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A Comparative Study of Intracervical Foley's Catheter Instillation Vs Intracervical Dinoprostone Gel for Pre - Induction Cervical Ripening

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Abstract: ***Background: This was a comparative study to compare use of intracervical foley's Cathter instillation vs intracervical Dinoprostone Gel for pre - induction cervical ripening. Method: It was a prospective randomised control study in 100 patients with an indication of labour induction, conducted in Nalanda Medical College and Hospital, Patna from Jnuary 2019 to October 2020.50 patients (Group - P) received PGE2 gel i.e. Dinoprostone Gel, upto maximum of 3 doses 6 hrs apart and 50 patients (Group - F) received foely's catheter instillation for 24 hrs or upto spontaneous expulsion. Result: In both groups induction was started with same Bishop Score of <5. Improvement in Bishop's Score was more in Group - P (3.09) vs Group - F (3.1) (P value<0.01). Mean Induction to delivery interval was shorter in Group - P vs Group - F.61% delivered within 16hrs in Group - P and 42% delivered within 16hrs. Need for Oxytocin augmentation to deliver was higher with Group - F compared to Group - P.70% delivered vaginally in Group - P and 56% in Group - F.32% patients had LSCS in Group - F and 14% in Group –P. Conclusion: Pre - induction Cervical ripening is more effective with Dinoprostone Gel (PGE2 Gel). Mean induction to lanour interval were shorter, oxytocin augmentation was less with Dinoprostone Gel. Thus Dinoprostone Gel is better and more effective agent than folley's catheter in pre - induction cervical ripening.***

Keywords: Dinoprostone Gel, Foley's Catheter, Oxytocin, pre - induction cervical ripening

1. Introduction

Induction of labour is the non - spontaneous initiation of uterine contractions, prior to their spontaneous onset leading to progressive effacement and dilatation of cervix and delivery of the baby (1). Sometimes it is essential to induce labour when the risk to the mother or fetus with pregnancy continuation outweighs the risk that is involved with intervention (2). According to ACOG 2009 - Goal of Induction of labour is to achieve vaginal delivery by stimulating uterine contraction before spontaneous onset of labour (3). After thorough examination of mother and fetus the indication as well as method for induction must be documented.

In 1971, KARIM & SHARMA first induced labour with use of oral PGE2. Since then a large number of reports have appeared in literature, evaluating the efficacy of oral PGE2 for induction of labour. Due to the unique effect of prostaglandins on the uterine cervix, they represent an excellent option for women who, on account of their unfavourable cervix, are poor candidates for induction using oxytocin. Furthermore, because prostaglandins are effective when administered either locally or systemically, local administration has the advantage of requiring much lower doses of prostaglandin and avoids the problem of untoward side effects provoked by intravenous prostaglandin administration.

Foley catheter have also proved to be a very effective preinduction ripening agent for unfavorable cervix. It acts by mechanical dilatation of cervix and stimulation of endogenous prostaglandins released from fetal membranes. It is cost effective and can be stored at room temperature.

2. Materials and Methods

This prospective randomised controlled study was conducted in labour room of Department of Obstetrics & Gynaecology, NMCH, Patna, Bihar frome January 2019 to October 2020.100 patients within inclusion criteria were randomly divided into two groups. Group - P consisted 50 patients who received intracervical Dinoprostone Gel (PGE2 gel), maximum 3 doses at interval of 6hrs. Group - F consisted of 50 patients who were intracervically instilled foley's catheter, bulb filled with 40ml Normal saline kept for atleast 24hrs.

Inclusion Criteria

1) Singleton pregnancy
2) Cephalic presentation
3) Absence of infection
4) Bishop score <4
5) 37 completed weeks of pregnancy
6) Intact fetal membrane
7) Reactive CTG
8) Absence of uterine contractions

Exclusion Criteria

1) Previous LSCS or any uterine surgery.
2) Low lying placenta.
3) Malpresentation
4) Grand multiparity.
5) Maternal infection
6) Rupture of membranes
7) Preterm
8) Maternal comorbid illnesses like Gestational diabetes, Heart disease, Chronic kidney disease.
9) Abnormal foetal heart rate pattern. (Non reassuring CTG)
10) Allergy to prostaglandins.
11) Premature Rupture Of Membrane
12) History of Antepartum haemorrhage
13) Patient's refusal for consent

- The study was approved by the ethical committee of the institute. Patients who needed induction were identified and selected for induction by random allocation table. Written informed consent was taken from patients before starting induction. At the beginning of the study a detailed history was taken regarding relevant medical, surgical and obstetrical information.
- In Group - P0.5 mg of Dinoprostone gel available in 2.5ml syringe with an applicator was introduced endocervically below internal os under aseptic precautions.
- Patient was recumbent for one hour after drug insertion. Patients reassessed after 6 hours (earlier if indicated). Bishop's score reassessed and if found to be unfavourable, second dose of dinoprostone gel i. e.0.5 mg will be inserted, upto maximum of three doses. Further doses withheld if cervical dilatation reaches 4cms.
- In Group - F - Prophylactic antibiotic injection ceftriaxone 1 gm iv given after test dose. Patient placed in the lithotomy position. Under good light supervision, perineum and vagina cleansed with Betadine solution. Under strict asepsis, Foley's catheter NO.18 introduced through the cervix in extra - embryonic space under direct vision. Bulb inflated with 40 ml of distilled water and bulb rests on the internal os. Patient repositioned to left lateral.

The catheter strapped to the thigh of the women (time limit for catheter to be inside - 24 hours, if it is not spontaneously expelled, as there is a concern regarding possibility of infection especially if catheter is inside for more than 24 hours. Patient instructed to pull the catheter every 30 minutes for a period of 1 - 2 minutes till expulsion of the bulb.

The data were presented as descriptive statistics was subjected to 't' test/ Chi - square test. In all parameters, the value of $p<0.05$ was considered significant.

3. Results

In this study, both intracervical Foley's catheter instillation and Dinoprostone gel group had patients of almost similar age group, parity and gestational age. Maximum number of patients induced belonged to the 20 – 25 years age group. Maximum number of patients in the study group were primigravida.

Induction was started in both groups with similar Bishop Score. The mean Bishop Score at '0' hours in PGE2 was in primis 2.11 when compared to the Foley's balloon dilatation group where it was 2.1. The mean Bishop score at 6 hours in multis was 8.3 hrs in the PGE2 gel group when compared to the Foley's balloon dilatation where the mean Bishop score at 6 hrs was 6.7 hrs. Similarly, the mean Bishop score at 12 hrs in mutis was 10 hrs in the PGE2 gel group when compared to the Foley's balloon dilatation where the mean Bishop score was 9.8 hrs change in mean Bishop score was significantly higher in the PGE2 gel group 3.09 versus catheter group 3.1, p value <0.01.

The mean induction labour interval in primigravida in the PGE2 gel group was 6.5 hours. The mean induction to active labour interval in primigravida with Foley's balloon dilatation group was 7.5 hours.

The mean induction labour interval in multipara with PGE2 gel was 5.2 hours. The mean induction labour interval in multipara in the Foley's balloon dilatation group was 6.6 hours. The difference between the two groups is statistically significant.

The need for oxytocin augmentation to deliver was higher with Foley's balloon dilatation when compared to the PGE2 gel group.78% of women in the Foley's balloon dilatation required oxytocin whereas only 36% of the PGE2 gel required oxytocin.70% patients had Vaginal delivery in PGE2 gel group, only 56% delivered Vaginally in Foley's balloon dilatation group.

32% LSCS rate in Foley's balloon dilatation, whereas only 14% underwent LSCS in PGE2 gel regimen. There is statistically significant difference in the mode of delivery between the two groups using chi - square test.

Table 1: Showing Comparison of Mean Bishop Score in Primigravida and multigravida in both groups at 0hr, 6 hr, 12 hr and 18 hrs

Bishop Score	GROUP - F		GROUP - P	
	Primi	Multi	Primi	Multi
0 Hours	2.1	2.4	2.11	2.71
Six hours	5.7	6.7	6.8	8.4
Twelve hours	8.2	9.8	9.3	10
Eighteen Hours	11	10.8	11.8	0

- There is a statistically significant difference in the mean Bishop score at 6 and 12 hours in the PGE2 compared to the Foley's group. The mean change in the score also significant in both nullipara and multipara in the PGE2 gel group compared to the Foley's balloon dilatation.

Table 2: Showing comparison of Induction of labour to active Labour Interval (ILI) in hours between both groups

Duration in hours	GROUP - F				GROUP - P			
	Primi		Multi		Primi		Multi	
	Number	(%)	Number	(%)	Number	%	Number	%
<6	11	35.4	3	21.4	15	41.66	10	28.58
6 – 12	17	54.2	11	78.5	20	55.55	4	71.42
>12	3	9.4	-	-	1	2.67	-	-
Total	31	100	14	100	36	100	14	100

- In Group - F, 35% of primi and 21% of multi established labour within 6 hours; 54% of primi and 78% of multi established labour within 12 hours; 9% crossed 12 hours in group F.
- In Group - P, 41% of primi and 28% of multi established labour within 6 hours; 55% of primi and 71% of multi established labour within 12 hours. Only 2% crossed 12 hours

Table 3: Showing number and percentage of Patients requiring oxytocin for augmentation of labour

Oxytoxin	Foley's Balloon dilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
Not used	11	22	32	64	43
Used	39	78	18	36	57
Total	50	100	50	100	100

- Table shows that oxytocin augmentation requirement is more - 78% in Foley's balloon dilatation than PGE2 gel regimen where it is only 36%. The difference is statistically significant using chi - square test

Table 4: Showing outcome of induction through various modes of delivery in both groups of patients -

Mode of Delivery	Foley's Balloon dilatation		PGE2 gel		Total
	Number	Percent (%)	Number	Percent (%)	
Vaginal delivery	28	56	35	70	63
LSCS	16	32	7	14	23
Forceps (instrumental vaginal delivery)	6	12	8	16	14
Total	50	100	50	100	100

70% patients had Vaginal delivery in PGE_2 gel group, only 56% delivered Vaginally in Foley's balloon dilatation group.

32% LSCS rate in Foley's balloon dilatation, whereas only 14% underwent LSCS in PGE_2 gel regimen. There is statistically significant difference in the mode of delivery between the two groups using chi - square test.

4. Conclusion

1) Both PGE2 gel group and Foley's balloon dilatation, induction was started with the same Bishop score of <5.
2) Both groups had majority of the women being primigravida.
3) Improvement in Bishop score was more in the PGE2 gel group when compared with the Foley's balloon dilatation group P value <0.05.
4) Mean induction to labour interval was shorter in the PGE2 gel when compared to the Foley's balloon dilatation group P value <0.05.
5) Mean induction to labour interval and mean induction to delivery interval were shorter in multis compared to primis in both groups of PGE2 gel and Foley's balloon dilatation.
6) Oxytocin for augmentation was higher in the Foley's balloon dilatation around 78% whereas the rate of usage of oxytocin for augmentation in the PGE2 gel group was 36%.
7) Mode of delivery being Vaginal delivery 76% for patients in the PGE2 gel group where it was only 56% in the Foley's balloon dilatation group.
8) Caesarean section rate in Foley's balloon dilatation was higher 32% whereas it was only 14% in the PGE2 gel group.

PGE2 gel was found to be more effective method of cervical ripening and induction of labour.

Response of multis in both groups better than primis. Fetal and maternal outcome were better with prostaglandin E_2 gel. From this study, it is known that prostaglandin E_2 gel is a better and more effective agent than Foley's balloon dilatation in cervical ripening and induction of labour.

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