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To compare time interval of repeat intracervical prostaglandin E2 gel insertion and intravenous oxytocin infusion after first application of intracervical prostaglandin E2 gel for induction of labour.

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#### **Abstract**

**Background:** The success of induction of labour depends largely on the parity and the pre-induction state of cervix. It is the prelabour softening, effacement and eventual dilatation that culminates in spontaneous labour.

**Methods:** A hospital based prospective comparative study was conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur from April 2018 to November 2018.160 patients at term attending antenatal clinic in Obstetrics and Gynaecology, in SMS Medical Collage, Jaipur were enrolled for the study.

**Results:** Duration of induction to active phase was  $11.96 \pm 2.57$  hrs in primipara,  $10.68 \pm 3.46$  hrs in multipara in repeat gel group &  $12.79 \pm 2.89$  hrs in primipara,  $11.07 \pm 2.96$  hrs in multipara in gel+oxytocin group, although it is not statistically significant.

**Conclusion:** The merits of repeat PGE2 gel group are slight short time interval duration of active labour and delivery.

Keywords: PGE2, Oxytocin, Duration.

#### Introduction

The success of induction of labour depends largely on the parity and the pre-induction state of cervix. It is the prelabour softening, effacement and eventual dilatation that culminates in spontaneous labour. Important structural and biochemical changes take place during ripening of cervix. There is a gradual dissociation and scattering of previously densely packed collagen along with qualitative and quantitative changes in proteoglycan content within ground substance.<sup>1</sup>

Prostaglandins have been used vaginally for the induction of labour for the past 20 years, during this time there has been a variety of different vehicles into which the prostaglandins have been incorporated, as well as different doses used and administration protocols recommended. Although by 1990 vaginal prostaglandins were in use by virtually every obstetric

unit in the United Kingdom<sup>4</sup>, there remained considerable uncertainty about which dose and protocol was most appropriate: by that time commercial preparations had been available for some years at doses of 1 mg to 10 mg with a recommendation that repeat administration of some preparations was appropriate after six hours.<sup>2</sup>

Local use of prostaglandin E2 (PGE2) by extraamniotic, intravaginal and intracervical route has been found to be effective in priming the cervix and inducing labour in patients at term with poor Bishop score.<sup>5-7</sup> Extra-amniotic use, besides being invasive is associated with increase risk of introducing infection.

The intravaginal application though less invasive and easy to use requires larger dose of the drug and hence associated with gastrointestinal side effects and uterine irritability. Besides its action is unpredictable and result often unsatisfactory.<sup>8</sup> The intracervical use has fewer side effects.<sup>3</sup>

Prostaglandins (PGE2) is available in two forms in India for cervical ripening.<sup>4</sup>

The low dose regimen of oxytocin for unfavourable cervical ripening begins with 1 to 2 mU/min, increase at 1 to 4 mU/min of every 30 minute interval. Infusion pump wherever available should be used. Oxytocin should be stored in refrigerator at 2 to 8 degree. Oxytocin can be used for induction as well as augmentation of labour. Induction of labour with a favourable cervix.<sup>5</sup>

## **Material & Methods**

Study Design: Randomized comparative study

Study Type: Hospital based comparative analysis

Place of Study: Dept. of Obstetrics and Gynecology,

SMS Medical College, Jaipur.

**Duration of Study:** April 2018 to November 2018.

### **Selection Criteria**

### **Inclusion Criteria**

- All term singleton pregnancy with cephalic presentation
- Pregnant women give consent for participation in the study.

## **Exclusion Criteria**

- Previous uterine scar
- Allergic to Prostaglandins and Oxytocin
- Contraindicated to vaginal delivery

# Methodology

Pregnant women attending the antenatal clinics were screened for possible participation in the study after explaining the nature of the study. All selected women were thoroughly evaluated regarding complete history, parity, thorough clinical examination, per-abdominal examination, pelvic examination and all risk factors were evaluated. A written informed consent was taken from all the cases. Total 800 patients were induced with single Dinoprostone intracervical gel (0.5 mg), 640 patients went in active labour out of them, so they were excluded from the study, because single intracervical Dinoprostone gel is also very good for induction of labour, remaining 160 patients were included in our study.

This study was conducted on 160 patients with 80 patients in each arm. In Group-A (Study group) patients received second dose of 0.5 mg of Dinoprostone gel which is repeated after 6 hours of first dose of Dinoprostone gel (cervical ripening agent). After application of gel intracervical the patient is made to remain recumbent for 30 minute to avoid spillage of gel.

In Group-B (Control group) patients received low dose oxytocin after 6 hours of first dose of Dinoprostone gel (cervical ripening agent).

# **Statistical Analysis**

All data thus collected was entered in excel sheet and was subjected for statistical analysis. Quantitative data was summarised as mean and SD whereas qualitative data as percentage. Significant difference in means was analysed by using unpaired student's t test and difference in proportion was analysed by using Chisquare' test.

## **Observations & Discussion**

This study was conducted on 160 patients with 80 patients in each arm. In Group-A (Repeat Gel) patients were received second dose of 0.5 mg of Dinoprostone gel which is repeated after 6 hours of first dose of Dinoprostone gel (cervical ripening agent). After application of intracervical gel the patient is made to remain recumbent for 30 minute to avoid spillage of gel. In Group-B (Gel + Oxytocin) patient were receive low dose oxytocin after 6 hours of first dose of Dinoprostone gel (cervical ripening agent).

In our study, maximum patients in both groups were 26-30 yrs age group. The mean age in Group-A in our study was 26-30 yrs and in Group-B it was 26-30 yrs. There was no statistical significant difference between the mean age of cases and controls (p = 0.808).

Table 1: Induction to Active Phase Interval (Duration)

Induction	to	Group-A		Group-B		
Active Ph	ase			{n=70}		
Interval		{n=62}	C-1)	(Gel +		
(Duration	in	(Repeat Gel)		Oxytocin)		
Hours)		No.	%	No.	%	
<12		54	87.00	56	80.00	
12 to 24		8	13.00	14	20.00	

p = 0.39

In present study, in the repeat gel group 54 (87.00%) patients induction to active phase interval was less than 12 hours and in gel+oxytocin group 56 (80.00%) patients induction to active phase interval was less than 12 hours. The difference was not statistically significant (p=0.39).

In Mahomed K et al (2018)<sup>6</sup> concluded that induction to active phase interval in gel group is 19.7 hrs and in oxytocin group it was 25.7 hrs.

Table2: Induction to Active Phase Interval (Duration in Hour) in Relation to Parity

Parity	Group-A		Group-B	(Gel+	
	(Repeat	Gel)	Oxytocin		
	Induction to		Induction to		,
	Active	Active Phase Active Phase		Phase	p- value
	Interval		Interval		value
	(Duration in		(Duration in		
	Hour)		Hour)		
	Mean	SD	Mean	SD	
Primipara	11.96	2.57	12.79	2.89	0.245
Multipara	10.68	3.46	11.07	2.96	0.058
p-value	0.286		0.0137		

In present study, in Group-A, mean time induction to active phase was  $11.96 \pm 2.57$  hrs in primi and  $10.68 \pm 3.46$  hrs in multi para. In Group-B, mean time induction to active phase was  $12.79 \pm 2.89$  hrs in primi and  $11.07 \pm 2.96$  hrs in multi para.

In Mahomed K et al (2018)<sup>6</sup> concluded that induction to active phase interval in gel group is 19.7 h and in oxytocin group it was 25.7 h.

Table 3: Induction to Delivery Time (Duration in Hour) in Relation to Parity

Parity	Group-A (Repeat Gel) Induction to Delivery Time (Duration in Hour)		Group-B (Gel+ Oxytocin) Induction to Delivery Time (Duration in Hour)		p- value
	Mean	SD	Mean	SD	
Primipara	19.30	2.92	21.62	1.78	0.001
Multipara	17.77	4.0	20.20	1.19	0.002
p-value	0.051		0.002		

In present study, in Group-A, mean time induction to delivery was  $19.30 \pm 2.92$  hrs in primi and  $17.77 \pm 4.00$  hrs in multi para. In Group-B, mean time induction to delivery was  $21.62 \pm 1.78$  hrs in primi and  $20.20 \pm 1.19$  hrs in multi para.

In the study conducted by Bhattacharyya TK et al (1998)<sup>7</sup> observed that the mean induction delivery interval in PGE2 group was longer in both primigravidas and multigravidas compared to the oxytocin group. The mean amniotomy delivery interval was more in primigravidas in the PGE2 group but almost similar amongst PGE2 and oxytocin group in multigravidas.

In study conducted by Parate S et al (2015)<sup>8</sup> was found that mean contraction delivery interval in study group (repeat gel) is 10.76 hrs as compared to 14.54 hrs in control group (single gel).

## Conclusion

The merits of repeat PGE2 gel group are slight short time interval duration of active labour and delivery.

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