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Comparative Analysis between Dinoprostone PGE2 gel (Cerviprime) and Dinoprostone PGE2 pessary (Propess) in Induction of Labour: A Randomised Controlled Trial

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Abstract

Labor induction is a common obstetric practice. Multiple methods such as Oxytocin, various prostaglandin cervical ripening agents and cervical dilating agents have recently been studied. However, only two prostaglandin cervical ripening agents dinoprostone gel and dinoprostone vaginal pessary are currently approved by the Food and Drug Administration (FDA). Dinoprostone vaginal pessary is a welcome method of Induction of Labour in the current scenario of rising un-avoidable cesarean sections.The RCT was carried out in Tertiary care Hospital in Mumbai for 6months to compare the efficacy of Cerviprime gel and Propess pessary in promoting cervical priming and achieving vaginal delivery and their Maternal and Fetal outcomes with both the methods. 176 patients were selected randomly into Dinoprostone gel and Dinoprostone vaginal pessary group. This RCT compared the Induction-cervical dilatation time interval and induction- delivery time interval and showed statistically significant difference with Propess group resulted in quicker delivery. The requirement for augmentation was less in Propess group. Fetal outcome was better in Propess group with 1 min and 5 min APGAR calculation. However the mode of delivery didn't show any significant difference in both the groups. The finding from this study is likely to have a favourable impact especially for elective IOL which is known to affect the workload in obstetric birth suite.

Keywords: Induction, PGE2 pessary, Dinoprostone , RCT , Delivery.

Introduction: Labor induction is a common obstetric practice [(1)]. Multiple methods such as, Oxytocin, various prostaglandin cervical ripening agents and cervical dilating agents have recently been studied. Prostaglandins have been shown to induce cervical ripening and to stimulate uterine contractions and are effective in numerous clinical trial.[(2-3).]However, only two prostaglandin cervical ripening agents

dinoprostone gel (Cerviprime) and dinoprostone vaginal pessary are currently approved by the Food and Drug Administration (FDA[4]. Dinoprostone vaginal pessary is a welcome method of Induction of Labour in the current scenario of rising un-avoidable cesarean sections. Induction of labour is the nonspontaneous initiation of uterine contractions to accomplish delivery prior to the onset of spontaneous labor.

This study is designed to compare efficacy and maternal and fetal outcomes of two preparations of PGE2-controlled release pessary vs PGE2- gel.

The study was carried out in Tertiary care Hospital in Mumbai with the aims and objectives as follows:

1. To compare the efficacy of PGE2 gel and PGE 2 pessary in promoting cervical priming and achieving vaginal delivery.
2. Need of oxytocin/ amniotomy for augmentation of labour.
3. Maternal and fetal outcomes with both the methods.
4. Side effects associated with both the drugs.

The Randomised Controlled Trial included 176 patients for a duration of 6 months

Materials and Methods: This Randomized controlled trial was carried out in patients requiring labour induction at Emergency department of Obstetrics and Gynaecology, Lokmanya Tilak Medical College and Sion General Hospital, Mumbai, India for a period of 6 months . The patients were selected randomly into 2 groups with the inclusion and exclusions criteria as follows:

Inclusion Criteria: Singleton pregnancies in cephalic presentations, Unfavorable Modified Bishops score ≤ 4, Unscarred uterus, and absence of contraindications to vaginal delivery.

Exclusion criteria: IUFD, Preterm labour, Active labour patient, Patient with medical disorder like bronchial asthma, Heart disease, Hepatitis, PPROM >18 hrs. , Previous scared uterus, maternal clinical contraindications to the administration of PGE2 analogues, Twin pregnancy, fetal malpresentation

In all cases, the patient consent was taken. Patients were randomly assigned to either the cerviprime gel group or propess group. Detailed history, thorough physical and abdominal examination was done along with pelvic examination before induction of labour. Modified Bishop's score was noted before start of procedure for all patients and also at 6th and 12th hour in dinoprostone gel group.

Methods used were as follows

1. PGE2 gel (0.5 mg dinoprostone) was placed inside the cervix, but not above the internal os. The application was repeated after 6 hours, not to exceed 3 doses in 24 hours.

2. Dinoprostone vaginal pessary (Propess):10 mg embedded in a mesh was placed in the posterior fornix of the vagina for 24 hours. Patients selected for intravaginal insert, received a single dose of 10 mg slow release dinoprostone vaginal insert placed transversely in the posterior fornix of the vagina. The insert was removed after 24 hours.

Also the insert was removed earlier if a nonreassuring FHS pattern persisted, or if regular painful uterine contractions started.

The success of the induction was defined as: Achievement of vaginal delivery within 24 hours of the insertion of the drug.

The time to active phase was defined as the interval from insertion of dinoprostone pessary/gel to the achievement of cervical dilation exceeding 5 centimeters or initiation of regular uterine contractions.

Time to vaginal delivery was defined as the interval from insertion of PG E2 pessary/gel to vaginal delivery. Induction failure is considered when the Bishop score is still less than 6 and in case regular contractions did not start after 24 hours of dinoprostone use.

Women were monitored with NST 4 hourly. Labour was followed with partograph.

Augmentation of labour with artificial rupture of membrane and/or oxytocin was done as and when required.

Various parameters were compared like the duration between the induction and cervical dilatation, duration between induction and delivery time, mode of delivery ,Number of cases with failure of induction, fetal outcome with Apgar at 1 minute and 5 minute, Number of instillations of PGE2 gel required for delivery were studied.

Results

Table 1: Comparison of Gravida between 2 Study Groups (N=176)

Gravida	Group		Total
	CP Gel (n=88) n (%)	CP Pessary (n=88) n (%)	
Primi	51 (58.0)	44 (50.0)	95 (54.0)
Multi	37 (42.0)	44 (50.0)	81 (46.0)
Chi-Square Test, P Value = 0.290, Not Significant			

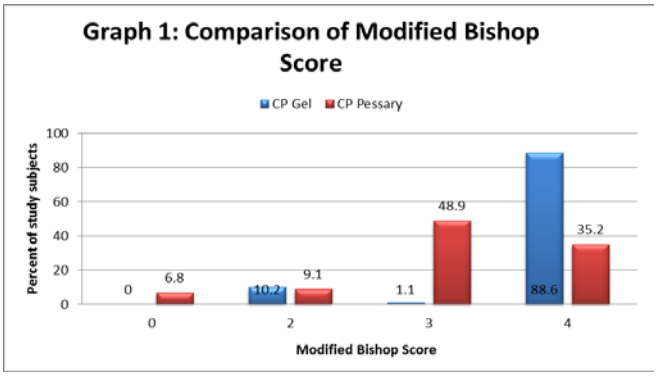

Table 2: Comparison of Duration between Induction and Cervical Dilatation between 2 Study Groups (N=176)

Duration (in Hours)	Group		Total
	CP Gel (n=88) Mean (SD)	CP Pessary (n=88) Mean (SD)	
	11.01 (2.53)	9.52 (2.51)	10.27 (2.62)
Unpaired t Test, P Value <0.001, Significant			

Table 3: Comparison of Duration between Induction and Delivery between 2 Study Groups (N=176)

Duration (in Hours)	Group		Total
	CP Gel (n=88) Mean (SD)	CP Pessary (n=88) Mean (SD)	
	16.08 (2.72)	14.50(3.41)	15.29 (3.17)
Unpaired t Test, P Value = 0.001, Significant			

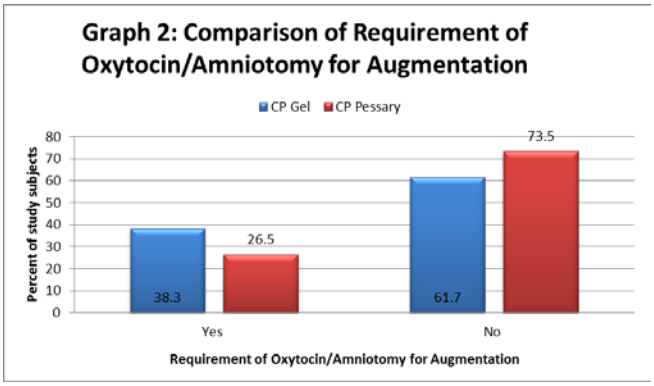

Table 4: Comparison of Adverse Effects between 2 Study Groups (N=176)

Adverse Effect	Group		P Value
	CP Gel (n=88) n (%)	CP Pessary (n=88) n (%)	

Diarrhoea	5 (5.7)	4 (4.5)	0.732
Fever	1 (1.1)	0	0.315
Hyperstimulation	2 (2.3)	3 (3.4)	0.650
N & V	8 (9.1)	7 (8.0)	0.787
None	72(81.8)	74 (84.1)	0.688
Chi-Square Test, P Value Not Significant			

Results

There were 176 women who were eligible for inclusion, 88 in the Cerviprime gel group, and 88 in the Propess pessary group after Randomisation. The results showed that there was no significant difference in Gravida status of both the group (Pvalue-0.290) (Table 1).

As expected, the commonest indication for IOL in both groups was prolonged pregnancy beyond 40 weeks of gestation (38.6%). Other common indications for IOL were Prelabour rupture of membranes (25.6%) Term hypertensive diseases in pregnancy (20.5%)and Term gestational diabetes mellitus(15.3%) . Caeserean Section rate was 34.1% in CP gel group and 22.7% in Propess group. Thirteen women were recorded as having a failed IOL, ten in the Cerviprime gel group and three in the Propess group. The number of women requiring amniotomy and oxytocin infusion to cause effective contractions and delivery did not differ between the two groups. (p value = 0.151; Not significant)(Graph 2) .The mean time between induction to cervical dilatation for all women also showed a significant difference, with women receiving Propess earlier on average than those having CP gel (9.52 versus 11.01 hrs; P <0.001 significant) irrespective of the mode of delivery (Table 2).The mean time between induction to delivery for all women also showed a significant difference, with women receiving Propess earlier on average than those having Cerviprime gel (14.50 versus 16.08 hrs P=0.001 significant.(Table 3). There was significant difference in 1min APGAR (P value =0.004) and 5min APGAR (P value =0.011) in both the study groups, with Propess fetal outcome better than Cerviprime gel group.

Adverse effects such as hyperstimulation in 3 patients, diarrhoea in 4 patients were noted in Propess group, whereas in CP gel group 3 had hyperstimulation and 5 patients had diarrhoea.(Table 4)

Data Analysis and Interpretation: Chi-Square test for categorical Variables. Unpaired t test was used to compare mean of quantitative variables between 2 study groups. Level of significance was set at 0.05.

Discussion

IOL is a common obstetric intervention. Judicious use and selection of agents using strict criteria for IOL is must. It is argued that IOL can place more strain on birthing suite workload than spontaneous labour [(5).] Therefore, timing of IOL is also of importance which again is related to the induction delivery interval. It appears that Propess is more likely to achieve a quicker delivery, regardless of the mode of delivery, irrespective of the Gravida status of the women than Cerviprime gel. The finding from this study is likely to have a favourable impact especially for elective IOL which is known to affect the workload in birth suite. The concern amongst women undergoing IOL about the length of labour is well known [(6)]. Hence, it is believed that women are likely to value a reduction in the interval between induction and delivery[(7)]. Therefore the finding that the preparation which is associated with a significant reduction in the delivery time irrespective of the mode of delivery being used in their care is likely to go down favourably with the women undergoing IOL. Rate of caesarean section in Primiparous women, does not appear to be increased

with either cervipime gel or propess, and hence there was no impact on the overall performance.

This study nevertheless has several limitations. The numbers are small, and the data relates to a single birthing unit in one hospital. The time frame used in this study is only six months.

Conclusions

This Randomised Control Trial compared the Induction- cervical dilatation time interval and induction- delivery time interval and showed statistically significant difference with Propess group resulted in quicker delivery. The requirement for augmentation was less in Propess group. Fetal outcome was better in Propess group with 1 min and 5 min APGAR calculation. However the mode of delivery didn't show any significant difference in both the group.

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Case Record Form:

Name of the patient: **IPD No:**

Age:

Gestational age:

Obstetric History: (Primigravidae, Multigravidae)

Indications for Induction of Labour (IoL)

- Post dated (prolonged pregnancy ≥ 40 weeks & beyond)
- Pregnancy induced hypertension with term gestation.
- Gestational diabetes with term gestation.
- PROM

Modified Bishop score

a) At the time of admission:

b) After 1st Cerviprime induction:

c) After 2nd Cerviprime induction:

Outcomes measured:

a) Duration between induction and cervical dilatation:

b) Duration between induction and delivery:

c) Number of attempts of Cerviprime gel required:

d) Mode of delivery: LSCS/ Vaginal delivery;

IF LSCS , indication:

Meconium stained liquor (MSL):

Fetal distress:

Failed induction :

Others:

e) Requirement of Oxytocin and Amniotomy for augmentation of labour:

f) Requirement of removal of pessary: Hyperstimulation/ Others

g)Fetal outcome:

1) APGAR at 1min:

2) APGAR at 5 min:

3) NICU/ TCU admission: Yes / No

4) Fetal weight:

h) Adverse effects of both:

1) Nausea and Vomiting:

2) Hyperstimulation:

3) Chills, fever

4) Diarrhea