

# Comparing The Effect of Local Prostaglandin-E<sub>2</sub> Gel and Intravenous Oxytocin in Induction of Labor: A Randomised Study

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## Abstract

**Introduction:** A healthy mother and a healthy baby are the ultimate desire of the patient and the treating doctor. Induction of labor leads to stress to the mother and the fetus. Research is on to find out an ideal inducing agent that does not affect the outcome adversely. The present study was undertaken with a view to compare the prostaglandin gel with oxytocin for induction of labour.

**Objectives:** To compare the efficacy and safety profile of prostaglandin-E<sub>2</sub> gel versus intravenous oxytocin in induction of labour.

**Study Design:** Prospective study, conducted at Teerthanker Mahaveer Medical College and research centre. 120 patients requiring induction of labor for various indications beyond 36 weeks of gestation were included in the study. 60 patients were included in group A (PGE<sub>2</sub> GEL group) and 60 patients were included in group B (oxytocin group).

**Results:** The mean induction delivery interval was 11.2 hours ± 5.2 hours in group A and in group B it was 12.6 ± 4.6 hours. Successful induction was achieved in a total of 90% of patients which includes 93.3% in group A and 86.6% in group B. Most common side effects with group A was gastrointestinal complaints and fetal distress was common in group B. Neonatal outcome was similar in both the groups.

**Conclusions:** In patients with high risk factors and where elective induction for safe confinement is required, PGE<sub>2</sub> gel was found to be more safe and effective without adversely affecting the maternal and fetal outcome.

**Keywords:** Induction of labour, Oxytocin, Prostaglandin gel

## INTRODUCTION

Induction of labor remains one of the major challenges in obstetrics.<sup>1</sup> Induction of labor is resorted in the condition where the continuation of pregnancy may be hazardous to the fetus or mother.<sup>2</sup> In this era of modern obstetrics with low risk practice the spectrum of indications for induction of labor has greatly increased to obtain an optimum pregnancy outcome in the interest of mother and fetus e.g.- Premature rupture of membranes (PROM), postdated pregnancy, Pregnancy induced hypertension (PIH) etc.

Intravenous oxytocin has been used as a major drug for induction of labor and has stood the test of time.

Introduction of prostaglandin in the field of induction opened a new chapter. PGE<sub>2</sub> gel has greatly revolutionized the method of induction of labor.<sup>3,4</sup>

## MATERIALS & METHODS

The study was carried out in the Department of Obstetrics and Gynecology of Teerthanker Mahaveer Medical College and Research Centre, Moradabad, India, between April 2013 to March 2014.

A total of 120 cases were included in the study and were divided into two groups each of 60 cases.

Patients of singleton pregnancy irrespective of parity with gestational age more than 37 weeks duration with vertex presentation and intact membranes without cephalopelvic disproportion were included in the study.

Patients having previous uterine surgery, vaginal bleeding of uncertain origin, hypersensitivity to prostaglandins, fetal distress, and previous caesarean section were excluded from the study. Medical conditions such as heart disease, asthma, and glaucoma were also ruled out.

Informed consent was taken from all patients.

Detailed history, general and obstetric examination was carried out. All routine investigations such as hemogram with ESR, bleeding and clotting time etc. including sonography were carried out.

Patients were randomly assigned to either of the two groups. All patients of group A received Prostaglandin E<sub>2</sub> gel (PGE<sub>2</sub> GEL) whereas patients of group B received intravenous Oxytocin for induction of labour.

Group A – The patients were placed in lithotomy position. A lubricated speculum was introduced and the cervix exposed. The PGE<sub>2</sub> gel was introduced into the posterior fornix. The woman was kept in head low position for about half an hour. The fetal heart rate (FHR) and uterine contractions were monitored periodically for about 6 hours. After 6 hours a per vaginal examination was done to assess the Bishop’s score. If the score did not exceed 6, a second instillation of PGE<sub>2</sub> gel was done. If cervix was ripe and Bishop’s score was more than 6, amniotomy was performed and later augmentation of labour with intravenous oxytocin was done, if required.

Group B – An oxytocin drip with 5 International Units (IU) of Oxytocin was started in 5% dextrose. Escalation of the initial dose of 5 units was done at 30 minutes interval until an optimum response of 4 sustained contractions/10 minutes was achieved. The dose was titrated according to the uterine contractions and at 3-4 cms of cervical dilatation, amniotomy was performed and oxytocin infusion was continued. The induction - onset of labor, induction-delivery interval, length of labour, maternal & neonatal side effects were noted & compared.

## RESULTS

120 women were included in the study of which 60 were in group A and 60 were in group B. The indications for

induction of labor were almost similar & are as shown in Table 1.

The mean duration of induction to onset of labor in group A patients was 4.5 ± 2.5 hours & group B was 4.4 ± 2.3 hours, as shown in Table 2.

The mean induction- delivery interval was 11.2 ± 5.2 hours in group A and 12.6 ± 4.6 hours in group B.

The labor pattern was more or less similar in both the groups. The time interval between medications to start of contractions was 4.5 ± 2.5 hours with PGE<sub>2</sub> gel whereas it was 4.4 ± 2.3 hours with Oxytocin. The induction to delivery interval was shorter with PGE<sub>2</sub> as compared to oxytocin group as shown in Table 2.

The outcome of labor has been outlined in Table 3. In group A overall success rate was 93.33% while in group B it was 86.6%. 80% patients in group A had normal vaginal delivery, 13.33% had instrumental or forceps delivery and 6.6% had caesarean section. While in group B, 83.33%

**Table 1: Indication for induction of labor**

Indication	Group A	Group B
PIH	16	18
Post dated pregnancy	24	20
PROM	8	10
IUGR	12	12

**Table 2: Relationship between bishop score & labor pattern in successful cases**

Labor (hours)	PGE <sub>2</sub> (hours)	Oxytocin (hours)
Medications to contractions	1.15±0.3	0.46±0.3
Medications to established labor	4.5±2.5	4.4±2.3
Latent phase	4.4±1.1	4.23±1
Active phase	3.5±1.2	3.8±0.4
2 <sup>nd</sup> phase	32.18±18.6 (in min)	32.4±14 (in min)
Induction to delivery	11.2±5.2	12.6±4.6

**Table 3: Outcome of labor**

Successful outcome	Patients in Group A		Patients in Group B	
	No.	%	No.	%
Total deliveries	56	93.33	52	86.66
1 <sup>st</sup> application or 1 <sup>st</sup> induction	32	53.33	16	26.66
2 <sup>nd</sup> application or 2 <sup>nd</sup> induction	8	13.33	36	60
Normal vaginal delivery	48	80	50	83.33
Oxytocin augmentation	16	26.66	-	-
Forceps	8	13.33	2	3.33
Caesarean section	4	6.66	8	13.33

had normal vaginal delivery, only 3.33% had instrumental delivery and 13.33% landed up into caesarean section.

Indications for caesarean section have been outlined in Table 4. The incidence of caesarean section was high in group B i.e., 13.3% as compare to 3.33% in group A.

Neonatal outcome was similar in both the groups

Mean neonatal weight in group A was 2.75 kg & in group B it was 2.8 kg.

Mean Apgar score in group A was 8 & in group B it was 8.4 (Table 5).

Gastrointestinal side effects were more common in prostaglandin group than oxytocin group i.e. 13% in group A while 3% in group B. while fetal distress & uterine hyper stimulation was seen more commonly in group A patients.

## DISCUSSION

Induction of labor includes pharmacological and mechanical methods like. foley's catheterization, oxytocin induction & prostaglandin. Elective induction is still practiced in many centers especially for the convenience of the patients.<sup>5</sup>

In our study the most common indication of induction was PIH, followed by postdated pregnancy. Agarwal observed PIH & PROM as the commonest cause.<sup>6</sup>

The induction to delivery interval in PGE<sub>2</sub> group was 11.2 hours in primipara & 8.7 hours in multipara. In the oxytocin group it was 12.6 hours in primipara & 10.33 hours in multipara respectively. These results are comparable to

**Table 4: Indication for caesarean section**

	Group A	Group B
Non progress of labor	-	-
Foetal distress	2	2
Incoordinate uterine action	-	4
Failed induction	2	2

**Table 5: Outlines the side effect of both the drugs**

Side-effects	Group A patients	Group B patients
Incordinated uterine action	-	4
Rigors	2	2
Uterine hyperstimulation	0	4
Foetal distress	2	2
PPH	-	-
Vomitings	8	2

studies conducted by Raybum<sup>7</sup> Al – Tanni et al found that induction to delivery interval was shorter in multiparas in comparison to primipara patients.

The overall success rate in group A was 93.39% & in group B was 86.69% in our study. Keirse have failed to show any advantage for either PGE<sub>2</sub> or placebo over the others as induction agents and overall reduction in induction failure was noted and reduction in caesarean section rate. In our study both agents were almost equally efficacious in inducing labor. And the incidence of LSCS was 3.33% in group A & 13.33% in group B. Parikh et al<sup>2</sup> observed a caesarean section rate of 6.69% with PGE<sub>2</sub> gel & 13.3 % in oxytocin group. They recommended PGE<sub>2</sub> gel as a successful inducing agent with less failure rate.

In our study the incidence of maternal & foetal side effects were much lower with the PGE<sub>2</sub> gel. The incidence of fetal distress & uterine hypersensitivity was high in oxytocin group. Similar results have been reported by studies Buccellato CA et al,<sup>5</sup> Al-Taani MI<sup>8</sup> & Keirse MJNC.<sup>9</sup> GI side effects like nausea & vomiting were more common with group A. Paul and Singh et al<sup>10</sup> have also observed a higher incidence of uterine stimulation and fetal heart variations on the oxytocin group.

There was no difference in the Apgar scores and neonatal outcome in two groups. This is comparable to other studies.<sup>6,10</sup>

## CONCLUSION

Modern obstetrics has enormously improved the outcome of pregnancy. Labor is induced in conditions where continuation of pregnancy may be hazardous to the mother or the fetus. With the introduction of prostaglandins induction of labor witnessed a major breakthrough. It is evident from the study that vaginal PGE<sub>2</sub> gel offers an advantage over the routine use of i.v oxytocin. Not only the induction to delivery interval is shorter but there is a low incidence of fetal distress and caesarean section. The only limitation in its use may be the cost of the gel.

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