ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 18, Issue, 05, pp.37100-37102, May, 2026
DOI: https://doi.org/10.24941/ijcr.50530.05.2026

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

A RANDOMIZED CONTROLLED TRIAL COMPARING ORAL AND VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR AT TERM

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ARTICLE INFO

Article History:
Received 14th February, 2026
Received in revised form
26th March, 2026
Accepted 15th April, 2026
Published online 29th May, 2026

Key Words:
Misoprostol; Induction of labour; Oral misoprostol; Vaginal misoprostol; Bishop score; Term pregnancy.

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ABSTRACT

Background: Induction of labour is a common obstetric intervention, and misoprostol is widely used due to its efficacy, stability, and low cost. However, the optimal route of administration remains controversial, particularly in terms of safety and efficacy. **Objectives:** To compare the efficacy and safety of oral versus vaginal misoprostol for induction of labour at term. **Methods:** This prospective randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology, Narayan Medical College and Hospital, Jamuhar, from November 2018 to November 2020. A total of 100 term pregnant women with singleton cephalic presentation, Bishop score ≤6, and intact membranes were randomized into two groups. Group A (n=50) received oral misoprostol 50 µg every 4 hours (maximum 5 doses), while Group B (n=50) received vaginal misoprostol 50 µg every 6 hours (maximum 4 doses). Primary outcomes included induction–delivery interval, number of doses required, failed induction, and need for oxytocin augmentation. Secondary outcomes included mode of delivery, maternal complications, and neonatal outcomes. Statistical analysis was performed using Epi Info™, with $p < 0.05$ considered significant. **Results:** Baseline characteristics were comparable between the groups. The mean number of doses required was significantly higher in the oral group compared to the vaginal group (3.8 vs 2.7; $p<0.05$). Failed induction was significantly more common in the oral group (14% vs 4%; $p<0.05$). Oxytocin augmentation was required more frequently in the oral group (42% vs 32%). Vaginal delivery rates were comparable between groups. Neonatal intensive care unit admission was significantly higher in the vaginal group (14% vs 10%; $p<0.05$). Maternal complications were minimal and comparable. **Conclusion:** Both oral and vaginal misoprostol are effective for induction of labour at term. Vaginal misoprostol requires fewer doses and has a lower failed induction rate, while oral misoprostol is associated with fewer neonatal intensive care admissions. Route selection should be individualized based on clinical context and fetal monitoring facilities.

Citation: Dr. Aishwarya and Dr. Vineeta Singh. 2026. "A randomized controlled trial comparing oral and vaginal misoprostol for induction of labour at term*". International Journal of Current Research*, 16, (05), 37100-37102.

INTRODUCTION

Induction of labour is one of the most frequently performed interventions in modern obstetric practice, with rates ranging from 10% to over 30% of all pregnancies. The success of induction is influenced by multiple factors, among which cervical favourability plays a pivotal role. An unfavourable cervix is associated with prolonged labour, increased need for augmentation, and higher cesarean section rates. Misoprostol, a synthetic prostaglandin E1 analogue, has gained widespread acceptance for cervical ripening and labour induction due to its effectiveness, low cost, ease of storage, and multiple routes of administration. It can be administered orally, vaginally, sublingually, or buccally. However, the optimal route remains a subject of debate. Vaginal misoprostol has been associated with higher efficacy but a greater risk of uterine hyperstimulation, while oral misoprostol is thought to provide a more predictable pharmacokinetic profile with potentially fewer adverse fetal effects.

Despite numerous studies comparing these routes, consensus regarding the most effective and safest route of administration has not been firmly established, particularly in low-resource settings. The present study was undertaken to compare the efficacy and safety of oral versus vaginal misoprostol for induction of labour at term.

MATERIALS AND METHODS

Study Design and Setting: This prospective randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology, Narayan Medical College and Hospital, Jamuhar, from November 2018 to November 2020.

Study Population: A total of 100 pregnant women admitted for induction of labour at term were enrolled after obtaining informed consent.

Inclusion Criteria.

- Term pregnancy beyond expected date of delivery
- Singleton pregnancy
- Cephalic presentation
- Bishop score ≤6
- Intact membranes
- No uterine contractions

Exclusion Criteria

- Previous uterine surgery
- Cephalopelvic disproportion
- Placenta previa or abruptio placenta
- Malpresentation
- Diabetes mellitus
- Pregnancy-induced hypertension
- PROM
- Grand multiparity
- Fetal distress
- Multiple gestation
- Known allergy to prostaglandins

Randomization and Intervention

Participants were randomly allocated into two groups of 50 each:

- **Group A (Oral group):** Oral misoprostol 50 µg every 4 hours, up to a maximum of 5 doses
- **Group B (Vaginal group):** Vaginal misoprostol 50 µg every 6 hours, up to a maximum of 4 doses

Cervical assessment using the modified Bishop score was performed before induction and prior to each subsequent dose.

Monitoring and Labour Management: Labour progress was monitored using a partograph. Fetal heart rate was monitored by intermittent auscultation. Oxytocin augmentation was initiated when required. Amniotomy was performed after adequate cervical dilatation. Failed induction was defined as failure to enter active labour after maximum allowable doses.

Outcome Measures

Primary outcomes included

- Number of doses required
- Induction–delivery interval
- Failed induction
- Requirement of oxytocin augmentation
- Secondary outcomes included:
- Mode of delivery
- Maternal complications
- Neonatal outcomes (NICU admission, APGAR score at 5 minutes)

Statistical Analysis

Statistical analysis was performed using Epi Info™ 3.5.3. Continuous variables were analyzed using Student's t-test, and categorical variables using Chi-square or Z-test. A p-value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics including maternal age, gestational age, parity, Bishop score, and indications for induction were comparable between the two groups. The mean number of doses required was significantly higher in the oral group compared to the vaginal group (3.8 ± 1.25 vs 2.7 ± 1.36; $p<0.05$). Failed induction was observed in 14% of women in the oral group and 4% in the vaginal group, which was statistically significant. Oxytocin augmentation was required more frequently in the oral group (42%) compared to the vaginal group (32%). Vaginal delivery rates were comparable between the two groups. Cesarean section rates did not differ significantly. Maternal complications were minimal, with fever reported in 2% of patients in each group. Uterine hyperstimulation was observed in one patient in the vaginal group. NICU admission was significantly higher in the vaginal group (14%) compared to the oral group (10%). APGAR scores at 5 minutes and mean birth weights were comparable.

DISCUSSION

Misoprostol has become an integral agent for induction of labour due to its proven efficacy, cost-effectiveness, and ease of storage. However, the choice of route of administration remains debated. This randomized controlled trial compared oral and vaginal misoprostol for induction of labour at term with respect to efficacy and safety. In the present study, vaginal misoprostol required significantly fewer doses and was associated with a lower failed induction rate compared to oral misoprostol. These findings are consistent with previous studies by Jindal *et al*. and Deshmukh *et al*., which reported superior efficacy of the vaginal route in achieving timely labour onset. The prolonged induction process observed with oral misoprostol may be related to its rapid systemic metabolism and shorter duration of uterine activity. Oxytocin augmentation was required more frequently in the oral group, supporting the hypothesis that vaginal administration maintains higher sustained uterine concentrations. Despite these differences, the overall mode of delivery and cesarean section rates were comparable between the two groups, indicating that both routes are effective in achieving vaginal birth.

Neonatal outcomes were largely comparable; however, NICU admissions were significantly higher in the vaginal group. Although most admissions were for mild and transient conditions, this finding underscores the need for careful fetal monitoring when vaginal misoprostol is used. Similar observations have been reported in earlier studies highlighting increased uterine activity with vaginal administration. Maternal complications were minimal in both groups, with no serious adverse events, reaffirming the safety profile of low-dose misoprostol. The strengths of this study include its randomized design and uniform induction protocol. Limitations include a single-center setting and modest sample size, which may limit generalizability.

CONCLUSION

Both oral and vaginal misoprostol are safe and effective for induction of labour at term. Vaginal misoprostol offers greater efficacy with fewer doses and lower failed induction rates, while oral misoprostol is associated with fewer neonatal intensive care admissions. The choice of route should be

individualized based on maternal-fetal condition and available monitoring facilities.

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