

## A Study on the Effect of Mifepristone in Cervical Ripening for Induction of Labour

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### Abstract

**Background:** Induction of labour is a common obstetric intervention, and successful induction largely depends on adequate cervical ripening. Oral mifepristone, a progesterone receptor antagonist, has emerged as an effective agent for improving cervical favourability prior to labour induction.

**Objectives:** To evaluate the effect of oral mifepristone on cervical ripening and its impact on labour outcomes in term pregnant women undergoing induction of labour.

**Materials and Methods:** This prospective interventional study was conducted in the Department of Obstetrics and Gynaecology, Kodagu Institute of Medical Sciences, Madikeri, from November 2023 to November 2025. A total of 150 term pregnant women with singleton pregnancies, cephalic presentation, and an unfavourable cervix (Bishop score  $\leq 6$ ) requiring induction of labour were included. All participants received oral mifepristone 200 mg, and the Bishop score was reassessed after 24 hours. Women were followed until delivery. Maternal characteristics, improvement in Bishop score, induction-to-delivery interval, mode of delivery, maternal complications, and neonatal outcomes were analysed using appropriate statistical tests, with  $p < 0.05$  considered statistically significant.

**Results:** The mean maternal age was  $25.9 \pm 3.8$  years, and 60% of participants were primigravidae. The mean Bishop score improved significantly from  $3.2 \pm 1.1$  before treatment to  $6.8 \pm 1.5$  after 24 hours ( $p < 0.001$ ). Successful cervical ripening was achieved in 80.7% of women, while 65.3% required no additional prostaglandin for induction. The mean induction-to-delivery interval was  $15.8 \pm 4.2$  hours. Vaginal delivery was achieved in 77.3% of cases, whereas the caesarean section rate was 22.7%. Maternal complications were minimal (12.0%), and 96% of neonates had an APGAR score  $\geq 7$  at 5 minutes. NICU admission was required in 6.7% of newborns, with no early neonatal deaths.

**Conclusion:** Oral mifepristone is an effective and safe cervical ripening agent that significantly improves Bishop score, facilitates successful vaginal delivery, and is associated with favourable maternal and neonatal outcomes. It represents a valuable option for pre-induction cervical preparation in women with an unfavourable cervix at term.

**Keywords:** Mifepristone, Cervical ripening, Induction of labour, Bishop score, Vaginal delivery, Maternal outcome, Neonatal outcome.

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### Introduction

Induction of labour (IOL) is one of the most frequently performed interventions in modern obstetrics and is indicated when the benefits of delivery outweigh the risks of continuing pregnancy. Approximately 20–30% of pregnancies require induction for maternal or fetal indications such as post-term pregnancy, hypertensive disorders, oligohydramnios, fetal growth restriction, diabetes mellitus, and premature rupture of membranes.[1] The success of labour induction

largely depends on the condition of the cervix at the time of initiation.

An unfavourable cervix is associated with prolonged labour, increased requirement for oxytocin augmentation, failed induction, and higher rates of operative delivery.[2] The Bishop score remains the most widely accepted clinical tool for assessing cervical readiness for induction. A Bishop score of less than six indicates an unfavourable cervix and predicts a lower likelihood of successful vaginal delivery without prior cervical ripening.[3]

Various pharmacological and mechanical methods have been employed to promote cervical ripening before induction of labour. Pharmacological agents include prostaglandins such as dinoprostone (PGE<sub>2</sub>) and misoprostol (PGE<sub>1</sub>), while mechanical methods include Foley catheter and hygroscopic dilators.[4] Although prostaglandins are effective, they are associated with uterine tachysystole, fetal heart rate abnormalities, gastrointestinal side effects, and require close maternal and fetal monitoring.[5]

Mifepristone is a synthetic steroid with potent antiprogesterone activity that competitively blocks progesterone receptors. Progesterone plays a vital role in maintaining uterine quiescence during pregnancy by suppressing uterine contractility and preserving cervical integrity. By antagonizing progesterone receptors, mifepristone promotes cervical softening, collagen degradation, increased prostaglandin synthesis, and enhances myometrial sensitivity to endogenous prostaglandins and oxytocin.[6]

Several clinical studies have demonstrated that oral mifepristone effectively improves cervical ripening before induction of labour. Women receiving mifepristone often show a significant improvement in Bishop score, shorter induction-to-delivery intervals, reduced need for prostaglandins and oxytocin augmentation, and higher rates of successful vaginal delivery compared with placebo or expectant management.[7]

Unlike prostaglandins, mifepristone itself does not usually stimulate excessive uterine contractions, making it a relatively safe agent for cervical preparation before active induction. Its oral route of administration, ease of use, and favourable maternal and fetal safety profile have increased its acceptance in obstetric practice.[8]

Despite encouraging evidence, variations remain regarding the optimal timing, dosage, and patient selection for mifepristone use. Differences in induction protocols, obstetric indications, and study populations have produced variable clinical outcomes. Therefore, further evaluation in different healthcare settings is required to establish its routine role in labour induction.[9]

The present prospective study was undertaken at Kodagu Institute of Medical Sciences, Madikeri, to evaluate the effectiveness of oral mifepristone in cervical ripening among women undergoing induction of labour. The study assessed improvement in Bishop score, induction characteristics, mode of delivery, maternal complications, and neonatal outcomes following administration of oral mifepristone.

## Materials and Methods

**Study Design and Setting:** This prospective, randomized, comparative interventional study was conducted in the Department of Obstetrics and Gynaecology, Kodagu Institute of Medical Sciences, Madikeri, Karnataka, India, over a period of 2 years, from November 2023 to November 2025. The study was undertaken after obtaining approval from the Institutional Ethics Committee (IEC). Written informed consent was obtained from all participants before enrolment.

**Study Population:** The study included 150 pregnant women admitted for induction of labour who fulfilled the eligibility criteria.

**Sample Size:** A total of 150 antenatal women requiring induction of labour were enrolled consecutively during the study period.

## Study Objectives

### Primary Objective

- To evaluate the effectiveness of oral mifepristone in cervical ripening before induction of labour.

### Secondary Objectives

- To compare the change in Bishop score following administration of mifepristone.
- To determine the induction-to-delivery interval.
- To assess the requirement for oxytocin augmentation.
- To evaluate the mode of delivery.
- To assess maternal and neonatal outcomes following induction.

## Inclusion Criteria

- Pregnant women aged 18–40 years.
- Singleton pregnancy.
- Cephalic presentation.
- Gestational age  $\geq 37$  weeks.
- Intact membranes.
- Unfavourable cervix (Bishop score  $\leq 6$ ).
- Reactive fetal heart rate tracing.
- Medical or obstetric indication for induction of labour.
- Willingness to participate in the study.

## Exclusion Criteria

- Previous uterine scar (previous caesarean section or myomectomy).
- Multiple pregnancy.
- Malpresentation.
- Placenta previa or vasa previa.
- Antepartum haemorrhage.
- Premature rupture of membranes.
- Severe fetal distress requiring immediate delivery.
- Contraindications to vaginal delivery.

- Known hypersensitivity to mifepristone.
- Severe maternal medical disorders contraindicating labour induction.

### Methodology

All eligible women underwent detailed history taking and complete clinical examination at admission. Baseline maternal demographic characteristics including age, parity, gestational age, body mass index (BMI), and indication for induction were recorded.

General physical examination and obstetric examination were performed. Baseline Bishop score was assessed by the same obstetrician whenever possible to minimize inter-observer variation. Baseline fetal well-being was confirmed by non-stress test (NST). Routine investigations were performed before induction.

**Intervention:** Each participant received oral Mifepristone 200 mg as a single dose for cervical ripening.

After 24 hours, the Bishop score was reassessed.

- Women with a favourable cervix (Bishop score  $\geq 6$ ) underwent induction with amniotomy and/or oxytocin infusion according to institutional labour protocol.
- Women with persistent unfavourable cervix received cervical ripening using prostaglandin (Dinoprostone gel or Misoprostol as per institutional protocol) before induction.

Labour was monitored using a standard WHO partograph. Continuous fetal heart rate monitoring and maternal vital signs were recorded throughout labour. Oxytocin augmentation was administered whenever clinically indicated. Women were followed until delivery and discharge.

**Data Collection:** The following variables were recorded:

### Maternal Variables

- Age
- Gravidity and parity
- Gestational age
- Body mass index
- Indication for induction
- Baseline Bishop score
- Bishop score after 24 hours
- Need for prostaglandins
- Need for oxytocin augmentation
- Induction-to-active labour interval
- Induction-to-delivery interval
- Mode of delivery
- Maternal complications

### Neonatal Variables

- Birth weight

- APGAR score at 1 and 5 minutes
- Meconium-stained liquor
- NICU admission
- Neonatal complications
- Perinatal mortality

### Outcome Measures

#### Primary Outcome

- Improvement in Bishop score after administration of oral mifepristone.

#### Secondary Outcomes

- Successful cervical ripening.
- Requirement for prostaglandins.
- Requirement for oxytocin augmentation.
- Induction-to-delivery interval.
- Rate of vaginal delivery.
- Caesarean section rate.
- Maternal complications.
- Neonatal outcomes including APGAR score and NICU admission.

### Investigations

The following investigations were performed before induction:

- Complete Blood Count (CBC)
- Blood Group and Rh typing
- Hemoglobin estimation
- Random Blood Sugar (if indicated)
- Urine routine examination
- Urine albumin and sugar
- Liver Function Tests (when indicated)
- Renal Function Tests (when indicated)
- Viral markers (HIV, HBsAg, HCV) as per institutional protocol
- Obstetric ultrasonography
- Non-Stress Test (NST)
- Fetal Heart Rate monitoring

### Ethical Considerations

- Institutional Ethics Committee approval was obtained before commencement of the study.
- Written informed consent was obtained from all participants.
- Confidentiality of patient information was maintained throughout the study.
- The study adhered to the ethical principles outlined in the Declaration of Helsinki.

**Statistical Analysis:** Data were entered into Microsoft Excel and analysed using SPSS software version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean  $\pm$  standard deviation (SD), while categorical variables were expressed as frequency and percentage.

The following statistical tests were applied:

- Paired t-test for comparison of Bishop scores before and after mifepristone administration.
- Independent Student's t-test for comparison of continuous variables where appropriate.
- Chi-square test or Fisher's exact test for categorical variables.
- A p-value <0.05 was considered statistically significant.

A total of 150 pregnant women requiring induction of labour were included in this prospective interventional study. All participants received oral Mifepristone 200 mg for cervical ripening and were followed until delivery. The maternal characteristics, cervical ripening outcomes, labour characteristics, maternal outcomes, and neonatal outcomes are presented below.

## Results and Observations

**Table 1: Maternal Demographic Characteristics (n = 150)**

| Variable          | Number | Percentage (%) |
|-------------------|--------|----------------|
| Age Group (years) |        |                |
| <20               | 12     | 8.0            |
| 20–24             | 54     | 36.0           |
| 25–29             | 58     | 38.7           |
| 30–34             | 20     | 13.3           |
| ≥35               | 6      | 4.0            |
| Parity            |        |                |
| Primigravida      | 90     | 60.0           |
| Multigravida      | 60     | 40.0           |

Mean maternal age:  $25.9 \pm 3.8$  years

Observation: Most women were aged 20–29 years (74.7%), and primigravidae constituted 60% of the study population.

**Table 2: Gestational Age at Induction**

| Gestational Age (Weeks) | Number | Percentage (%) |
|-------------------------|--------|----------------|
| 37–38+6                 | 40     | 26.7           |
| 39–40                   | 76     | 50.7           |
| >40                     | 34     | 22.6           |

Mean gestational age:  $39.2 \pm 1.1$  weeks

Observation: Half of the women underwent induction between 39 and 40 weeks of gestation.

**Table 3: Indications for Induction of Labour**

| Indication                    | Number | Percentage (%) |
|-------------------------------|--------|----------------|
| Postdated pregnancy           | 55     | 36.7           |
| Gestational hypertension      | 28     | 18.7           |
| Oligohydramnios               | 20     | 13.3           |
| Gestational diabetes mellitus | 18     | 12.0           |
| Fetal growth restriction      | 12     | 8.0            |
| Elective induction            | 10     | 6.7            |
| Others                        | 7      | 4.6            |

Observation: Postdated pregnancy (36.7%) was the commonest indication for induction.

**Table 4: Change in Bishop Score Following Mifepristone**

| Variable                    | Mean $\pm$ SD |
|-----------------------------|---------------|
| Baseline Bishop Score       | $3.2 \pm 1.1$ |
| Bishop Score after 24 hours | $6.8 \pm 1.5$ |
| Mean Improvement            | $3.6 \pm 1.3$ |

Paired t-test:  $p < 0.001$

Observation: Oral mifepristone significantly improved the Bishop score after 24 hours.

**Table 5: Requirement of Additional Induction Methods**

| Variable                                             | Number | Percentage (%) |
|------------------------------------------------------|--------|----------------|
| Successful cervical ripening with Mifepristone alone | 98     | 65.3           |
| Required prostaglandin                               | 52     | 34.7           |
| Required oxytocin augmentation                       | 81     | 54.0           |
| Artificial rupture of membranes performed            | 118    | 78.7           |

Observation: Nearly two-thirds achieved adequate cervical ripening with mifepristone alone, while 34.7% required prostaglandins.

**Table 6: Induction-to-Delivery Interval**

| Variable                           |        | Mean $\pm$ SD  |
|------------------------------------|--------|----------------|
| Induction to Active Labour (hours) |        | 9.4 $\pm$ 2.8  |
| Induction to Delivery (hours)      |        | 15.8 $\pm$ 4.2 |
| Duration                           | Number | Percentage (%) |
| <12 hours                          | 38     | 25.3           |
| 12–18 hours                        | 82     | 54.7           |
| >18 hours                          | 30     | 20.0           |

Observation: More than half of the women delivered within 12–18 hours of induction.

**Table 7: Mode of Delivery**

| Mode of Delivery        | Number | Percentage (%) |
|-------------------------|--------|----------------|
| Normal Vaginal Delivery | 108    | 72.0           |
| Instrumental Delivery   | 8      | 5.3            |
| Caesarean Section       | 34     | 22.7           |

**Table 8: Indications for Caesarean Section (n = 34)**

| Indication              | Number |
|-------------------------|--------|
| Fetal distress          | 14     |
| Failed induction        | 10     |
| Non-progress of labour  | 6      |
| Meconium-stained liquor | 4      |

Observation: Vaginal delivery was achieved in 77.3% of women, while the caesarean section rate was 22.7%.

**Table 9: Maternal Outcomes and Complications**

| Variable               | Number | Percentage (%) |
|------------------------|--------|----------------|
| Uneventful labour      | 132    | 88.0           |
| Postpartum haemorrhage | 6      | 4.0            |
| Hyperstimulation       | 3      | 2.0            |
| Fever                  | 5      | 3.3            |
| Chorioamnionitis       | 2      | 1.3            |
| Blood transfusion      | 2      | 1.3            |

Observation: Maternal complications were infrequent, with 88% experiencing uncomplicated labour.

**Table 10: Neonatal Outcomes**

| Variable                     | Number | Percentage (%) |
|------------------------------|--------|----------------|
| APGAR $\geq$ 7 at 5 minutes  | 144    | 96.0           |
| APGAR <7 at 5 minutes        | 6      | 4.0            |
| NICU admission               | 10     | 6.7            |
| Meconium aspiration syndrome | 3      | 2.0            |
| Neonatal sepsis              | 2      | 1.3            |
| Early neonatal death         | 0      | 0              |

**Table 11: Birth Weight**

| Birth Weight | Number | Percentage (%) |
|--------------|--------|----------------|
| <2.5 kg      | 24     | 16.0           |
| 2.5–3.5 kg   | 108    | 72.0           |
| >3.5 kg      | 18     | 12.0           |

Mean birth weight: 2.94  $\pm$  0.42 kg

Observation: Most newborns had satisfactory APGAR scores, and NICU admission was required in only 6.7% of neonates.

**Table 12: Overall Effectiveness of Mifepristone for Cervical Ripening**

| Outcome                                              | Number | Percentage (%) |
|------------------------------------------------------|--------|----------------|
| Successful cervical ripening (Bishop score $\geq$ 6) | 121    | 80.7           |
| Successful vaginal delivery                          | 116    | 77.3           |
| Caesarean section                                    | 34     | 22.7           |
| Maternal complications                               | 18     | 12.0           |
| Neonatal complications                               | 15     | 10.0           |

Observation: Oral mifepristone effectively promoted cervical ripening in 80.7% of women, resulting in a high rate of successful vaginal delivery with low maternal and neonatal complication rates, supporting its safety and efficacy as a cervical ripening agent before induction of labour.

## Discussion

Successful induction of labour depends primarily on cervical favourability before the initiation of uterine contractions. An unfavourable cervix is associated with prolonged labour, failed induction, increased oxytocin requirement, and higher caesarean section rates. Therefore, effective cervical ripening remains a critical component of induction protocols.[2]

In the present study, the majority of women (74.7%) belonged to the 20–29-year age group, with a mean maternal age of  $25.9 \pm 3.8$  years, and 60% were primigravidae. Similar demographic characteristics have been reported by Wing et al., who observed that labour induction is most frequently performed among young reproductive-age women with a predominance of primigravidae.[10]

Postdated pregnancy (36.7%) was the most common indication for induction in the present study, followed by gestational hypertension and oligohydramnios. Similar findings have been documented in previous obstetric studies, where prolonged pregnancy remains the leading indication for induction because of increasing fetal and maternal risks beyond 40 weeks of gestation.[1,11]

One of the most important findings of this study was the significant improvement in Bishop score after administration of oral mifepristone. The mean Bishop score increased from  $3.2 \pm 1.1$  before treatment to  $6.8 \pm 1.5$  after 24 hours ( $p < 0.001$ ). This confirms the effectiveness of mifepristone as a cervical ripening agent. Similar improvements have been demonstrated by Yelikar et al. and Hapangama and Neilson, who reported significantly greater cervical ripening following mifepristone compared with placebo.[6,12]

In the present study, 65.3% of women achieved adequate cervical ripening with mifepristone alone, while only one-third required additional prostaglandin administration. These findings indicate that pretreatment with mifepristone reduces the need for further cervical ripening agents. Comparable observations have been reported in several randomized controlled trials evaluating mifepristone before labour induction.[7,8] The mean induction-to-delivery interval in the present study was  $15.8 \pm 4.2$  hours, which is comparable to previously published studies demonstrating that mifepristone shortens the duration of labour induction by improving cervical readiness before active induction begins.[6,9] Improved cervical favourability

facilitates earlier onset of labour and decreases prolonged induction.

A successful vaginal delivery was achieved in 77.3% of women, whereas the caesarean section rate was 22.7%. The common indications for caesarean section included fetal distress, failed induction, and non-progress of labour. Similar vaginal delivery rates have been reported in previous clinical studies evaluating oral mifepristone, where cervical ripening resulted in reduced operative intervention.[10,12]

Maternal safety remains an important consideration during labour induction. In the present study, maternal complications were infrequent, with postpartum haemorrhage occurring in only 4%, uterine hyperstimulation in 2%, and fever in 3.3% of women. No serious maternal adverse events attributable to mifepristone were observed. These findings are consistent with published evidence demonstrating that mifepristone is generally well tolerated and carries a lower risk of uterine hyperstimulation compared with prostaglandins.[5,8]

Neonatal outcomes were also favourable in this study. Most neonates (96%) had an APGAR score of  $\geq 7$  at five minutes, while NICU admission was required in only 6.7% of cases. There were no early neonatal deaths. Similar neonatal safety profiles have been reported by previous investigators, indicating that cervical ripening with mifepristone does not adversely affect neonatal outcomes.[7,11]

The strengths of the present study include its prospective design, standardized cervical assessment, and comprehensive evaluation of maternal and neonatal outcomes. However, the study was conducted at a single tertiary care centre and lacked a direct comparison group receiving placebo or another cervical ripening agent. Multicentre randomized controlled trials with larger sample sizes are warranted to further establish the comparative effectiveness of mifepristone against other induction methods.

Overall, the findings of the present study demonstrate that oral mifepristone is an effective, safe, and well-tolerated cervical ripening agent. It significantly improves Bishop score, reduces the need for additional prostaglandins, facilitates successful vaginal delivery, and is associated with favourable maternal and neonatal outcomes. These findings support its use as a valuable option for pre-induction cervical ripening in appropriately selected women.

## Conclusion

Oral mifepristone is an effective and safe agent for cervical ripening before induction of labour. It significantly improves the Bishop score, facilitates successful vaginal delivery, reduces the need for additional cervical ripening agents, and is associated with favourable maternal and neonatal outcomes.

Therefore, mifepristone can be considered a reliable option for pre-induction cervical preparation in women with an unfavourable cervix at term.

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