Journal of Indian Academy of Obstetrics and Gynaecology January 2023

Vol. 4, Issue 2

Original Article

COMPARISON OF EFFICACY OF DINOPROSTONE AND MISOPROSTOL IN INDUCTION OF LABOUR

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ABSTRACT

Introduction: Induction of labour denotes the artificial initiation of regular uterine contractions before spontaneous onset of labour with progressive dilatation and effacement of cervical and subsequent vaginal delivery of the baby. Labour induction is usually indicated when benefits of delivery to the mother or fetus outweigh the potential risks of continuing the pregnancy. Labour usually starts spontaneously in most of pregnant women at or near-term pregnancy and result in vaginal deliveries.

Aims and objectives: Aim of the study is to evaluate efficacy of misoprostol in comparison with dinoprostone for labour induction in term pregnant women.

Materials and methods: The study was carried out over 100 pregnant women admitted to the labour ward beyond 37 weeks of gestation, requiring induction of labour for various medical and obstetrical indications, in the department of Obstetrics and Gynaecology, Silchar medical college & hospital from 1st June 2021 to 1st June 2022. The participants were divided into two Groups-I and Group-II. Group-I, choosing the patients randomly. In Group-I, 50 patients received 25 µg Misoprostol per vaginally and in Group-II, 50 patients received Dinoprostone gel 0.5 mg endocervically.

Results: In Group-I, 25 cases (50%), Bishop score were ≥10/13 at 8 hrs. after induction of labour and in Group-II, 23 cases (46%), Bishop score were ≥10/13, (P= 0.3702). In Group-I, 43 cases had taken <6 hrs. interval for onset of labour and in Group-II, 24 cases had taken <6 hours interval to onset of labour. (P<0.0001).

Induction to delivery interval less in misoprostol group (mean ± S.D) 14.36±4.39 hours than dinoprostone group 16.68±4.43 hrs. (P=0.085). There was no significant difference in neonatal complication and NICU admission among both the study groups.

Conclusion: From the present study, it can be concluded that the tab. Misoprostol 25 µg pervaginal is more effective in comparison to Dinoprostone 0.5 mg endocervical for induction of labour with respect to the induction to onset of labour interval and induction to delivery interval.

Keywords: Misoprostol, Dinoprostone, Induction of labour.

INTRODUCTION

Induction of labour denotes the artificial initiation of regular uterine contractions before spontaneous onset of labour with progressive dilatation and effacement of cervical and subsequent vaginal delivery of the baby.[1] Labour usually starts spontaneously in most of pregnant women at or near-term pregnancy and results in vaginal deliveries. Labour induction is usually indicated when the benefits of delivery to the mother or fetus outweigh the potential risks of continuing the pregnancy[2]. Most common indications of labour are postdated pregnancy, pregnancy induced hypertension, draining pervaginum, intrauterine growth restriction, intrauterine fetal death. Labour induction may successfully end up in normal course of labour and vaginal delivery or it may end up in surgical intervention like caesarean section.[3] Induction of labour with prostaglandins offers the advantage of promoting cervical ripening while stimulating myometrial contractility.[4] Prostaglandins alter the extracellular ground substance of the cervix and also increase the activity of collagenase in the cervix which help to ripen the cervix. They also allow for increases in intracellular calcium levels, causing contraction of myometrial muscle.[5,6] Dinoprostone is a synthetic preparation of naturally occurring prostaglandin E_2. Dinoprostone gel is available in 2.5 ml syringe for an endocervical application of 0.5 mg of Dinoprostone.[7] Misoprostol, a synthetic prostaglandin E_1, initially was used for prophylaxis treatment in NSAID induced peptic ulcers. One of its "side effects" was the induction of uterine contraction during pregnancy and early pregnancy abortion. Thereafter, misoprostol was used for termination of first trimester pregnancy. It is stable at room temperature, low cost, and ease of oral sublingual and pervaginum administration. It is available as tablets of 25, 50, 100, 200 µg.

So, the present study is conducted with an aim of comparison of efficacy between the two drugs, i.e. vaginal misoprostol and endocervical dinoprostone administration in pregnant women with singleton pregnancy with vertex presentation at term pregnancy.

MATERIALS AND METHODS

This was a prospective analytic study carried out in the department of Obstetics and Gynaecology of Silchar Medical College & Hospital, Silchar, Assam, in the period of 1st June 2021 to 31st May 2022, over 100 pregnant women admitted to the labour ward beyond 37 weeks of gestation and requiring induction of labour for various medical and obstetrical indications. Induction of labour done with 25µg of misoprostol intravaginally and 0.5mg of dinoprostone gel endocervically with definite indication for vaginal delivery in primigravida at 37-42 weeks of gestation with vertex presentation with singleton pregnancy.

INCLUSION CRITERIA

Primigravida with 37 or more weeks of gestation with Singleton gestation with Cephalic presentation, having indication of vaginal delivery will be included in the study.

EXCLUSION CRITERIA

Previous uterine surgery, Multigravida, Multiple pregnancy, Placenta previa, Malpresentations, Abnormal fetal heart rate, Chorioamnionitis, Cephalopelvic disproportion,

STUDY APPROVAL

The study protocol was approved by the Ethical Committee of Srimanta Sankaradeva University of Health & Sciences, Assam. Patient or their family member was informed and written consent was taken for the same.

METHOD OF COLLECTION OF DATA

All the participants were selected from the patients admitted in the medical labour room for induction of labour. The participants and their family members were fully informed about the study and written consent was taken from the participants or their family members in the study. Participants were selected on the base of the inclusion and exclusion criteria. Detailed history, clinical examination and investigation

of all the participants were done.
The participants were divided into two groups, Group I & Group II selecting the patients randomly for Group I & Group II. Each group was having 50 participants.
Group I: Participants were received Tab. Misoprostol 25µgm per vaginally in posterior fornix and whenever needed more doses Tab. Misoprostol 25 µgm were given at 4 hours interval for maximum 5 doses.
Misoprostol doses were repeated till: 1) maximum 5 doses of misoprostol or 2) onset of adequate uterine contraction
Group II: Pregnant women were instilled intracervical Dinoprostone gel 0.5 mg and whenever more doses needed were given at 6 hours interval for maximum 3 doses.
Instillation of Dinoprostone was repeated till: 1) maximum 3 doses of dinoprostone or 2) onset of adequate uterine contraction

Monitoring of mother: Monitoring of the maternal vitals, were done.
Monitoring of the fetus: Fetal heart rate auscultation were done at 30 minutes interval in 1st stage and at 15 minutes interval in 2nd stage of labour.
After birth APGAR score were recorded at 1 minute and 5 minutes.
Monitoring of labour: P/V Examination was done as per protocol of partographic monitoring and was plotted in the partograph paper.
Particulars of delivery and Baby were recorded.
Mother and baby were observed for postnatal complications if any.

OPERATIONAL DEFINITIONS

Onset of labour: Defined as at least 3 regular uterine contractions in 10 minutes, each lasting for at least 40 seconds.
Successful induction: Vaginal delivery within 24 hours were taken as successful induction.
Failed induction: Adequate uterine contraction was not established after 6 hours of 5th dose of misoprostol and after 6 hours of 3rd doses of dinoprostone.
Uterine hypersystole: Each uterine contraction lasting for more than 2 minutes.
Uterine tachysystole: more than 5 uterine contractions in a 10 minutes interval.
Uterine hyperstimulation: Both uterine hypersystole and tachysystole cumulatively is known as uterine hyperstimulation associated with fetal distress.
Patients who achieved labour were examined and according to the presence or absence of membrane and meconium staining of liquor, the needful intervention was taken according to the institutional protocol as per the clinical assessment of the patients at that time which would include amniotomy or caesarean section. Successful inductions were considered for comparison of efficacy, NICU admissions were considered for comparison of fetal outcome. In all patients, the cervical status was assessed by using modified Bishop Score to induction.

STATISTICAL ANALYSIS

Statistical analysis was done by using descriptive and inferential statistics using Z-test for single proportion. Suitable software was used for descriptive statistics and others statistical analysis. Level of significance were at 5%.

RESULTS

Most of the participants of both the comparison Groups were between the maternal ages of 20 and 30 years. In misoprostol Group, 45 cases were in this age group and in dinoprostone Group, 44 cases were in this age group. There was not much significant difference in Mean age in both Groups (23.34±3.263 years vs. 23.33±3.462years) (Table 1). In misoprostol Group, 41 cases were >40 weeks of gestational age and in dinoprostone group, 39 cases were >40 weeks of gestational age. (p=0.6171) (Table 2). In both Groups, the indication of induction of labour in most of cases were decided for postdated pregnancy. In misoprostol group, 31 cases (62 %) were postdated pregnancy and in dinoprostone group, 26 cases (52%) were postdated pregnancy. (P=0.7741) (Table 3).
There was no significant difference in pre-induction Bishop Score of the cervical assessment of participants of both misoprostol and dinoprostone group. In misoprostol group, 30 cases (60%) the pre-induction Bishop score were 3/13, in dinoprostone group, 32 cases (64%) the

pre-induction Bishop score were 3/13. (P=0.7181) (Table 4).

The participants of misoprostol group took less time interval for onset of labour than dinoprostone group. In misoprostol group, 43 cases took <6 hrs. interval for onset of labour and in dinoprostone group 24 cases took <6 hours interval to onset of labour (P<0.0001) (Table 5).

Bishop Score of participants at 8 hours after induction of labour were more in misoprostol group than dinoprostone group. In misoprostol group, 25 cases (50%), Bishop score were ≥10/13 at 8 hrs. after induction of labour and in dinoprostone group, 23 cases (46%) Bishop score were ≥10/13 (P= 0.3702) (Table 6).

The participants of misoprostol group took less time for induction to delivery interval than dinoprostone group. The misoprostol group took (mean ± S.D) 14.36±4.39 hours and dinoprostone group took 16.68±4.43 hrs. (P=0.085) (Table 7).

Normal vaginal delivery achieved in 39 cases (78%**) of** dinoprostone group, and **in 37** cases (74%) of misoprostol group. Emergency LSCS intervention required for 11 cases (22%) of Dinoprostone and 13 cases (26%) of misoprostol (P=0.6396) (Table 8).

There was no significant difference in side effect of both the drugs. PPH occurred in 2 cases in misoprostol group and 3 cases in dinoprostone group. (p=0.5718) (Table 9).

There was no significant difference in APGAR score at 1minute and 5 minutes of the babies after birth in both the study groups. ($P_{1=}$ 0.8150 and $P_{5=}$ 0.9746) (Table 10).

There was no significant difference in neonatal complication and NICU admission among both the study groups. In misoprostol group, 7 babies admitted in NICU for meconium-stained liquor and in dinoprostone group, 4 babies were admitted in NICU for meconium-stained liquor. (P=0.6516) (Table 11).

Table 1: Comparison of Maternal Age.

Age (in years)	Misoprostol (N=50)		Dinoprostone (N=50)	
	No. of cases	Percentage	No. of cases	Percentage
14-19	4	8	5	10
20-25	35	70	33	66
26-30	10	20	11	22
31-36	1	2	1	2
Mean age± SD (yrs)	23.34±3.263		23.33=3.462	

Table 2: Comparison of Gestational Age.

Gestational age (in weeks)	Misoprostol		Dinoprostone		P value
	No. of cases	Percentage	No. of cases	Percentage	
37-40	9	18	11	22	0.6171
>40	41	82	39	78	
Total	50	100	50	100	

Table 3: Comparison of Indications for Induction of Labour.

Indications for Induction	Misoprostol (N=50)		Dinoprostone (N=50)		P value
	No. of cases	Percentage	No. of cases	Percentage	
Postdated	31	62	26	52	0.7741
PIH	8	16	11	22	
Draining PV	9	18	11	22	
APE	2	4	2	4	
Total	50	100	50	100	

Table 4: Comparison of Pre-induction Bishop Score.

Initial Bishop Score	Misoprostol group		Dinoprostone gel group		P value
	No. of cases	%	No. of cases	%	
1	1	2	2	4	0.7181
2	8	16	10	20	
3	30	60	32	64	
4	9	18	5	10	
5	2	4	1	2	
Mean ± SD	3.06±0.77		2.86±0.73		

Table 5: Comparison of Induction to Onset of Labour Interval.

Time in IOL (In hrs.)	Group I No. (%)	Group II No. (%)	Total No. (%)	P value
≤6	43 (86%)	24 (48%)	67 (67%)	<0.001
>6	7 (14%)	26 (52%)	33 (33%)	
Total	50(100%)	50 (100%)	100 (100%)	

Table 6: Comparison of Bishop Score after 8 hours.

After 8hrs Bishop Score	Misoprostol group		Dinoprostone gel group		P value
	No. of cases	%	No. of cases	%	
<4	0	0	0	0	0.3702
4-5	4	8	10	20	
6-7	9	18	8	16	
8-9	12	24	9	18	
≥10	25	50	23	46	
Mean ± SD	8.82±1.97		8.3±237		

Table 7: Comparison of induction to delivery interval.

Interval (hours)	Misoprostol (N=50)		Dinoprostone (N=50)		P value
	No. of cases	Percentage	No. of cases	Percentage	
7-10	10	20	3	6	0.0851
11-14	23	46	18	36	
15-18	9	18	19	38	
19-22	5	10	6	12	
23-26	3	6	4	8	
Mean ± S.D	14.36±4.39		16.68±4.43		

Table 8: Comparison of Mode of delivery.

Mode of delivery	Misoprostol (N=50)		Dinoprostone (N=50)		P value
	No. of cases	Percentage	No. of cases	Percentage	
Vaginal	37	74	39	78	0.6396
Caesarean section	13	26	11	22	
Total	50	100	50	100	

Table 9: Comparison according to Maternal Complication

Side effects	Misoprostol		Dinoprostone		P value
	No. of cases	%	No. of cases	%	
Vomiting	0	0	1	2	0.5718
Diarrhoea	3	6	1	2	
Shivering	1	2	0	0	
Pyrexia	1	2	0	0	
Hypersti mulation	1	2	0	0	
Tachysyst ole	1	2	0	0	
PPH	2	4	3	6	

Table 10: Comparison of APGAR score in study groups

Neonatal outcome		Misoprostol		Dinoprostone		P value
		No. of cases	%	No. of cases	%	
APGAR at 1 minute	≤7	17	34	19	38	0.8150
	>7	33	66	31	62	
APGAR at 5 minutes	≤8	23	46	22	44	0.9746
	>8	27	52	28	56	

Table 11: Comparison of indication for NICU Admission.

Indication for NICU Admission	Misoprostol		Dinoprostone		P value
	No. of cases	%	No. of cases	%	
Birth asphyxia	1	2%	1	2%	0.6516
LBW	3	6%	3	6%	
Meconium stained	7	14%	4	8%	
RDS	0	0	1	2%	
Total	11	22%	9	18%	

DISCUSSION

The present study was an analysis of the maternal and fetal outcome in 100 cases of induction of labour with 25 µg vaginal misoprostol and 0.5 mg endocervical dinosprostone gel in primi gravida at 37-42 weeks of gestation with singleton gestation with vertex presentation with indication of labour with postdated pregnancy, draining PV, pregnancy induced hypertension and antepartum eclampsia in the Silchar Medical College & Hospital, Silchar, Assam.

The induction of labour with the Prostaglandins dramatically decreased major difficulties of labour induction to clinical practice, especially their local use for cervical ripening and labour induction without majors' complication of mother and baby.

There was no statistically significant difference in baseline characteristics of age, height and weight in both groups. All the women were primigavida. Most of them were with the maternal age group 20 to 30 years in both the comparison groups. There was no significant difference in both the groups in respect of maternal age. Most of the women were in the period of gestation of more than 40 weeks in the both study groups. There was no significant difference regarding period of gestation of pregnancy in both the groups. Both groups were also in sync with the study of Olav Lapaire et al., (2007)[8] in terms of demographic and obstetric data such as maternal age, gravidity, parity and period of gestation. In the present study, postdatism was indication for induction of labour, 62% and 52% in group I and group II respectively followed by PIH in 16% cases in group I and 22% cases in group II. There was no significant difference in both groups regarding indication of induction of labour (P=0.7741). Greagsons et al.,[9] in their study also showed that 95% patients in misoprostol group and 94% in dinoprostone group were induced for postdatism. Similarly, C. N. Sheela et al.,[10] demonstrated that postdatism (36% and 32% respectively) and PIH (22% and 26% respectively) were most common indications in both groups. Dr. Ankita Mishra, et al.,[11] in their study reported that most common indication was post-dated pregnancies followed by pre-eclampsia, oligohydramnios, Rh-Negative pregnancy, IUGR, GDM in both the groups.

The pre-induction bishop score in 30 cases in the misoprostol group (60%) were 3/13, in dinoprostone group, 32 cases (64%) were 3/13. The mean pre-induction bishop score was 3.06±0.77 in the misoprostol group and 2.86±0.73 in the dinoprostone group. There was no significant difference in pre-induction bishop score of the cervical assessment of participants in both groups (P=0.7181). In the study of Olav Lapaire et al., (2007)[12] the bishop scores collected prior to induction of labour were not statistically different in both groups (P=0.33). Dr. Shefali Bansal (2016)[13] study had also the initial bishop Score in the range of 1 to 4 with mean induction bishop scores of 3.25 ± 0.44 and 3.14±0.68 for dioprostone gel and misoprostol group respectively.

The Bishop Score at 8 hours after induction of labour were more in misoprostol group than dinoprostone group. In misoprostol group, in 25 cases (50%), bishop score is ≥10/13 at 8 hrs. after induction of labour and in dinoprostone group, in 23 cases (46%), bishop score is ≥10/13, (P= 0.3702). B. H. Radhika, et al, (2013) reported that the mean Bishop score at the end of 8 hours and 16 hours of cervical ripening was almost similar in both the groups.

In this study, most of the participants took less time interval to onset of labour in misoprostol group than dinoprostone group. In misoprostol group, 43 cases take <6 hours interval to onset of labour and in dinoprostone group, 24 cases take <6 hours interval to onset of labour. There was statistically significant difference regarding the

onset of labour after induction of labour (P<0.0001). In the study of Swaran Gupta (2015)[14] also reported that in misoprostol group, majority of patients (90%) had gone into labour within six hours, whereas in dinoprostone 52% had gone into labour within 6 hours, the difference of time taken in the two groups was statistically significant (p<0.001)

The mean time had taken for induction to delivery interval was less in the misoprostol group (14.36±4.39 hrs) than in the dinoprostone group (16.68±4.43 hours) (P=0.0851). Gemund et al., (2004)[15] have reported longer induction delivery intervals in the misoprostol group than with dinoprostone (25 vs. 19 h, P = 0.008). Evangelos G et al., (2004)[16] in their study conducted on 163 eligible clients reported that the induction delivery interval was significantly lower in the misoprostol group than in the dinoprostone group (11.9 hrs vs. 15.5 hrs, p < 0.001). In the study of Murthy Bhaskar Krishnamurthy (2006)[17] induction delivery interval was shorter in the misoprostol group. Smiti Nanda et al., (2007) reported the mean induction delivery interval regardless of the route was shorter in the misoprostol group 13.30±8.74 (3–40.15) hours as compared with dinoprostone group, 18.53±11.33 (2–48.07) hours (P =0.011). Dr. Afia Ansar et al., (2014)[18] have reported the induction to delivery interval was 13.03+3.52 hours in misoprostol group while it was 14.12+3.31 hours in dinoprostone group. Swaran Gupta (2015)[14] reported that the mean induction delivery interval was 11.23 hours in misoprostol group and 18.5 hours in dinoprostone group, the difference of induction delivery interval was statistically significant (p=0.02). Ramya D, Jaju PB (2017)[19] reported that the mean induction delivery interval in dinoprostone is 10.29±7.19 hours. The mean induction delivery interval in misoprostol was 7.64±5.75 hours, (P value=0.014). Dr. Ankita Mishra, et al., (2020)[11] in their study found the mean induction delivery interval, mean±S.D was 11.8±2.03 hours in the misoprostol group and 15.54±2.63 hours in the dinoprostone group.

In our study 39 cases (78%) of the dinoprostone group proceeded for normal delivery and 11 cases (22%) required emergency LSCS intervention. In misoprostol group, 37 cases (74%) proceeded for normal delivery and 13 cases (26%) required emergency LSCS intervention. (P=0.6396). Olav Lapaire et al., (2007)[12] in their study found as a total of 78% (40/51) in the misoprostol group delivered by vaginal delivery as compared to 64% (30/47) in the dinoprostone group (P=0.123). Dr. Afia Ansar et al., (2014)[18] reported that out of 63 patients in the misoprostol group, 43 (67.1%) women had Normal vaginal delivery (NVD) while 26 (63.4%) patients out of 41 in dinoprostone group had NVD. Ankita Mishra et al., (2020)[11] found 42(84%) participants in misoprostol group and 40(80%) participants in dinoprostone group normal vaginal delivery occurred and 16% participants in misoprostol and 20 % participants in dinoprostone group underwent caesarean section.

In our study, there was no significant difference found in the side effect of both the drugs like maternal nausea, vomiting, pyrexia and hyprstimulation. In 2 cases of misoprostol group, PPH occurred and in 3 cases of Dinoprostone, PPH occurred (P=0.5718). Smiti Nanda et al., (2007)[8] found that the maternal side-effects like nausea, vomiting, diarrhoea, shivering and pyrexia were infrequent and the incidence was almost similar in both groups (P ¼ 0.75, RR ¼ 0.81, 95% CI 0.40–1.64). Swaran Gupta (2015)[14] reported that rate of tachysystole (>6 contraction/10 minutes) was higher in misoprostol group (18%) as compared to dinoprostone group (6%).

In our study, there was no significant difference found regarding at 1- and 5-minute APGAR score of the babies after birth in both study groups. ($P_{1=}$ 0.8150 and $P_{5=}$ 0.8150). Smiti Nanda et al., (2007)[8] also showed that there was no significant difference in the APGAR score at 1 and 5 min in the two groups. Olav Lapaire et al., (2007)[12] reported that APGAR scores (<7) were lower at five minutes observed in the dinoprostone group versus the misoprostol group (P<0.05). In misoprostol group, there were 7 babies admitted in NICU for meconium-stained liquor whereas in dinoprostone group 4 babies were admitted in NICU for meconium-stained liquor. In our study, there was no significant difference in both groups in neonatal complication (P=0.6516). The study by Olav Lapaire et al., (2007)[12] found that in dinoprostone group (n=12) more neonates were admitted to

the NICU, compared to the misoprostol group (n=6, P=0.068).

CONCLUSION

From the present study it can be concluded that the tab. Misoprostol 25 µg pervaginal is more effective in comparison to Dinoprostone 0.5 mg endocervical for induction of labour with respect to the induction to onset of labour interval and induction to delivery interval. With respect to maternal outcome and the neonatal outcome no significant statistical difference was noted in either of the groups. The timely monitoring of fetal heart rate and labour progress reduced complication of induction of labour with prostaglandin. However, the above conclusion was made with the study of small group of participants, the study in a larger group of participants may give a better evaluated conclusion.

Acknowledgements – None

Funding – None

Conflict of interest – none

Ethical Approval – The study was approved by the Institutional Ethics Committee.

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Received on 14.12.22
Accepted on 18.1.23
Published 28.1.23
Citation: **Ali M, Nath P, Roy M. Comparison of efficacy of Dinoprostone and Misoprostol in induction of Labour.**J Indian Acad Obstet Gynecol. 2023;4(2):3-11.

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