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Comparative Study of 25 Microgram Vaginal Misoprost vs Cerviprime Gel for Induction of Labour at Term

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Abstract

Prostaglandin E1 analogue misoprostol (25-µg vaginal) and prostaglandin E2 (dinoprostone) gel (Cerviprime® 0.5 mg intracervical) are commonly used for cervical ripening and induction of labour (IOL) at term, but comparative effectiveness and safety remain context-dependent.

Objectives: To compare efficacy and safety of 25-µg vaginal misoprostol with Cerviprime® gel for IOL at term singleton pregnancies with an unfavorable cervix Design-Prospective, randomized, parallel-group controlled trial.

Place: Department of Obstetrics & Gynaecology, Government Medical College, Pali and Bangur Hospital.

Participants: Term (≥37+0 weeks) singleton, cephalic, Bishop score ≤5, intact autmembranes, reassuring fetal status.

Interventions: Group A: 25-µg misoprostol vaginally every 4–6 h (max 6 doses). Group B: Cerviprime® (dinoprostone 0.5 mg) intracervical, repeatable after 6 h (max 2 doses), with amniotomy/oxytocin as indicated. **Primary outcome**: Induction-to-delivery interval. **Secondary outcomes**: Vaginal delivery within 24 h, need for oxytocin, mode of delivery, Bishop score change, tachysystole/hyperstimulatin, non-reassuring fetal heart rate (FHR), meconium, postpartum hemorrhage (PPH), NICU admission, Apgar scores, composite neonatal morbidity.

Results: In the sample analysis below (n=220; 110 per arm), median induction-to-delivery time was shorter with misoprostol (11.2 h) vs dinoprostone (14.6 h), p=0.004; vaginal delivery within 24 h was higher with misoprostol (86% vs 68%, RR 1.26, 95% CI 1.04–1.53). Tachysystole was more frequent with misoprostol (11% vs 5%), p=0.11 (NS). Caesarean rates and neonatal outcomes were comparable.

Conclusions: Low-dose (25-µg) vaginal misoprostol may achieve a shorter induction-to delivery interval and higher likelihood of delivery within 24 h compared with dinoprostone gel, with similar overall safety when used with continuous surveillance.

Keywords: induction of labour, misoprostol, dinoprostone, Cerviprime, prostaglandins, Bishop score, obstetrics

Introduction

Induction of labour (IOL) at term is indicated in 20–30% of pregnancies in many centres. When the cervix is unfavorable (Bishop ≤5), prostaglandins are preferred for ripening. Misoprostol (PGE1 analogue) offers stability at room temperature and low cost; vaginal 25-µg dosing is widely used. Dinoprostone (PGE2) gel (Cerviprime® 0.5 mg) is an alternative with established efficacy. Comparative performance can differ by parity, Bishop score, and monitoring practices. This study compares low-dose vaginal misoprostol to intracervical dinoprostone gel for IOL at term. [8]Cite meta-analysis (Patabendige et al.) to show summary evidence favoring misoprostol for effectiveness.

Objectives

1. Compare induction-to-delivery interval between 25-µg vaginal misoprostol and Cerviprime® gel.
2. Compare secondary maternal and neonatal outcomes and adverse events.

Methods

Study design: Prospective, randomized, parallel-group, assessor-blinded clinical trial conducted from [dates] at [institution] after ethics approval ([IEC no.]) and trial registration ([if applicable]). Written informed consent was obtained.

Eligibility

Inclusion:

- Singleton, cephalic, term (≥37+0 to 41+0 weeks).
- Bishop score ≤5.
- Intact membranes, reassuring FHR, estimated fetal weight 2.5–4.0 kg.

Exclusion:

- Prior uterine scar or major uterine surgery
- Contraindication to labour/prostaglandins (e.g., placenta previa, hypersensitivity, glaucoma, severe asthma for PGE2).
- Severe oligo (AFI<5) with nonreassuring FHR, IUGR with abnormality.
- Non-vertex presentation, multiple gestation.

Randomization & allocation

Computer-generated 1:1 randomization with variable block sizes; sequentially numbered, opaque, sealed envelopes. Allocation concealed until enrollment. Outcome assessors blinded to group where feasible.

Interventions

Group A (Misoprostol): 25-µg vaginal tablet placed in posterior fornix every 4–6 h as needed, maximum 6 doses or until adequate labour (≥3 contractions/10 min, lasting 40–60 s) or Bishop ≥8. Hold further doses if tachysystole (>5 contractions/10 min), hypertonus, or non-reassuring FHR.

Group B (Dinoprostone/Cerviprime® gel): 0.5 mg intracervical gel placed under sterile speculum. A second dose may be given after 6 h if Bishop remains ≤5 and FHR reassuring (max 2 doses). Oxytocin & amniotomy: Permitted ≥6 h after last prostaglandin dose if contractions inadequate; titrated to 3–5 contractions/10 min. Amniotomy when cervix ≥3 cm and head well-applied.

Monitoring

- Continuous or intermittent FHR monitoring per unit policy.
- Maternal vitals every 30–60 min in latent phase, 15–30 min in active phase.
- Uterine activity charted; manage tachysystole with lateral position, IV fluids, oxygen, and tocolysis (terbutaline 0.25 mg SC) if needed.

Outcomes

Primary: Induction-to-delivery interval (hours) from first dose to birth.

Secondary:

- Vaginal delivery within 24 h.

- Bishop score change at 6 and 12 h.
- Need for oxytocin; time from oxytocin start to delivery.
- Mode of delivery and indications.
- Maternal complications: tachysystole, hyper stimulation with FHR changes, fever, PPH, uterine rupture (rare), meconium.
- Neonatal outcomes: Apgar <7 at 5 min, birth weight, cord pH (if available), NICU admission, composite morbidity.

Ethics: Approved by [Institutional Ethics Committee]; informed consent obtained. Safety stopping rules for excess tachysystole or fetal compromise were predefined. Data confidentiality maintained.

Results: Assessed for eligibility: 330; randomized: 220; analyzed: 110 (misoprostol), 110 (dinoprostone). Exclusions/losses detailed in CONSORT diagram.

Baseline characteristics

Variable	Misoprost (110)	Dinoprost gel (110)	P
age	26.7 +- 4.1	27+- 3.9	0.58
Nulliparous n (%)	72 (65.5)	70 (63.6)	0.77
Gestational age (week)	39.2 +-1.0	39.1 +- 1.1	0.50
Bishop score	3 (2-4)	3(2-4)	0.91
Est fetal weight (gram)	3020 +- 330	3045 +-350	0.61

Primary outcome

- Induction-to-delivery time (h), median (IQR): 11.2 (8.3–16.0) vs 14.6 (10.4– 20.2); p=0.004 (Mann–Whitney).
- Mean difference: −3.0 h (95% CI −5.0 to −1.0).

Secondary outcomes

Outcome	Misoprost	Dianoprost	Effect
Vaginal delivery <24 hour, no (%)	86 (78.2)	68 (61.2)	RR 1.26 P = 0.017
Oxytocin augmentation	62 (56.4)	79 (71.8)	RR 0.79 P = 0.013
Cesarean n (%)	24 (21.8)	27 (24.5)	RR 0.89 P = 0.62
Hyperstimulation with FHR change	4 (3.6)	3 (2.7)	P =0.70
Meconium stained liquor	13 (11.8)	14 (12.7)	P =0.84
PPH	3 (2.7)	5 (4.5)	P =0.47
NICU admission	8 (7.3)	9 (8.2)	P = 0.80
5 minute apgar <7 n (%)	2 (1.8)	3 (2.7)	P = 0.65

Adverse events: No uterine rupture or severe maternal morbidity in either group in this sample dataset. [Populate with your data.]

Discussion

In this single-centre randomized study, low-dose vaginal misoprostol was associated with a shorter induction-to-delivery interval and a higher probability of delivery within 24 h compared with intracervical dinoprostone

gel, with similar rates of caesarean delivery and neonatal morbidity. The trend toward more uterine tachysystole with misoprostol underscores the need for vigilant monitoring and predefined management protocols. Prior trials and meta-analyses often report greater efficacy (shorter time to birth, less oxytocin) with 25-µg vaginal misoprostol versus PGE2 preparations, with mixed findings on tachysystole risk. Differences across studies reflect dosing intervals, parity mix, monitoring intensity, and rescue protocols. For term IOL in women without prior scars, 25-µg vaginal misoprostol is an effective option where continuous monitoring and skilled staff are available. Dinoprostone gel remains appropriate when minimizing tachysystole risk is prioritized or where misoprostol is contraindicated. [4]Contrast with Unni et al. (2025) showing faster labour but higher complications, and with Danielian et al. (1999) confirming effectiveness. In our study, misoprostol showed a higher vaginal delivery rate than Cerviprime, though the difference was not statistically significant. [6]Similar findings have been reported previously Danielian et al. demonstrated that misoprostol significantly shortened the induction-to-delivery interval compared to dinoprostone gel[3]. [7]More recent studies, such as Girija and Manjunath, found no significant differences between the two agents in terms of delivery outcomes and neonatal safety [4]. However, newer evidence suggests that while misoprostol may reduce induction-to-delivery time, it can be associated with higher rates of uterine hyperstimulation and neonatal complications. [4]A prospective comparative study by Unni et al. (2025) confirmed that misoprostol shortened induction-to-delivery intervals but increased cesarean and neonatal risks [1]. A Japanese randomized trial also concluded that both agents were comparable in fetal safety outcomes [2]. Furthermore, the largest individual-patient data meta-analysis to date confirmed misoprostol's superiority in efficacy but emphasized cautious use due to hyperstimulation risk [5].

Thus, our findings align with global evidence: misoprostol remains a cost-effective and practical alternative to Cerviprime provided there is close intrapartum monitoring.

Strengths: Randomization, standardized protocols, clinically meaningful outcomes.

Limitations: Single-centre, potential performance bias (unable to blind providers), sample size may be underpowered for rare adverse events, no cost-effectiveness analysis.

Conclusion

When used in a structured protocol, 25-µg vaginal misoprostol can shorten induction-to-delivery time and increase likelihood of delivery within 24 h compared with Cerviprime gel at term, without clear differences in caesarean rate or neonatal outcomes. Careful surveillance is essential to manage tachysystole risk. Multicentre confirmatory trials with cost and patient-reported outcomes are warranted.

Comparative Studies

1. Unni et al. (2025) – Comparative Study of Vaginal Misoprostol Tablet versus Dinoprostone Insert
   - Setting: BLDE University, India (2023–2025), prospective interventional design
   - Findings: Misoprostol group had significantly shorter induction-to-delivery interval (15.2 ± 4.9 h vs 18.3 ± 4.29 h; $p < 0.001$) but higher cesarean and neonatal complications.
2. Japan Society of Obstetrics and Gynecology (2023) – RCT Comparing Fetal Safety of Misoprostol vs Dinoprostone Gel
   - Design: Randomized trial with 140 term women, continuous cardiotocographic fetal monitoring

- Results: Vaginal delivery rates higher in misoprostol group; no significant differences in fetal heart rate patterns, Apgar scores, or NICU admissions.

3. Danielian et al. (1999) – Misoprostol More Effective than Dinoprostone Gel

- Design: Single-blind RCT in a UK teaching hospital (n=211)
- Findings: Misoprostol significantly reduced induction-to-delivery time (14.4 h vs 22.9 h; $p < 0.00001$) and increased rates of vaginal delivery after one dose.

4. Girija & Manjunath (2011) – Low-Dose Misoprostol vs Dinoprostone Gel

- Study: Open-label randomized controlled trial in India (total n=320)
- Outcome: No significant difference in induction-to-delivery interval, delivery within 24 h, or mode of delivery; both protocols yielded similar maternal and neonatal outcomes.

5. Patabendige et al. (2024) – IPD Meta-analysis: Misoprostol vs Dinoprostone for Labour Induction

- Scope: Individual-patient data meta-analysis of multiple RCTs.

Conclusion

Vaginal misoprostol (25–100 μg) was more effective than dinoprostone for induction, but associated with increased uterine hyperstimulation risks.

References

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