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RESEARCH ARTICLE

A comparative study between oral misoprostol and intracervical dinoprostone gel for induction of labour at term in primigravida

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ABSTRACT

Objectives: To compare the safety and efficacy of oral misoprostol with intracervical dinoprostone gel in terms of progress of labour, maternal and fetal complications when used for induction of labour at term in primigravida. **Materials and method**: A prospective randomized study from October 2017 to October 2019 was carried out in which 120 primigravida patients with gestational age from 37 to 41 weeks with an indication for induction of labour were randomly divided into 2 groups. In group 1, multiple doses of oral misoprostol (50mcg 4 hourly, maximum up to 6 doses) and in group 2, intracervical dinoprostone gel (0.5mg 6 hourly maximum up to 4 doses) was given for induction of labour. Progress of labour, need for oxytocin augmentation, mode of delivery, maternal and fetal outcome were compared in both groups. **Results:** Our study showed that in the misoprostol group, 8 (18.2%), 31(43.7%) and 5 (11.4%) patients had induction to delivery time interval of <12 hours, 12-24 hours and >24 hours respectively in comparison with patients in the dinoprostone group where 17(28.3%), 22(36.7%) and 3(5%) patients had induction to delivery time interval of <12, 12 to 24 and >24 hours respectively. The mean induction to delivery interval was significantly higher in the misoprostol group on comparison with the dinoprostone group (18.06 ± 5.64 vs 15.11 ± 6.99 hours) (p - value < 0.05). However, no statistically significant difference was seen concerning to maternal and fetal complications, mode of delivery and need for oxytocin augmentation in between the two groups. **Conclusion:** Our study showed that intracervical dinoprostone gel shortens the induction to delivery interval significantly when compared with oral misoprostol. However, no statistically significant difference was seen in maternal and fetal complications and the need for oxytocin augmentation in between the groups.

Keywords: Misoprostol, dinoprostone, oxytocin, cesarean section.

Induction of labour implies stimulation of uterine contractions before the spontaneous onset of labour, with or without ruptured membranes.[1] Successful induction aims to achieve vaginal delivery and reduce cesarean section rates. The fetus should be delivered in a good condition with minimal maternal side effects.[2] The success of induction of labour is depended on the cervical status at the time of induction. It was shown that increased rates of cesarean sections, failed induction and fetal asphyxia is associated with low bishop score.[3,4] Various methods of induction of labour includes administration of prostaglandins, prostaglandin analogs, oxytocin, and mechanical procedures like amniotomy, foley's catheter, etc.[5]

Prostaglandin preparations are well known and widely accepted for inducing labour. Dinoprostone which is a prostaglandin E2 analog was approved for medical use by food and drug administration (FDA), the USA in 1977.[6]

Misoprostol which is a prostaglandin E1 analog can be

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administered through vaginal, oral, and sublingual routes. It is cost-effective and can be stored at room temperature.[7]

Methodology

We conducted a prospective randomized study from October 2017 to October 2019 in which 120 primigravida patients with gestational age from 37 to 41 weeks with an indication for induction of labour fulfilling the inclusion criteria of a singleton viable pregnancy with cephalic presentation, adequate pelvis, intact membranes, bishop score of <5, reactive nonstress test and normal obstetric doppler and biophysical profile in high-risk patients like gestational diabetes mellitus, intrauterine growth retardation, pregnancy-induced hypertension. Patients were randomly divided into 2 groups after a detailed history and clinical examination. Randomization was done as per even and odd method where patients with even number where included in the misoprostol group and patients with odd number where included in the dinoprostone group.

In group 1, patients received oral misoprostol 50 mcg every 4 hourly maximum up to 6 doses, and in group 2, patients received intracervical dinoprostone gel 0.5mg every 6 hourly maximum up to 4 doses for induction of labour. Fetal heart rate, uterine activity, and progress of labour were regularly monitored. Repeat dose of oral misoprostol or dinoprostone gel was given until there was adequate uterine activity or spontaneous rupture of membranes or P/V finding was suggestive of active labour (minimum 3 cm cervical dilatation with >60% effacement). Before each dose of prostaglandin, NST, bishop score, and uterine activity were assessed. In the active stage of labour, augmentation was done with the help of oxytocin infusion, but only after an appropriate time interval from the last dose of prostaglandin (6 hours for dinoprostone and 4 hours for misoprostol) to avoid uterine hyperactivity. A cesarean section was performed at any stage of labour for maternal and fetal indications and in failed induction (failure to enter into active labour after 24 hours of the first dose or maximum prescribed doses).

Following parameters in both the groups was noted and compared statistically:

- Duration of latent phase and induction to delivery interval
- Intrapartum and postpartum maternal complications
- Intrapartum fetal complication
- Need for oxytocin augmentation during the course of labour
- Mode of delivery
- Neonatal outcome

Quantitative data is presented with the help of mean and standard deviation. Association among the study groups is assessed with the help of fisher test, student 't' test and chi-square test. P value less than 0.05 is taken as significant. Appropriate statistical software, including but not restricted to MS Excel SPSS ver.20 was used for statistical analysis.

Results

There was no significant difference in the mean duration of the latent phase in groups 1 and 2 (11.45 ± 4.039 vs 10.36 ± 3.87 hours) as per the student t-test (p >0.05). As shown in table 1, the mean induction to the delivery interval was significantly higher in the misoprostol group as compared to the dinoprostone group (18.06 ± 5.64 vs 15.11 ± 6.99 hours) according to student t-test (p<0.05).

Table 1: Comparison of induction to delivery interval between groups

Induction delivery interval	Group 1 (Misoprostol)		Group 2 (Dinoprostone)		P Value*
	N	%	N	%	
<12 hours	8	18.2%	17	28.3%	<0.05 (significant)
12-24 hours	31	43.7%	22	36.7%	
>24 hours	5	11.4%	3	5%	
Total	44	73.3%	42	70%	
Mean ± SD	18.06 ± 5.64		15.11 ± 6.99		
*p value – significant if it is <0.05					

Table 2: Need for oxytocin for augmentation of labour

Oxytocin augmentation	Group 1 (Misoprostol)		Group 2 (Dinoprostone)		P Value*
	N	%	N	%	
Required	40	66.7%	36	60%	>0.05 (Not significant)
Not Required	20	33.3%	24	40%	
Total	60	100%	60	100%	
*p value – significant if it is <0.05					

As shown in table 2, 40(66.7%) patients in group 1 and 36(60%) patients in group 2 required oxytocin for augmentation of labour. However, the difference between the groups was statistically not significant as per the chi-square test (p-value >0.05). No significant difference was seen between the groups concerning maternal and intrapartum fetal complications as per the chi-square test (p-

Table 3: Comparison of intrapartum and postpartum maternal complications

Maternal complications	Intrapartum		P value*	Maternal complications	Postpartum		P value*
	Group 1	Group 2			Group 1	Group 2	
Vomiting	5(8.30%)	8(13.3%)	>0.05	Postpartum hemorrhage	2(3.30%)	2(3.30%)	>0.05
Diarrhea	3(5%)	3(5%)		Cervical tear	2(3.30%)	3(5%)	
Tachysystole	2(3.33%)	2(3.33%)		Perineal tear	1(1.60%)	2(3.30%)	
Hyperstimulation	0	2(3.33%)					
*P value – significant if it is <0.05							

value >0.05) (table 3, 4). As shown in table 5, no significant difference was seen between the misoprostol group and the dinoprostone group as per the chi-square test (p-value >0.05).

Table 4: Comparison of intrapartum fetal complication between the groups

Intrapartum Fetal complications	Group 1 (Misoprostol)		Group 2 (Dinoprostone)		P value*
	N	%	N	%	
Fetal distress	10	16.7%	8	13.33%	>0.05
Meconium stained liquor	12	20%	7	11.67%	(Not significant)

*p value – significant if it is <0.05

Table 5: Comparison of mode of delivery between the groups

Mode of delivery		Group 1 (Misoprostol)		Group 2 (Dinoprostone)		P Value*
		N	%	N	%	
Vaginal	Spontaneous	38	63.3%	37	61.7%	>0.05 (Not significant)
	Instrumental	6	10%	5	8.3%	
LSCS		16	26.7%	18	30%	
Total		60	100%	60	100%	

*p value – significant if it is <0.05

In the misoprostol and dinoprostone group, the mean APGAR score at 1 min was 7.78 ± 0.66 & 7.68 ± 0.77 respectively. However, the APGAR score at 5 mins was 8.88 ± 0.32 & 8.91 ± 0.27 respectively. 11 neonates from the misoprostol group and 16 neonates from the dinoprostone group required NICU admission. No statistically significant difference was seen concerning neonatal outcomes in both groups.

Discussion

In our study, we found that patients who were induced with intracervical dinoprostone gel had a shorter induction to delivery interval than patients who were induced with oral misoprostol. However, no significant difference was seen between the 2 groups with regards to maternal and fetal complications.

In this study, we found no significant difference in the duration of the latent phase in both groups (11.45 ± 4.039 vs 10.36 ± 3.87 hrs). Langenegger EJ et al [8] conducted a similar study between oral misoprostol and intracervical dinoprostone gel and found no statistically significant difference between the mean time interval from induction to artificial rupture of membranes in both the groups.

In our study, we found a statistically shorter duration of induction to the delivery interval in the dinoprostone group when compared with the misoprostol group. Balasubramaniyan R et al [9] conducted a similar study comparing the effects of oral misoprostol with cerviprime gel for induction of labour and found that cases induced with misoprostol had a longer induction to the delivery interval when compared to dinoprostone. Langenegger EJ et al [8] in their study found that the difference between the meantime from induction to delivery was not statistically significant between the oral misoprostol and intracervical dinoprostone group (1322 mins vs 1448 mins).

No statistically significant difference was seen between the 2 groups concerning oxytocin requirement for augmentation of labour in this study. Langenegger EJ et al [8] found that 12(13%) and 8(8%) patients required oxytocin for augmentation in the misoprostol and dinoprostone groups respectively. However, Veena B et al [10] in their study found that 62.1% in the PGE2 group and 46.3 % in the PGE1 group required oxytocin or artificial rupture of membranes for augmentation of labour, and the difference between the groups was found to be statistically significant.

In our study, no significant difference was found between the 2 groups concerning intrapartum and postpartum maternal complications. Langenegger EJ et al [8] in their study found that there was no significant difference in both the groups in the incidence of intrapartum and postpartum maternal complication. However, Yadav S et al [11] reported a higher incidence of tachysystole in the misoprostol group as compared to the dinoprostone group (22% vs 10%). However, the difference was statistically not significant. Parmar et al [12] in their study found minimal maternal side effects in both misoprostol and cerviprime gel group.

In this study, no significant difference in the intrapartum fetal complication was found between the 2 groups. A similar study conducted by Balasubramaniyan R et al [9] found that there was a 2% incidence of meconium-stained amniotic fluid in both the groups and there was no statistically significant difference between the 2 groups concerning the neonatal outcome. Langenegger EJ et al [8] found a nonsignificant increased incidence of meconium-stained amniotic fluid (19 vs 8) in the misoprostol group compared to the dinoprostone group respectively. Veena B et al [10] in their study found that 27 mothers had fetal-related complications out of which 7.3% (7/95) were from the PGE1 group and 21% (20/95) were from the PGE2 group.

In our study, no significant difference in the mode of delivery was seen between the 2 groups. Also in a study conducted by Langenegger EJ et al [8], they found that no significant difference was seen in the number of vaginal deliveries within 24 hrs between the 2 groups. Similarly, Windrim et al [13] found no significant difference in the mode of delivery between the misoprostol group and the control group. However, a study conducted by Balasubramaniyan R

et al [9] reported a higher incidence of vaginal delivery in the dinoprostone group (84%) as compared to the misoprostol group (74%).

In this study, no significant difference is seen in the neonatal outcome between the groups. Langenegger EJ et al [8] as well as Balasubramaniyan R et al [9] in their study, found no significant difference between the 2 groups concerning neonatal outcome in both the groups. Also, Kalpana et al [14] found no significant difference in the mean APGAR score at 1 min and 5 min in both the groups.

Conclusion

Our study showed that intracervical dinoprostone gel shortens the induction to delivery interval significantly when compared with oral misoprostol. However, no statistically significant difference was seen in maternal and fetal complications and the need for oxytocin augmentation in between the groups.

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

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