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COMPARISON BETWEEN MISOPROSTOL AND DINOPROSTONE IN INDUCING LABOUR

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Abstract

Background: The objective of this study was to evaluate safety and efficacy of labour inducing prostaglandins E1 and E2. We compared the obstetrical outcomes of intra-vaginal misoprostol (PGE1) and intra-cervical dinoprostone gel (PGE2) in our study. **Materials and Methods:** The study included 100 full term pregnant women of 19 to 30 years age group, with a cephalic presentation of single live fetus. Fifty women were included in each group (study and control). Women in study group were given 50 micrograms of Misoprostol intravaginal, while the control group received 0.5 mg of intracervical dinoprostone gel each. Key parameters studied in both groups were average time taken for start of labour, induction time at birth, duration of delivery, oxytocin requirement and delivery method. **Conclusion:** In comparison to dinoprostone, our study found misoprostol to be a better option in inducing labour for both the mother and the fetus, due to its efficacy, safety, and affordability.

INTRODUCTION

Induction of labour (IOL) is a common obstetric intervention, in which onset of labour is stimulated through pharmaceutical or other means. FOGSI defines induction of labour as "Artificial initiation of contractions in a pregnant woman who is not in labour to help her achieve a vaginal birth within 24 to 48 hours".^[1] Generally, this modality is opted when the benefits of prompt vaginal delivery outweigh maternal / fetal risk of waiting for spontaneous onset of labour. Common indications for IOL are conditions like post-term pregnancy, premature rupture of membranes (PROM), decrease in amniotic fluid, health risk to women in continuing the pregnancy, problems with placenta or fetus, and previous history of still birth, etc.

In recent years, there has been an increase in the rate of labour induction in several countries. For instance, in the United States, the rate has risen from 9.6% in 1990 to 25.7% in 2018, with 31.7% of first-time births being induced.^[2] In Australia, 44% of mothers underwent induced labour in 2021.^[3]

Most common drugs for inducing labour are prostaglandins, which are lipids with hormone-like

properties. This class of drugs induce changes in extracellular fundamental substance of cervix, leading to cervical maturation and increased collagenase activity in the cervix. The increase in intracellular calcium level caused by prostaglandins induces contraction of myometrial muscles.^[4]

Misoprostol and Dinoprostone gel are the two most common prostaglandin analogues used for cervical ripening, which is the first component of labour induction.

Misoprostol (C22H38O5) is a synthetic analogue of prostaglandin PGE1. Originally developed in 1973 for the prevention and treatment of peptic ulcers, it is now widely used in labour induction, as an effective agent for uterine contractions and ripening of the cervix. Can be administered sublingual or intravaginal in tablet form.

Dinoprostone is chemically identical to endogenous prostaglandin E2 (PGE2). It achieves cervical ripening and softening by stimulating uterine contractions as well as directly acting on the collagenase present in the cervix to soften it. Dinoprostone requires cold storage for chemical stability. The gel is administered into the cervical canal through a syringe.

MATERIALS AND METHODS

In this study 100 women who were admitted for birth induction were chosen at random. In half of this group 50 μ g of Misoprostol was given intravaginal, which was retained in the posterior fornix after wetting. Dinoprostone 0.5mg in gel form was administered intracervical in the other group of 50 women. In both groups same doses were repeated at 6 hours interval, maximum up to 3 doses.

The criteria for inclusion in the study were singleton pregnancies of 37 weeks or over on ultrasound with cephalic presentation. Twin or multiple pregnancies, fetuses in transverse or breech positions, previous caesarean and pregnancy of less than 37 weeks, in utero fetal death and medical termination of pregnancy were excluded. In this comparative study those who received Misoprostol for labour induction were treated as Study group and other group who received dinoprostone gel were the control group.

Women who had reached an active phase of uterine contraction with cervical dilation of atleast 34 cm were administered oxytocin. If active labour with uterine contractions was not achieved within 24 hours, it is considered as failed induction and a caesarean section was performed.

Statistical significance was determined by applying unpaired tests and calculating the mean and deviation. The qualitative variables were represented in terms of percentages. APGAR score was used to evaluate the neonatal outcome.

RESULTS

Gestational Age: The study population's reference data is consisted of maternal age, pregnancy and a gestational age of 42 weeks. 70% of women in the study group and 86% of women in control group were pregnant between 37 and 40 weeks. [Table 1] **Indications for Induction of Labour:** Post-term pregnancy in 32% and preeclampsia in 40% were the two main indications for the induction of labour in the Study (Misoprostol) Group. Similar indications were observed in the Control (Dinoprostone) Group also, which was 36% and 42% respectively. [Table 2]

Onset of Labour (Mean Time): The study group, who were given misoprostol had a significantly shorter average time spent at the onset of labour (42.30 minutes) with a p-value of 0.00039, against (1 hour 35 minutes) by the control group, who received dinoprostone. [Table 3] Results of Misoprostol were of earlier delivery than dinoprostone.

Induction Delivery Intervals: The time taken for induction of the active phase of labour was significantly lower in the Misoprostol – study group (1 hour and 44 minutes) compared to the Dinoprostone – control group (4 hours and 25 minutes) with a p-value of 0.004. As shown in table 4, the active phase during the administrative interval was significantly lower, for the shorter duration (3 hours 00 minutes) compared to the control group (4 hours and 48 minutes) with a

pvalue of 0.08. None of the patients in the misoprostol group in this study required oxytocin augmentation, whereas 3 patients (6%) in the dinoprostone group required it. [Table 4]

Mode of Delivery and Indications for LSCS: With respect to mode of delivery and indications for caesarean section, the findings are summarised in Table 5. In the study group (misoprostol) normal vaginal delivery was significantly higher (88%) against 68% in the control group. Control group required more caesarean section (26%), whereas it was only 6% in study group. Only one patient experienced induction failure, while in the control group (dinoprostone) induction failure was observed in seven patients. Lack of induction was the main indicator for caesarean section in the control group. Meconium-Stained Liquor was the primary reason for caesarean section in the control group.

Misoprostol group experienced more complications such as fever with chills, tachycardia, hypersystole and more colored liquor than the dinoprostone group. Other than these, no other significant side effects were observed. The cost of induction was much lower in the misoprostol group than in the dinoprostone group, as shown by the average cost of overall induction. [Table 5]

Table 1: Gestational Age		
Gestational Age	Study Group	Control Group
	(Misoprostol)	(Dinoprostone Gel)
	35	38
37-40 Weeks	(70%)	(86%)
40-42 Weeks	15	12
40-42 weeks	(30%)	(24%)

Table 2: Indications for Induction of Labour		
Gestational Age	Study Group (Misoprostol)	Control Group (Dinoprostone Gel)
Post term Programov	16	18
Post-term Pregnancy	(32%)	(36%)
	14	11
IUGR	(28%)	(22%)
Gestational Hypertension	20	21
Preeclampsia	(40%)	(42%)

Table 3: Onset of Labour (Mean time)			
Categories	Study Group (Misoprostol)	Control Group (Dinoprostone Gel)	Mean Difference
In All Pregnancies	42.30 Mnts.	1 Hour 35 Mnts.	55.80 Mnts.
In Primigravida Pregnancies	48.40 Mnts.	1 Hour 30 Mnts.	43.40 Mnts.
In Multigravida Pregnancies	40.25 Mnts.	1 Hour 25 Mnts.	50.30 Mnts.

Table 4: Induction delivery intervals			
Categories	Study Group (Misoprostol)	Control Group (Dinoprostone Gel)	Mean Difference
Induction to active phase	1 Hour 44 Mnts.	4 Hours 25 Mnts.	2 Hours 18 Mnts.
Active Phase of Delivery	3 Hours 00 Mnts.	4 Hours 48 Mnts.	1 Hour 06 Mnts.
Induction to delivery	4 Hours 02 Mnts.	10 Hours 45 Mnts.	6 Hours 10 Mnts.

Table 5: Mode of Delivery and Indications for LSCS		
Categories	Study Group(Misoprostol)	Control Group (Dinoprostone Gel)
Normal Vaginal Delivery	44 (88%)	34 (68%)
Instrumental Delivery	3 (6%)	3 (6%)
Caesarean Section	3 (6%)	13 (26%)
Failure of Induction	1	7
Meconium-Stained Liquor	2	3
Fetal Distress		3

DISCUSSION

Prostaglandins are lipids with hormone-like actions, vital in a wide array of physiological functions of the body. With reference to women specific physiological functions, prostaglandins are also responsible for uterine contractions during menstruation, helping release of endometrium. During labour uterine cells produce prostaglandins to dilate cervix and cause uterine contractions. To the same effect, synthetic prostaglandins is routinely used in obstetrics practices for induction of labour. In this study we compared the safety, efficacy and obstetrical outcomes of two commonly used synthetic prostaglandins for induction, namely misoprostol (PGE1) verses dinoprostone gel (PGE2). Latika & Biswajit,^[5] and Agarwal et. Al,^[6] were studies similar to ours.

Our study found post-term pregnancy and preeclampsia as the two primary indications for induction of labour. Post-term pregnancy in 32% and preeclampsia in 40% were the main indications for induction of labour in the Study (Misoprostol) Group. Similar indications were observed in the Control (Dinoprostone) Group also, which was 36% and 42% respectively.

The onset of labour in the group given misoprostol averaged at 42.30 minutes while the dinoprostone group the time was much longer, averaging 1 hour and 35 minutes. Results of misoprostol were of earlier delivery than dinoprostone. Gravidity showed no significant time difference for onset of labour in both groups.

The time taken for induction of the active phase of labour was significantly lower in the

Misoprostol – study group (1 hour and 44 minutes) compared to the Dinoprostone – control group (4 hours and 25 minutes) with a p-value of 0.004. The

active phase during the administrative interval was significantly lower, for the shorter duration (3 hours 00 minutes) compared to the control group (4 hours and 48 minutes) with a p-value of 0.08. None of the patients in the misoprostol group in this study required oxytocin augmentation, whereas 3 patients (6%) in the dinoprostone group required it. Significant difference was found in induction to delivery time among two groups. The average time in misoprostol group was 4 hours 55 minutes whereas in the dinoprostone group it was 10 hours and 45 minutes. Shorter induction to delivery time is reported in other studies as well.^[7,8]

In our study, three patients in the dinoprostone group required oxytocin augmentation, whereas none in the misoprostol group warranted any such need. Niger & Greaves in their study reported oxytocin augmentation requirement in 50% patients of misoprostol group and 90% of dinoprostone group.^[9]

With respect to mode of delivery and indications for caesarean section, in the study group (misoprostol) normal vaginal delivery was significantly higher (88%) against 68% in the control group. Control group required more caesarean section (26%), whereas it was only 6% in study group. Kumari A, et. al. reported 73.97% vs 47.22% vaginal deliveries in favour of misoprostol group.^[10]

Incidents of caesarean sections were much higher in dinoprostone group (26%) compared to misoprostol group (6%). In the study by Kumari A, et. al. the LSCS in dinoprostone group was double that of misoprostol group (35.71% against 17.85%).^[10] In our study lack of induction was observed in seven,^[7] patients of dinoprostone group against only one,^[1] in misoprostol group.

Meconium-Stained Liquor was the primary reason for caesarean section in the study group (2 out of 3 c-section cases), whereas it was second key indicator (3 out of 13) in the control group.

Side effects were relatively common in misoprostol group compared to dinoprostone group. Though not serious, side effects like tachycardia, tachysystole, colored liquor, fever with chills were observed more in this group. Other than these, no other significant side effects were observed. These findings about misoprostol matches with other studies also.^[11] Average cost of induction is much lower in misoprostol group compare to dinoprostone group.

No significant difference in neonatal outcome was noted between these two groups. Though an APGAR score of <7 at one minute was seen in 3 cases of dinoprostone group, at five-minute APGAR score was similar in both groups.

CONCLUSION

Our study found that misoprostol is more effective than dinoprostone jelly in inducing labour. Misoprostol resulted in shorter duration from induction to delivery periods, lower need for augmentation with oxytocin, and higher number of vaginal births compared to dinoprostone. Additionally, misoprostol was found to be a safe, effective, and economical drug for inducing labour in and for the fetus as well.

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