ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 05 | May - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

"ORAL MIFEPRISTONE VERSUS MISOPROSTOL FOR TERM INDUCTION OF LABOUR- A RANDOMISED CONTROLLED TRIAL"

Obstetrics And Gynaecology

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ABSTRACT

Aim: To evaluate the efficacy of oral mifepristone versus misoprostol for term induction of labour. **Material And Methods:** A prospective, randomized comparative study was conducted at Rohilkhand Medical College & Hospital, Bareilly, from November 2022 to October 2023, involving 100 full-term pregnant women. Participants were randomly allocated into two groups of 50 each. Group A received 200 mg oral mifepristone, while Group B received 25 mcg vaginal misoprostol every 4 hours (maximum 4 doses). Bishop's score, induction-to-delivery interval, maternal and fetal outcomes, and mode of delivery were recorded. **Results:** Baseline demographic characteristics were comparable in both groups. The mean induction-to-delivery interval was significantly shorter in the misoprostol group (21.58 ±4.37 hours) than in the mifepristone group (28.60 ±3.34 hours, $p<0.001$). Vaginal delivery rates were higher with misoprostol, while cesarean section rates were 8% in Group A and 16% in Group B. Mean APGAR scores at 5 minutes were significantly better in the mifepristone group (7.38 ±0.75 vs. 6.32 ±0.65, $p<0.001$). Maternal and neonatal complications were similar in both groups. **Conclusion:** Both mifepristone and misoprostol were effective and safe for labor induction. Misoprostol had a shorter induction-to-delivery interval and higher vaginal delivery rates, while mifepristone showed slightly better neonatal outcomes.

KEYWORDS

Labor induction, Mifepristone, Misoprostol, Bishop's score, Term pregnancy.

INTRODUCTION

Induction of labor is a critical obstetric procedure aimed at stimulating uterine contractions before spontaneous labor begins. It is commonly indicated in conditions such as post-maturity, pre-eclampsia, eclampsia, intrauterine fetal death, and premature rupture of membranes[1]. The success of labor induction largely depends on the process of cervical ripening, which involves biochemical changes that soften and dilate the cervix, making it favourable for labor[2]. The Bishop's score is a widely used assessment tool to evaluate cervical readiness, guiding the choice of induction methods. Various pharmacological and mechanical techniques are available for cervical ripening, with mifepristone and misoprostol being two of the most commonly used agents.

Mifepristone, a progesterone receptor antagonist, plays a crucial role in cervical ripening by inhibiting the effects of progesterone, which otherwise maintains cervical rigidity. By blocking progesterone, mifepristone increases estrogen activity, enhances prostaglandin synthesis, and facilitates collagen breakdown in the cervix, leading to softening and dilatation[3]. Additionally, mifepristone promotes uterine contractility, further aiding in labor induction. Its use has been widely studied in early pregnancy termination, second-trimester abortion, and labor induction at term.

Misoprostol, a synthetic prostaglandin E1 analog, has both uterotonic and cervical-ripening properties. It stimulates smooth muscle contractions in the myometrium while also promoting cervical effacement and dilation[4]. Initially developed to prevent gastric ulcers, misoprostol was later recognized for its potent effects on the reproductive system, leading to its widespread use in labor induction, medical abortion, and postpartum hemorrhage management. Misoprostol can be administered via oral, sublingual, or vaginal routes, with the vaginal route demonstrating prolonged action and effectiveness in labor induction[4].

The prevalence of labor induction varies significantly, with reported rates ranging from 9.5% to 33.7% of all pregnancies annually. In cases where the cervix is unripe, successful vaginal delivery is less likely, and the force required to induce cervical dilation increases significantly. The estimated uterine pressure required to dilate an unripe cervix is nearly five times greater than that needed for a ripe cervix. This highlights the importance of proper cervical preparation before induction.

Existing research suggests that mifepristone effectively promotes cervical ripening by inhibiting progesterone's stabilizing effect on the cervix, thereby allowing natural estrogenic and prostaglandin activity to facilitate cervical softening. Misoprostol, on the other hand, directly induces uterine contractions and cervical changes, making it an effective agent for labor induction. Studies have demonstrated that vaginal misoprostol effectively induces labor within 24 hours without increasing the rate of cesarean section or causing adverse fetal outcomes. However, while various studies have compared oral versus vaginal misoprostol regimens, and others have examined the combination of mifepristone and misoprostol for labor induction, direct comparative research between mifepristone and misoprostol as standalone agents for cervical ripening and labor induction remains limited.

Given the widespread use of both agents and their potential advantages in labor management, further investigation is needed to determine their relative effectiveness and safety. This study aims to compare the efficacy of mifepristone and misoprostol in cervical ripening and labor induction at full term. By analyzing their individual effects on labor progression, maternal outcomes, and neonatal well-being, this research seeks to provide valuable insights into optimizing labor induction strategies. The findings of this study could help refine clinical protocols and improve patient care by identifying the most effective pharmacological approach for inducing labor in full-term pregnancies.

MATERIALS AND METHODS

This was a prospective comparative clinical study conducted at the

Department of Obstetrics and Gynaecology, Rohilkhand Medical College & Hospital, Bareilly, from 1st November 2022 to 31st October 2023. The study included a total of 100 pregnant women with gestational age more than 37 weeks, all willing for normal vaginal delivery and meeting the defined inclusion and exclusion criteria.

The inclusion criteria were uncomplicated singleton pregnancies with cephalic presentation beyond 37 weeks, intrauterine foetal death, gestational hypertension, and intact membranes at the time of induction, with no contraindications to the use of prostaglandins or mifepristone. Exclusion criteria included premature rupture of membranes, malpresentations, cephalopelvic disproportion, bad obstetric history, prior caesarean section or uterine surgery, multiple pregnancy, placental complications such as abruption or placenta praevia, abnormal foetal heart rate patterns, active herpes infection, and contraindications for prostaglandin use.

The objectives were to compare the effects of mifepristone versus misoprostol on Bishop's score, to evaluate their adverse effects on mother and foetus, and to study the duration of induction-to-delivery intervals between the two drugs.

Ethical clearance for the study was obtained from the Institutional Ethics Committee prior to data collection. Data was recorded and analyzed using SPSS version 23.0.[5]

METHODS

A prospective comparative study was conducted on 100 full-term pregnant women meeting inclusion criteria. After informed consent, obstetric history and clinical assessment was done. Cervical status was assessed by modified Bishop score. Routine investigations including obstetric ultrasound was done. Participants were randomly allocated by lottery into two groups of 50 each; Group 1 received 200 mg oral mifepristone with Bishop's score reassessed after 24 hours, followed by oxytocin if the score was ≤6 or labor began, or cerviprime gel if ≥4. Group 2 received 25 mcg vaginal misoprostol every 4 hours up to 4 doses, with induction labeled as failed if labor did not commence within 6 doses, followed by oxytocin or cerviprime gel as needed. Maternal vitals, uterine activity, fetal heart rate, labor progress, complications, and mode of delivery were monitored, and drug efficacy was assessed by improvement in Bishop's score within 24 hours, rate of spontaneous labor onset, and mode of delivery.

RESULTS

Demographic Characteristics

Parameter	Group A (Mifepristone)	Group B (Misoprostol)	P-value	Significance
Age distribution	Majority 21–25 years	Majority 21–25 years	> 0.05	Not significant
Parity distribution	Comparable	Comparable	> 0.05	Not significant
Mean gestational age (days)	277.78 ± 7.92	277.38 ± 8.01	> 0.05	Not significant

Indications For Induction

The difference in indications between the groups was not statistically significant ($p > 0.05$), indicating comparable study populations.

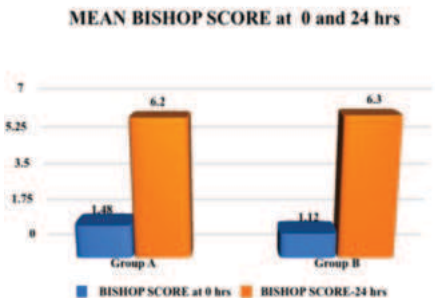
Bishop Score Improvement

TABLE - COMPARISION OF BISHOP SCORE AT 0 and 24 HOURS IN BETWEEN GROUP A and GROUP B.

	Group A	Group B	P-Value
BISHOP SCORE-0 hrs (Mean ± SD)	1.48 ± 0.95	1.12 ± 0.92	0.057#
BISHOP SCORE-24 hrs (Mean ± SD)	6.20 ± 1.60	6.30 ± 1.63	0.758#

P>0.05 statistically not significant.

Fig : BAR DIAGRAM SHOWING COMPARISION OF BISHOP SCORE AT 0 and 24 HOURS IN BETWEEN GROUP A and GROUP B.

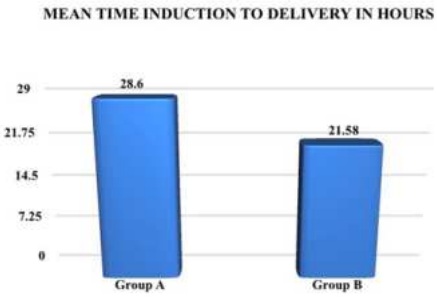


Induction To Active Labor And Delivery Interval

The induction to delivery interval was significantly shorter in the misoprostol group (21.58 ±4.37 hours) compared to the mifepristone group (28.60 ±3.34 hours), with a p-value < 0.001.

Group	Mean Induction-to-Delivery Time (hours)
Mifepristone (Group A)	28.60 ± 3.34
Misoprostol (Group B)	21.58 ± 4.37

Fig : BAR DIAGRAM SHOWING COMPARISION OF TIME DURATION FROM INDUCTION TO DELIVERY IN BETWEEN GROUP A AND GROUP B



Mode Of Delivery

The study found that vaginal delivery rates were higher in the misoprostol group than in the mifepristone group. The rate of cesarean section (LSCS) was 8% in Group A and 16% in Group B. The primary reasons for LSCS were fetal distress and meconium-stained liquor.

Maternal And Fetal Outcomes

Outcome Parameter	Group A (Mifepristone)	Group B (Misoprostol)	P-value	Significance
Maternal complications	Similar	Similar	> 0.05	Not significant
Mean birth weight (kg)	2.94 ± 0.33	2.93 ± 0.32	> 0.05	Not significant
Mean APGAR score at 5 minutes	7.38 ± 0.75	6.32 ± 0.65	< 0.001	Highly significant
NICU admission requirement	Similar	Similar	> 0.05	Not significant

DISCUSSION

The process of labour initiation remains a mystery. It is well known, however that progesterone is integral in the maintenance of pregnancy. It is hypothesized that anti progestin exposure in pregnancy will enhance the iniation of parturition.In this study, study population comprised of 100 patients with equal number of patients in the two groups. The study was conducted in a tertiary care hospital where majority of women belonged to low socio economic status & usually get married around the age of 20 years and conceive soon.

In terms of maternal age distribution, the mean maternal age in the present study was 23.28 years in Group A and 23.08 years in Group B. These findings are comparable to previous studies such as Lata G et al.[3], where the mean age in Group 1 and Group 2 was 25.54 and 25.75 years respectively, and to C. Rekha et al.[6], which reported 23.52 and 22.72 years in the respective groups. Similarly, N. Deepika et al.[7] observed a mean maternal age of 25.54 years in Group A and 25.75

years in Group B, confirming that the demographic characteristics in the present study were in alignment with existing literature.

Regarding pre induction bishop's score, all women in both Group A and Group B presented with unfavourable cervices, reflected by pre-induction Bishop scores of less than 6. This finding mirrors results from other studies including those by Lata G et al. and C. Rekha et al., which also recorded pre-induction Bishop scores below 6 in their patient populations. As is well recognised, the Bishop score is a valuable tool to assess cervical favourability and predict the likelihood of successful induction, with scores below 6 indicating a need for cervical ripening.

In the present study, the mean induction to delivery interval in group A was 28.60 hours and in group B was 21.58 hours which was statistically significant (p=0.00). In Lata G study shorter induction to delivery interval was seen in women induced with 400 milligrams of Mifepristone when compared to placebo. But in C Rekha et al study the mean induction to delivery interval in group A was 31.86 and group B was 16.11 , in Deepika N et al . mean induction to delivery interval in group A was 35.38 and group B was 49.52, in Uma H et al.[8] mean induction to delivery interval in group A was 35.53 and group B was 50.49.

In our study, caesareans section was required in 8% of the cases in group A and 16% of cases in group B, the reasons being fetal distress and meconium stained liquor. Similarly, rate of caesarean sections in C Rekha was 20% in group 1 and 24% in group 2 the reason being fetal distress and non progress of labor. Similarly in R. Das[9] study the rate of caesarean section in group A 4% and Group B 6%.

CONCLUSION

Both drugs, Mifepristone and Misoprostol were well tolerated, with no significant adverse maternal or fetal effects. While vaginal delivery rates increased in both groups, misoprostol demonstrated greater efficacy, with a significantly shorter induction-to-delivery interval, higher rates of successful vaginal delivery, and favorable neonatal outcomes compared to mifepristone.

Limitations

This study was limited by its single-center design and relatively small sample size, which may affect the generalizability of the results. The subjective assessment of Bishop's score could introduce observer bias. Additionally, neonatal outcomes were assessed only in the immediate postpartum period, without long-term follow-up. The socio-demographic homogeneity of the study population may also limit the applicability of findings to broader, more diverse populations.

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