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To Compare the Safety and Efficacy of 25mcg Intravaginal Misoprostol And 0.5mg Intracervical Dinoprostone Gel For Induction of Labour

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Abstract:
Background- *This was a comparative study conducted to compare safety and efficacy of 25mcg intravaginal misoprostol with intracervical dinoprostone gel for induction of labour.*
Methods -*100 patients with an indication of labour induction were included in this prospective cross sectional study conducted at Nalanda Medical College and Hospital from January 2018 to December 2018. 50 of them received 25mcg intravaginal misoprostol every 4 hourly for a maximum of 6 doses and 50 of them received 0.5mg intracervical dinoprostone gel for a maximum of 3 doses.*
Results- *The mean induction-delivery interval of the misoprostol was shorter 11.8±2.03 hours as compared to the dinoprostone group 15.54±2.63 hours (pvalue=<0.0001), 44% subjects required oxytocin augmentation in the misoprostol group and 70% in the dinoprostone, indicating that misoprostol group required less oxytocin augmentation(p=0.0086). 84% delivered vaginally in the misoprostol group and 80% in the dinoprostone group(p=0.602). No significant difference was found in terms of intrapartum complications and fetal outcome.*
Conclusion- *25mcg intravaginal misoprostol is safe and effective induction agent and has significant shorter induction-delivery interval, when compared to intracervical dinoprostone gel. It is stable at room temperature and is cost effective.*
Key words- *misoprostol, dinoprostone gel, oxytocin, induction of labour*

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I. 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].To be successful, induction of labour must fulfill three aims. First it should result in adequate uterine contractions and progressive dilatation of cervix. Second this labour should result in vaginal delivery. Third, in viable pregnancies, these aims must be achieved with minimum discomfort or side effects to both mother and fetus[2].Dinoprostone, a PGE2 analogue has long been used for cervical ripening and labor induction and is a very efficacious drug with a good safety profile. But it is costly and requires refrigeration for storage[3,4]. PGE2(dinoprostone gel) is FDA, USA approved for cervical ripening and induction of labour[5]. Recently the most fascinating synthetic prostaglandin E1 analogue Misoprostol has been the focus of attention amongst various labour inducing agents[6].Misoprostol was originally made for healing of gastric ulcers induced by NSAIDs[7,8]. In April 2002 FDA finally approved a new label for use of misoprostol during pregnancy [9].The initial trials have used much higher dose of drug. But the American College of Obstetricians and Gynecologists (ACOG), warns that higher doses(50mcg every 6hourly) could result in uterine hyperstimulation and FHR decelerations, and recommends the use of low dose of 25 µg vaginal misoprostol every 3 to 6 hours[10].This prospective study was conducted to compare safety and efficacy of 25mcg of misoprostol with 0.5mg dinoprostone gel for induction of labour, to compare induction-delivery interval, need for oxytocin augmentation, mode of delivery, maternal and fetal side effects and cost effectiveness.

II. Materials And Methods

This prospective randomized controlled study was conducted in labour ward of Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna, Bihar from January 2018 to December 2018.100 patients fitting to inclusion criteria were randomly divided into two group. Group A-consists of 50 patients, they received 25mcg misoprostol intravaginally in the posterior fornix, doses were

repeated every 4 hourly for a maximum of 5 doses. Group B -consists of 50 patients, who received 0.5mg dinoprostone gel intracervically below internal os, doses were repeated every 6 hourly for a maximum of 3 dose.

Inclusion criteria

1. Singleton pregnancy
2. Completed 37 weeks
3. Vertex presentation
4. Intact membranes
5. Reactive NST
6. Bishop score ≤ 4
7. Absence of uterine contractions
8. Need for Induction

Exclusion criteria

1. Non reassuring fetal heart pattern
2. Malpresentation
3. Multiple pregnancy
4. Cephalopelvic disproportion
5. History of previous caesarean section or scar on the uterus
6. Antepartum hemorrhage
7. Grandmultiparas, elderly primigravida
8. Allergy to prostaglandins
9. Preterm
10. Patient refusal to give 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.

Consent for induction was taken after explaining the method of induction, the drug used for the purpose, route of administration and side effects of the drug. Any patient coming under exclusion criteria were excluded.After induction the patients were monitored for signs of labor, when labour ensued. They were closely monitored for maternal vital signs, progress of labor & fetal heart, which was monitored by intermittent auscultation in majority of cases.

Artificial rupture of membranes was done when cervix was completely effaced with a cervical dilation of $\geq$ 4cm, if spontaneous rupture of membrane did not occur. Oxytocin may be started dependent on modified Bishop's score and in absence of adequate uterine contractions after 4 hours of the last dose or for augmentation of labor in case of arrest of dilatation.

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 as significant.

III. **Results**

The baseline data of the study population like maternal age, parity, gestational age, pre-induction Bishop's score were comparable.There was no difference in the parity distribution in both groups, most of the women were primigravida (64%in misoprostol group and 60% in dinoprostone group). The mean gestational age on admission in misoprostol group was 39.3±1.68weeks and the mean gestational age in the dinoprostone group was 39.61±1.63weeks (p=0.35). In this study most common indication was post-dated pregnancies followed by pre-eclampsia, oligohydramnios, Rh-Negative pregnancy, IUGR, GDM in both the groups. The change in the mean Bishop's score after 12 hours was significantly higher in misoprostol group as compared to dinoprostone group.

Table 1: INDUCTION–DELIVERY INTERVAL

	MISOPROSTOL(n=50)		**DINOPROSTONE (n=50)**	
Interval (Hours)	Number	Percentage	Number	Percentage
7 – 10	18	36 %	02	04 %
11 – 14	26	52%	21	42 %
15 – 18	04	08%	18	36 %
19 – 22	01	02 %	07	14%
22 – 24	01	02%	02	04%
Mean ± S.D	11.8 ± 2.03		15.54 ±2.63	

Table-1 shows that more than half of the patients delivered within 14 hours in the misoprostol group,the mean induction-delivery interval (mean±s.d.) was 11.8±2.03 hours in the misoprostol.The mean induction-delivery interval (mean±s.d.)was 15.54±2.63 hours in the dinoprostone group.The Chi square value is 27.07, and the p value is <0.0001, which is highly significant. Induction-delivery interval was significantly shorter in misoprostol group.

TABLE 02: AUGMENTATION WITH OXYTOCIN

Oxytocin	MISOPROSTOL (n=50)		DINOPROSTONE (n=50)	
	Number	Percentage	Number	Percentage
Yes	22	44%	35	70%
No	28	56%	15	30%
Total	50	100%	50	100%

Table 02 shows that only 22(44%) subjects in misoprostol group required oxytocin augmentation whereas 35(70%) subjects in dinoprostone group required oxytocin augmentation. More oxytocin augmentation was required in the dinoprostone group (p=0.0086).

TABLE 03: MODE OF DELIVERY

Mode of Delivery	MISOPROSTOL (n=50)		DINOPROSTONE (n=50)	
	Number	Percentage	Number	Percentage
Vaginal	42	84%	40	80%
Caesarean section	8	16%	10	20%
Total	50	100%	50	100%

Table 03-shows that majority of cases delivered vaginally in both the groups, 42(84%) subjects in misoprostol and 40(80%) subjects in dinoprostone group.16% subjects in misoprostol and 20 % subjects in dinoprostone group underwent caesarean section. There was no statistically significant difference in the mode of delivery in both the groups(p=0.602).

TABLE 04 : MATERNAL COMPLICATIONS

Complications	MISOPROSTOL(n=50)		DINOPROSTONE (n=50)	
	Number	Percentage	Number	Percentage
Gastro intestinal side-effects	9	18%	8	16%
Intrapartum fever	4	8 %	3	6 %
Uterine hyperstimulation	3	6 %	1	2 %

Table 04 shows that in majority of cases had gastrointestinal side effects9 (18%) subjects in misoprostol and 8(16%) subjects in dinoprostone group.8% subjects in misoprostoland6% subjects in dinoprostone group had Intrapartum fever. 3(6%) subjects in misoprostol and 1(2%) subjects in dinoprostone group had Uterine hyperstimulation. Uterine hyperstimulation was slightly more in misoprostol group but it was not statistically significant(p=0.724).

In the present study, the liquor stained with meconium was more common in the misoprostol group(30% in misoprostol vs 20% in dinoprostone) but it was not statistically significant. There was no difference between neonatal outcome in terms of NICU admission. There were no still birth in both the groups. There was no difference in the Apgar score at 1 minute and 5 minutes, and mean birth weight.

TABLE 05- NEONATAL OUTCOME

Out come	**MISOPROSTOL(n=50)**		**DINOPROSTONE (n=50)**		
	Number	**Percentage**	**Number**	**Percentage**	**P. Value**
Birth weight	2.814±0.30		2.900±0.22		0.65
1 minute APGAR					
>6	44	88	45	90	
<6	6	12	5	10	0.749
5 minute APGAR					
>8	42	84	44	88	
<8	8	16	6	12	0.564

The incidence of PPH was similar in both the groups.

IV. **Discussion**

There was no statistically difference in the general and obstetrics characterstics of patients in both misoprostol and dinoprostone group. The mean induction delivery interval in this study was 11.8±2.03hours in the misoprostol group and 15.54±2.63 hours in the dinoprostone group(pvalue=<0.0001). Misoprostol has significantly shorter induction-delivery interval. Murthy Bhaskar et al[11](2006), Nanda et al[12] (2007), Chitrakar et al[13](2012) reported significantly shorter induction delivery interval in the misoprostol group.

In the present study only 44% women needed oxytocin augmentation in the misoprostol group whereas 70% women required oxytocin augumentation in the dinoprostone group(p=0.0086) . Wing et al[14](1995) also reported that 47.5% of women in the misoprostol group compared with 72.6% in the dinoprostone group required oxytocin augmentation. Study done by Nanda et al[12] , also reported lesser use of oxytocin augmentation with misoprostol as compared to dinoprostone .

In the present study 84% women the misoprostol group delivered vaginally, in the dinoprostone group 80% women delivered vaginally . Caesarean section was 20% in dinoprostone group as compared to 16% in misoprostol group. The outcome of mode of delivery in both the group was comparable(p=0.602). This finding is comparable to Rowland S et al[15], Moodley J[16] , they also reported no significant difference in the mode of delivery with the intravaginal misoprostol and intracervical dinoprostone gel.

In the present study most common maternal complication was gastro-intestinal side effect like nausea, vomiting and diarrohea, 18% subjects in the misoprostol group and 16%subjects in dinoprostone group. 8% subjects in misoprostol group and 6% in the dinoprostone group had intrapartum fever. Uterine hyperstimulation was seen in 6% subjects in misoprostol group whereas it was seen in only 2% subjects in the dinoprostone group(p=0.724). Studies by Wing et al[14] showed similar incidence of uterine hyperstimulation in both the groups. Side effects of the misoprostol are directly related with dose and interval between doses. HofmeyrGJ[17]found meconium stained liquor was more common with misoprostol than with dinoprostone. Wing DA[14] found similar incidence of meconium stained liquor in both the groups. Sanchez-Ramos et al[18](1997),Meyer M et al[19] (2005), found that there was no statistically significant differences regarding adverse neonatal outcome.

V. **Conclusion**

25mcg intravaginal misoprostol is a safe and effective drug for induction of labour.Misoprostol shortens the induction-delivery interval significantly compared to dinoprostone.Misoprostol use is associated with decreased requirement for oxytocin augmentation of labour as compared to dinoprostone.The low doses 25mcg is safe and is not associated with any significant complications like hyperstimulation, fetal distress or rupture uterus.There is no difference in outcome of labour in both groups with respect to mode of delivery, rate of caesarean section.There is no difference in neonatal outcome in both groups in terms of APGAR score at 1 and 5 minutes and NICU admission rate.Misoprostol is cheap, stable at room temperature and easy to administer .

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