ORIGINAL ARTICLE

A Comparison of Misoprostol and Dinoprostone Gel for Induction and Cervical Ripening

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DOI: 10.55489/njmr.12032022907

ABSTRACT

Introduction: Labour induction at term is a universal conventional obstetric interference with an objective to stimulate uterine contractions artificially to attain a spontaneous vaginal delivery. The current study was aimed to compare the efficacy and safety profile of low dose vaginal Misoprostol with Dinoprostone gel for induction of labour in term pregnancies with unfavorable cervix and intact membranes.

Methodology: This Randomized Controlled Trial was conducted among pregnant women with term pregnancy with obstetrical or medical indication for induction of labour after institutional ethical committee approval. A detailed history, complete physical examination and investigations were done for all patients.

Result: Misoprostol and Dinoprostone gel are equally effective inducing agents. Both are equally effective in Primigravida and Multigravida. Failure of induction rate for Misoprostol and Dinoprostone was statistically not significant. The need of Oxytocin augmentation, maternal complication rate, NICU admission rate, caesarean section rate and occurrence of meconium-stained liquor are statistically not significant in both the study groups. Our study was unable to demonstrate superiority of any single drug compared to other. Only the difference is cost, induction with

Conclusion: considering the easy to preserve and administer, we recommend use of Misoprostol as a safe, effective, cheaper, and more convenient drug for induction of labour.

Keywords: Misoprostol, Dinoprostone, Induction of labour, Cervical Ripening

INTRODUCTION

Labour induction at term is a universal conventional obstetric interference with an objective to stimulate uterine contractions artificially to attain a spontaneous vaginal delivery. The efforts must be done to make the cervix favourable. Introducing of intravaginal or intracervical prostaglandins has the main job of that.[1]

In the past decades there has been an increase in the incidence of induction of labour. Data from WHO Global survey on maternal and perinatal health has shown that all over the world 9.6% of deliveries required labour induction. In the developed countries the incidence of labour induction is as high as 25%.[2]

A lot of studies have shown the benefits of using prostaglandins vaginally in priming of cervix and then induction of labour in terms with reduction of induction-delivery gap and subordinate operative rate.[3] Misoprostol is a prostaglandin E1 analogue originally registered as oral tablets for the management peptic ulcer. Nearly all countries had extensive studies about its security, effectiveness, and dosage-reaction outcome in induction of labour at term pregnancies.[4]

Until a moment ago, prostaglandin E2, or Dinoprostone, has been the mainly broadly used one. Dinoprostone, a PGE2 analogue has long been used for cervical ripening and labour induction and is a very efficacious drug with a good safety profile. But it is costly and requires refrigeration for storage.[5]

On the other hand, it has many disadvantages like, instability at room temperature and its high price. Misoprostol, or prostaglandin E1 is cheap, stable at room temperature and could be taken vaginally, orally, or sublingually.[6]

The World Health Organization, the International Federation of Gynecology and Obstetrics and the American College of Obstetrician and gynecologists introduced Misoprostol in the list of the important agents to be used for obstetrical require.[7] This revises the contraindication and the precaution that Misoprostol should not be used in pregnant women by stating that the contraindication is only for pregnant women who are using the medication to reduce the risk of NSAID-induced stomach ulcers. Misoprostol is now a part of the FDA approved regime for use with mifepristone to induce abortion in early pregnancy and is also recognized for its use for induction of labour.[8]

A large data exists in the literature regarding the use of Misoprostol by oral, vaginal, or sublingual routes for use in cervical ripening and labour induction in varied doses but there have been concerns about hyperstimulation, meconium and non-reassuring fetal heart rates with the higher doses.

ACOG has recommended the use of vaginal Misoprostol in doses of 25μg every 3 to 6 hourly[9], WHO has

recommended it 6 hourly now.[2] Still the lowest effective dose of Misoprostol and the optimal dosing interval that achieves a balance between high doses, which result in rapid delivery but frequent hyperstimulation and lower doses which take longer to achieve delivery but have a better safety profile is under investigation and people are using different protocols.

With this background, the current study was aimed to compare the efficacy and safety profile of low dose vaginal Misoprostol with Dinoprostone gel for induction of labour in term pregnancies with unfavorable cervix and intact membranes.

OBJECTIVES

The present study was conducted with an objective to compare induction procedures with Dinoprostone and Misoprostol in terms of induction to delivery time, requirement of Oxytocin augmentation, fetal outcome, maternal outcome, and rate of Caesarian section.

METHODOLOGY

The study was conducted in the department of obstetrics and gynaecology of a tertiary care hospital in India. This Randomized Controlled Trial was conducted among pregnant women with term pregnancy with obstetrical or medical indication for induction of labour after institutional ethical committee approval. A detailed history, complete physical examination and investigations will be done for all patients. Informed written consent will be taken.

Eligibility criteria: Only singleton pregnancy with cephalic presentation, more than 37 weeks of gestation, Bishop score of six or less, amniotic fluid index of five or more and reactive non stress test was included in the study.

Pregnancy with ny of the following condition like previous uterine scar, multiple pregnancy, placenta previa, non-reactive NST, severe IUGR, severe oligohydramnios, Hypersensitivity to prostaglandin, Ruptured Membranes, Contractions >3 for 10 min or Major medical diseases.

Sample size: It was by using formula

$$sample\ size\ n = \frac{(p1q1 + p2q2)\ x\ 7.84}{(p1-p2)^2}$$

Where p1 is prevalence of variables among study group, q1 = 1-p1, p2 is prevalence of variables among control group and q2 = 1-p2. The calculated sample size was 46 patients in Misoprostol group and 46 patients in Dinoprostone group.

Procedure

After a detailed history and examination, vaginal examination was be done to assess the Bishop score. NST was done in all cases prior to induction of labor. After written Informed consent eligible candidates was randomized into two groups. The randomization was done according to simple random method. Alternate patients were be allotted group 1 and 2 respectively based on time of admission**.** The women in GROUP 1 were induced with 25μg tablet of Misoprostol placed in the vagina every six hourly up to maximum five dose. The women in GROUP 2 were induced with Dinoprostone gel 0.5 mg instilled intracervically six hourly up to maximum three doses. The progress of labor was monitored as per the institutional protocol. Fetal monitoring will be done by intermittent auscultation every 30 min. in first stage and every 15 min. in the second stage of labor. Subsequent dose of drug weas withheld if the woman goes in established labor or ruptured her membranes as well as in cases with non-reassuring fetal heart rate.

Data Analysis: Interpretation of the data was be carried out and analyzed using Microsoft excel and by the software Statistical Package for Social Sciences SPSS version 14.0. Standard formula will be used for data analysis. We will use standard t-test for statistical analysis and $P \leq 0.05$ would be considered statistically significant.

The **primary outcome** measures assessed were mode of delivery and induction to delivery interval. **Secondary maternal outcome** measures assessed were be requirement of oxytocin, number of dose of drug used, incidence of cesarean section for fetal distress, meconium stained liquor, or failed induction and side effects like hyper stimulation, hyperpyrexia, vomiting , diarrhea, postpartum hemorrhage, cervical tears and vaginal tears. Fetal outcome will be assessed in terms of birth weight, APGAR scores at one and five minutes and admission to neonatal intensive care unit.

RESULTS

The present study was conducted to compare Misoprostol and Dinoprostone gel for induction and cervical ripening. The study conducted among two study groups, Misoprostol group and Dinoprostone group with 46 cases in each group.

Mean age of women in Misoprostol group was 23.22 year with standard deviation of 2.67. Mean age of women in Dinoprostone group was 24.63 year with standard deviation of 3.02

In Misoprostol group 32 (69.6%) women were inducted because of post term while it was 18 (39.1%) casesin Dinoprostone group. Gestational hypertension was indication in 15.2% and 28.3% in Misoprostol group and Dinoprostone group respectively. In Misoprostol group 32 (69.6%) women were Primigravida while it was 26 (56.5%) cases in Dinoprostone group. Multigravida women were indication in 30.4 and 43.4% in Misoprostol group and Dinoprostone group respectively. The difference was statistically not significant (p>0,05).

In Misoprostol group failure of induction rate was 12.5% while in Dinoprostone group it was 15.4% in Primigravida women. The difference in failure rate in both the group was statistically not significant (p>0,05) in Primigravida women. In Misoprostol group failure of induction rate was nil while in Dinoprostone group it was 5% in multigravida women. The difference in failure rate in both the group was statistically not significant (p>0.05) in multigravida women.

In Misoprostol group highest cases had score 4 (59.4%) followed by score 3 in 28.1% in primigravida. In Dinoprostone group highest cases had score 3 (34.6%) followed by score 5 in 30.8% in primigravida. In Misoprostol group highest cases had score 4 (42.9%) followed by score 3 in 28.6% in multigravida. In Dinoprostone group highest cases had score 5 (45%) followed by score 3 in 30.0%in

multigravida. After induction in 23 (71.9%) cases of Primigravida the Bishop score was 6 and above in Misoprostol group. In Dinoprostone group, after induction in 23 (88.5%) cases of Primigravida the Bishop score was 6 and above. After induction in 12 (85.7%) cases of multigravida the Bishop score was 6 and above in Misoprostol group. In Dinoprostone group, after induction in 16 (80%) cases of multigravida the Bishop score was 6 and above.

Median Induction to delivery time in Misoprostol group was 16 hours (4 – 43 hr) in Primigravida while in Dinoprostone group it was 15 hours (2.5 – 29hr). However, there was no statistical difference in induction to delivery time in Primigravida cases. (p>0.05). Median Induction to delivery time in Misoprostol group was 11.8 hours (4 – 29 hr) in multigravida while in Dinoprostone group it was 12 hours (4 – 21hr). However, there was no statistical difference in induction to delivery time in multigravida cases (p>0.05).

In Misoprostol group Oxytocin was required in 3 (9.4%) cases in Primigravida while in Dinoprostone group it was required in 5 (19.2%) cases in Primigravida women. The difference in Oxytocin requirement in both the group was statistically not significant (p>0,05) in Primigravida women. In Misoprostol group Oxytocin was required in none of the cases in Multigravida while in Dinoprostone group it was required in 2 (10%) cases in Multigravida women. However, the difference in Oxytocin requirement in both the group was statistically not significant (p>0.05) in multigravida women. In Misoprostol group LSCS was conducted in 13 (40.6%) and ventouse in 1 (3.1%) case in Primigravida while in Dinoprostone group LSCS and ventouse were required in 12 (46.2%) and 1 (3.8%) case respectively in Primigravida women. However, the difference in mode of delivery in both the group was statistically not significant (p>0.05) in Primigravida women. In Misoprostol group LSCS was conducted in 3 (21.4%) and ventouse in 1 (7.1%) case in Multigravida while in Dinoprostone group LSCS was required in 4 (20%) cases in Multigravida women. However, the difference in mode of delivery in both the group was statistically not significant (p>0.05) in Multigravida women.

In Misoprostol group main reasons for LSCS include Foetal distress (31.3%), Failure of induction (25%) and non-progress of labour (18.8%).In Dinoprostone group main reasons for LSCS include Fetal distress (31.3%),Failure of induction (31.3%) and n on progress of labour (31.3%).

In Misoprostol group the rate of Failure of induction was 25% and in Dinoprostone group the rate of Failure of induction was 31.3%. However, the difference in rate of failure of induction as a cause of LSCS in both the group was statistically not significance (p>0.05). In Misoprostol group none of the women develop any complication while in Dinoprostone group 3 cases develop maternal complication including Tachysystole in one case. However, the difference in rate of maternal complication was statistically not significant (p>0.05).

In Misoprostol group liquor was clear in 39 (84.8%) cases while in Dinoprostone group 41 (89.1%) cases had clear liquor. However, the difference in rate of clear liquor was statistically not significant (p>0.05).

In Misoprostol group NICU admission required in 2 (4.3%) women while in Dinoprostone group 3 (6.5%) cases required NICU admission. However, the difference in requirement of NICU admission rate was statistically not significant(p>0.05).

In Misoprostol group APGAR score at 1 min was 7 in 44 (95.7%) women while in Dinoprostone group 7 and above score was in 42 (43.3%) cases. In Misoprostol group APGAR score at 5 min was 7 in 45 (97.9%) women while in Dinoprostone group 7 and above score was in 44 (97.8%) cases. Application of test of significance (t test) found that there was no significant difference in mean APGAR score at 1 (p vale >0.05) and mean APGAR score at 5 min (p value >0.05) in both, the Misoprostol group and the dinoprostone group.

Table 1: Comparison of based line indicators between Misoprostol group and Dinoprostone group.

Variables	Misoprostol (%)	Dinoprostone (%)	P value
Age of women (mean ± SD)	23.22 (2.67)	24.63 (3.21)	0.024
Indication for induction			
Post term	32 (69.6)	18 (39.1)	
Gestational diabetes mellitus	0 (0)	1 (2.2)	
Gestational hypertension	7 (15.2)	13 (28.3)	
Severe pre eclampsia	1 (2.2)	7 (15.2)	
Oligohydramnios	6 (13)	7 (15.2)	
Gravida			
Primigravida	32 (69.6)	26 (56.5)	0.1953
Multigravida	14 (30.4)	20 (43.5)	
Failure of Induction in Primigravida	4 (12.5)	4 (15.4)	0.7514
Failure of Induction in Multigravida	0 (0)	1 (5)	0.3957
Preinduction Bishop Score in Primigravida			
1	1 (3.1)	0 (0)	0.128
2	1 (3.1)	3 (11.5)	
3	9 (28.1)	9 (34.6)	
4	19 (59.4)	4 (15.4)	
5	2 (6.3)	8 (30.8)	
6	0 (0)	2 (7.7)	
Preinduction Bishop Score in Multigravida			
2	0 (0)	2 (10)	0.268
3	4 (28.6)	6 (30)	
4	6 (42.9)	3 (15)	
5	3 (21.4)	9 (45)	

Table 2: Comparison of intrapartum, post-partum and neonatal indicators between Misoprostol group and Dinoprostone group.

Variables	Misoprostol (n=46) (%)	Dinoprostone (n=46) (%)	P value
Induction to delivery time in Primi	16 (4.0 - 43.0)*	15 (2.5 – 29.0)*	0.475
Use of Oxytocin in Primigravida	3 (9.4)	5 (19.2)	0.2803
Use of Oxytocin in Multigravida	0 (0)	2 (10)	0.2231
Postinduction Bishop Score in Primigravida			
4	4 (12.5)	0 (0)	
5	5 (15.6)	3 (11.5)	
6 and above	23 (71.9)	23 (88.5)	
Postinduction Bishop Score in Multigravida			
4	1 (7.1)	2 (10)	
5	1 (7.1)	2 (10)	
6 and above	12 (85.7)	16 (80)	
Mode of delivery in Primigravida			
LSCS	13 (40.6)	12 (46.2)	0.8922
Normal Vaginal	18 (56.3)	13 (50)	
Ventouse Vaginal	1 (3.1)	1 (3.8)	
Mode of delivery in Multigravida			
LSCS	3 (21.4)	4 (20)	0.4686
Normal Vaginal	10 (71.4)	16 (80)	
Ventouse Vaginal	1 (7.1)	0 (0)	
Indication for LSCS			
Deep Transfer Arrest	1 (6.3)	0 (0)	
Failure of induction	4 (25)	5 (31.3)	
Fetal distress	5 (31.3)	5 (31.3)	
Maternal request	2 (12.5)	1 (6.3)	
Non progess of labour	3 (18.8)	5 (31.3)	
Non-reactive NST	1 (6.3)	0 (0)	
Indication for LSCS			
For failure of induction	4 (25)	5 (31.3)	0.6942
For other reason	12 (75)	11 (68.8)	
Maternal Complications			
No complication	46 (100)	43 (93.5)	0.0782
Fever	0 (0)	1 (2.2)	
Tachysystole	0 (0)	1 (2.2)	
Other	0 (0)	1 (2.2)	
Liquor			
Clear	39 (84.8)	41 (89.1)	0.5358
Thick MSL	4 (8.7)	3 (6.5)	
Thin MSL	3 (6.5)	2 (4.3)	
NICU admission			
Required	2 (4.3)	3 (6.5)	0.6456
Not required	44 (95.7)	43 (93.5)	
APGAR score at 1 min	6.93 ± 1.04	7.04 ± 1.28	0.382
APGAR score at 5 min	8.91 ± 1.12	8.98 ± 1.34	0.764

***** Median (hr) (Min-Max) #Mean ± SD

DISCUSSION

In near term pregnancy induction of labour required in estimated 10-20% cases. In modern era of medicine, drugs are available which can fasten the process of cervical ripening in a short period of time which play very important role in today's obstetrical practices. However, till date no medication or procedure has been established to be ideal for induction of labour in near term pregnancy with an unripe cervix. The techniques frequency used for the induction of labour are artificial rupture of membranes (ARM) or use of medications like oxytocin, Misoprostol and prostagandins like Dinoprostone gel. The introduction of Prostaglandins to obstetrical practice, for induction of labour by mean of cervical ripening, has helped obstetrician to overcome major difficulties of labour induction.

The present study was conducted to compare Misoprostol and Dinoprostone gel for induction and cervical ripening. The study conducted among two study groups, Misoprostol group and Dinoprostone group with 46 cases in each group. Following are the observations of the study. The base line indicators like age of t=mother, parity, indication for induction and Bishop score was almost similar in both e study group (p>0.05).

Induction to delivery time

Median Induction to delivery time in Misoprostol group was 16 hours (4 – 43 hr) in Primigravida while in Dinoprostone group it was 15 hours (2.5 – 29hr). However, there was no statistical difference in induction to delivery time in Primigravida cases. (p>0.05). Median Induction to delivery time in Misoprostol group was 11.8 hours (4 – 29 hr) in multigravida while in Dinoprostone group it was 12 hours (4 – 21hr). However, there was no statistical difference in induction to delivery time in multigravida cases (p>0.05). In a study by Patil P et al,[10] author has compared both time of onset of labour as well as time of delivery. In this study in Misoprostol group the mean time taken for onset of

labour was 43.22 min and was 1 hr 40 min in Dinoprostone which was less in Misoprostol group compared to cerviprime group. Time taken for onset of labour statistically not differ between primigravida and multigravida in both the study groups. In the same study the mean induction to delivery interval was 5 hrs 02 min in Misoprostol group whereas 11 hrs 12 min Dinoprostone group. The time was significantly less in the Misoprostol group (P =<.001). In a study by Malathia J et al[11] the difference in induction to delivery time was non-significant (>0.05). In the same study the mean induction to delivery interval in multigravida was 5.5 hours in Misoprostol group whereas 6.7 hours inDinoprostone group, however, the difference was not significant (>0.05). In a study by Malathia J et al[11], the mean induction to delivery interval was 972.5 min in Misoprostol group whereas 1010.5 min Dinoprostone group, however, the difference was non-significant (>0.05). Similar results were seen in study in astudy by Agarwal et al[12] and Murthy B K et al.[13]

Requirement of Oxytocin

In the present study, oxytocin requirement in both the group was statistically not significance (p>0.05). In a study by Patil P et al[10] in Misoprostol group Oxytocin augmentation was not required at all in any case while in Dinoprostone group 3 cases (6%) require Oxytocin augmentation. However the difference was statistically not significant (p>0.05). Siilar results were observed by Malathia J et al[11] and Neiger R. Greaves et al[14].

Mode of Delivery

In the present study, the difference in LSCS rate was statistically non-significant between both the group. In a study by Patil P et al[10] LSCS rate was 6% in Misoprostol group and 22% in Dinoprostone group. However, statistically the difference was not significant (p>005). Similarly in a study by Malathia J et al[11] LSCS rate was 4% in Misoprostol group as well as in Dinoprostone group. There was no difference in LSCS rate in both groups (p>005). In a study by Wing et al[15] LSCS rate was 14.7% in Misoprostol group and 19.4% in Dinoprostone group. However, again the difference was statistically non-significant (p>005). So all the studies indicate that the LSCS rate doesn't differ in Misoprostol group and Dinoprostone group.

Development of Complications

In the present study, there was no much difference in the development of complication between both the group (p>0.05). The groups show very low rate of complication. In a study by Patil P et al[10] in Misoprostol group Meconium-stained liquor was found in 12% cases while in Dinoprostone group 6% cases had Meconium-stained liquor. However, the difference in rate of clear liquor was statistically not significance (p>0.05). In a study by Barrilleaux et al[16] in Misoprostol group Meconium-stained liquor was found in 6.1% cases while in Dinoprostone group 6.4% cases had Meconium-stained liquor. However, the difference in rate of clear liquor was statistically not significance (p>0.05). In a study by Wing et al[15] in Misoprostol group Meconium-stained liquor was found in 27.9% cases while in Dinoprostone group 10.5% cases had Meconium-stained liquor. In Misoprostol group Meconium-stained liquor incidence was significantly more compared to Dinoprostone group (p<0.05).

NICU Admission rate

In the present study, the difference in requirement of NICU admission rate was statistically not significance between both te groups (p>0.05). In a study by Patil P et al[10] in Misoprostol group NICU admission required none while in Dinoprostone group 4% cases required NICU admission. However, the difference in requirement of NICU admission rate was statistically not significant (p>0.05). In a study by Malathia J et al[11] in Misoprostol group NICU admission required in 6% cases while in Dinoprostone group 8% cases required NICU admission. However, the difference in requirement of NICU admission rate was statistically not significant (p>0.05).

APGAR Score

In the present study in Misoprostol group APGAR score at 1 min was 7 in 44 (95.7%) women while in Dinoprostone group 7 and above score was in 42 (43.3%) cases. In Misoprostol group APGAR score at 5 min was 7 in 45 (97.9%) women while in Dinoprostone group 7 and above score was in 44 (97.8%) cases. In a study by Patil P et al[10] in Misoprostol group APGAR score at 1 min was less than 7 in no case while in Dinoprostone group score was less than 7 in 6% cases. In Misoprostol group APGAR score at 5 min was less than 7 in no case while in Dinoprostone group less than 7 score was in 4% cases. In a study by Malathia J et al[11] in Misoprostol group APGAR score at 1 min was less than 6 in 8% cases while in Dinoprostone group score was less than 6 in 8% cases. In Misoprostol group APGAR score at 5 min was less than 6 in 0% cases while in Dinoprostone group less than 6 score was in 4% cases. The difference in APGAR score at 1 min and 5 min was statistically not significant. In a study by Barrilleaux et al[16] in Misoprostol group APGAR score at 1 min was less than 8 in none case while in Dinoprostone group score was less than 8 in 0.9% cases. APGAR score at 5 min was 8 or more in all cases in both the groups. In a study by Wing et al[15] in Misoprostol group APGAR score at 1 min was less than 7 in 13.2% cases while in Dinoprostone group score was less than 7 in 9% cases. In Misoprostol group APGAR score at 5 min was less than 7 in 1.5% cases while in Dinoprostone group less than 7 score was in 0% cases. The difference in APGAR score at 1 min and 5 min was statistically not significant.

CONCLUSION

Our study results revealed that, both, Misoprostol and Dinoprostone gel are equally effective inducing agents. Both are equally effective in Primigravida and Multigravida. In Primigravida, failure of induction rate for Misoprostol and Dinoprostone gel is 12.5% and 15.5% respectively. In Multigravida also the difference in failure rate was statistically not significant. Induction to labour time in primigravida is 15 and 16 hours for Misoprostol and Dinoprostone gel respectively while the induction to delivery duration was 12 hours in Multigravida of both the study groups. The need of Oxytocin augmentation, maternal complication rate, NICU admission rate, caesarean section rate and occurrence of meconium-stained liquor are statistically not significant in both the study groups. So, Misoprostol and Dinoprostone are both good inducing agents. Our study was unable to demonstrate superiority of any single drug compared to other. Only the difference is cost, induction with

However, considering the easy to preserve and administer, we recommend use of Misoprostol as a safe, effective, cheaper, and more convenient drug for induction of labour.

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