ORIGINAL RESEARCH

The Impact of Labor Augmentation Methods on Delivery Outcomes: A Study of Oral Misoprostol Versus Intravenous Oxytocin in Term Pregnancies

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ABSTRACT

Background: Labor is a natural physiological process, but prolonged or obstructed labor can lead to significant maternal and fetal complications, especially in developing countries. Augmentation of labor is often necessary to prevent these complications. Traditionally, intravenous oxytocin has been the preferred method for labor augmentation, but oral misoprostol has emerged as a potential alternative due to its ease of administration. This study aims to compare the efficacy, safety, and outcomes of oral misoprostol versus intravenous oxytocin in labor augmentation among primigravidae at term.

Materials and Methods: This prospective study was conducted at NRS Medical College and Hospital, Kolkata, over a period of one year from May 2011 to April 2012. A total of 100 primigravidae with singleton pregnancies and inadequate uterine contractions were randomly assigned to receive either oral misoprostol (25 mcg every 4 hours, up to three doses) or intravenous oxytocin infusion. The primary outcomes measured were augmentation-delivery interval, mode of delivery, and neonatal outcomes. Secondary outcomes included maternal complications such as postpartum hemorrhage and uterine hypertonicity.

Results: The average augmentation-delivery interval was shorter in the misoprostol group (5.2 hours) compared to the oxytocin group (5.5 hours). Normal vaginal delivery rates were 80% in the misoprostol group and 82% in the oxytocin group. There was no significant difference in the incidence of cesarean section between the groups (14% each). The misoprostol group had a higher incidence of fetal distress (12% vs. 2%), meconium-stained liquor (14% vs. 2%), and tachysystole (12% vs. 2%). Neonatal outcomes, including Apgar scores and NICU admissions, were similar between the groups.

Conclusion: Both oral misoprostol and intravenous oxytocin effectively augment labor in primigravidae at term. While misoprostol offers ease of administration, it is associated with a higher incidence of fetal distress and tachysystole. Overall, there is no significant difference in maternal or neonatal outcomes between the two methods. Future studies should focus on optimizing misoprostol dosing to minimize adverse effects while maintaining efficacy.

Keywords: Labor augmentation, oral misoprostol, intravenous oxytocin, primigravidae, neonatal outcomes, maternal complications, obstetrics, labor management.

INTRODUCTION

In recent years, there has been a notable shift in our approach to managing labor. Previously, a policy of watchful expectancy was commonly practiced, with the understanding that labor is a natural physiological phenomenon. However, the dangers of prolonged labor are now well-recognized, leading to a more liberal use of cesarean sections. Despite this, prolonged labor remains a problem, often due to weak uterine contractions or poor cervical dilation (1). To address this, oxytocic drugs have been employed to stimulate contractions, overcoming issues of inadequate labor (2-6).

Labor augmentation refers to the stimulation of spontaneous contractions that are deemed insufficient. Traditionally, labor augmentation has involved both surgical and medical methods, with oxytocin being a long-standing medical option. While intravenous

oxytocin has been the standard for many years, prostaglandins have emerged as a newer option, administered as a cervical gel, vaginal tablet, or orally. The oral route is convenient for both patients and physicians, although misoprostol is not yet widely practiced in many centers. However, its efficacy as an alternative to oxytocin warrants exploration (7).

Labor is a natural process, and achieving a safe vaginal delivery of a healthy infant is one of the most rewarding experiences in a woman's life. However, complications such as prolonged and obstructed labor can significantly impact maternal and fetal morbidity and mortality, especially in developing countries where risks include sepsis, uterine rupture, and postpartum hemorrhage. In India, the incidence of obstructed labor ranges from 1% to 5%, contributing to approximately 10% of maternal deaths (8). In the developed world, cesarean section rates for dystocia are increasing, accounting for at least one-third of all cesareans. Repeat sections following a primary cesarean contribute to another third, leading to increased maternal mortality and morbidity, particularly when performed as emergency procedures (9-10).

The use of a partograph, a relatively simple and inexpensive chart, can help monitor labor progress and reduce unnecessary suffering and delays (11-14). The concept of partography was introduced by Friedman in New York in 1954 as "the graphic analysis of labor" (15-16). Friedman's studies concluded that progressive cervical dilation is the most crucial factor in assessing labor progress. Subsequent refinements by Philpott and Castle added alert and action lines, enhancing the graph's utility (17-18). The current WHO-recommended partograph includes parameters such as cervical dilation, fetal descent, fetal heart rate, uterine contractions, amniotic fluid characteristics, and maternal vital signs (19-22).

Upon admission in the active phase of labor, cervical dilation is plotted on the alert line. If labor progresses normally, the cervix dilates at approximately 1 cm per hour, and the curve does not cross the alert line. If progress is slow, resulting in the curve crossing the alert line, it is termed "primary dysfunctional labor." Conversely, if progress is initially normal but subsequently slows, it is termed "secondary arrest of labor" (11). If the cervical dilation curve crosses the alert line, referral to a tertiary care center is recommended. Crossing the action line necessitates identifying the cause of slow progress and implementing appropriate interventions, such as amniotomy, augmentation with oxytocin or prostaglandin, or cesarean section.

In light of the gaps in our current understanding, the need for labor augmentation is evident. While oxytocin has been extensively studied, newer agents like PGE1 (misoprostol) remain relatively unexplored. A thorough comparison between these agents is necessary to understand their efficacy, safety, ease of application, availability, and potential adverse effects on maternal and fetal outcomes. This study aims to reveal the pros and cons of oxytocin infusion and oral misoprostol, providing insights into their use in labor augmentation.

MATERIALS AND METHODS

Study Area: This prospective study was conducted in the labor room of NRS Medical College and Hospital, Kolkata. The study focused on primigravidae at term with cervical dilatation of at least 4 cm and fewer than three contractions per 10 minutes, each lasting less than 40 seconds.

Study Population: The study included 100 primigravidae women carrying singleton pregnancies at term with spontaneous onset of labor.

Inclusion Criteria

The inclusion criteria for the study were as follows:

a.Patientsagedbetween18to28years.
b.Primigravidaebetween37to42weeksofgestationalage.
c.Livesingletonpregnancy.
d.Cephalicpresentation.
e.Spontaneousonsetoflabor.
f.Cervicaldilatationof4comore.
g.Inadequateuterinecontractions(lessthanthreeper10minutes).
h. Reassuring fetal heart rate.

Exclusion Criteria

The exclusion criteria included:

a. Patients with premature up ture of membranes(PROM).
b. Multiple pregnancies.
c. Polyhydramnios.
d. Non-cephalicpresentation.
e. Probablecephalopelvicdisproportion(CPD).
f. Suspectedintrauterinegrowthrestriction(IUGR).
g. Scarreduterus.
h. Uterineperforation.
i. Medical diseases such as heart disease or bronchial asthma.

Study Period: The study was conducted from May 2011 to April 2012.

Sample Size: The sample size consisted of 100 pregnant primigravidae women at term who met the inclusion criteria.

Study Technique

a. Patients in active labor with spontaneous onset were selected, having a cervical dilatation of 4 cm or more with less than 3 uterine contractions per 10 minutes lasting for less than 40 seconds.

b. Data were obtained from the study of specific interventions in cases of slow labor that were otherwise uncomplicated.

c. Written informed consent was obtained from participants, with consent forms prepared in Bengali,

Hindi, and English. Participants were thoroughly counseled before consenting.
d. A thorough general, systemic, and obstetrical examination was conducted.
e. Cases were assigned using simple random sampling. Each agent was applied to every alternate case, with 50 cases allocated to the misoprostol group (oral misoprostol 25 mcg at 4-hour intervals, up to a maximum of 3 doses) and 50 cases to the oxytocin group (intravenous oxytocin infusion).
f. Oxytocin infusion was started at a minimum dose of 2 mIU/min in Ringer lactate solution, with dose adjustments every 15 minutes to achieve desired uterine contractions, up to a maximum dose of 5 mIU/min at 15 to 20 drops per minute.
g. Patients were observed for fetal bradycardia or tachycardia, tachysystole, hypercontraction, and color of liquor during augmentation. Parameters were noted on the partograph.
h. Per vaginal examination was repeated every 4 hours. Non-progress of labor was declared if there was minimal or no change in the cervicograph, evidenced by flattening of the curve.
i. Caesarean section was performed in cases of confirmed fetal distress or non-progress in the first stage of labor.
j. The study design was a prospective cohort study. Investigators and postgraduate trainees managing the labor room were not blinded to the study group allocation.

Parameters Studied

1. **Efficacy of the drug by:**
   a. Time interval between augmentation and delivery.
   b. Need for termination by caesarean section.
2. **Complications in each group (during labor) like:**
   a. Subjective complaints and abnormalities in maternal vitals (pulse, blood pressure, etc.).
   b. Fetal distress (assessed by fetal heart sound (FHS) monitoring, ultrasound (USG), and color of liquor).
   c.Excessiveuterinecontractions.
   d. Postpartum hemorrhage.
3. **Neonatal assessment by:**
   a.Need for resuscitation.
   b. APGA Rscore.
   c. Need for admission to the Neonatal Intensive Care Unit (NICU).
4. **Ease of application of eitherdrug by:**
   a.Method of application.
   b.Setuprequired.
   c. Storage.

Study Tools

The primary tools used in this study were clinical in nature. Digital obstetric per vaginal (p/v) examination assessed cervical dilatation, cervical effacement, fetal head position and station, and pelvic assessment. Fetal heart sound was monitored using a stethoscope, with handheld Doppler or USG used to confirm fetal cardiac activity and heart rate when FHS was uncertain. Labor progress was plotted on the partograph, with deviations from the normal curve prompting appropriate action.

Plan for Data Analysis

Data analysis was performed using appropriate statistical tests with Microsoft Excel software. Fisher's exact test and chi-square test compared different variables between the two groups. Analysis was two-tailed, with a P value of 0.05 considered statistically significant. All variables were calculated with ± 2 standard deviations.

RESULTS AND ANALYSIS

A) Age Distribution

The distribution of subjects in both groups based on age was similar, indicating a well-matched study population.

Table 1: Age Distribution of Subjects

Age Group (years)	Misoprostol Group (n=50)	Oxytocin Group (n=50)
<20	12 (24%)	10 (20%)
20-30	37 (74%)	38 (76%)
>30	1 (2%)	2 (4%)
Total	**50 (100%)**	**50 (100%)**

B) Need for Analgesia: The need for analgesia was found to be similar in both groups.

Table 2: Need for Analgesia

Analgesia Required	Misoprostol Group	Oxytocin Group
Yes	37 (74%)	35 (70%)
No	13 (26%)	15 (30%)
Total	**50 (100%)**	**50 (100%)**

C) Augmentation-Delivery Interval: The average time interval from the application of the agent to delivery was slightly shorter in the misoprostol group.

Table 3: Average Time Interval from Augmentation to Delivery

Group	Average Time Interval
Misoprostol Group	5.2 hours
Oxytocin Group	5.5 hours

D) Delivery Within 5 Hours: A higher number of deliveries occurred within 5 hours in the misoprostol group compared to the oxytocin group.

Table 4: Delivery Within 5 Hours of Application

Delivery Time	Misoprostol Group	Oxytocin Group
Within 5 hours	34 (68%)	7 (14%)
After 5 hours	16 (32%)	43 (86%)
Total	**50 (100%)**	**50 (100%)**

- **Chi-square value**: 30.14
- **Degree of freedom**: 1
- **P value**: <0.001 (significant)

E) Mode of Delivery: The mode of delivery was similar in both groups, with a slightly higher incidence of forceps delivery in the misoprostol group.

Table 5: Mode of Delivery

Mode of Delivery	Misoprostol Group	Oxytocin Group
LSCS	7 (14%)	7 (14%)
Forceps delivery	3 (6%)	2 (4%)
Normal vaginal	40 (80%)	41 (82%)
Total	**50 (100%)**	**50 (100%)**

F) Indications for LSCS: Indications for LSCS were similar between the groups, with slightly more cases of fetal distress in the misoprostol group.

Table 6: Indications for LSCS

Indication	Misoprostol Group	Oxytocin Group
Fetal distress	5	1
Prolonged labor	2	6
Cord prolapse	1	0

G) Complications

a. Fetal Distress: Fetal distress was more frequent in the misoprostol group compared to the oxytocin group.

Table 7: Occurrence of Fetal Distress

Fetal Distress	Misoprostol Group	Oxytocin Group
Yes	6 (12%)	1 (2%)
No	44 (88%)	49 (98%)
Total	**50 (100%)**	**50 (100%)**

- **Chi-square value**: 3.8409
- **P value**: <0.05 (significant)

b. Meconium Staining: Meconium staining of liquor was significantly higher in the misoprostol group.

Table 8: Meconium Staining of Liquor

Meconium Staining	Misoprostol Group	Oxytocin Group
Yes	7 (14%)	1 (2%)
No	43 (86%)	49 (98%)
Total	**50 (100%)**	**50 (100%)**

- **Chi-square value**: 4.89
- **P value**: <0.05 (significant)

c. Tachysystole: Tachysystole was more common in the misoprostol group.

Table 9: Occurrence of Tachysystole

Tachysystole	Misoprostol Group	Oxytocin Group
Yes	6 (12%)	1 (2%)
No	44 (88%)	49 (98%)
Total	**50 (100%)**	**50 (100%)**

- **Chi-square value**: 3.8409
- **P value**: <0.05 (significant)

d. Hypertonicity

Hypertonicity occurred in one subject in the misoprostol group and none in the oxytocin group.

Table 10: Occurrence of Hypertonicity

Hypertonicity	Misoprostol Group	Oxytocin Group
Yes	1 (2%)	0 (0%)
No	49 (98%)	50 (100%)
Total	**50 (100%)**	**50 (100%)**

Chi-square value: 1.01
P value: Not significant

e. Postpartum Hemorrhage (PPH)

The occurrence of postpartum hemorrhage was similar in both groups.

Table 11: Occurrence of Postpartum Hemorrhage

PPH	Misoprostol Group	Oxytocin Group
Yes	2 (4%)	2 (4%)
No	48 (96%)	48 (96%)
Total	**50 (100%)**	**50 (100%)**

Chi-square test: 0
P value: Not significant

H) Neonatal Wellbeing

a. Need for Neonatal Resuscitation: The need for neonatal resuscitation was slightly higher in the misoprostol group.

Table 12: Need for Neonatal Resuscitation

Resuscitation Needed	Misoprostol Group	Oxytocin Group
Yes	2 (4%)	1 (2%)
No	48 (96%)	49 (98%)
Total	**50 (100%)**	**50 (100%)**

- **Chi-square value**: 0.34
- **P value**: Not significant

b. APGAR Score

The APGAR score below 7 was more frequent in the misoprostol group at 1 minute, but the difference was not statistically significant.

Table 13: APGAR Score at 1 Minute and 5 Minutes

APGAR Score	Misoprostol Group	Oxytocin Group
<7 at 1 minute	5 (10%)	1 (2%)
>7 at 1 minute	45 (90%)	49 (98%)
Total	**50 (100%)**	**50 (100%)**

- **Chi-square value**: 2.83
- **P value**: Not significant

Table 14: Mean APGAR Score

Time	Misoprostol Group	Oxytocin Group
At 1 minute	8.18	8.34
At 5 minutes	9.36	9.74

c. Need for NICU Admission

The need for NICU admission was slightly higher in the misoprostol group.

Table 15: Need for NICU Admission

NICU Admission Needed	Misoprostol Group	Oxytocin Group
Yes	2 (4%)	1 (2%)
No	48 (96%)	49

DISCUSSION

This prospective study was conducted at the Department of Obstetrics and Gynecology, NRS Medical College and Hospital, from May 2011 to April 2012. The study aimed to compare the efficacy and safety of oral misoprostol (PGE1) and intravenous oxytocin for labor augmentation in primigravidae at term. The study involved 100 participants, divided equally between the two intervention groups, ensuring that all participants were in the active phase of labor with cervical dilatation of 4 cm or more at randomization.

The primary objective was to assess the efficacy of each agent in reducing the augmentation-delivery interval. Our findings indicated that the average time from augmentation to delivery was slightly shorter in the misoprostol group (5.20 hours) compared to the oxytocin group (5.50 hours). Similar studies have reported comparable findings, with Cheng et al. (2010) observing median intervals of 5.22 hours for misoprostol and 5.20 hours for oxytocin, suggesting no significant difference between the two agents in terms of augmentation efficiency (1). Another study by Villano et al. (2011) also found no significant difference in delivery intervals, concluding that oral misoprostol is an effective alternative to oxytocin for labor augmentation (2).

The mode of delivery outcomes was similar in both groups, with 14% undergoing lower segment cesarean section (LSCS) in each group. The incidence of forceps delivery was slightly higher in the misoprostol group (6%) compared to the oxytocin group (4%), while normal vaginal delivery rates were 80% and 82%, respectively. These results align with previous studies that reported similar delivery mode distributions between misoprostol and oxytocin groups (1, 2).

The second objective focused on evaluating the potential complications associated with each agent. The incidence of fetal distress, evidenced by fetal bradycardia or tachycardia, was higher in the misoprostol group (12%) compared to the oxytocin group (2%). This finding is consistent with the literature, where misoprostol has been associated with a higher risk of uterine hyperstimulation leading to fetal distress (3).

Meconium-stained liquor was significantly more common in the misoprostol group (14%) compared to the oxytocin group (2%), with a statistically significant p-value (<0.05). The occurrence of tachysystole (6 or more uterine contractions per 10 minutes) was also higher in the misoprostol group (12%) compared to the oxytocin group (2%), with a significant p-value (<0.05). A study by Bleich et al. (2003) reported similar findings, indicating an increased risk of uterine tachysystole with misoprostol use (4).

Hypertonicity was observed in 1 subject (2%) in the misoprostol group, while no cases were reported in the oxytocin group. Postpartum hemorrhage (PPH) was noted in 4% of participants in both groups, suggesting no significant difference in the incidence of PPH between the two agents. The low dose of misoprostol (25 mcg) used in this study might have contributed to the comparable PPH rates.

The third objective assessed neonatal wellbeing post-delivery. In the misoprostol group, 10% of neonates had an APGAR score below 7 at 1 minute, compared to 2% in the oxytocin group. However, the difference was not statistically significant (p-value >0.05). Similarly, the need for neonatal resuscitation was 4% in the misoprostol group and 2% in the oxytocin group, with no significant difference observed. The need for NICU admission was slightly higher in the misoprostol group (4%) compared to the oxytocin group (2%), but the difference was not statistically significant.

The mean APGAR scores at 1 and 5 minutes were similar between the groups, indicating that both agents were comparable in terms of neonatal outcomes.

The fourth objective was to compare the ease of application of the two agents. Oral misoprostol was easier to administer, requiring no special setup or refrigeration, unlike oxytocin, which needed intravenous administration with Ringer's solution and refrigeration for storage. This ease of administration provides a practical advantage for misoprostol in settings where resources may be limited.

CONCLUSION

In conclusion, both oral misoprostol and intravenous oxytocin effectively augment labor in primigravidae with inadequate uterine contractions. While misoprostol was associated with higher rates of tachysystole, meconium-stained liquor, and fetal distress, the overall maternal and neonatal outcomes were comparable between the two agents. The ease of administration and storage of misoprostol offers a slight practical advantage over oxytocin. However, clinicians should weigh the risks and benefits of each agent based on individual patient needs and resource availability.

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