Original Article

Incidence of Fetal Distress in 6 Hourly Vaginally Administered 3 Doses, of Misoprostol Versus Dinoprostone for Labour Induction: A Comparative Study

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ABSTRACT:

Background: Artificial labor pain always poses the risk of fetal distress and is more painful than spontaneous labour. The pharmacological agents that are involved in stimulating uterine contraction may initiate a chain of processes that may lead the baby to suffocate, being deficient of essential oxygen and suffer from distress. The accelerated efforts to adapt safe and advanced measures are inevitable to make the labour induction easier and more secure for both lives involved.

Objective: The objective of this study was to compare the incidence of fetal distress in 6 hourly vaginally administered 3 doses, of misoprostol versus dinoprostone for labour induction.

Methods: This observational type of comparative study was conducted in Obstetrics Ward Lady Aitchison Hospital Lahore. A total of 200 postdate primigravidas undergoing induction of labour at 41 weeks were selected for this study. They were randomly divided into misoprostol and dinoprostone group, each containing 100 patients. The dose of misoprostol was 50 microgram each time up to a maximum of 150 microgram (3 doses) and dose of dinoprostone was 2 mg and only 2 doses of dinoprostone were used with an interval of 6 hours. Continuous fetal heart rate monitoring was done after induction. Signs of fetal distress like meconium staining of liquor after rupture of membranes and CTG changes were noted. After delivery of baby Apgar score at 5 minutes was taken and any resuscitation required or need for keeping the baby in nursery was noted.

Results : The mean age of the patients in misoprostol group was 25.4±4.5 years and in dinoprostone group was 23.3±3.4 years. The mean duration of induction to delivery interval in misoprostol group was 16.4±6.4 hours and in dinoprostone group was 13.1±4.6 hours. In misoprostol group, 40 (40%) patients delivered with LSCS and 60 (60%) patients delivered with spontaneous vaginal delivery. In dinoprostone group, 36 (36%) patients delivered with LSCS and 64 (64%) patients delivered with spontaneous vaginal delivery. The mean Apgar score at 5 minutes in misoprostol group was 8.5±0.9 and in dinoprostone group was 8.6±0.9. In misoprostol group, there were 5 (5%) patients who were admitted in intensive care unit and in dinoprostone group 2 (2%) patients were admitted in intensive care unit.

Conclusion: It is concluded from this study that the incidence of fetal distress did not increase when compared to dinoprostone when misoprostol is used at the dose of 50 mcg for induction of labour without decreasing its efficacy regarding induction and delivery.

Key Words: Fetal distress, induction of labour, misoprostol, dinoprostone.

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INTRODUCTION

The circumstances that enforce the implication of artificial labour induction appear when natural onset of labour becomes dangerous for both mother and the child. Though, the risk of fetal distress and probability of more painful delivery than from spontaneous labour persists is an associated fact, the necessity of artificial labour induction sometimes becomes inevitable. A little excessive stimulation may results, by pharmacological agents involved in uterine contraction. It has long been known that pharmacological agents that stimulate uterine contraction may result in shearing off the placenta or rupturing the uterus. It may also cause a lengthy and durable contraction of the uterus depriving the baby of essential oxygen.[1, 2]

Considering all possible hazards of inducing labor, a number of biophysical and biochemical techniques have been devised to monitor fetal distress. These include monitoring fetal scalp blood ph, fetal heart rate and cardiotocography. Misoprostol is a potential drug and synthetic analogue of prostaglandin E_1. It was firstly used in 1987 with a dead fetus and since then, more than a hundred trials have found it effective drug for a viable fetus too. This advantageous drug is being marketed as gastric cytoprotective agent. Though not approved from Federal Drug Association (FDA) labour induction, this has proved to be quite inexpensive, effectual and secure agent for cervical ripening and inducing artificial pain. Misoprostol can easily be given through various routs e.g. oral, vaginal, buccal or sublingual. Particularly when it is taken orally, it gets absorbed immediately via gastrointestinal tract and endure de-esterifiaction to its free acid that is the basis of its function. Studies show that total systemic bioavailability of vaginally administered misoprostol is three folds higher than orally administered misoprostol. The additional benefits associated with misoprostol include its equivalency with respect to effectiveness with superior elements like oxytocin and dinoprostone, its stability at room temperature, economic availability and the case of oral administration. Thus, all these potential benefits have made it an ideal drug for inducing labor particularly, where prostaglandin E1 is scarce.[3, 4] Various studies have focused and concluded different standard doses for optimum results and most of them have agreed on 50mcg drug administered vaginally every 4-6 hours.[4]

Another reason of Misoprostol being chosen as foremost choice of inducing labour and cervical ripening is its ability to mostly result simple vaginal delivery within 24 hours of application, stepping aside the need of caesarean section and even avoiding any requirement for oxytocin augmentation.[4, 5] Yet, there are certain contraindications or risks involved with this drug. Any sensitivity towards Misoprostol, it's over dosage and hyperactivity may affect fetal heartbeat and other systems, making the fetus suffer from stress.

Tachysystole, that is particularly defined as six or more uterine contractions in minutes for two consecutive 10 minutes period has direct relation with use of misoprostol. 10 It is important to mention here that tachysystole has gross impacts on cardiotocographic changes in fetal heart.[6]

Dinoprostone PGE2 drug is another effective agent used to support cervical ripening by softening and stimulation of uterus contractions. This drug is widely used for artificial induction of labour (IOL). In case of spontaneous labor disturbance, or delay or among post date women, Dinoprostone is recommended for effacement of cervix and labor pain.[7] Dinoprostone E2 has long been known as a useful and in most of the countries only licensed drug for the purpose of labor induction. But recently, studies have focused and developed more interest in the efficacy of PGE_1 (Misoprostol). The major upper handing attributes of which are its stability at room temperature, quick response and inexpensiveness.

Though, Dinoprostone (PGE2) is another analogue of Prostaglandin, and is approved by FDA too, yet in most of the studies its efficacy has not been as remarkable as of Misoprostol.[8] A number of studies have established clearly higher effectiveness of vaginally administered misoprostol as compared to vaginal dinoprostone for both cervical ripening as well as labor induction. The Cochrane Pregnancy and Childbirth Group have concluded after critical review of 45 studies that Misoprostol, administrated vaginally shows better results as compared to both oxytocin and dinoprostone. [9-11]

The main role in usage and administration of either drug is of staff that needs to be well trained and can govern the entire process for best outcomes. Considering the fact that no standard dosage measurements are established up till now, we have used 50 microgram prepared from 200 microgram oral tablet to be used vaginally.

PATIENTS AND METHODS

SETTING: This study was conducted in the Department of Obstetrics & Gynaecology, Lady Aitchison Hospital, Lahore.

STUDY DESIGN: Observational type of comparative study.

SAMPLE SIZE: A total of 200 post dates primigravidas between 18-35 years of age undergoing induction of labour at 41 weeks with alive pregnancy and an unfavorable cervix were included in study. They were randomly divided into misoprostol and dinoprostone group, each containing 100 patients.

SAMPLING TECHNIQUE: Postdate primigravidas women having no evidence of any medical disorder or intra uterine growth retardation were selected.

INCLUSION CRITERIA

1. Primigravidas between 18-35 years.
2. Post date pregnancy.
3. Patient with bishop score not more than

EXCLUSION CRITERIA

1. Multigravida
2. Patient with bishop score more than 5.
3. Patient, with intrauterine death
4. Congenitally malformed fetus
5. Multiple gestations
6. Term and preterm pregnancy
7. Term pregnancy with spontaneous rupture of membranes.
8. Patient with intrauterine growth retardation.
9. Pregnancy with medical disorders.

DATA COLLECTION PROCEDURE: A total of 200 postdate primigravidas undergoing induction of labour at 41 weeks and who fulfilled the inclusion criteria were selected from outpatients department of Lady Aitchison Hosptial Lahore. They were randomly divided into misoprostol and dinoprostone group, each containing 100 patients. An informed consent for induction was taken from all the patients. CTG was performed at start of induction and prior to each dose of the inducing agent, continuous monitoring was done for next 3 hours, fetal heart rate was taken after every fifteen minutes with dopton and CTG was done after every thirty minutes. The dose of misoprostol was 50 microgram each time up to a maximum of 150 microgram (3 doses) and dose of dinoprostone was 2 mg and only 2 doses of dinoprostone were used with an interval of 6 hours as recommended by World Health Organization (WHO). Continuous fetal heart rate monitoring was done after induction. Sign of fetal distress like meconium staining of liquor after rupture of membranes and CTG changes were noted. After delivery of baby, Apgar score at 5 minutes was taken and any resuscitation required or needed to keep the baby in nursery was noted. All the information was collected on a prescribed proforma (attached).

STATISTICAL ANALYSIS: The collected data were entered into SPSS version 18 and analyzed accordingly. The quantitative variables like age and duration of pregnancy were presented as mean and standard deviation. The qualitative variables were presented as frequency and percentages. The differences in outcome like CTG changes during induction, meconium staining, induction delivery interval, mode of delivery, Apgar score of baby at 5 minutes and admission to NICU between two groups were assessed by applying Chi Square test. P value ≤ 0.05 was considered as significant.

RESULTS

A total of 200 post dates primigravidas between 18-35 years of age undergoing induction of labour with alive pregnancy and an unfavorable cervix were included in study. They were randomly divided into misoprostol and dinoprostone group, each containing 100 patients. The mean age of the patients in misoprostol group was 25.4±4.5 years and in dinoprostone group was 23.3±3.4 years. In misoprostol group, there were 22 (22%) patients in the age range of 18-20 years, 31 (31%) patients in the age range of 21-25 years, 39 (39%) patients in the age range of 26-30 years and 8 (8%) patients in the age range of 31-35 years. In dinoprostone group, there were 23 (23%) patients in the age range of 18-20 years, 60 (60%) patients in the age range of 21-25 years, 14 (14%) patients in the age range of 26-30 years and 3 (3%) patients in the age range of 31-35 years. The mean gestational age of

the patients in misoprostol group was 41.2±0.4 weeks and in dinoprostone group was 41.2±0.4 weeks. In misoprostol group, there were 76 (76%) patients in the gestational age of 41 weeks and 24 (24%) patients of 42 weeks of gestation. In dinoprostone group, there were 77 (77%) patients in the gestational age of 41 weeks and 23 (23%) patients in the gestational age of 42 weeks. When the distribution of patients for CTG changes during admission was administered, it was found that in misoprostol group, 46 (46%) patients were reactive and 54 (54%) patients were non reactive. In dinoprostone group, 29 (29%) patients were reactive and 71 (71%) patients were non reactive. While for the distribution of patients by meconium staining, in misoprostol group, there were 19 (19%) patients of grade-I meconium staining, 16 (16%) patients of grade-II, 12 (12%) patients of grade-III and 53 (53%) patients had no meconium staining. In dinoprostone group, there were 10 (10%) patients of grade-I meconium staining, 18 (18%) patients of grade-II, 8 (8%) patients of grade-III and 64 (64%) patients had no meconium staining. The mean duration of induction to delivery interval in misoprostol group was 16.4±6.4 hours and in dinoprostone group was 13.1±4.6 hours. Further detailing the intervals, in misoprostol group, there were 27 (27%) patients observed for lying in duration of induction to delivery interval range of 5-10 hours, 15 (15%) patients of 11-15 hours, 38 (38%) patients of 16-20 hours, 16 (16%) patients of 21-25 hours and 4 (4%) patients of 26-30 hours. In dinoprostone group, there were 30 (30%) patients lying in duration of induction to delivery interval range of 5-10 hours, 52 (52%) patients of 11-15 hours, 14 (14%) patients of 16-20 hours, and 4 (4%) patients of 26-30 hours. In misoprostol group, there were 40% patients who delivered with LSCS and 60% patients delivered with spontaneous vaginal delivery. In dinoprostone group, 36% patients delivered with LSCS and 64% patients delivered with spontaneous vaginal delivery. The mean Apgar score at 5 minutes in misoprostol group was 8.5±0.9 and in dinoprostone group was 8.6±0.9. In misoprostol group there were 47% patients had 7-8 Apgar score at 5 minutes and 53% patients had 9-10 Apgar score. In dinoprostone group, there were 43% patients had 7-8 Apgar score at 5 minutes and 57% patients had 9-10 Apgar score. In misoprostol group, there was 1% patient who was admitted in intensive care unit and in dinoprostone group there were 3% patients who admitted in intensive care unit.

Table – 1: Comparison of different outcome in both study groups

		Group-A	Group- B	p-value
		N=100	N=100	
CTG Changes	***Reactive***	46	29	0.013
	Non reactive	54	71	
Meconium staining	***Grade-I***	19	10	0.198
	Grade-II	16	18	
	Grade-III	12	8	
	Nil	53	64	
Induction to delivery interval (hours)	***5-10***	27	30	0.000
	11-15	15	52	
	16-20	38	14	
	21-25	16	0	
	26-30	4	4	
Mod of Dilivery	***LSCS***	40	36	0.001
	SVD	60	64	
APGAR Score	***7-8***	47	43	0.707
	9-10	53	54	
Admission in ICU	***Yes***	1	3	0.001
	No	99	97	

Group A: Misoprostol

Group B: Dinoprostone

P-value less or equal to 0.05 were taken as significant

DISCUSSION

Induction of labor has become a necessity now, in cases where natural process of birth can be fetal to either mother or the child. Almost 20% of the deliveries around the world require artificial labor induction. Most of which are usually successful, but around 20% of them fail leading to Cesarean Section.[2] The frequency and incidence of induction is increasing with the time. A study showed that 1 out of every 5 deliveries require induction of labor.[12, 13] The chief reason for this increase is a sudden increase of elective or marginal reasons. Additionally, delayed gestational periods of 40 to 41 weeks also necessitate the artificial labor induction. Recent studies have shown that this increase is mainly due to a rise of inductions for marginal or elective reasons. [13, 14] Some Women undergo distress if labor does not initiate around their expected date.[15] In this situation, obstetricians have double responsibility of surviving the pressure from these patients and also the persuasion of using prostaglandins. In order to avoid fetal distress and circumstances that lead to it e.g. delayed gestational period, complications related to maternal or fetal health and appropriate selection of delivery method can be gained by following authentic and apposite evaluation and consultation.

In our study, in misoprostol group the mean duration of induction to delivery interval was 13.1±4.6 hours and in dinoprostone group was 16.4±6.4 hours. These results were compatible with the study of Papanikolaou et al.,[16] in which the misoprostol group had mean duration of induction to delivery interval to be 11.9 hours and in dinoprostone group it was 15.5 hours. While in another study conducted by Danielian et al.,[17] misoprostol group had the mean duration of induction to delivery interval as 14.4 hours and in dinoprostone group it was 22.9 hours, which is also comparable with our study. In another study conducted by Chang and Chang[18] Thus, in misoprostol group the mean duration of induction to delivery interval was shorter i.e. 16.5±2.7 hours than in dinoprostone group (25.7±3.8 hours), which is also analogous to our study.

Furthermore, in our study, in misoprostol group, 30% patients delivered with LSCS and 70% patients delivered with spontaneous vaginal delivery and in dinoprostone group, 36% patients delivered with LSCS and 64% patients delivered with spontaneous vaginal delivery. Again somewhat identical to the results shown by Papanikolaou et al.,[16] in which, among misoprostol group, cesarean section percentage was observed in 7.5% patients as compared to 13.3% patients in dinoprostone group i.e. dinoprostone group having a higher percentage.

In these carefully selected patients, misoprostol at the dose used, not merely shortened the time between induction and delivery, but it also proved to be significantly more effective than dinoprostone. The positive point was that this result was achieved with a low CS rate in the misoprostol group, (30%, vs 36%), respectively. A difference of 6% in favor of misoprostol, although not statistically significant, might have clinical importance in terms of patient health and cost effectiveness. Although in the recent large metanalysis[10] published by the Cochrane Library, the CS rates were inconsistent, they tended to be lowered by misoprostol; an earlier study by Sanchez-Ramos et al found a statistically significant difference in favor of misoprostol.[3]

In misoprostol group, there were 5% neonates while in dinoprostone group 2% neonates were admitted in intensive care unit in present study. When compared with the study of Papanikolaou et al, it was observed that in misoprostol group 13.5% neonates were admitted in intensive care unit and among dinoprostone group 4.8% neonates were admitted in intensive care unit, which is again supportive to the results of our study i.e. dinoprostone group showed less percentage for nronates to be admitted in NICU. [16]

Despite of the established success of Misoprostol in its effectiveness, rapid mechanism and inexpensiveness over dinoprostone, risks are still involved particularly for survival and wellness of intrapartum fetal. In order to avoid uterine hyperstimulation and abnormal FHR tracings, we used, mentioning hereby for first time in the literature, a 9 hrs interval between the prostaglandin doses. Although we achieved a low rate of uterine hyperstimulation syndrome (2.5% with misoprostol and 1.2% with dinoprostone, respectively), a trend towards a high rate of abnormal FHR tracings during induction with misoprostol was still noticed. Our findings, in accordance with the previous Cochrane metanalysis[10], showed that with misoprostol there was an increased probability of meconium staining

of amniotic fluid as well as of uterine tachysystole and of abnormal FHR tracings. In the misoprostol group, the majority of women also underwent either a CS or a vacuum operative delivery due to non-reassuring FHR. If neonatal outcomes such as neonatal resuscitation, low Apgar score in the first minute and admittance to the neonatal unit within the first 24 hours (none of the above were statistically significant but they were more frequent within Misoprostol group holding some probability of clinical significance) are taken into account, misoprostol may increase these complications in labor. Thus, varily our sample size may not be able to certify documented safety, misoprostol use tend to be associated with a higher chance of admittance to the neonatal unit within 24 hours even in the absence of asphyxia. This evidence indicates that the faster approach to childbirth is not necessarily the better one.

In order to endeavor the explanation to the abovementioned side effects of misoprostol usage and taking into account other reports[10, 19, 20], it appears that the increase in clinically relevant adverse effects is not only related to misoprostol but it may also be dose dependent. Lyons et al have revealed in term pregnant rats that it is required to provide a higher dose of misoprostol to induce PGE2 secretion in the cervix than in the myometrium. Additionally, EP3 receptors (prostaglandin E2 receptors) are expressed in the myometrium (increased) in a different way than in the cervix (unaltered) retorting towards misoprostol.[21] The above findings indicate that misoprostol not only acts better on the myometrium than on the cervix, but an even higher dose is needed in order to ripen the cervix. Thus, it seems reasonable that increasing the interval between repeated misoprostol doses should reduce the risk of an asynchrony between a well or even hyper-stimulated uterus and a still not efficiently ripened cervix. Misoprostol probably has a large inter-patient variability in terms of pharmacokinetics, but it is also probable that the 50 mcg dosage may induce asynchrony between immature cervix effacement and uterine contractions, resulting in a more rapid but also more "stressful" labor. An initial lower dose of misoprostol (20–25 mcg), followed by 50 mcg should be considered in trying to achieve priming of the cervix without inducing such high uterine contractility and neonatal complications. Indeed, in a recent study comparing 25 mcg misoprostol with 1 mg dinoprostone administered vaginally every four hours, the admission rate to neonatal intensive unit was significantly lower in the misoprostol group.[22]

It still has to be mentioned that in many of the participants, the vertex was not engaged in the pelvic inlet on the day of admittance and this should have been included as an independent risk factor. The exact cause of the stillbirth in the dinoprostone group remains unclear, emphasizing thus, the need for continuous FHR monitoring during labor induction if regular uterine contractions persist.[23, 24]

CONCLUSION

To conclude, 50 mcg misoprostol at a 6 hours interval is more effective in promoting cervical ripening and in inducing labor, compared to dinoprostone. However, certain aspects concerning fetal well being during labor induction remain questionable. Larger prospective studies comparing elective induction to expectant management after a completed 40-week gestation (on the basis of early ultrasound biometry) might reveal a subgroup of women, such as primigravidas with an unfavorable cervix, who might benefit from an elective induction, preferably with a 25 mcg misoprostol initial dose.

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