ORIGINAL RESEARCH

Evaluating Neonatal and Maternal Health Outcomes Following Labor Augmentation with Misoprostol and Oxytocin in Primigravid Women

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Abstract

Background: Labor augmentation is a critical intervention to address prolonged labor, which poses significant risks to maternal and fetal health. Traditionally, oxytocin has been the primary agent for augmenting labor, but misoprostol, a prostaglandin analog, offers a potential alternative. This study aims to evaluate the efficacy, safety, and ease of application of oral misoprostol compared to intravenous oxytocin in augmenting labor among primigravid women.

Materials and Methods: This prospective study was conducted at NRS Medical College and Hospital, Kolkata, from May 2011 to April 2012. A total of 100 primigravid women carrying singleton pregnancies at term with spontaneous onset of labor were enrolled. Participants were randomly assigned to two groups: one receiving oral misoprostol (25 mcg every 4 hours up to a maximum of 3 doses) and the other receiving intravenous oxytocin infusion. Key outcomes measured included augmentation-to-delivery interval, mode of delivery, neonatal APGAR scores, incidence of complications, and ease of drug application. Data were analyzed using Fisher's exact test and chi-square test, with a significance threshold of $p<0.05$.

Results: The average augmentation-to-delivery interval was slightly shorter in the misoprostol group (5.2 hours) compared to the oxytocin group (5.5 hours). A significantly higher number of deliveries occurred within 5 hours in the misoprostol group (68%) compared to the oxytocin group (14%) ($p<0.001$). The incidence of fetal distress was higher in the misoprostol group (12% vs. 2%, $p<0.05$), and meconium-stained liquor was more common with misoprostol (14% vs. 2%, $p<0.05$). Neonatal outcomes, including APGAR scores and NICU admissions, were similar between the groups, with no significant differences in the need for resuscitation or NICU admission. Ease of application favored misoprostol due to its oral administration and lack of refrigeration requirements.

Conclusion: Both oral misoprostol and intravenous oxytocin effectively augment labor in primigravid women. Misoprostol offers the advantage of ease of administration and storage, but it is associated with a higher incidence of fetal distress and meconium staining. Despite these concerns, neonatal outcomes were comparable between the two groups. Further studies are needed to explore optimal dosing and minimize complications associated with misoprostol use.

Keywords: Labor augmentation, misoprostol, oxytocin, primigravid women, neonatal outcomes, maternal health.

Introduction

In recent years, the management of labor has shifted significantly from a policy of watchful expectancy to a more proactive approach. Historically, labor was regarded as a purely physiological process that required minimal intervention. However, the dangers associated with prolonged labor, such as maternal and fetal morbidity and mortality due to sepsis, uterine rupture, and postpartum hemorrhage, have become well recognized, particularly in developing countries like India, where obstructed labor accounts for approximately 10% of maternal deaths .

In response to these dangers, the use of caesarean sections has increased, particularly in cases of dystocia or difficult labor, where it contributes to at least one-third of the overall caesarean section rates in the developed world . However, caesarean sections, especially when performed as emergency procedures, significantly increase maternal mortality and morbidity . To address prolonged labor, medical

augmentation using oxytocic drugs such as oxytocin has been a longstanding practice .

Oxytocin has been the primary agent used to augment labor through intravenous administration. Recently, misoprostol, a prostaglandin E1 analog, has been introduced as an alternative for labor augmentation. Misoprostol can be administered orally, vaginally, or as a cervical gel, with the oral route being convenient for both patients and clinicians. Despite its potential benefits, misoprostol is not widely practiced in many centers .

The concept of augmenting labor is to stimulate contractions that are considered inadequate for effective labor progression. The importance of monitoring labor progression is highlighted by the introduction of partography by Friedman in 1954, which emphasizes cervical dilatation as a key indicator of labor progress . The World Health Organization (WHO) recommends using the partograph to monitor labor, including parameters such as cervical dilatation, fetal heart rate, and uterine contractions .

Given the need for effective labor augmentation, it is crucial to explore newer agents like misoprostol, which present relatively unexplored fields compared to well-studied agents like oxytocin. This study aims to compare the efficacy, safety, ease of application, and potential adverse effects of oxytocin infusion and oral misoprostol in the augmentation of labor . Understanding these aspects is vital for optimizing maternal and neonatal health outcomes and may provide insights into adopting misoprostol as a feasible alternative to oxytocin in clinical practice.

Materials and Methods

Study Design and Setting: This prospective cohort study was conducted at the NRS Medical College and Hospital, Kolkata, over a period from May 2011 to April 2012. The study focused on primigravid women admitted to the labor room at term with specific inclusion criteria to compare the effectiveness of labor augmentation using oral misoprostol and intravenous oxytocin.

Study Population: The study included 100 primigravidae women with singleton pregnancies at term. All participants were admitted with spontaneous onset of labor and met the following inclusion and exclusion criteria:

Inclusion Criteria

1. Age between 18 to 28 years.
2. Gestational age between 37 to 42 weeks.
3. Live singleton pregnancy in cephalic presentation.
4. Spontaneous onset of labor with cervical dilatation of 4 cm or more.
5. Inadequate uterine contractions, defined as less than three contractions per 10 minutes, each lasting less than 40 seconds.
6. Reassuring fetal heart rate.

Exclusion Criteria

1. Premature rupture of membranes (PROM).
2. Multiple pregnancies.
3. Polyhydramnios.
4. Non-cephalic presentation.
5. Probable cephalopelvic disproportion (CPD).
6. Suspected intrauterine growth restriction (IUGR).
7. Scarred uterus.
8. Uterine perforation.
9. Presence of significant medical diseases (e.g., heart disease, bronchial asthma).

Sample Size: The study involved 100 women meeting the inclusion criteria, divided equally into two groups of 50 each: the misoprostol group and the oxytocin group.

Randomization and Intervention

Participants were randomly assigned to one of the two intervention groups:

- **Misoprostol Group**: Received oral misoprostol 25 mcg every 4 hours, with a maximum of three doses.
- **Oxytocin Group**: Received intravenous oxytocin infusion, starting at 2 mIU/min in Ringer's lactate solution. The dose was adjusted every 15 minutes until desired uterine contractions were achieved, with a maximum dose of 5 mIU/min at the rate of 15 to 20 drops per minute.

Data Collection

All participants provided written informed consent in Bengali, Hindi, or English, the three principal languages of the area. Detailed obstetric and systemic examinations were conducted at admission.

Monitoring and Outcome Measures

Patients were monitored for:

- Fetal heart rate and signs of fetal distress (e.g., fetal bradycardia or tachycardia).
- Uterine contractions (frequency and duration) using a partograph.
- Maternal vital signs, including pulse and blood pressure.
- Progress of labor, assessed by cervical dilatation plotted on the partograph.
- Maternal and neonatal outcomes, including the mode of delivery, need for neonatal resuscitation, Apgar scores at 1 and 5 minutes, and NICU admission.

Statistical Analysis: Data were analyzed using appropriate statistical tests, including Fisher's exact test and chi-square test. Statistical significance was set at a P value of 0.05. All variables were calculated with a ±2 standard deviation to evaluate differences

between the two groups. Microsoft Excel was used for data management and analysis.

Results and Analysis

Demographics and Baseline Characteristics

Table 1: Age Distribution

Age Range (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%)

The age distribution of subjects in the misoprostol and oxytocin groups was similar, with the majority of participants aged between 20 to 30 years.

Analgesia Requirements

Table 2: Need for Analgesia

Analgesia Required	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Yes	37 (74%)	35 (70%)
No	13 (26%)	15 (30%)

The need for analgesia was similar in both the misoprostol and oxytocin groups.

Augmentation-Delivery Interval

Table 3: Average Time Interval from Augmentation to Delivery

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

The average time interval from augmentation to delivery was slightly shorter in the misoprostol group compared to the oxytocin group.

Delivery Outcomes

Table 4: Delivery within 5 Hours of Agent Application

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

Chi-squarevalue:30.14Degreeoffreedom1P value <0.001 (significant)A significantly higher number of deliveries occurred within 5 hours in the misoprostol group compared to the oxytocin group.

Table 5: Mode of Delivery

Mode of Delivery	Misoprostol Group (n=50)	Oxytocin Group (n=50)
LSCS	7 (14%)	7 (14%)
Forceps Delivery	3 (6%)	2 (4%)
Normal Vaginal	40 (80%)	41 (82%)

The mode of delivery was similar in both groups, with a high percentage of normal vaginal deliveries.

Indications for LSCS

Table 6: Indications for LSCS

Indication	Misoprostol Group	Oxytocin Group
Fetal Distress	5	1
Prolonged Labor	2	6
Cord Prolapse	1	0

Complications

Table 7: Fetal Distress

Fetal Distress	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Fetal Bradycardia/Tachycardia	6 (12%)	1 (2%)
No Fetal Distress	44 (88%)	49 (98%)

Chi-squarevalue:3.84 Degreeoffreedom:1P value <0.05 (significant)The occurrence of fetal distress was significantly higher in the misoprostol group compared to the oxytocin group.

Table 8: Meconium Staining of Liquor

Meconium Staining	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Stained	7 (14%)	1 (2%)

Not Stained	43 (86%)	49 (98%)

Chi-squarevalue:4.89Degreeoffreedom:1
P value <0.05 (significant)The incidence of meconium staining was significantly higher in the misoprostol group.

Table 9: Tachysystole

Tachysystole	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Present	6 (12%)	1 (2%)
Absent	44 (88%)	49 (98%)

Chi-squarevalue:3.84Degreeoffreedom:1P value <0.05 (significant)The occurrence of tachysystole was significantly higher in the misoprostol group.

Table 10: Hypertonicity

Hypertonicity	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Present	1 (2%)	0 (0%)
Absent	49 (98%)	50 (100%)

Chi-squarevalue:1.01Degreeoffreedom:1P value >0.05 (not significant)There was no significant difference in the occurrence of hypertonicity between the two groups.

Table 11: Post-Partum Hemorrhage (PPH)

PPH	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Present	2 (4%)	2 (4%)
Absent	48 (96%)	48 (96%)

Chi-squarevalue:0Degreeoffreedom:1P value (not significant)The incidence of post-partum hemorrhage was similar in both groups.

Neonatal Wellbeing

Table 12: Need for Neonatal Resuscitation

Neonatal Resuscitation	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Required	2 (4%)	1 (2%)
Not Required	48 (96%)	49 (98%)

Chi-squarevalue:0.34
Degreeoffreedom:1P value >0.05 (not significant)There was no significant difference in the need for neonatal resuscitation between the two groups.

Table 13: APGAR Scores

APGAR Score	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Below 7 (Asphyxia)	5 (10%)	1 (2%)
Above 7 (No Asphyxia)	45 (90%)	49 (98%)

Chi-squarevalue:2.83
Degreeoffreedom:1P value >0.05 (not significant)The occurrence of APGAR scores below 7 was not significantly different between the two groups.

Table 14: Mean APGAR Scores

Time (minutes)	Misoprostol Group (Mean)	Oxytocin Group (Mean)
1 Minute	8.18	8.34
5 Minutes	9.36	9.74

The mean APGAR scores at 1 and 5 minutes were similar in both groups.

Table 15: Need for NICU Admission

NICU Admission	Misoprostol Group (n=50)	Oxytocin Group (n=50)
Needed	2 (4%)	1 (2%)
Not Needed	48 (96%)	49 (98%)

Chi-squarevalue:0.34
Degreeoffreedom:1P value >0.05 (not significant)There was no significant difference in the need for NICU admission between the two groups.

Ease of Application

PGE1 (Misoprostol):

- Supplied as 25 mcg tablets.
- Easy to administer orally with no special setup required.
- Does not require storage at low temperatures.

Oxytocin Injection:

- Supplied in 1 ml ampoules containing 5 units of the drug.
- Requires Ringer's solution/normal saline, infusion set, and intravenous channel for administration.
- Requires refrigeration, which may cause inconvenience.

DISCUSSION

This study was conducted to compare the efficacy, safety, and ease of application of oral misoprostol with intravenous oxytocin for labor augmentation. Our findings indicate that both oral misoprostol and intravenous oxytocin are effective in reducing the duration of labor in patients with poor uterine contraction and slow cervical dilatation.

The average time interval from augmentation to delivery was slightly shorter in the misoprostol group (5.2 hours) compared to the oxytocin group (5.5 hours), suggesting that misoprostol may have a faster onset of action (1). However, the mode of delivery, including rates of cesarean section, forceps delivery, and vaginal delivery, was similar in both groups. This aligns with other studies that have found no significant difference in delivery outcomes between the two agents (4,5).

Complications such as fetal distress, meconium-stained liquor, and tachysystole were more prevalent in the misoprostol group. Specifically, fetal distress occurred in 12% of the misoprostol group compared to 2% in the oxytocin group. Meconium-stained liquor was observed in 14% of the misoprostol group versus 2% in the oxytocin group. Tachysystole was also more common in the misoprostol group (12% vs. 2%), indicating that higher doses of misoprostol may increase the risk of uterine hyperstimulation (6,7).

Despite these differences, the incidence of postpartum hemorrhage was similar in both groups, suggesting that the risk of significant bleeding may not be exacerbated by either agent when used in the doses studied. The occurrence of hypertonicity was low and not significantly different between the groups, though this study was not powered to detect subtle differences in hypertonicity rates.

Neonatal outcomes, as assessed by the need for resuscitation, APGAR scores, and NICU admissions, were generally comparable between the two groups. While 10% of neonates in the misoprostol group had an APGAR score below 7 at 1 minute, compared to 2% in the oxytocin group, this difference was not statistically significant ($p>0.05$). This suggests that, while there may be a trend towards more neonatal asphyxia with misoprostol, the overall impact on neonatal health is not markedly different between the two agents (8,9).

Misoprostol offers advantages in terms of ease of administration and storage. Being a tablet, it can be administered orally without the need for intravenous access, which simplifies its use in low-resource settings. Additionally, it does not require refrigeration, unlike oxytocin, which must be stored at low temperatures to maintain efficacy. This logistical advantage could make misoprostol a more feasible option in settings where cold chain maintenance is challenging (10).

CONCLUSION

Overall, both oral misoprostol and intravenous oxytocin are effective for labor augmentation, with similar efficacy in reducing labor duration. However, the higher incidence of fetal distress and tachysystole with misoprostol suggests that caution is needed in its use, particularly regarding dosage. The ease of use and storage of misoprostol could make it a valuable option in certain settings, though further research is needed to optimize dosing and minimize adverse effects. As always, clinical decisions should be guided by individual patient circumstances and the availability of resources.

REFERENCES

1. Friedman EA. Primigravid labor: A graphicostatistical analysis. Obstet Gynecol. 1955;6(5):567-89.
2. Williams JW, Cunningham FG, Leveno KJ, et al. Williams Obstetrics. 23rd ed. New York: McGraw-Hill; 2010. p. 406-547.
3. Clark SL, Belfort MA, Dildy GA, Herbst MA, Meyers JA, Hankins GD. Maternal death in the 21st century: causes, prevention, and relationship to cesarean delivery. Am J Obstet Gynecol. 2008;199(1):36.e1-5.
4. Philpott RH, Castle WM. Cervicographs in the management of labour in primigravidae. I. The alert line for detecting abnormal labour. J Obstet Gynaecol Br Commonw. 1972;79(7):592-8.
5. O'Driscoll K, Foley M, MacDonald D. Active management of labor as an alternative to cesarean section for dystocia. Obstet Gynecol. 1984;63(4):485-90.
6. Hofmeyr GJ, Gulmezoglu AM. Vaginal misoprostol for cervical ripening and induction of labor. Cochrane Database Syst Rev. 2003;(1)
7. Impey L, Hobson J, O'Herlihy C. Graphic analysis of actively managed labor: prospective computation of labor progress in 500 consecutive nulliparous women in spontaneous labor at term. Am J Obstet Gynecol. 2000;183(2):438-43.
8. Wing DA, Park MR, Paul RH. A randomized comparison of oral and intravaginal misoprostol for labor induction. Obstet Gynecol. 2000;95(6 Pt 1):905-8.
9. Bleich AT, Reed KL, Cuellar AM, et al. Misoprostol versus oxytocin for labor augmentation: a double-blind randomized controlled trial. Obstet Gynecol. 2009;114(5):1017-24.

10. Lavender T, Alfirevic Z, Walkinshaw SA. Effect of different partogram action lines on birth outcomes: a randomized controlled trial. Obstet Gynecol. 2006;108(2):295-302.