

Original Research Article

SAFETY AND EFFICACY OF ORAL MIFEPRISTONE PRETREATMENT VERSUS DINOPROSTONE ALONE FOR LABOUR INDUCTION IN NULLIPAROUS WOMEN AT 40 WEEKS

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ABSTRACT

Background: Cervical ripening influences the success of labour induction. Oral mifepristone, a progesterone-receptor antagonist, has been investigated as a pretreatment agent for cervical ripening and labour induction. The objective is to evaluate the safety and efficacy of oral mifepristone pretreatment followed by dinoprostone when required, compared with dinoprostone alone, by assessing cervical ripening, delivery mode and maternal and neonatal outcomes. **Materials and Methods:** In this single-centre randomized trial, 100 nulliparous women with singleton cephalic pregnancies at 40 weeks, intact membranes and modified Bishop scores below 6 were allocated equally to two groups. The intervention group received oral mifepristone 200 mg, followed after 24 hours by intracervical dinoprostone when required. Controls received intracervical dinoprostone 0.5 mg, repeated every 8 hours to a maximum of three doses. Delivery outcomes were analysed in all allocated participants.

Results: Vaginal birth occurred in 31/50 women (62.0%) after mifepristone pretreatment and 18/50 (36.0%) after dinoprostone alone. Caesarean delivery occurred in 19/50 versus 32/50 women (38.0% versus 64.0%; risk ratio 0.59, 95% confidence interval 0.39–0.90; $p = 0.009$). Oxytocin augmentation was documented in 20 versus 40 women. NICU admission or observation was recorded for eight versus six neonates. Postpartum haemorrhage was reported in three versus two women. No severe neonatal complications were reported following oral mifepristone pretreatment.

Conclusion: In nulliparous women at 40 weeks, oral mifepristone pretreatment followed by dinoprostone when required was associated with a higher vaginal birth rate and a lower caesarean delivery rate than dinoprostone alone. No severe neonatal complications were reported in the mifepristone group, providing reassuring neonatal safety findings in this study population.

Keywords: Mifepristone; dinoprostone; cervical ripening; labour induction; nulliparity; caesarean delivery.

INTRODUCTION

Induction of labour is considered when planned delivery offers benefits over continuing pregnancy. The clinical decision depends on gestational age, maternal and fetal condition, the indication for delivery and the woman's preferences. Cervical readiness influences the selection of an induction method and the subsequent course of labour. With an unfavourable cervix, pharmacological or mechanical

ripening may be required before amniotomy or oxytocin can establish effective labour. Guidance emphasizes assessment of the cervix and fetal wellbeing, explanation of treatment options and appropriate monitoring during the induction process.^[1] WHO recommendations address the timing of induction at or beyond term.^[2] A Cochrane review comparing induction with expectant management found fewer perinatal deaths with an induction policy, although the absolute event rates

were low.^[3] These findings provide context for the timing of delivery; they do not determine which cervical-ripening regimen is preferable.

The Bishop score provides a clinical assessment of cervical dilatation, effacement or length, consistency and position, together with fetal station.^[4] Although useful for planning induction, the score represents only one component of a successful vaginal birth. Cervical change, effective uterine contractions and delivery are separate stages of the induction pathway. A cervical-ripening agent should therefore be assessed not only by improvement in the score but also by the need for additional treatment, mode of delivery and maternal and neonatal outcomes.

Dinoprostone, a prostaglandin E2 preparation, promotes cervical ripening and can stimulate uterine activity. Mifepristone is a progesterone-receptor antagonist that has been studied as a preparatory agent before labour induction. The Cochrane review reported evidence of improved cervical readiness and reduced oxytocin augmentation compared with placebo, but found insufficient evidence to support routine induction use, particularly because neonatal safety information was limited.^[5] Its role in term pregnancy with a live fetus therefore remains a research question rather than an established alternative for routine induction.

Earlier randomized trials evaluated mifepristone before subsequent misoprostol or other induction treatment.^[6,7] A trial comparing mifepristone with expectant management also reported improved cervical readiness, but used a different comparator and treatment sequence.^[8] Direct comparisons with dinoprostone have shown variable cervical and delivery outcomes.^[9,10] Interpretation requires attention to eligibility criteria, observation periods and subsequent induction agents. A regimen beginning with mifepristone and allowing later dinoprostone compares a treatment sequence with dinoprostone alone; it does not isolate the independent effect of mifepristone throughout labour.

Earlier placebo-controlled studies also used different mifepristone doses and assessment periods. Elliott and colleagues compared 50 mg and 200 mg in primigravid women with unfavourable cervixes.^[11] Giacalone and colleagues evaluated 400 mg with cervical reassessment within 48 hours in post-term pregnancies.^[12] Stenlund and colleagues investigated mifepristone in a randomized, double-blind trial against placebo in post-term women with unripe cervixes.^[13] These differences in dose, population and reassessment timing limit direct extrapolation to a 200-mg pretreatment protocol with reassessment at 24 hours.

This randomized trial evaluated the safety and efficacy of oral mifepristone pretreatment followed by dinoprostone when required versus intracervical dinoprostone alone in nulliparous women at 40 weeks with an unfavourable cervix. The objectives were to compare cervical ripening, oxytocin augmentation, delivery mode and maternal and neonatal outcomes.

MATERIALS AND METHODS

Study design and setting: This single-centre, parallel-group randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology, ESIC Medical College and PGIMS, KK Nagar, Chennai, India, between August 2022 and February 2024. Participants were assessed in the antenatal clinic and labour room and followed during their hospital stay through labour and delivery. One hundred women were allocated in a 1:1 ratio to mifepristone pretreatment or dinoprostone alone.

Participants: Eligibility required nulliparity, a singleton pregnancy in cephalic presentation at 40 weeks, intact membranes, a modified Bishop score below 6, willingness to participate and no contraindication to vaginal delivery or either study drug. Women with previous abortions but no previous birth were represented in the cohort. Baseline assessment included obstetric history, clinical examination and cervical scoring.

The recorded eligibility criterion was maternal age greater than 19 years; the enrolled dataset includes women aged 19 years. This discrepancy requires review against the approved protocol.

Exclusion criteria comprised breech presentation, multiple pregnancy, known cephalopelvic disproportion, estimated fetal weight below 2 kg or above 4.5 kg, three or more previous abortions, diabetes, placenta praevia or placental abruption, abnormal fetal heart-rate patterns, rupture of membranes, active genital infection, chorioamnionitis, uterine myoma or anomalies, intrauterine fetal death, conception by in vitro fertilization and contraindications to mifepristone. Women with a previous birth were excluded.

Sample size and randomization: The planned sample comprised 100 participants, with 50 allocated to each group.

The planned sample size was 100 women. The available study description refers to a moderate effect size, 80% power and 95% confidence, but does not provide the expected primary-outcome difference, variance, calculation method or missing-data allowance needed to reproduce the calculation.

A computer-generated random-number table and 100 identical envelopes were used to allocate participants. Each woman selected an envelope identifying the assigned intervention. Block randomization was described in the study methods.

The available study documentation does not specify the block size, sequence generator or allocation implementer, whether envelopes were opaque and sealed, or whether cervical-score assessors were masked.

Interventions: The intervention group received a single oral dose of mifepristone 200 mg with water under medical supervision. Cervical status was reassessed after 24 hours. When additional ripening was required, intracervical dinoprostone gel 0.5 mg was administered and repeated at 8-hour intervals

according to cervical response, to a maximum of three doses.

The control group received intracervical dinoprostone gel 0.5 mg from the start of induction. Further doses were administered every 8 hours when required, with a maximum of three doses. Maternal and fetal condition and the progress of labour were monitored during the hospital stay. Oxytocin augmentation and operative delivery were recorded in both groups.

Routine labour management was provided during the hospital admission, with monitoring of maternal and fetal condition and labour progress. The available documentation does not specify a monitoring schedule, oxytocin dose-escalation regimen, interval between dinoprostone and oxytocin, amniotomy criteria or standardized treatment-stopping criteria.

Outcomes: The primary outcome was change in modified Bishop score at 24 hours. Secondary outcomes were oxytocin augmentation, mode of delivery, induction-to-active-labour and induction-to-delivery intervals, maternal complications and neonatal outcomes. Vaginal birth was classified as spontaneous, vacuum-assisted or forceps-assisted birth. Maternal outcomes included postpartum haemorrhage and blood transfusion. Neonatal outcomes included NICU admission or observation and Apgar scores below 7 at 1 and 5 minutes.

The available documentation does not establish a consistent favourable-cervix threshold or provide operational definitions for active labour, failed induction or postpartum haemorrhage. NICU admission and observation were combined where the patient-level chart did not distinguish them consistently. Cervical assessments and labour intervals were not subjected to comparative inference because timing and source values require reconciliation.

Statistical analysis: Categorical variables were summarized as counts and percentages. Baseline Bishop scores were summarized as mean $\pm$ standard deviation. Delivery outcomes were analysed according to allocated group, using 50 participants in each arm. Pearson's chi-square test was used for the caesarean-delivery comparison. The unadjusted risk ratio and its 95% confidence interval were calculated using the log-risk-ratio method. A two-sided p value below 0.05 was considered statistically significant. Secondary findings were interpreted as exploratory, without adjustment for multiple comparisons.

Oxytocin use was reported descriptively with a separate category for unavailable exposure entries; unavailable entries were not classified as absence of augmentation. No inferential comparison of oxytocin use was performed. Cervical-response and labour-time analyses require reconciliation of assessment timing and discrepant source values. Adverse-event counts were described without an equivalence claim or a combined maternal-complication rate, because haemorrhage and transfusion may overlap.

Ethical considerations: Institutional ethics approval was obtained before study commencement, and

written informed consent was obtained from participants. Participation was voluntary, and withdrawal did not affect clinical care. Participant information was handled confidentially.

RESULTS

Participants and baseline characteristics: One hundred participants were allocated, with 50 women in each group. Delivery outcomes were available for all allocated participants. In the mifepristone group, 46 women were primigravidae and four had one previous abortion; the corresponding counts were 45 and five in the dinoprostone group. All were nulliparous. The age distributions and baseline cervical-score categories are presented in [Table 1]. Baseline Bishop scores ranged from 2 to 5 in both groups, with means of 3.18 ± 0.94 and 3.14 ± 0.88 , respectively. Figure 1 shows the available participant disposition.

Cervical response: One participant in the mifepristone group underwent emergency caesarean delivery for fetal distress after 14 hours and lacked the scheduled 24-hour cervical assessment.

The patient-level chart contains 49 post-treatment Bishop scores in the mifepristone group, with a mean of 5.69 ± 2.20 ; 25/49 scores were ≥ 6 and 23/49 were >6 . The summary table instead gives a mean of 5.76 ± 2.14 and 28/49 scores ≥ 6 . The dinoprostone chart contains 50 post-treatment scores, with a mean of 4.72 ± 1.09 , but their assessment time is not established. These descriptive chart values are not a verified matched 24-hour primary-outcome analysis. No between-group cervical-response estimate is reported pending reconciliation.

Delivery outcomes: Vaginal birth occurred in 31 women (62.0%) after mifepristone pretreatment and 18 women (36.0%) after dinoprostone alone. Caesarean delivery occurred in 19 women (38.0%) and 32 women (64.0%), respectively. The unadjusted risk ratio for caesarean delivery was 0.59 (95% confidence interval 0.39–0.90; $p = 0.009$), with an absolute difference of 26 percentage points. Spontaneous vaginal birth occurred in 26 versus 13 women, vacuum-assisted birth in five versus four, and forceps-assisted birth in none versus one [Table 2 and Figure 2].

Augmentation and labour intervals: Oxytocin augmentation was documented in 20 women (40.0%) in the mifepristone group and 40 women (80.0%) in the dinoprostone group. Absence of augmentation was explicitly documented in 19 versus nine women; exposure entries were unavailable in 11 versus one [Table 3]. These incomplete exposure records preclude a definitive comparison of augmentation rates.

Labour-time records were inconsistent between the summary tables and individual charts. The mifepristone summary gives an induction-to-delivery interval of 26.76 ± 10.34 hours, whereas the individual chart entries give 27.68 ± 20.49 hours.

Definitions of the starting point and analysis population could not be confirmed. Comparative labour-time results were therefore withheld pending review of the original records.

Maternal and neonatal outcomes: Postpartum haemorrhage was reported in three women (6.0%) in the mifepristone group and two (4.0%) in the dinoprostone group. Two women in each group (4.0%) required blood transfusion. NICU admission

or observation was recorded for eight neonates (16.0%) versus six (12.0%). Apgar scores below 7 at 1 minute were reported in four versus three neonates, and at 5 minutes in two neonates in each group [Table 4]. No severe neonatal complications were reported in the mifepristone group. Detailed outcome records for uterine tachysystole, hyperstimulation and all fetal heart-rate abnormalities were not available for complete assessment.

Table 1: Baseline characteristics of the participants

Characteristic	Mifepristone first (n = 50)	Dinoprostone (n = 50)
Age 18–25 years	23 (46.0)	20 (40.0)
Age 26–30 years	23 (46.0)	25 (50.0)
Age ≥31 years	4 (8.0)	5 (10.0)
Primigravida	46 (92.0)	45 (90.0)
Second pregnancy with one previous abortion	4 (8.0)	5 (10.0)
Baseline modified Bishop score	3.18 ± 0.94	3.14 ± 0.88
Bishop score 2	14 (28.0)	12 (24.0)
Bishop score 3	17 (34.0)	23 (46.0)
Bishop score 4	15 (30.0)	11 (22.0)
Bishop score 5	4 (8.0)	4 (8.0)

Values are n (%) or mean ± SD. Baseline means and sample SDs were calculated from the patient-level scores. The highest age category includes all women

aged 31 years or older. Mifepristone first denotes pretreatment followed by dinoprostone when required.

Table 2: Mode of delivery by allocated group

Delivery mode	Mifepristone first (n = 50)	Dinoprostone (n = 50)
Any vaginal birth	31 (62.0)	18 (36.0)
Spontaneous vaginal birth	26 (52.0)	13 (26.0)
Vacuum-assisted birth	5 (10.0)	4 (8.0)
Forceps-assisted birth	0 (0.0)	1 (2.0)
Caesarean delivery	19 (38.0)	32 (64.0)

Values are n (%). Caesarean-delivery risk ratio 0.59 (95% CI 0.39–0.90), comparing mifepristone first with dinoprostone; Pearson’s chi-square $p = 0.009$. Any vaginal birth comprises the next three

subcategories and should not be added to them. Delivery counts agree between the summary tables and individual charts.

Table 3: Documentation of oxytocin augmentation

Exposure entry	Mifepristone first (n = 50)	Dinoprostone (n = 50)
Augmentation documented	20 (40.0)	40 (80.0)
No augmentation documented	19 (38.0)	9 (18.0)
Entry unavailable or unspecified	11 (22.0)	1 (2.0)

Values are n (%) from patient-level charts. Blank entries and unspecified dashes were retained as unavailable, not converted to no augmentation. No

between-group hypothesis test was performed because exposure ascertainment is incomplete.

Table 4: Reported maternal and neonatal outcomes

Outcome	Mifepristone first (n = 50)	Dinoprostone (n = 50)
Postpartum haemorrhage	3 (6.0)	2 (4.0)
Blood transfusion	2 (4.0)	2 (4.0)
NICU admission or observation	8 (16.0)	6 (12.0)
Apgar score <7 at 1 minute	4 (8.0)	3 (6.0)
Apgar score <7 at 5 minutes	2 (4.0)	2 (4.0)

Values are n (%). NICU, neonatal intensive care unit. Maternal and Apgar outcomes follow the summary tables and require confirmation against clinical records. NICU counts include chart entries describing either admission or observation. Haemorrhage and transfusion may overlap and should not be added. No equivalence in safety is inferred.

The diagram shows allocated groups and available assessment and delivery denominators. Screening totals, prerandomization exclusions, treatment deviations and withdrawals require confirmation before a complete CONSORT diagram can be prepared.

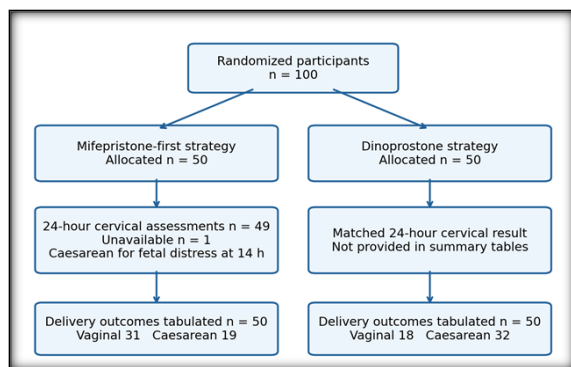


Figure 1: Participant disposition

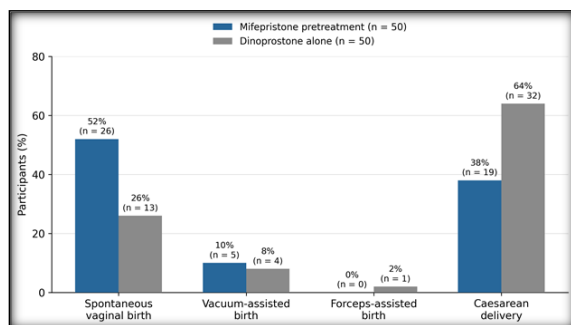


Figure 2: Mode of delivery by allocated group

Percentages use all 50 allocated women in each group. The four delivery categories are mutually exclusive and sum to 100% within each group. Mifepristone pretreatment included subsequent dinoprostone when required. Counts agree between the thesis summary tables and patient-level charts.

DISCUSSION

The verified delivery outcomes showed fewer caesarean births after mifepristone pretreatment followed by dinoprostone when required than after dinoprostone alone. The difference was accompanied by a higher proportion of vaginal births, including both spontaneous and instrumental deliveries. The risk-ratio confidence interval was compatible with a reduction in caesarean delivery in this selected nulliparous population. However, the unresolved primary cervical outcome prevents a conclusion that improved cervical ripening explains the difference in delivery mode.

The rationale for mifepristone pretreatment is antagonism of progesterone action before induction. Trials have investigated its effect on cervical readiness and the need for later induction agents. Yelikar and colleagues reported improved cervical readiness and a lower subsequent misoprostol requirement compared with placebo.^[7] Baev and colleagues found improved cervical scores compared with expectant management, although their treatment sequence and comparator differed from those used here.^[8] Such findings support a possible preparatory effect, but they do not replace a verified between-group comparison of the prespecified primary outcome in this trial.

Our delivery finding is stronger than the differences reported in some direct comparisons. Sah and Padhye reported a higher cervical-ripening response with mifepristone, but no statistically significant difference in vaginal delivery or other maternal and fetal outcomes.^[9] Sailatha and colleagues reported broadly comparable delivery modes and a shorter induction-to-delivery interval with dinoprostone.^[10] Sivadas and colleagues subsequently reported a lower mean oxytocin requirement with mifepristone, while cervical-score and delivery-mode differences were not statistically significant.^[14] These variations indicate that the effect of pretreatment may depend on patient selection, the waiting period and subsequent management.

The present comparison concerns induction strategies. Some women allocated to mifepristone subsequently received dinoprostone, while controls received dinoprostone from the outset. Delivery outcomes consequently reflect the complete pathway, including the preparatory period, cervical reassessment and decisions about further stimulation. They cannot be attributed solely to mifepristone exposure. The high caesarean proportion in the comparator group also means that the absolute difference may not transfer to centres with different populations or thresholds for operative delivery.

Oxytocin was recorded more often in the dinoprostone group. This pattern is compatible with earlier evidence of reduced additional stimulation following mifepristone pretreatment. Wing and colleagues reported lower oxytocin exposure after mifepristone compared with placebo, and the Cochrane review found reduced augmentation.^[5,6] Nevertheless, unavailable exposure entries in the present trial prevent a reliable categorical comparison. Treating a blank field as no augmentation would introduce an unsupported assumption. Complete records of whether oxytocin was given, total dose, infusion duration and treatment indication are necessary to interpret this outcome.

Timing also affects comparison of induction methods. A planned 24-hour period after mifepristone differs from immediate dinoprostone treatment. Intervals measured from the first allocated intervention include that preparatory period; intervals measured from later dinoprostone administration answer a different question. This distinction should be retained when reconciling the labour-time results. Evidence across protocols has not been uniform: a dose-finding trial by Berkane and colleagues did not demonstrate significant efficacy across the tested mifepristone doses.^[15] A reduction in caesarean delivery should therefore not be interpreted automatically as faster induction or delivery.

The neonatal findings were reassuring in this cohort, with no severe neonatal complications reported following oral mifepristone pretreatment. NICU admission or observation occurred in eight neonates in the mifepristone group and six in the dinoprostone group; admission or observation alone should not be equated with a severe neonatal complication. Apgar

scores below 7 at 5 minutes were reported in two neonates in each group. Postpartum haemorrhage occurred in three versus two women, and two women in each group required blood transfusion. These events remain relevant to the maternal safety assessment. Wing and colleagues reported no statistically significant difference in neonatal outcomes, although non-reassuring fetal heart-rate patterns and uterine contractile abnormalities were more frequent after mifepristone.^[6] The present findings describe the safety outcomes observed in this study population; the small sample limits assessment of rare adverse events.

The clinical findings should also be considered alongside guidance. NICE does not support mifepristone for routine induction with a live fetus and distinguishes its use in combination regimens for intrauterine fetal death.^[1] This trial provides a delivery-outcome signal within a monitored hospital pathway; it does not establish a routine replacement for recommended induction methods. Applicability is limited to women resembling the study population, without a previous birth, with intact membranes and no major contraindication to attempted vaginal delivery.

Strengths and limitations: The study compared clinically relevant induction pathways, and delivery-mode counts were available for all 100 allocated women. Limitations include the single-centre setting, small groups, incomplete documentation of allocation concealment and masking.

CONCLUSION

In nulliparous women at 40 weeks with an unfavourable cervix, oral mifepristone pretreatment followed by dinoprostone when required was associated with a significantly higher vaginal birth rate and a lower caesarean delivery rate than dinoprostone alone. No severe neonatal complications were reported in the mifepristone group, providing reassuring neonatal safety findings. These results support the effectiveness of the mifepristone pretreatment regimen in improving delivery outcomes in the study population.

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