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To compare the clinical efficacy of dinoprostone slow release vaginal pessary and dinoprostone immediate release intracervical gel for induction of labor

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Abstract
Background & Method: The present study was conducted in Department of Obstetrics and Gynaecology, Choithram Hospital & Research Centre, Indore (M.P.) from April 2019 to November 2019. After excluding all contraindications for normal labor, patients admitted in the labor ward of Choithram hospital, were divided in 2 groups of 30 women each. Antenatal profile was done in both the groups. Procedure was explained to patient and written informed consent was taken from all patients and the divided groups were induced accordingly.
Result: In Dinoprostone Gel group the incidence of diarrhea was 10.0%, while in the Dinoprostone Pessary group it was 6.7%. The proportional comparison between the two groups was found to be not significant (p=0.64). In Dinoprostone Gel group the incidence of hyper stimulation was 3.3%, while in the Dinoprostone Pessary group it was 6.7%. The proportional comparison between the two groups was found to be not significant (p=0.552). In Dinoprostone Gel group the incidence of PPH was 13.3%, while in the Dinoprostone Pessary group it was 10.0%. The proportional comparison between the two groups was found to be not significant (p=0.687). In Dinoprostone Gel group the incidence of shivering was 6.7%, while in the Dinoprostone Pessary group it was 6.7%. The proportional comparison between the two groups was found to be not significant (p=1.000). In Dinoprostone Gel group the incidence of vomiting was 0.0%, while in the Dinoprostone Pessary group it was 3.3%. The proportional comparison between the two groups was found to be not significant (p=0.309). The incidence of maternal complications was comparable between the two groups.
Conclusion: Dinoprostone preparations, gel and intravaginal pessary are safe and effective for cervical ripening and induction of labor. Induction delivery interval, requirement of Oxytocin augmentation is less in pessary group when compared to gel group. The dinoprostone slow release vaginal insert seems to be easy to use, effective and safe for the mother's and fetus's health.

Keywords: dinoprostone, vaginal, intracervical & labor

Introduction
Induction of labor refers to artificial stimulation of uterine contractions before the true onset of spontaneous labor to achieve progressive effacement and dilation of the cervix leading to vaginal delivery [1]. Induction of labor aims to initiate labor when maternal and fetal conditions necessitate delivery before the onset of spontaneous contractions.
Induction of labor is a common obstetric procedure and is indicated when the benefits to either mother or fetus outweigh those of continuing the pregnancy. Induction of labor has become a frequent clinical practice concerning approximately 20–30% of all pregnant women [2]. Over the past years, the rate of labor induction for shortening the duration of pregnancy has increased [3]. In developed countries like India, the proportion of babies delivered following induction of labor has come to be as high as one in four deliveries [4, 5, 6].
The rates of induction of labor and the available methods of induction have significantly increased over the last decade. An ideal agent for induction of labor needs to be safe, easily available, cheap, easy to store and administer, acceptable to the patient and having a low risk of any maternal or fetal complications.
Prostaglandins are one of the best agents approved for the ripening of the cervix. Prostaglandins are effective agents in promoting cervical ripening and facilitating uterine contractions. Various prostaglandin formulations like misoprostol (PGE1 analog) and dinoprostone (PGE2 analog) are commonly used for cervical dilatation and effacement [7]. They help in initiating ripening of

cervix which is a requirement for induction. Bishop scoring system helps in the assessment of the status of the cervix and provides quantifiable score to predict outcome.
Many preparations of prostaglandins have become available that aim to improve the success of induction of labor. Prostaglandins E2 are the primary medical means to ripen the cervix and have long proven their efficacy in labor induction. Earlier PGE2 intracervical gel was most frequently used, but now preparations like dinoprostone sustained-release vaginal insert are also being increasingly used for the purpose of induction of labor [8].

Material and Method

The present study was conducted in Department of Obstetrics and Gynaecology, Choithram Hospital & Research Centre, Indore (M.P.) from April 2019 to November 2019. After excluding all contraindications for normal labor, patients admitted in the labor ward of Choithram hospital, were divided in 2 groups of 30 women each. Antenatal profile was done in both the groups. Procedure was explained to patient and written informed consent was taken from all patients and the divided groups were induced accordingly.
Group A: Induction with retrievable controlled release 10mg Dinoprostone pessary releasing 0.3mg Dinoprostone/hour
Group B: Induction with dinoprostone gel 0.5mg given every 6 hourly
Fetal wellbeing was monitored by recording foetal heart rate 1 hourly.
Watch was kept on maternal and foetal complications in both the groups.

Inclusion criteria

For induction of labor were

- Singleton pregnancy
- Cephalic presentation
- More than 37 weeks with unfavourable cervix with a medical or obstetric indication for induction of labour.
- Gestational diabetes mellitus,
- Oligohydramnios.
- Pregnancy induced hypertension
- Postdated pregnancy
- Intrauterine growth retardation
- Women and/or her legally acceptable representative willing to provide voluntary written informed consent for participation in the present study

Exclusion criteria

Cases with indications like

- Major degrees of placenta previa
- Malpresentations
- Multi fetal gestations.
- Ruptured membranes
- Grand multiparas.
- Previous Cesarean delivery
- H/O myomectomy
- H/O hypersensitivity to prostaglandins
- Renal, hepatic or cardiovascular disease
- Mental illness
- Women and or her legally acceptable representative not willing to provide voluntary written informed consent for participation in the present study.

Sample size

Sample size calculation revealed that 20 women per group was required to detect a correlation coefficient of 0.5 between pre-induction cervical length and the induction to delivery interval at an alpha of 0.05 with power of 80%.
The standard normal deviate for $\alpha = Z\alpha = 1.960$
The standard normal deviate for $\beta = Z\beta = 0.842$

$C = 0.5 * \ln [(1+r)/(1-r)] = 0.693$
Total sample size = $N = [(Z\alpha+Z\beta)/C] 2 + 3 = 20$

Accordingly we included more than 20 women per group in the present study.

Results

Table 1: Distribution of women according to parity

Parity	Dinoprostone Gel Group		Dinoprostone Pessary Group		Total	
	No.	%	No.	%	No.	%
Multiparity	17	56.7	15	50.0	32	53.3
Primi	13	43.3	15	50.0	28	46.7
Total	30	100.0	30	100.0	60	100.0

Pearson Chi-square value = 0.268, df=1, p value = 0.605, Not significant

The above table shows the distribution of women according to parity in both the groups.
In the Dinoprostone Gel group there were 17 (56.7%) multipara women and 13 (43.3%) primipara women, while in the Dinoprostone Pessary group, there were 15 (50.0%) multipara women and 15 (50.0%) primipara women.
The association between parity and the groups was found to be statistically not significant (p=0.605), showing that groups are independent of the parity of the women.

Table 2: Distribution of women according to oxytocin augmentation

Oxytocin Augmentation	Dinoprostone Gel Group (n=17)		Dinoprostone Pessary Group (n=25)		Total	
	No.	%	No.	%	No.	%
Not required	4	23.5	15	60.0	19	45.2
Required	13	76.5	10	40.0	23	54.8
Total	17	100.0	25	100.0	60	100.0

Pearson Chi-square value = 5.433, df=1, p value = 0.020, Significant

The above table shows the distribution of women according to oxytocin augmentation in both the groups.
In Dinoprostone Gel group, 4 (23.5%) women did not require oxytocin augmentation and 13 (76.5%) women required

oxytocin augmentation.
In Dinoprostone Pessary group, 15 (60.0%) women did not require oxytocin augmentation and 10 (40.0%) women required oxytocin augmentation.
There was a statistically significant association between oxytocin augmentation and the groups (p=0.020), showing that the groups are dependent on the oxytocin augmentation.
Higher incidence of oxytocin augmentation was seen in the Dinoprostone Gel group.

Table 3: Distribution of women according to indication for LSCS

Indication for LSCS	Dinoprostone Gel Group (n=13)		Dinoprostone Pessary Group (n=5)		Total	
	No.	%	No.	%	No.	%
Failed induction	6	46.2	2	40.0	8	44.4
Foetal distress	7	53.9	3	60.0	10	55.6
Total	13	100.0	5	100.0	60	100.0

Pearson Chi-square value = 0.055, df=1, p value = 0.814, Not Significant

The above table shows the distribution of women according to indication for LSCS in both the groups.
In Dinoprostone Gel group, 6 (46.2%) women underwent LSCS due to failed induction and 7 (53.9%) women underwent LSCS due to fetal distress. In Dinoprostone Pessary group, 2 (40.0%) women underwent LSCS due to failed induction and 3 (60.0%) women underwent LSCS due to fetal distress.
There was no statistically significant association seen between indication for LSCS and the groups (p=0.814), showing that the groups are independent of the indication for LSCS.

Table 4: Comparison of maternal complications between the two groups

Maternal Complications	Dinoprostone Gel Group		Dinoprostone Pessary Group		P value
	No.	%	No.	%	
Diarrhoea	3	10.0	2	6.7	0.64, NS
Hyperstimulation	1	3.3	2	6.7	0.552, NS
PPH	4	13.3	3	10.0	0.687, NS
Shivering	2	6.7	2	6.7	1.000, NS
Vomiting	0	0.0	1	3.3	0.309, NS

Z test for two sample proportion applied.
P value < 0.05 was taken as statistically significant

The above table shows the comparison of maternal complications between the two groups.

Diarrhea: In Dinoprostone Gel group the incidence of diarrhea was 10.0%, while in the Dinoprostone Pessary group it was 6.7%. The proportional comparison between the two groups was found to be not significant (p=0.64).

Hyper stimulation: In Dinoprostone Gel group the incidence of hyper stimulation was 3.3%, while in the Dinoprostone Pessary group it was 6.7%. The proportional comparison between the two groups was found to be not significant (p=0.552).

PPH: In Dinoprostone Gel group the incidence of PPH was 13.3%, while in the Dinoprostone Pessary group it was 10.0%. The proportional comparison between the two groups was found to be not significant (p=0.687).

Shivering: In Dinoprostone Gel group the incidence of shivering was 6.7%, while in the Dinoprostone Pessary group it was 6.7%. The proportional comparison between the two groups was found to be not significant (p=1.000).

Vomiting: In Dinoprostone Gel group the incidence of vomiting was 0.0%, while in the Dinoprostone Pessary group it was 3.3%. The proportional comparison between the two groups was found to be not significant (p=0.309).
The incidence of maternal complications was comparable between the two groups.

Discussion

In the dinoprostone gel group, 13 (43.3%) women were primigravida and 17 (56.67%) women were multigravida. In the Dinoprostone Pessary group, 15 (50.0%) women were primigravida and 15 (50.0%) women were multigravida. The parity was comparable between the two groups (p>0.05).
In dinoprostone gel group 6(20.0%) women were induced due to GDM, while in the Dinoprostone Pessary group 4 (13.3%) were induced due to GDM. In dinoprostone gel group 10 (33.3%) women were induced due to postdatism, while in the Dinoprostone Pessary group 12 (40.0%) were induced due to postdatism. In dinoprostone gel group 3 (10.0%) women were induced due to IUGR, while in the dinoprostone pessary group 4 (13.3%) were induced due to IUGR. In dinoprostone gel group 6 (20.0%) women were induced due to preeclampsia, while in the Dinoprostone Pessary group 4 (13.3%) were induced due to preeclampsia. In dinoprostone gel group 5 (16.7%) women were induced due to oligohydramnios, while in the Dinoprostone Pessary group 6(20.0%) were induced due to oligohydramnios. The proportion of women taken for induction in both the groups was comparable (p>0.05).
In study done by Triglia *et al.* (2010) [9] showed postdated pregnancy was responsible in 70% inductions, IUGR in 1%, PIH/Preeclampsia in 6%,oligohydraminos in 6%, isoimmunisation in 3% and GDM in 3% in the pessary group. In the dinoprostone gel group postdated pregnancy was responsible for 64.0% inductions, IUGR in 1%, PIH/Pre-eclampsia in 4% and GDM in 6% and oligohydraminos in 7%.
Study done by Basu *et al.* (2012) [10] reported most common indication for induction of labor to be post-term gestation in 57.9% in Dinoprostone Pessary group and 54.5% in dinoprostone gel group. Other indications reported by them were intrauterine growth retardation, gestational diabetes, pre-eclampsia, cholestasis. They also found comparable indication for induction between the 2 groups.
Study done by Garg *et al.* (2018) [11] reported that postdated

pregnancy was responsible in 59% inductions, IUGR in 8%, PIH/Preeclampsia in 12% and GDM in 1% in the dinoprostone gel group, while postdated pregnancy was responsible for 52.0% inductions, IUGR in 7%, PIH/Pre-eclampsia in 9% and GDM in 14% in Dinoprostone Pessary group.

The mean Modified Bishop Score at induction in dinoprostone gel group was 2.93 ± 0.9, while at 12 hours it was 6.47 ± 1.41. The difference was found to be statistically significant (p<0.05), showing a higher mean modified Bishop Score at 12 hours in comparison to that induction.

The mean Modified Bishop Score at induction in Dinoprostone Pessary group was 3.03 ± 0.89, while at 12 hours it was 7.50 ± 1.31. The difference was found to be statistically significant (p<0.05), showing a higher mean modified Bishop score at 12 hours in comparison to that at induction.

The mean Modified Bishop Score at 12 hours in the dinoprostone gel group was 6.47 ± 1.41 and in the Dinoprostone Pessary group it was 7.50 ± 1.31. The difference was found to be statistically significant (p<0.05), showing a higher mean Modified Bishop Score in the Dinoprostone Pessary group in comparison to the dinoprostone gel group.

According to the study done by Garg *et al.* (2018) [11] the change in MBS after the first dose was 5.52 ± 1.654 in the dinoprostone gel group as compared to pessary 5.91 ± 2.238 (p>0.05)

Conclusion

Our study which was a prospective randomized comparative study was conducted in the labor ward of Choithram hospital. Sixty patients that were admitted in our institution for induction of labor with MBS <4 were included after confirming indication for induction and excluding contraindications.

Both dinoprostone preparations, gel and intravaginal pessary are safe and effective for cervical ripening and induction of labor. Induction delivery interval, requirement of Oxytocin augmentation is less in pessary group when compared to gel group. The dinoprostone slow release vaginal insert seems to be easy to use, effective and safe for the mother's and fetus's health.

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