Original Article

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Comparison of Vaginal and Oral Doses of Misoprostol for Labour Induction in Post-Term Pregnancies

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Considering maternal complications, it is preferred to induce labour after 40 weeks. Labour induction is a procedure used to stimulate uterine contractions during pregnancy before the beginning of the labour.

Aim: The aim of this study was to compare oral misoprostol with vaginal misoprostol for induction of labour in post-term pregnancies.

Materials and Methods: This double blind clinical-trial study was performed on 180 post-term pregnant women who were admitted to the labour ward of Besat Hospital Sanandaj, Iran in 2013-2014. Participants were equally divided into three groups using block randomization method. The induction was performed for the first group with 100 µg of oral misoprostol, for the second group with 50 µg of oral misoprostol, and for the third group with 25 µg of vaginal misoprostol. Vaginal examination and FHR was done before repeating each dose to determine Bishop Score. Induction time with misoprostol to the start of uterine contractions, induction time to delivery, and mode of delivery, systolic tachycardia, hyper stimulation and fetal outcomes were studied as well.

Results: First minute Apgar scores and medication dosage of the study groups were significantly different (p=0.0001). But labour induction, induction frequency, mode of delivery, complications, and 5 minutes Apgar score in the groups had no significant difference (p>0.05). The risk of fetal distress and neonatal hospitalization of the groups were statistically significant (p=0.02). There was no significant difference between the three groups in terms of mean time interval from the administration of misoprostol to the start of uterine contractions (labour induction), the time interval from the start of uterine contractions to delivery and taking misoprostol to delivery. From the administration of misoprostol to start of the uterine contractions the mean difference between time intervals in the three groups were not statistically significant.

Conclusion: Based on our findings it can be concluded that prescribing 100µg oral misoprostol is effective than 50 µg oral or 25 µg vaginal misoprostol in terms of induction time, maternal and neonatal outcomes in post- term pregnancy. However, the best dose and route should be decided according to evidence based information.

Keywords: Induction of labor, Prostaglandins, Uterine contractions

INTRODUCTION

Normal vaginal delivery (NVD) occurs between weeks 37 and 42 of pregnancy and its time is calculated from the first day of the last menstrual period. Post-term pregnancy extends to more than 42 weeks and its prevalence is 3-12 % [1]. Due to increase in the gestational age, especially after 41 weeks, complications such as maternal and fetal morbidity and mortality increase significantly [2]. Maternal complications include increased rates of cesarean, trauma due to carrying fetal macrosomia, postpartum haemorrhage, and fetal complications, including dystocia, oligohydramnios and meconium aspiration [1]. Considering the above mentioned risks, it is preferred to induce labour after 40 weeks. Labour induction is a procedure used to stimulate uterine contractions during pregnancy before the beginning of the labour [2]. The status of the cervix, its form, consistency and dilatation has a significant impact on the prognosis of labour induction [3]. Different methods are used to prepare the cervix, which include two main mechanical and pharmacological methods. Mechanical methods include membrane stripping, hygroscopic dilators, balloon catheter and amniotomy. Pharmacological methods include the use of prostaglandin E2 (Dinoprostone), prostaglandin E1 (misoprostol), oxytocin, estrogen, Mifepristone and Anapristone [2,4]. Mechanical methods are usually invasive and because of its painful nature and manipulation of the cervix its acceptance by the patient is low. Among the available pharmacological methods, prostaglandins play an important role in labour induction and are available in two forms; Dinoprostone and Misoprostol [2]. Dinoprostone is available only in vaginal form; it is expensive and needs to be kept in the refrigerator [5]. In comparison, misoprostol is prescribable in both oral and vaginal forms are widely used to induce labour for its high efficacy, considerable safety, reasonable price, easy to use, and easy to store at room temperature [6]. Also, misoprostol may influence fewer side effects such as nausea, vomiting, diarrhea, fever and abdominal pain [7]. In addition, unlike other prostaglandins, misoprostol has a selective effect on the uterus and cervix and has no inconvenient effect on the bronchi and blood vessels [8]. Maximum plasma concentration of orally administered misoprostol is produced faster than vaginal method, so that in oral method, it occurs within 30 minutes and in the vaginal method, it takes about an hour [9,10], but the plasma concentration of the medication in vaginal method stay longer, so that oral misoprostol is removed after 2-3 hours, but vaginal misoprostol removal takes more than 4 hours [5]. Meanwhile, oral misoprostol causes fewer vaginal examinations, reduces the risk of maternal and fetal infection and provides more freedom for the mother to move which may help in the progress of labour. Oral administration of Misoprostol is not only easier, but mother satisfaction is higher and it can be used outside the hospital [2]. Considering the routine use of both vaginal and oral procedures, and lack of accurate statistics, advantages and disadvantages on the effectiveness of both methods and also remaining challenges on this issue; this study was conducted to compare the effect of oral misoprostol with vaginal misoprostol for induction in post-term pregnancies to shorten the route of delivery, cost reduction, and reduction in maternal and fetal morbidity and mortality.

MATERIALS AND METHODS

This randomized double blind clinical trial was conducted on 180 pregnant women who were referred to labour ward of Besat Hospital in Sanandaj, Iran in 2013 and 2014 in a 14 month period. The inclusion criteria were: gestational age more than or equal to 41 weeks (based on first trimester sonography) and with cephalic presentation, bishop score less than 4 and height more than 150 cm. Exclusion criteria were: contraindications to receive misoprostol (allergies, asthma, Acute Cerebrovascular Disease, Coronary Artery Disease, seizures) and also placenta previa, history of previous cesarean section or uterine surgery, cephalopelvic disproportion, a bishop score of more than 4, abnormal vaginal bleeding and oligohydramnion. The sample size was 180 patients who were selected randomly and divided into three groups using block method design. Group one: 100 µg of oral misoprostol, second group was induced with oral misoprostol of 50 µg and third group of 25 µg vaginal misoprostol. The medication was made by Pharmacia Searle Ltd. England.

After describing the purpose of the study to the patients, informed consent was taken. This study was approved by the ethics committee of Kurdistan University of Medical Sciences and has been registered in the Iranian Registry of Clinical Trials (No. IRCT2014 110812789N9).

Gestational age was determined based on first trimester sonography. Bishop Score was determined thorough pelvic examination by obstetrics and gynecology resident. Initial tests, including blood group, RH and CBC were requested. In order to ensure the health of the fetus, stress test (NST) was carried out. Medications were in the same boxes and were given to women based on the group they were located. The researcher was not aware of the grouping.

Labour induction was performed in group 1 using 100 µg of oral misoprostol, in group 2 by 50 µg of oral misoprostol, and in group three by 25 µg of vaginal misoprostol (posterior fornix). Medications were repeated every 6 hours for 4 doses based on the patients' condition [2]. Vaginal examination to determine Bishop Score was done before repeating each dose. Maternal vital signs were taken and FHR were monitored every 4 hours. Induction was started with oxytocin in case of increasing Bishop Score and inadequate uterine contractions. Indications for cesarean section were failure of induction: hyper stimulation and defecation of meconium, both with fetal distress.

Induction starting time with misoprostol, initiation of uterine contractions, induction starting time to delivery, cesarean section and vaginal delivery rate and other variables, including; tachysystole, hyper stimulation were recorded on the checklist for all three groups.

STATISTICAL ANALYSIS

Data were analyzed using SPSS and descriptive statistics. After Kolmogorov-Smirnov absolute and relative frequency, average, standard deviation, and median were also used. One-way ANOVA was used to compare time interval in the starting of uterine contractions, the time interval of initiating labour, neonates' Apgar scores at 1 and 5 minutes, and uterine tachysystole and pH value of umbilical cord artery. Chi-square test or Fisher's exact test were used to compare the hyper stimulation of the uterus, fetal distress frequency, and the frequency of meconium defecation in the three groups.

RESULTS

In the mean age of the pregnant women no significant difference was found in three groups (p=0.68). The number of nulliparous and multiparous, labour, abortion and living childbirth in the three groups were not statistically significant (p>.05). In First minute Apgar Score of three groups differences were statistically significant (p =0.0001). But in Apgar score at 5 minutes there were no statistically significant differences between three groups (p=0.06). There was no statistically significant difference between three groups, in terms of umbilical cord pH and all were above 7.1 (p=0.13). Mean total dose in the vaginal and oral 100 µg, and 50 µg groups were 1.9, 1.2, 1.7 µg which showed a significant difference (p =0.0001) [Table/Fig-1].

Labour induction with oxytocin was performed in 36.7% of the 100 µg group, 55% of the 50 µgm group, and 51.7% of the vaginal group. The three groups did not differ in terms of induction frequency (p = 0.66). Cesarean section frequency of vaginal misoprostol group, 100 µg, oral and 50 µg oral were 25%, 10%, and 15% respectively (p = .24). There was no statistically significant difference between three groups in terms of fetal distress and neonatal hospitalization (p <0.05) [Table/Fig-2].

The interval time from the administration of misoprostol to the start of the uterine contractions for the three groups were 8.1±4.3,

Group Variable	Vaginal misoprostol µg±sd	100µg oral misoprostol µg±sd	50µg oral misoprostol µg±sd	F	p
Age	27.6±5.1	27.7±4.7	28.4±5.9	0.39	0.68
BMI	29.1±3.8	31.5±3.9	30.3±4.5	5.3	0.006
Gravidity	1.7±0.8	1.6±0.9	1.9±1	1.5	0.22
Parity	1.4±0.6	1.5±0.6	1.7±0.8	1.2	0.29
No. of Abortion	1±0	1.1±0.38	1.2±0.55	0.26	0.77
No. of Child	1.3±0.48	1.4±0.49	1.7±0.8	2.3	0.1
First Minute Apgar Score	9.6±0.5	9.7±0.5	9.2±0.6	14.2	0.0001
Five Minute Apgar Score	10±0	9.9±0.2	9.9±0.3	2.9	0.06
Weight	3365±254	3388±212	3410±304	0.45	0.64
Umbilical Cord pH	7.27±0.07	7.28±0.09	7.21±0.18	5.3	0.13
Dosage	1.9±0.77	1.2±0.53	1.7±0.74	13.6	0.0001

[Table/Fig-1]: Comparison of study variables in three groups. Kruskal–Wallis test

Group Variable		Vaginal misoprostol No. (%)	100µg oral misoprostol No. (%)	50µg oral misoprostol No. (%)	p
Induction	Yes	31(51.7)	22(36.7)	33(55.0)	0.1
	No	29(48.3)	38(63.3)	27(45.0)	
No. of induction	One	25(80.6)	19(86.4)	30(90.9)	0.66
	Two	4(12.9)	3(13.6)	2(6.1)	
	Three	2(6.5)	0	1(3.0)	
Mode of labour	Natural	43(71.7)	50(83.3)	47(78.3)	0.24
	CS	15(25.00)	6(10.0)	9(15.0)	
	Instrumental	2(3.3)	4(6.7)	4(6.7)	
Induction Complications	Fetal distress	5(55.6)	5(71.4)	4(26.7)	0.32
	meconium defecation	3(33.3)	2(28.6_	7(46.7)	
	Both	1(11.1)	0	4(26.7)	
Cause of CS	meconium defecation	5(33.3)	2(33.3)	4(50.0)	0.8
	Fetal distress	5(33.3)	3(50.0)	3(27.5)	
	No response to Induction	5(33.3)	1(16.7)	1(12.5)	
Gender	Male	33(55.00)	32(53.3)	31(51.7)	0.98
	Female	27(45.00)	28(46.7)	29(48.3)	
Fetal distress	Yes	1(1.7)	4(6.7)	8(13.3)	0.05
	No	59(98.3)	56(93.3)	52(86.7)	
Neonate hospitalization	Yes	1(1.7)	3(5.2)	9(15.0)	0.02
	No	59(98.3)	57(94.8)	51(85.0)	

[Table/Fig-2: Comparison of the frequency of variables in three groups.

Variable	Group	The mean and standard deviation (hour)	F	p
The time interval from the administration of misoprostol to start uterine contractions (labour induction)	Vaginal misoprostol	8.1± 4.3	1.7	0.19
	100µg oral misoprostol	7.5± 4.4		
	50µg oral misoprostol	6.6 ±3.6		
The time interval between the start of uterine contractions to delivery	Vaginal misoprostol	4.5± 2.8	0.07	0.93
	100µg oral misoprostol	4.6 ± 2.7		
	50µg oral misoprostol	4.4 ± 3.2		
The time interval between labour induction to labour	Vaginal misoprostol	12.6 ±5.7	1.27	0.28
	100µg oral misoprostol	11.6 ±4.9		
	50µg oral misoprostol	11.0 ± 5.0		

[Table/Fig-3]: Comparison of the average time between the study groups.

7.5±4.4, and 6.6 ±3.6 hours respectively (p=0. 19). Also, the time interval between labour inductions of labour for three groups was 12.6 ±5.7, 11.6 ±4.9, and 11.0 ± 5.0 hours respectively (p=0. 28) [Table/Fig-3].

DISCUSSION

Vaginal dinoprostone is the current gold standard drug for cervical ripening during labour induction, but misoprostol is a good alternative in low resource settings. The purpose of this study was to investigate the effect of different doses of misoprostol for labour induction in post-term pregnancies. In this study, three groups 100 µg oral misoprostol, 50 µg oral misoprostol, and 25µg vaginal misoprostol groups were compared.

There were no statistically significant differences between the three groups in terms of interval time from the administration of misoprostol to the start of uterine contractions (labour induction), the interval time between the start of uterine contractions to delivery and interval time between labour inductions to labour. Mean of interval time between labour inductions to labour were 12.6 hours in vaginal group, and 11.6 and 11 hours in 100µg and 50µg groups respectively; however, the differences were not statistically significant. Sheela et al., study results showed that there was no significant difference between the two methods of oral 50µg misoprostol and vaginal 25 µg misoprostol [11]. In Wing et al., study, the effectiveness of oral and vaginal misoprostol for labour induction was the same [12]. In Jindal et al., study, delivery time was lesser in women who had vaginal misoprostol compared to those who received oral misoprostol (p=0.004) [13].

In Jalilian study the period between induction and labour in the misoprostol group was 3.6±10.1 hour [14]. In Squeela Ayaz et al., study, labour time in the oral misoprostol group was lower than vaginal group (p=0.03) [15]. In the study conducted by Diro, consumption of 25 µg and 50 µg of misoprostol did not make a statistically different result. However, in the first and second stages of labour, a dose of 50 µg made the period shorter [16]. Also, in a study by Hanji oral misoprostol 25 mcg was as effective as vaginal misoprostol 25mcg for induction of labour in post dated pregnancy with less induction-delivery interval and good perinatal outcome with minimal maternal side effects [17]. Hofmeyr in a review study confirmed that oral route of administration is preferable to the vaginal route [18]. The findings of similar studies proved better effects of oral misoprostol than vaginal one which are consistent with the results of our study.

In our study, number of doses in each groups showed a significant statistical difference (p=0.0001). In the vaginal type 63.3%, in the 50 µg group 53.4%, and in the 100 µg groups 18.3% need second and third doses of the medication (p=0. 0001). But Jindal study was in contrast to the findings of our study [13]. This difference may be due to differences in the prescribed doses of the study. In this study, complications of fetal distress and meconium passage in the 50 µg group were 25%, which were more than the vaginal group (15%) and 100 µg group (11.7%). In a study by Mohammadyari women who received misoprostol 25 µg, Meconium staining and fetal distress was higher [19]. In the study conducted by Aquila Ayaz et al., maternal and fetal complications in oral and vaginal misoprostol were reported as similar [15]. Diro study showed no statistically different fetal outcome in the 25 and 50 µg groups [16], which are consistent with the findings of our study. Hyper-stimulation and meconium passage of the fetus increases in doses higher than 25 µg of misoprostol [16,20]. It is not clear yet, whether the passage of meconium in the fetus is due to the direct effect of medication on the digestive system of the fetus or results from hyper-stimulation of the uterus [21]. No significant statistical difference was shown in the study on induction and frequency in the three groups; however, it was lower in the 100 µg group. In the study conducted by Aquila Ayaz et al., induction success rates in recipients of vaginal type were more than oral type (84% vs. 77%) [15]. This lack of consistency may be related to differences in the medication doses and also population of study. In our study, we used 50 and 100 µg oral doses. While in Ayaz study, only 50 µg was used and also in that study postdate multigravida women were population of study.

Our findings indicated that there was no statistically significant difference in the mode of delivery in the three groups. The number of vaginal and cesarean delivery group was more than oral group and frequency of vaginal delivery was reduced in order in the oral 100 µg group, 50 µg, and vaginal group. In the study conducted by Mohammayari 70% of the women receiving misoprostol had vaginal delivery [19]. In the study conducted by Sheela et al., the frequency of vaginal delivery in the oral method was less than vaginal method, which was inconsistent with the findings of our study [11]. Diro study showed no difference in the delivery according to different methods of medication [16]. Differences in the frequency of delivery could be related to the differences in the study population medication dosages and type of medication. In our study, we measured the umbilical artery pH which was not conducted in other studies; however, no statistically different result was shown in the three groups.

Tandon et al., compared the safety and efficacy of oral vs vaginal misoprostol in equivalent doses (50mcg) for induction of labour. They showed that there was no significant difference between the groups in terms of mode of delivery, neonatal and maternal outcomes. Misoprostol (50 mcg) is effective in inducing labour whether it is given orally or vaginally [22]. Bearing in mind that their study population was term pregnancies while our study population was post term pregnancies. The results of Zhang review study revealed the efficacy and safety of oral misoprostol to induce labour [23]. Abdul Rahim also in a clinical trial study showed cost effectiveness of oral misoprostol to induce labour [24]. Voigt et al., in a study have explained that the most common reasons given for using misoprostol in labour induction were: effectiveness, good patient acceptance, established/well proven in clinical practice, and cost-effectiveness [25]. A clinical trial by Faucett et al., reported that oral misoprostol administered during labour induction in nulliparous women resulted in shorter time to vaginal delivery without adverse outcomes [26]. Alfirevic et al., evaluated the use of oral misoprostol for labour induction in women with a viable fetus. They concluded that oral misoprostol as an induction agent is effective at achieving vaginal birth [27].

CONCLUSION

In terms of labour induction and maternal outcomes in the post-term pregnant women, oral misoprostol 100µg is more useful than misoprostol 50 µg or the vaginal type of the medication. In mothers receiving oral 100µg misoprostol, lower doses and lesser induction is required, meconium passage is lower, frequency of vaginal delivery is higher, but fetal distress is not lower. Misoprostol can be used to significantly reduce the risk of maternal and neonatal mortality. Misoprostol is a strong medication and should be taken under full supervision. To prevent its misuse; the best dose and rout should be taken according to evidence based information.

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