Original Research Article

Use of misoprostol for induction of labor in full term pregnancy- A randomised control trial

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Abstract

Background: Induction of labor at full term of pregnancy needs uterine stimulation with resultant progressive uterine contractions, cervical effacement and dilatation for delivery of the baby. Vaginal Misoprostol is a safe and inexpensive agent for cervical ripening and Induction of labor. The present study was aimed to compare the efficacy of vaginal Prostaglandin E2 (Dinoprostone) and vaginal Misoprostol for induction of labor in full term pregnancies. **Material and methods:** It was a randomized control trial done in Maternity ward of two private nursing homes. All expecting mothers coming at full term pregnancy for labor induction were enrolled. 258 women fulfilled the criteria for induction of labor, out of which 208 women gave their consent freely to be the part of the study. These women were then randomized into two groups to receive the treatment. Group I received vaginal Misoprostol (Treatment 1) while Group II received vaginal ProstaglandinE2(PgE2) (Treatment II). Compilation of the observed data i.e. Induction delivery interval, Maternal and/ Fetal complications if any, APGAR SCORE of the baby, of 200 expecting mothers was done. **Results:** Study Group I and Group II, each comprised of 100 full term pregnant women. Initiation of labor pains took a mean of 6.67(±3.6) hours in Group I, while it took a mean of 8.41(± 5.13) hours in Group II. Actual time taken for the delivery of the baby from induction with misoprostol was mean 11.68(±4.5) hours, while with PgE2, it was mean 15.37(±5.3) hours. No cases of cervical tear or uterine rupture were observed in any of the study group but 10 cases of hyper-stimulation were observed in group I and 4 in Group II. **Conclusion:** It was observed in the above study that vaginal Misoprostol is more effective as compared to vaginal Prostaglandin E2 in induction of labor.
Key Word: misoprostol, induction of labor.

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INTRODUCTION

Induction of labor at full term of pregnancy needs uterine stimulation with resultant progressive uterine contractions, cervical effacement and dilatation for delivery of the baby. Oxytocin has been used for the same since its synthesis in 1950. 10% of the live births take place after induction mostly in post date pregnancy.[I] Most widely used pharmacological agent for cervical ripening is Prostaglandin E2 gel(Dinoprostone, Cerviprime).[2,3,4] Misoprostol (Cytotec) has been extensively investigated in the past few years for use in cervical ripening and induction of labor[5]. Marketed as a safe gastro protective agent, the drug also is a safe and inexpensive agent for cervical ripening and Induction of labor. The aim of the study is to compare the efficacy of vaginal Misoprostol and vaginal PgE2 gel for induction of labor at term pregnancy.

MATERIAL AND METHODS

A randomized controlled trial was undertaken. Estimation was undertaken separately for induction and delivery interval in hours(11.9±7hours for misoprostol and 15.6±7 hours for PgE2).Also estimation of need for oxytocin was observed as 65.80% in misoprostol and 80.70% in PgE2

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gel and estimation of fetal effect was done(< 7 APGAR SCORE at 1 minute , 12.5% with Misoprostol and 6%in PgE2 group.).The sample size calculated was 85 per group. It was increased to 108 to make up for refusals during the trial or fallacious data. The inclusion criteria was expecting mothers at 38 weeks or more, Parity less than 4 with all live babies, normotensive, normal uterus (no scar or uterine abnormality),singleton pregnancy with cephalic presentation, normal amount of liquor, normal fetus, normal placentation, poor Bishops score (<6).258 women were found eligible after evaluation, out of which 208 nwomen consented to be a part of the study.8 cases did not complete the trial and were exclude later. Expecting mothers were randomized to receive either treatment. Two groups were made each comprising 104 expecting women, labeled as Group I to receive Treatment I i.e. vaginal Misoprostol and Group II to receive Treatment Ii i.e Vaginal Prostaglandin E2 for the induction of labor. 208 envelopes were made, out of which 104 contained vaginal Misoprostol treatment plan and 104 contained vaginal PgE2 treatment plan. These were stacked randomly. As soon as a patient of the study came in labor, she was asked to choose an envelope, the envelope was numbered (the patient coming 1st, labeled as No.1, coming second labeled as No.2 and so on up to the last patient with No 208). The patient was given the treatment mentioned in her envelope, and the plan adhered to strictly. Thus the study was a double-blinded study as neither the patient nor the doctor had the choice of treatment. The patients with Treatment I, 50 micrograms of Misoprostol and those under Treatment II, 3mgs of PgE2 was inserted in the posterior vaginal fornix. For each patient Bishops score at induction, Time of Induction and Partogram was recorded. Besides, the Progress of labor and Fetal cardiotocogram(CTG) was recorded . Throughout close fetal heart monitoring was done. On commencement of labor, uterine contractions and Bishops score was reassessed. In cases with no labor pains or changes in Bishops score after 6 hours, reinsertion of the drug after CTG was done. A maximum of three doses were given, and with failed progress the case was termed as Drug failure. In patients where the Bishop score reached a score of "7", Artificial Rupture of Membrane was done and labor allowed to progress. Mode of delivery Apgar score of baby and complications if any, viz. hyperstimulation of the uterus, cervical tear, fetal distress, PPH were recorded. Cases with 5 or more uterine contractions in 10 minutes, persisting for next 20 minutes were labeled as uterine tachysystole. Persistent fetal bradycardia, fetal tachycardia, late decelerations, variable deceleration, decreased baseline variability (abnormal CTG) were recorded and intervened if and as needed. Data entry and analysis was done in SPSS version 10(SPSS Inc. Chicago, IL, U.S.A.). Independent sample t Test was used for comparison of quantitative variables (Induction, labor and delivery interval). For Comparison of categorical variables like fetal and maternal complications Pearson X square test was applied. Statistical significance was p=0.06.

RESULTS

Out of the total 208 women included in the study, 200 had completed the data making 100 in each group. Matching of confounding variables such as Age, Gavidity and Bishops score was done. Mean age in the study group was 26.2 years. The mean Bishops score was very poor in both the groups and the difference not statistically significant.

Table 1: Descriptive Statistics.

Parameters	*n*	Mean ± Standard Deviation
Age (yr)	200	26.22 ± 3.40
Gravidity	200	2.20 ± 1.24
Gestational age	200	40.11 ± 1.37
Bishop score	200	3.12 ± 1.28.

Table 2: results of primary outcome measures

Primary Outcome Measures	Mode of induction	*n*	Mean ± SD	*p*	95% confidence interval	
					Lower	Upper
Number of doses	Misoprostol	100	1.77 ± 0.84	0.003	−0.565	−0.114
	Dinoprostone	100	2.11 ± 0.78	0.003	−0.565	−0.114
Induction labor interval	Misoprostol	100	6.67 ± 3.63	0.006	−2.971	−0.490
	Dinoprostone	100	8.40 ± 5.13	0.007	−2.972	−0.489
Induction-delivery interval	Misoprostol	97	11.69 ± 4.56	0.000	−5.105	−2.265
	Dinoprostone	91	15.37 ± 5.30	0.000	−5.111	−2.258.

Table B shows the Primary outcome measure i.e. number of doses of drugs administered, Induction to commencement of labor Interval and induction to delivery interval. On comparing the Modes of delivery in both the groups, Group I had 84 while Group II had 71 normal deliveries. Out of the total Instrumental deliveries in both the groups, nearly 2/5 belonged to Group I and 3/5 to Group II. Out of the total Lower segment cesarian sections done in both the groups, ¼ belonged to Group I and ¾ belonged to Group II, but the total number was statistically insignificant.

Table 3: results of secondary outcome measures:

Secondary Outcome Measures		Misoprostol	Dinoprostone	*p*
Use of oxytocin		36 (43.4)	47 (56.6)	0.114
Uterine hyperstimulation		10 (71.4)	4 (28.6)	0.096
Post-partum hemorrhage		9 (36)	16 (64)	0.134
Abnormal CTG (% age within fetal complication)		14 (50)	14 (50)	
Meconium (% age within fetal complication)		0	7 (100)	
Apgar score	⩽6	8 (8)	15 (15)	0.36
	> 6	92 (92)	85 (85)	

Data are presented as *n* or *n* (%). CTG = cardiotocography. Table C shows secondary outcome measure results viz. Use of oxytocin. Uterine hyperstimulation, PPH, abnormal CTG, Meconium staining, Apgar score of the baby.

DISCUSSION

The main outcome was Induction to labor and Induction to delivery interval. There was a decrease in the time taken from induction to onset of labor in the group I receiving Vaginal Misoprostol and it was statistically significant. In Group I this time was mean 6.67 hours while in Group II it was mean 8.40 hours (p= 0.00). The dose required in Group I was less as compared to that in Group II. Mean dose of Misoprostol was 1.7 while that of PgE2 was 2.1. Fewer doses and shorter induction to delivery interval were reported by Neiger and Greaves[6] and Chang *et al*[7].According to Danielian and Porter, single 50 microgram dose of Misoprostol sufficed for many women for delivery[8].This was opined by Hassan too[9].The other important conclusion was regarding Induction Delivery interval. In the study, the induction to delivery interval in Group I was mean 3.68hours(p=0.000) hours lesser than Group II. which is in accordance with the reports published by Khoury(21.3 hours vs 27.2hrs)[11].Hofmeyr and olmezoglu found Misoprostol to be associated with lower failure rates as compared to prostaglandins.[12]. Also, in Group I intervention in terms of LSCS was much less compared to Group II. (Out of total 12 Lower segment caesarean sections performed, a total 3 were from Group I while 9 were from Group II. Ramos and Kaunitz also reported a lesser LSCS rate in cases induced by Misoprostol[10]. It was noted that in Group II, there was a greater need for Oxytocin for acceleration of labour. Cochrane database definitions[13] were used while evaluating uterine tachysystole and CTG abnormalities. No cases of uterine hyperstimulation were observed but tachysystole occurred

in 10 cases of Group I and 4cases of Group II, but the statistical significance of this factor was not determined as the study was not powered so. Equal number of CTG abnormalities were found in both the study groups, except Meconium staining of the liquor, which was higher in Group II (7 as compared to none in Group I). The 1 minute Apgar was > 6 in 8% of Group I cases and 15% in Group II cases. Montvale NJ, reported lesser neonatal care admissions with Misoprostol induction of labor in comparison with PgE2[14]. Neither cases of toxicity to fetus, teratogenicity in foetuses or carcinogenic effects to mother or fetus nor ill effects on the neonates have been reported[15-19]. As the route used was vaginal, gastro intestinal side effects were curtailed.

CONCLUSION

It was observed in the above study that vaginal Misoprostol is more effective as compared to vaginal Prostaglandin E2 in induction of labor.

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