUSION :. – Vaginal pH has an effect on the efficacy of gel for cervical ripening.Thus reducing unnecessary labour induction, caesarean section for failed induction in a cost effective way.
KEYWORDS *: Dinoprostone gel, Vaginal PH, Modified Bishop's score.*

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I. Introduction:

Induction is indicated when there is risk either to the mother or the baby of continuing the pregnancy. In modern times 10-33% of obstetric cases require induction of labour. The success of induction depends largely on the condition of the cervix. An unripe cervix fails to dilate well in response to myometrial contraction. Cervical Ripening is a series of complex biochemical changes in the cervix which is mediated by the hormones.

The mainstay of induction of labour with an unfavorable cervix is the use of exogenous prostaglandins. Prostaglandins induce enzymatic changes that promote collagen breakdown. Facilitate the rearrangement of collagen fibers and alter the cervical extracellular matrix, which result in cervical softening and effacement. PGE_2 is primarily important for cervical ripening it has greater collagenolytic properties and also sensitizes the myometrium to oxytocin. Intracervical application of dinoprostone (PGE_2-0.5mg) gel is the gold standard for cervical ripening.[2]

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. The lactic acid produced from glycogen by lactobacillus present in vagina plays an important role in maintaining acidic pH environment.[3] A variety of factors can alter the normal vaginal pH. Several factors such as lower genital tract infection; bacterial vaginosis, rupture of membrane, douching etc can alter the vaginal pH. 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. The aim of this study to evaluate the effect of vaginal pH with dinoprostone gel on cervical ripening between rural and urban primegravida.

II. Material & Methods:

This is a hospital based longitudinal study on 100 pregnant women admitted in labour room for induction of labour and fulfilling inclusion/exclusion criteria and give written and informed consent in obstetrics and gynaecology department S.M.S Medical College Jaipur from April 2016 to March 2017.

Inclusion criteria:

- Singleton primi pregnancy with vertex presentation
- No contraindication to vaginal delivery.
- Unfavorable cervix as per modified Bishop's score≤ five.

Exclusion criteria

- Any past history of drug allergy (prostaglandins) or any contraindication to prostaglandins.
- Suspected chorioamnionitis or presence of any active vaginal infection.
- History of any previous uterine surgery.

III. Methodology:

Before other examinations were performed, each participant underwent a speculum examination and vaginal pH value was assessed by using pH indicator paper (both broad & narrow spectrum). The indicator paper was placed on the lateral vaginal wall between the two valves of Cusco's speculum until it became wet. Color change of the strip was immediately compared with the manufacturer's colorimetric scale and the finding was recorded. Patients were dived into two groups as Group I & Group II on basis of their vaginal pH. Group I included patients with vaginal pH $\leq$4.5 and Group II included vaginal pH>4.5.

A vaginal examination was then performed to determine the Bishop's score. After ruling out all contraindications Dinoprostone gel was applied endocervically. Following application the patient is instructed to remain recumbent for at least 30 minutes. The patient is then continuously monitored for FHS, fetal moment etc. Reassessment will be done after 6 hours for progress and non progress of labour then statistical analysis were done in form of primary outcome i.e. time to active labour, induction-delivery interval and Mode of delivery and form of secondary outcome Maternal complication, Fetal complications and result was noted.

Results:

Our study showed that the mean age of pregnant women was 24.60±2.748 in rural and 23.96±2.539 in urban patients, but statistically non significant (p=0.2295). The mean weight, religion & socioeconomic status of patients was statistically significant (P=0.0451*, P=0.009* & P=0.0141* respectively) (table 1). The hemoglobin & period of amenorrhoea was statistically insignificant (P=0.0767 & P=0.2501) (table 2).

Our study found that the acidic vaginal ph more in rural patient and alkaline ph more in urban patients, these comparison was statistically significant (P=0.0022**). Augmentation required, increasing in delivery interval time of induction and time to active labor was also increased in rural pregnant women as compared to urban patients, but not significant (table 4 & 5). More caesarean section occurred in in rural patients as compared to urban (table 3).

Table 1: Demographic profile of patients

	Rural	Urban	P-value
Mean Age	24.60±2.748	23.96±2.539	0.2294 NS
Weight	50.28±2.997	51.56±3.302	0.0451*
Religion			
Hindu	44	33	0.0090**
Muslim	6	17	
Socio-economic status			
Upper class	2	1	0.0141*
Upper middle class	25	39	
Middle class	23	10	

Table 2 Clinical & biochemical profile of patients

	Rural	Urban	P-value
Period of Amenorrhea	38.74±0.7775	38.92±0.7783	0.2501 NS
Primary Gravida	50	50	
Hemoglobin	11.84±0.7918	12.12±0.7730	0.0767 NS

Table 3: Progress of labour in rural and urban pregnant women

Vaginal Ph		Rural	Urban	P-value
>4.5		29	13	0.0022**
<4.5		21	37	
Progress of labour				
Augmentation required	Yes	8	5	0.5536
	No	42	45	
Time to active labour		5.114±3.258	4.417±1.889	0.2080 NS

Induction delivery interval		7.558±3.494	6.667±2.157	0.1421 NS
Maternal Outcome				
Non progress labour	Yes	6	2	0.2687
	No	44	48	
PPH/Pyrexia/Any other	Yes	1	2	1.00 NS
	NO	49	48	
Fetal Outcome				
Apgar Score	6	3	2	0.5464
	7	7	4	
	8	40	44	
Baby weight		2.598±0.1835	2.612±0.1722	0.6949
Birth asphyxia	Yes	1	2	1.00 NS
	No	49	48	
Mode of Delivery				
FTNVD		43	48	0.1945 NS
LSCS (FD)		2	1	
LSCS (MSL)		5	1	

Table 4: Association between Ph and Progress of labour in rural pregnant women

	Ph <4.5	Ph>4.5
Augmentation required	7	1
Time to active labour	12 hour	9 hour
Induction delivery interval	15 hour	12 hour

Table 5: Association between Ph and Progress of labour in urban pregnant women

	Ph <4.5	Ph>4.5
Augmentation required	2	3
Time to active labour	9.5 hour	9.7 hour
Induction delivery interval	12 hour	12 hour

IV. Discussion:

Cervical ripening is the process that culminates in the softening and distensibility of the cervix, which facilitates labor and delivery. The cervix contains relatively few smooth muscle cells and derives its rigidity from collagen bundles surrounded by proteoglycans. In pregnancy nearing term, there are various factors that induce certain changes in the cervix leading to cervical ripening. There are agents that can artificially induce these changes if it has not occurred. It is difficult to separate methods of cervical ripening and labor induction. The human uterine cervix can produce nitric oxide (NO), a free radical with an ultra-short half-life. Nitric oxide in the human uterine cervix acts as an endogenous ripening factor with an unknown mechanism of action. In two studies conducted by Vaisanen-Tommiska M et al, it was found that cervical fluid nitric oxide metabolite level rises after cervical ripening, nitric oxide donor administration, or cervical manipulation, which supports a role for cervical nitric oxide in cervical ripening.[4,5]

Recently, vaginal pH has been investigated as a potential factor influencing the efficacy of prostaglandins for cervical ripening and labor induction but the results have been conflicting. Studies have been conducted on the effects of vaginal pH on the efficacy of controlled-release PGE2 vaginal insert and PGE2 gel for cervical priming/labor induction in which overall vaginal pH seemed to influence the PGE2 release.[6-8]

The vaginal pH in pregnancy is known to be acidic and not much is known about the variations in vaginal pH throughout pregnancy. There are studies that mention that pH may change the degree of ionization of a drug and affect the absorption of the drug resulting in variable clinical responses.[9,10] Vaginal pH changes also has a role in preterm delivery which suggests that it has a role in influencing cervical ripening.[11,12]

Our study found that the acidic vaginal ph more in rural patient and alkaline ph more in urban patients, these comparison was statistically significant (P=0.0022**). Augmentation required, increasing in delivery interval time of induction and time to active labor was also increased in rural pregnant women as compared to urban patients, but not significant. More caesarean section occurred in rural patients as compared to urban.

Basirat et al also found that the incidence of Cesarean section was lower in women with high vaginal pH as in the present study. Vaginal pH has been investigated in several recent studies as a factor that may account for the variability observed clinically with prostaglandin used as cervical ripening/labor induction agents. Two in vitro studies by Johnson et al. and MacDonald and Weir describes an increased PGE2 release in solutions with a higher pH. (6.5 to 7.5) It was also reported in the two in vitro studies that along with the increased release of PGE2, it is also predominantly ionized at a pH of 7.5 (pKa, 4.9), which diminishes the potential of its systemic absorption.[9,10]

Onen et al (2008) in their study found that in the high vaginal pH group, bishop's score change over 12 hour after commencement of the first Dinoprostone vaginal insert was statistically higher than those in the low vaginal pH group (5.5±3.4 versus 3.9±3.3, $p<0.05$). But there was no significant difference in time to active labor and time to complete delivery between the high and low pH groups.[8]

V. Conclusion:

The result of this study shows that vaginal pH may have influence on the functions of Dinoprostone gel. Higher vaginal pH more often responds to a single induction and is more often associated with vaginal deliveries than LSCS. Hence knowing the vaginal pH prior induction could prove to be a useful tool in assessing the labor outcome of a patient undergoing labor induction with PGE2 gel. Further research is required to find various agents that would increase the vaginal pH thereby creating a favorable environment for PGE2 gel induction.

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