

Comparative Study of Low Dose Vaginal Misoprostol versus Oxytocin in Induction of Labor

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Abstract

Objective: The aim of this study is to compare the efficacy, side effects and complications of low dose vaginal misoprostol with intravenous oxytocin infusion for induction of labor.

Methods: One hundred forty-two pregnant women with indication for induction of labor were assigned randomly to receive either vaginal misoprostol 25 µgm 6 hrly to a maximum of 6 doses (misoprostol group, n = 72) or escalating dose of oxytocin infusion upto 20 mIU/min in primigravida and upto 10 mIU/min in multigravida (oxytocin group, n = 70).

Results: Demographic characteristics were similar in both the groups. The difference in mean induction to delivery interval (11.2 ± 6 hrs in misoprostol group vs 12.2 ± 6 hrs in oxytocin group) was statistically insignificant when two groups were compared. The incidence of vaginal delivery (86.1% in misoprostol group vs 84.2% in oxytocin group), and cesarean delivery (13.9% in misoprostol group vs 15.8% in oxytocin group), was almost similar in both the groups. The causes of cesarean delivery were dystocia (40% in misoprostol group vs 67% in oxytocin group), and fetal distress (60% in misoprostol group vs 33% in oxytocin group) and the difference was statistically significant (P < 0.01). The complications were almost similar in both the group, with no significant difference.

Conclusion: Misoprostol when used in low dose of 25 µgm is safe, effective and cheaper drug for induction of labor with fewer maternal and fetal complications.

Keywords: Misoprostol, Oxytocin, Pregnancy, Induction of labor.

INTRODUCTION

Induction of labor is common in obstetric practice. According to the most current studies, the rate varies from 9.5 to 33.7% of all pregnancies annually.¹ In absence of ripe/favorable cervix, successful vaginal birth is less likely. A variety of methods have been used for this intervention, which include misoprostol and oxytocin. Misoprostol, which is a prostaglandin E1 analogue, is a potent uterotonic agent that has been shown to be highly effective for cervical ripening and labor induction.^{2,3} Clinical trials indicate that the optimal dose and dosing interval is 25 µgm intravaginally every 4 to 6 hours.^{4,5} Misoprostol is more effective than oxytocin or prostaglandin E₂ for inducing vaginal delivery within 24 hours, however uterine hyperstimulation with associated changes in fetal heart rate was more common in women who received misoprostol than in women who received oxytocin.⁶ 50 µgm dose results in shorter induction to delivery time, however 25 µgm is more prudent because it is associated with lower incidence of hyperstimulation. It is also comparable to 50 µgm dose in achieving delivery within 24 hours.⁷⁻⁹ Misoprostol is a cheap drug, which needs no cold chain maintenance in comparison to oxytocin,

which requires cold chain maintenance. So, this study was carried out to evaluate the safety of low dose vaginal misoprostol and to compare its efficacy, side effects and complications with oxytocin for induction of labor.

MATERIALS AND METHODS

The study was conducted in the Department of Obstetrics and Gynecology from June 2007 to May 2008 at Jawaharlal Nehru Medical College Hospital, AMU, Aligarh. A total of 142 pregnant women were included in the study who were presented to the hospital for indicated labor induction. Criteria for exclusion were spontaneous labor regular intensive contractions with cervical dilatation, contra-indication to prostaglandins, partial or complete placenta previa, previous cesarean section or major uterine surgery and cephalopelvic disproportion. Women were categorized into two groups:

1. *Misoprostol group:* pregnant women who received 25 µgm vaginal misoprostol (n = 72).
2. *Oxytocin group:* Pregnant women who received oxytocin infusion in escalating dose (n = 70).

In misoprostol group, 25 µgm vaginal misoprostol was given at 6 hourly intervals, maximum of 6 doses were given. Before

repeating the next dose, patient was examined for vitals, uterine contractions, fetal heart sound and per vaginum findings.

The dose was not repeated, if 2 contractions lasting for 30 seconds or more were coming in 10 minutes.

In oxytocin group, infusion was started for labor induction. Primigravida was started with 5 IU of oxytocin in 500 ml of normal saline (NS). Dose was escalated according to intensity and duration of uterine contraction at 30 minutes interval; maximum dose given was 20 mIU/min. Multigravida was started with 2.5 IU of oxytocin in 500 ml of normal saline; maximum dose given was 10 mIU/min. The primary study outcome was the rate of vaginal delivery and the secondary outcome was assessed as induction to delivery interval, maternal and neonatal side effects, and complications. Data were compared by using student t-test and z-test for proportion.

RESULTS

Out of 142 pregnant women, 72 were randomly allocated to the use of 25 mg vaginal misoprostol and 70 were allocated to the use of oxytocin infusion. No significant difference was found between the two groups when they were compared regarding age, parity, gestational age at the time of labor induction (Table 1). Compared with women receiving oxytocin, a greater percentage of women in the misoprostol group had bishop score of 3 or less (mean 1.9 ± 1.6 vs 3.4 ± 1.6, p < .001) (Table 1).

Mean induction to delivery interval in misoprostol group was 11.2 ± 6 hrs and in oxytocin group, it was 12.2 ± 6 hrs. The difference was statistically insignificant when the two groups were compared (Table 1). Indication for induction was almost similar between the two groups with the predominant indication being pregnancy induced hypertension (Fig. 1). But no statistically significant difference was found between the two groups regarding indication for labor induction.

62.5% of women delivered with one dose of misoprostol, 22.22% required 2 doses, 13.89% required 3 doses, and only 1.39% required 4 doses. 25% of women in misoprostol group required oxytocin augmentation.

Sixty two patients (86.1%) in misoprostol group had vaginal delivery while 59 patients (84.2%) in oxytocin group had vaginal delivery. The difference was statistically insignificant when the two groups were compared. 10 patients (13.9%) in misoprostol group had cesarean delivery while 11 patients (59.8%) in oxytocin group had cesarean delivery. The difference was statistically insignificant when the two groups were compared (Table 2). Dystocia was the cause of cesarean in 29 patients (40%) in misoprostol group vs in 47 patients (67%), and the difference was statistically significant when two groups were compared p < 0.01 (Table 2). Fetal distress was the cause of cesarean in 43 patients (60%) in misoprostol group vs in 23 patients (33%), in oxytocin group, and the difference was statistically significant when two groups were compared p < 0.01 (Table 2).

The complications were almost similar in both groups. Hyperstimulation (2.77%), cervical tear (2.77%) and perineal

Table 1: Demographic parameters and mean induction to delivery interval in misoprostol group and oxytocin group

	Misoprostol group	Oxytocin group
Mean age (years)	26.9 ± 4.9	27.5 ± 4.9
Mean parity (numbers)	2.4 ± 1.7	2.3 ± 1.7
Mean gestational age at the time of labor induction (weeks)	37.1 ± 4.0	38.0 ± 3.4
Mean bishop score	1.9 ± 1.6	3.4 ± 1.6
Mean induction to delivery interval (hours)	11.2 ± 6	12.2 ± 6

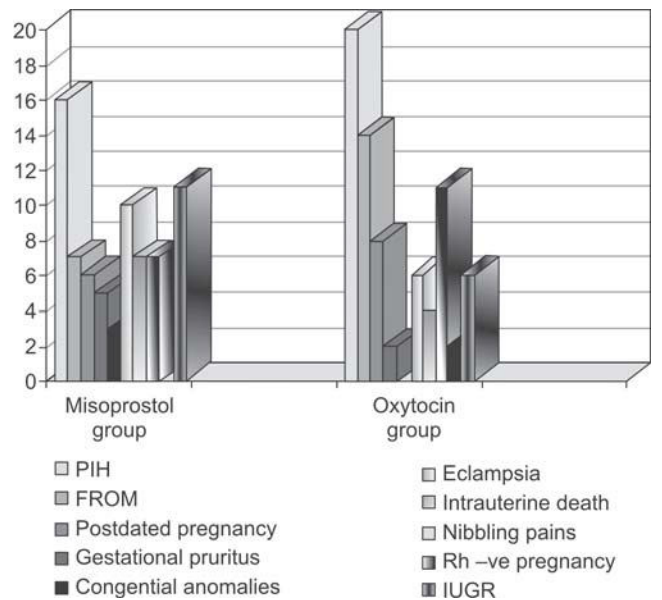


Fig. 1: Distribution of cases according to indication for induction of labor

Table 2: Distribution of cases according to the mode of delivery and the cause of cesarean in misoprostol group and oxytocin group

	Misoprostol group	Oxytocin group
Vaginal delivery	62	59
Cesarean delivery	10	11
Dystocia	29	47
Fetal distress	43	23

tear (2.77%) occurred in misoprostol group while in oxytocin group, hyperstimulation (1.42%), cervical tear (1.42%) and perineal tear (2.86%). The incidence of complications was very less in both groups and the difference did not reach the statistical significance.

Meconium aspiration occurred in eight newborns (12.30%) in misoprostol group, while in oxytocin group it occurred in six newborns (9.09%). The difference was not statistically significant. Four newborns (6.15%) in misoprostol group were admitted to neonatal ICU while three newborns (4.54%) in oxytocin group were admitted to neonatal ICU.

DISCUSSION

Misoprostol is safe and inexpensive agent for labor induction.¹⁰ The present study used 25 µgm of misoprostol vaginally at 6 hours interval as the Committee on obstetrics of the ACOG (1999b) recommended the use of a 25 µgm intravaginal dose.¹¹ The present study showed that the rate of vaginal delivery and cesarean are comparable in both groups. According to Cochrane review 2000, vaginal misoprostol (25-100 µgm) was more effective than oxytocin for inducing vaginal delivery within 24 hours, however uterine hyperstimulation with associated changes in fetal heart rate was more common in women who received misoprostol. There was no difference in the rate of cesarean, neonatal, and maternal morbidity and mortality.¹² The complications were less in our study because we had used the lowest recommended vaginal dose and not repeated the dose once the moderate contractions had started. In our study, total percentage of cesarean delivery was not significantly different, although the percentage of cesarean delivery for dystocia was lower in misoprostol group 29% vs 47%, $p < 0.01$, compatible with the findings of study done by Kremer et al.¹³ The present study showed that mean time interval between induction to delivery was shorter in misoprostol group but when compared with oxytocin group, it was not statistically significant. Other studies showed average time interval between induction to delivery was shorter in misoprostol group as compared to oxytocin group.^{10,14}

Our study showed no statistical significant difference when complications were compared but some studies have shown greater prevalence of hyperstimulation syndrome with misoprostol.^{6,15,16} The complications were less in our study because we had used the lowest recommended vaginal dose and not repeated the dose once the moderate contraction had started. Our study showed no difference between the groups when neonatal outcome was compared.

In the present study, we have seen that the use of misoprostol is highly efficacious as an agent for labor induction. Although comparable rates of induction success were noted between the misoprostol and oxytocin but misoprostol is cheaper, easily available and may not require repeat doses to induce labor. The main advantage with misoprostol induction is that women remain mobile during induction of labor. Another advantage of misoprostol over oxytocin is that it is stable at room temperature and does not require cold chain maintenance therefore, it is very useful medication for low resource country as India where refrigerator is not available everywhere and it is more cost effective as there is no requirement of waste disposal as syringes and needles.

CONCLUSION

Misoprostol is one of the most important medications in obstetrical practice. The present study favors the use of

misoprostol as an inducing agent. Its major complication can be minimized by exercising caution when medication is in use.

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