

A Comparative Study between Intra-Vaginal Misoprostol and Intra-Cervical Dinoprostone Gel for Induction of Labor

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ABSTRACT

Background: Labor is the final consequence of pregnancy. Induction of labor (IOL) implies the artificial initiation of uterine contractions after a period of viability for the purpose of vaginal delivery whereas augmentation of labor is a process of stimulation of uterine contractions. Aim of the study: The aim of this study was to evaluate the safety and efficacy of intravaginal misoprostol with intra-cervical dinoprostone gel for induction of labor. **Methods:** In total 132 labor induction patients were included in this prospective cross-sectional as the study population, conducted in the Department of Gynecology & Obstetrics, Uttara Adhunik Medical College and Hospital, Dhaka, Bangladesh during the period from January 2017 to December 2019. Among the patients, 66(50%) of them received 0.5mg intra-cervical Dinoprostone gel (PGE2), and the rest 66(50%) received 50µg of intra-vaginal Misoprostol tablet. Factors of parity, gestation age, indication for induction, induction to delivery time, indication for induction required doses, need of Oxytocin, Modified Bishop's score, prior to induction, mode of delivery, and indication for C-section side effects were studied in detail. **Results:** In analyzing the parity, GA, number of required doses of induction, MBS, mode of delivery, the delivery interval between Dinoprostone and Misoprostol groups we did not find any significant correlation. But in analyzing the side effects in Dinoprostone group's we found fever and TPH were 7.58%, vomiting 4.55%, APH 3.03%, TS 1.52%, HS 0.00%, diarrhoea 0.00% and chills 0.00%. On the other hand, in Misoprostol group's side-effects of fever 3.03%, TPH 0.00%, vomiting 1.52%, antepartum hemorrhage 0.00%, turner syndrome 6.06%, HS 12.12%, diarrhea 7.58% and chill 19.7% respectively. p-value was found 0.042. **Conclusion:** Regarding the parity, gestation age, number of required doses of induction, Modified Bishop's score, mode of delivery, delivery interval, we did not find any significant correlation between the groups of Misoprostol and Dinoprostone. But considering the side effects, Dinoprostone gel may be a better choice than Intra-Vaginal Misoprostol as induction.

Keywords: Induction, delivery, dinoprostone, labor, misoprostol, intravaginal gel.

1

INTRODUCTION

Labor is that the final consequence of the physiological conditions. Induction of labor (IOL) implies the bogus initiation of female internal reproductive organ contractions once an amount of viability for the aim of epithelial duct delivery whereas augmentation of labor could be a method of stimulation of female internal reproductive organ contractions. Induction of labor is outlined because of the method of unnaturally stimulating the womb to begin labor.^[1] With the aim of achieving epithelial duct delivery in an exceedingly pregnant girl with intact membranes, World Health Organization defines IOL because of the initiation of labor by artificial means before its spontaneous onset at a viable fertilization age. IOL accounts for concerning twenty-fifth of all deliveries, in developed countries.

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In developing countries, the rates vary.^[2] Labor induction additionally be indicated by medical or obstetric complications of a physiological condition or even requested or chosen for non-medical or social reasons also. once a lady and her care supplier decide that labor induction is in would like, they need to next indicate a technique of induction. many factors could influence the selection of methodology for induction of labor as well as cervical and membrane standing, parity, and patient and supplier preference.^[3] Indications for labor induction realize of each maternal and craniate conditions. to reduce maternal morbidity, induction could also be supported to decrease craniate or infant morbidity. Mortality like post-term physiological condition, oligohydramnios, suspected intrauterine growth restriction (IUGR) and craniate gastroschisis, like maternal viscus malady and pre-eclampsia/eclampsia, or to learn each mother and vertebrate like pre-labor rupture of membranes (PROM) at term and craniate macrosomia.^[4] prostaglandins have evolved attributable to their twin action of cervical ripening and muscular contraction causation impact, prostaglandins have evolved because of the most well-liked and regularly used pharmacological agents for IOL. autocoid E2 (Cerviprime gel), a registered causation agent in

Farhad et al; Intra-Vaginal Misoprostol and Intra-Cervical Dinoprostone Gel for Induction of Labor

several countries is dear and wishes to be cold because of its sensitivity to temperature variations. it's instilled intra-cervically or placed high within the posterior fornix of the channel and will have to be compelled to be re-installed once half a dozen hours if required. Another difference, that is employed in numerous dosages is misoprostol of 15-deoxy-16-hydroxy-16-methyl autocoid EL. it's stable at temperature, relatively cheaper, and might lean via many routes (oral, vaginal, sublingual, buccal, and rectal).^[5] The key aim of this study was to judge the protection and effectualness of intravaginal misoprostol with intra-cervical dinoprostone gel for induction of labor.

Objectives

General Objective:

- To compare the safety and efficacy of intra-vaginal misoprostol with intra-cervical dinoprostone gel for induction of labor procedures.

Specific Objective:

- To collect comparative information regarding the parity, gestation age, number of required doses of induction, Modified Bishop's score, mode of delivery, delivery interval and side-effects of participants.

MATERIALS & METHODS

In total 132 patients who required labor induction were included in this prospective cross-sectional study as the study population. This study was conducted in the Department of Gynecology & Obstetrics, Uttara Adhunik Medical College and Hospital, Dhaka, Bangladesh during the period from January 2017 to December 2019. Among the patients, 66(50%) of them received 0.5mg intra-cervical Dinoprostone gel (PGE2) and the rest 66(50%) patients received 50 mcg of intra-vaginal Misoprostol tablet and the dose was repeated every 6 hours for up to a maximum of 3 doses. Factors such as parity, GA, induction to delivery time, number of doses required, indication for induction, the need of oxytocin, MBS prior to induction, mode of delivery, indication for C-section, side effects, Number of NICU admissions and indication, MSL were studied in detail. Mild to severe pre-eclampsia, postdated pregnancy, mild polyhydramnios, mild oligohydramnios, gestational DM, chronic hypertension, mild IUGR, and chorioamnionitis were the indications for induction in this study. According to the inclusion criteria of this study patients with an indication for labor induction, singleton pregnancy, gestational age more than 28 weeks, vertex presentation, and patients with a Bishop score ≤ 5 were included in this study. On the other hand, according to the exclusion criteria of this study, patients with previous L.S.C.S or any uterine surgery, malpresentation, contracted pelvis or cephalopelvic disproportion, antepartum hemorrhage,

unsatisfactory CTG, severe IUGR, active genital herpes, pelvic tumors, and patients with bronchial asthma were excluded from the study. The patients selected for the study, after informed consent had been obtained were evaluated initially by modified Bishop's score and admission test for fetal safety. Patients with a modified bishops score ≤ 5 and a positive admission test was induced. In total 66 patients with an indication for labor, induction received 50 μ g of intravaginal misoprostol and repeated for a maximum of 3 doses every 6 hours as needed. On the other hand, 66 patients with an indication for induction of labor received 0.5mg intracervical dinoprostone gel and repeated for a maximum of 3 doses every 6 hours as needed. After drug insertion, patients were monitored for signs of labor, maternal vital signs, fetal heart rate, and progress of labor. The fetal heart rate was monitored by intermittent auscultation. In the absence of adequate uterine contractions after 6 hrs, oxytocin was started depending on the modified Bishop's score. of the last dose, or for augmentation of labor in case of an arrest of dilation. Oxytocin was started at the dose of 5 units in 500ml RL in Prim gravida and 2.5 units in 500ml RL in multigravida and titrated accordingly. Membranes were ruptured when the cervix was completely effaced with a cervical dilatation of more than 3 cms or at the onset of the active stage of labor. In results generation, statistical analysis by students 't' test, odds ratio, chi-square test, and a 'p' value of < 0.05 was considered as significant. As definition induction was considered 'failed induction' if contractions did not start or if bishop score did not increase at end of 24 hours. Without fetal heart rate (FHR) changes for 2 consecutive 10 minute periods, tachysystole was defined as more than 5 uterine contractions per 10 minutes. By fetal heart rate decelerations or tachycardia, hyperstimulation was defined as exaggerated uterine response accompanied.

RESULTS

Table 1: Distribution of cases by parity between study groups (n=132)

Parity	Dinoprostone		Misoprostol	
	n	%	n	%
Multi	28	42.42	30	45.45
Primi	38	57.58	36	54.55
Total	66	100	66	100

Table 2: Distribution of cases by gestation age between study groups (n=132)

Gestation age	Dinoprostone		Misoprostol		P value
	n	%	n	%	
<37 weeks	8	12.12	6	9.09	0.731
37-40 weeks	22	33.33	40	60.61	
>40 weeks	36	54.55	20	30.30	
Total	66	100	66	100	

Farhad et al; Intra-Vaginal Misoprostol and Intra-Cervical Dinoprostone Gel for Induction of Labor

Table 3: Distribution of cases by number of doses required

Doses	Dinoprostone		Misoprostol		P value
	n	%	n	%	
Dose 1	37	56.06	23	34.85	0.430
Dose 2	29	43.94	37	56.06	
Dose 3	0	0.00	6	9.09	
Total	66	100	66	100	

Table 4: Distribution of cases by Modified Bishop's Score between study groups

Modified Bishop's Score	Dinoprostone		Misoprostol	
	n	%	n	%
3	49	74.24	40	60.61
4	17	25.76	26	39.39
Total	66	100	66	100

Table 5: Distribution of cases by mode of delivery between study groups

Mode of Delivery	Dinoprostone		Misoprostol	
	n	%	n	%
CS	21	31.82	23	34.85
VD	45	68.18	43	65.15
Total	66	100	66	100

Table 6: Mean induction delivery interval between study groups

Mean induction delivery interval	Dinoprostone	Misoprostol	P value
Mean \pm SD	9.89 \pm 8.44	8.17 \pm 6.05	0.181

Table 7: Distribution of cases by side-effects between study groups

Side Effects	Dinoprostone		Misoprostol		P value
	n	%	n	%	
Fever	5	7.58	2	3.03	
Transplacental haemorrhage (TPH)	5	7.58	0	0.00	0.042
Vomiting	3	4.55	1	1.52	
Antepartum hemorrhage (APH)	2	3.03	0	0.00	
Turner syndrome (TS)	1	1.52	4	6.06	
Hidradenitis suppurativa (HS)	0	0.00	8	12.12	
Diarrhoea	0	0.00	5	7.58	
Chills	0	0.00	13	19.7	
Total	16	24.24	33	50.00	

In this study, in Dinoprostone group 42.42% participants were with multi parity whereas in Misoprostol group it was 45.45%. In Misoprostol group 57.58% participants were with primi parity whereas in Misoprostol group it was 54.55%. In analyzing the gestation age between study groups we observed, in Dinoprostone group in 12.12%, 33.33% and 54.55% participants the gestation age were found <37, 37-40 and >40 weeks respectively. On the other hand, in Misoprostol group in 9.09%, 60.61% and 30.30% participants the gestation age were found <37, 37-40 and >40 weeks respectively. Here the P value was 0.731. In analyzing the required doses between study groups we observed, in Dinoprostone group in 56.06%, 43.94% and 0.00% participants the

required doses were found 1, 2 and 3 doses respectively. On the other hand, in Misoprostol group in 34.85%, 56.06% and 9.09% participants the required doses were found 1, 2 and 3 doses respectively. Here the P value was 0.430. According to the Modified Bishop's Score we observed, in Dinoprostone group in 74.24% and 25.76% participants the Modified Bishop's Score were found 3 and 4 respectively. On the other hand, in Misoprostol group in 60.61 and 39.39% participants the Modified Bishop's Score were found 3 and 4 doses respectively. According to the mode of delivery we observed, in Dinoprostone group in 31.82% and 68.18% participants the mode of delivery was CS (Cesarean section) and VD (Vaginal delivery) respectively. On the other hand, in Misoprostol group in 34.85% and 65.15% participants the mode of delivery was found 3 and 4 doses respectively. In this study the mean induction delivery interval was 9.89 \pm 8.44 hours in Dinoprostone group whereas it was 8.17 \pm 6.05 hours in Misoprostol group. The p value was 0.181. Finally, in analyzing the side-effects between study groups we observed in Dinoprostone group as the side-effects antepartum hemorrhage(APH) 3.03%, diarrhea 0.0%, fever 7.58%, hidradenitis suppurativa (HS) 0.0%, transplacental haemorrhage (TPH) 7.58%, turner syndrome(TS) 1.52%, vomiting 4.55% and chills were found 0.0% in the participants respectively. On the other hand, in Misoprostol group as the side-effects antepartum hemorrhage (APH) 0.0%, diarrhea 7.58%, fever 3.03%, hidradenitis suppurativa(HS) 12.12%, transplacental haemorrhage (TPH) 0.0%, turner syndrome(TS) 6.06%, vomiting 1.52% and chills were found 19.7% in the participants respectively. In side effect assessment we found significant correlation between the groups where the p value was found 0.042.

DISCUSSION

The aim of this study was to compare the safety and efficacy of intravaginal misoprostol with intra-cervical dinoprostone gel for induction of labor. The introduction of prostaglandins to clinical practice, particularly their local use for cervical ripening, has reduced major difficulties of major induction. The duration between induction and delivery has been decreased dramatically by the introduction of prostaglandins. Similarly, it also decreased associated complications of amnionitis and fetal infection. The baseline data of our study population including maternal age, gravidity, and gestational age were compared with similar studies.^[6,7] In this study there was no significant difference between the primigravida and the multigravida in both the groups regarding the time taken for onset of labor. In this study, the mean induction to the delivery interval was less in the misoprostol group (8.17 \pm 6.05 hours). Similar results were seen in a study in 2003 by

Farhad et al; Intra-Vaginal Misoprostol and Intra-Cervical Dinoprostone Gel for Induction of Labor

Agarwal et al⁸ where it was $(12.8 \pm 6.4\text{hrs}$ v/s $18.53 \pm 8.5\text{hrs}$) and in a study in 2017 by Yadav S et al ($5.39 \pm 2.97\text{hrs}$ vs $10.88 \pm 7.33\text{hrs}$ respectively).⁹ In 2003 Garry D et al and in 2014 Liu A et al, also concluded in their study that the interval between from start of induction to vaginal delivery was significantly shorter in the Misoprostol group.^[10] Thus Misoprostol reduces the mean duration of labor which reduces the period of suffering of a patient in labor and also ensures fast delivery. In the present study, indications for induction in the Misoprostol group were post-date pregnancy in 24.24% and PIH and preeclampsia in 31.81% whereas in the Dinoprostone group 34.85% and 19.70% respectively induced for postdate and PIH and Preeclampsia. Thus, majority of induction was due to these two conditions. In the present study oxytocin augmentation required in 10 patients in the Misoprostol group and in 11 patients in the Dinoprostone group. In a study by Herabutya et al, oxytocin augmentation required in 35% and 34% of patients in the Misoprostol group and Dinoprostone group respectively.^[11] In this study, according to the mode of delivery we observed, in the Dinoprostone group in 31.82% and 68.18% participants the mode of delivery was CS (Cesarean section) and VD (Vaginal delivery) respectively. On the other hand, in the Misoprostol group in 34.85% and 65.15% of participants, the mode of delivery was found 3 and 4 doses respectively. In the present study, in the Misoprostol group, out of 5 patients who underwent cesarean section only 1 was for the failure of induction whereas in the Dinoprostone group 7 out of 11 patients were operated for cesarean section due to failure of induction which was consistent with the study by Patil K et al and Bhaskar M et al.^[6] Finally in analyzing the side-effects between study groups we observed in Dinoprostone group as the side-effects antepartum hemorrhage (APH) 3.03%, diarrhea 0.0%, fever 7.58%, hidradenitis suppurativa (HS) 0.0%, transplacental hemorrhage (TPH) 7.58%, Turner syndrome (TS) 1.52%, vomiting 4.55% and chills were found 0.0% in participants respectively. On the other hand, in the Misoprostol group as the side-effects, antepartum hemorrhage (APH) 0.0%, diarrhea 7.58%, fever 3.03%, hidradenitis suppurativa (HS) 12.12%, transplacental hemorrhage (TPH) 0.0%, Turner syndrome (TS) 6.06%, vomiting 1.52%, and chills were found 19.7% in participants respectively. In side effect assessment we found a significant correlation between the groups where the p-value was found 0.042. Uterine hyperstimulation is when either of these conditions (hypertonus v/s tachysystole) leads to a non-reassuring fetal heart rate pattern. Because of the frequency of tachysystole with vaginal administration of Misoprostol, some researchers are studying oral and sublingual /buccal routes to determine if effectiveness can be maintained while decreasing the incidence of tachysystole. The neonatal outcomes in both groups were similar.

Mundle and Younge evaluated the effect of Misoprostol for labor induction on neonatal admission.^[12]

CONCLUSION

Regarding the parity, gestation age, number of required doses of induction, Modified Bishop's score, mode of delivery, delivery interval we did not find any significant correlation between the groups of Misoprostol and Dinoprostone. But considering the side effects of those procedures we found some superiority of Dinoprostone over Misoprostol. So considering the side effects Dinoprostone gel may be better choice than Intra-Vaginal Misoprostol as induction. This was a single centered study with limited sample size. So the findings of this may not reflect the exact scenario of the whole country.

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Farhad et al; Intra-Vaginal Misoprostol and Intra-Cervical Dinoprostone Gel for Induction of Labor

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