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RESEARCH ARTICLE

Sublingual misoprostol versus dinoprostone gel in labour induction

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ABSTRACT

Objective: This study was carried out to compare the outcome and safety of intravaginal misoprostol (PGE1) and intra-cervical dinoprostone gel (PGE 2) in induction of labour. **Methods:** In this study, 100 women between 19 and 30 years of age with a single live fetus, cephalic presentation and full-term pregnancy were included for induction of labour. Fifty women received 50 micrograms of Misoprostol intravaginal (study group) and 50 women received 0.5 mg of intracervical dinoprostone gel (control group). The comparison were made on the average time taken for the start of labour, the induction time at birth, the average duration of delivery, the need for oxytocin, the method of delivery. **Results:** The average time taken for the onset of labour was lower in the misoprostol group than in the dinoprostone group (40.30 min v/s 1 hour and 35 minutes). Similarly, the induction phase to the active phase (1 hour and 44 min v/s 4 hours and 25 min) and the active phase at the time of administration to delivery (3 hours 00 min v / s 4 hours 48 min) was lower for the misoprostol group. The rate of caesarean section was lower in the misoprostol group (6% v / s 26%). Maternal side effects were negligible in both groups and the neonatal outcome was good in both groups. The cost of induction was much lower in the misoprostol group. **Conclusion:** Misoprostol is a safe, effective and economical drug, suitable for the mother and the fetus for the induction of labour.

Keywords: Dinoprostone gel, induction of labour, misoprostol.

Induction of labour is defined as the process of artificially stimulating the uterus to start labour[1]. In about 5 to 25% of pregnancies, there comes a time when the fetus and / or the mother would be better if the birth is guided [2]. Prostaglandins alter the extracellular fundamental substance of the cervix, mature the cervix and also increase the activity of collagenase in the cervix. They also allow an increase in intracellular calcium levels, causing contraction of the myometrial muscle [3, 4]. Currently, there are two prostaglandin analogs available for cervical ripening: Misoprostol and Dinoprostone Gel. Misoprostol (15-deoxy-16-hydroxy-16-methyl-PGE1) was the first synthetic analog of prostaglandin available for the treatment of peptic ulcer. Impressed by his stimulating actions on the uterus, Sánchez Ramos in 1993 used it to control various obstetric conditions. Misoprostol is available in tablets of 50, 100, 200 micrograms. Dinoprostone (PGE) is a synthetic preparation of natural

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prostaglandin E2. The PGE 2 gel is available in a 2.5 ml syringe for an intracervical application of 0.5 mg of Dinoprostone [5]. This study was carried out to compare the outcome and safety of intravaginal misoprostol (PGE1) and intra-cervical dinoprostone gel (PGE 2) in induction of labour.

Materials and Methods

Randomly selected 100 women who were admitted for birth induction. Fifty women received 50 micrograms of intravaginal Misoprostol and another 50 women received 0.5 mg intracervical dinoprostone in a gel. Misoprostol (50 μg) remained in the posterior fornix after wetting. Doses were repeated in both groups every 6th hourly upto maximum of 3 doses.

Inclusion criteria: Cephalic single pregnancy, > 37 weeks pregnancy on ultrasound.

Exclusion criteria: Multiple pregnancy, abnormal presentation, pregnancy <37 weeks, previously caesarean.

Study group: Misoprostol for labour induction.

Control group: Patients who received dinoprostone gels for labour induction.

The patients were evaluated in an active phase with cervical dilatation of at least 3-4 cms. When they entered in active phase of the uterine contraction, oxytocin was started. If women have not reached in active labour in 24-hours, a caesarean section was performed for the failed induction. The results were expressed as a means and deviation tests and unspent tests were applied to identify the statistical significance. The qualitative variables were expressed as a percentage. The neonatal outcome was measured based on an APGAR score.

Results

Reference data for the study population included maternal age, pregnancy, and gestational age. They were comparable in two groups. The average gestational age was identical from 37 to 42 weeks. Thirty six number of women (72%) in the main group and 86% in the control group were pregnant between 37 and 40 weeks, as shown in table 1.

Table 1: Gestational age

Gestational age	Misoprostol	Dinoprostone gel
37-40 wks	36(72%)	38(86%)
40-42 wks	14(28%	12(24%)

The average time spent at the onset of labor was significantly lower (P = 0.00039) in the misoprostol group (42.30 min compared to 1 hour and 35 minutes), as shown in table 3. Therefore, misoprostol causes premature delivery and, therefore, earlier delivery than dinoprostone.

Table 2: Induction indications

Indications	Misoprostol	Dinoprostone
Postdated pregnancy	16(32%	18(36%)
IUGR	14(28%)	11(22%)
PIH/Pre-eclampsia	20(40%)	21(42%)

Table 3: Mean time onset of labour

Categories	Misoprostol	Dinoprostone	Mean difference
In all patients	42.30 min	1 hr 35min	55.80 min
In Primigravida	48.40 min	1hour 30 min	43.40 min
In Multigravida	40.25 min	1 hour 25min	50.30min

In the Misoprostol group, the time required for induction of the active phase (1 hour 44 minutes compared to 4 hours 25 minutes) was lower, statistically significant at P = 0.004. Similarly, the active phase in the administrative interval (3 hours 00 minutes vs 4 hours 48 minutes) was also lower and was statistically significant with P = 0.08 (Table 4). There was no need of augmentation of labour with oxytocin in any case in the misoprostol group, but in 3 (6%) patient of dinoprostone group, augmentation was needed.

Table 4: Induction delivery intervals

Categories	Misoprostol	Dinoprostone	Mean difference
Induction to active phase	1hr 44 min	4 hrs 25 min	2 hrs 18 min
Active phase to delivery	3 hrs 00 min	4 hrs 48min	1hr 6 min
Induction to delivery	4 hrs 2min	10 hrs 45 min	6 hrs 10 min

Only one patient in the study group had an induction failure, and seven patients in the control group had an induction failure. The main indicator for the caesarean section of the control group was the lack of induction, as shown in table 5. In the study group, a caesarean section was predominantly for the meconium liquor, which was the second key indicator for the caesarean part of the control group.

Although fever with chills, hyperstimulation (hypersystole and tachycardia) and more colored liquor in the misoprostol group were in complications than in dinoprostone group, no other significant side effects were

Table 5: Mode of delivery and indications for caesarean section.

Categories		Misoprostol (Number & % of Patient)	Dinoprostone (Number & % of Patient)
Normal vaginal		44 (88 %)	34 (68%)
Instrumental delivery		3 (6 %)	3 (6 %)
Caesarean section		3 (6%)	13 (26%)
Indications of caesarean section	Failure of induction	1	7
	Meconium stained liquor	2	3
	Fetal distress	-	3

detected. The average cost of the overall induction in the misoprostol group was significantly lower than the high cost of induction in a dinoprostone group.

Discussion

The use of prostaglandins into clinical practice for maturation of the cervix, has reduced the difficulties in stimulating labor. The time between induction and delivery was sharply reduced with use of prostaglandins. In addition, it also reduced the associated complication of amnionitis and fetal infection. Baseline data from our study population, including maternal age, severity, and gestational age, were comparable to similar studies [6-8].

In our study, indications for induction in the misoprostol group were post dated pregnancy in 32% and preeclampsia in 40%, while in the misoprostol group 36% and 46% respectively caused a pregnancy after pregnancy and preeclampsia. Therefore, most of the evidence was related to these two conditions. The subsequent pregnancy was the main indicator of induction in other studies [6-8].

The average time spent at the start of labor was lower in the misoprostol group (42.30 minutes compared to 1 hour and 35 minutes). There was no significant difference between primigravida and multigravida in both groups compared to the time taken to start labor.

In this study, the average induction of delivery was lower in the misoprostol group (4 hours 55 minutes versus 10 hours 45 minutes), which is statistically significant (P = <. 002). Similar results were observed in a study by Agarwal et al. [8] in 2003, where they were found 12.8 ± 6.4 hours versus 18.53 ± 8.5 hours. In 2003, Garry et al[9] in his study also concluded that the interval between the initiation of induction and vaginal delivery was significantly shorter in the misoprostol group. Also in another study by Murthy Bhaskar Krishnamurthy [8] in 2006, the interval between induction and vaginal delivery was shorter in the misoprostol group. Similar observation was seen in some other studies also [10-12]. Therefore, misoprostol reduces the average duration of labor, which reduces the duration of the patient's suffering during childbirth, and also provides the fast delivery needed in case of premature rupture of the membranes, eclampsia and fetal distress.

In our studies, there was no need for an increase in oxytocin in any case in the misoprostol group, but in 3 patients in dinoprostone group; oxytocin augmentation was needed. Neiger R Greaves [12] in his study observed an increase in oxytocin 50% of patients in the study group and where as 90 % in the control group.

The current study proved that misoprostol was able to increase the rate of vaginal delivery in study group, as 88% compared to the control group 68%. Therefore, misoprostol decreased the incidence of caesarean section (6%) compared to dinoprostone positions (26%). Similar findings were observed by Murthy Bhaskar et al[7] and Sahu Latika et al [6].

In the current study, in the misoprostol group out of 3 caesarean sections, there was only one case of insufficiency of induction, but in the dinoprostone group 7 of 13 patients were posted for caesarean section due to insufficiency of induction. Thus, the main indicator of caesarean section in the dinoprostone group was the lack of induction, which is consistent with the study of Sahu Latika et al [6] and Murthy Bhaskar et al [7]. In the misoprostol group, 2 out of 3 patients had a caesarean section due to stain liquor, while 3 patients in the dinoprostone group had caesarean section due to stain liquor.

Both groups had minimal maternal side effects. In the Misoprostol group, 18% of patients had fever with chills, 6% had nausea and vomiting, 4% had gastrointestinal disturbances, and 8% had hypertonicity. In 2000, GD Scarle & Company told doctors that misoprostol is not

allowed to be given for childbirth or to terminate a pregnancy. Despite this, the College of American Obstetricians and Gynaecologists (2000) has confirmed its urgent need to use this drug to ensure safety and efficacy[13].

Birth weight was similar in both groups. An Apgar score of <7 was seen after 1 minute in 3 cases from the dinoprostone group, and two of them were to be admitted to the intensive care unit. The total average cost of induction in the misoprostol group was significantly lower.

Conclusion

The results of our studies showed that misoprostol efficacy is better than dinoprostone jelly. It takes short duration from induction to delivery periods. The need of augmentation with oxytocin was lower in misoprostol and the number of vaginal births was higher in misoprostol than dinoprostone. Misoprostol is a safe, effective and economical drug, suitable for the mother and the fetus for the induction of labor.

Conflict of interest: None. **Disclaimer:** Nil.

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