

Effect Of Mifepristone on Serum Progesterone Level and Modified Bishop Score in Induction of Labour at A Tertiary Care Centre in Bihar

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Cite this paper as: Shweta, Ranjana, Neeru Goel, (2025) Effect of Mifepristone on Serum Progesterone Level and Modified Bishop Score in Induction of Labour at A Tertiary Care Centre in Bihar, *Journal of Neonatal Surgery*, 14 (30s), 226-235

ABSTRACT

Background: Induction of labour is a pivotal intervention in obstetric practice, aimed at facilitating a safe and timely vaginal delivery. A favourable or "ripe" cervix is a fundamental prerequisite for its success. The present study aimed to evaluate the efficacy of oral mifepristone in inducing labour by examining its effect on cervical ripening, as measured by changes in the Modified Bishop's score, and its impact on serum progesterone levels.

Materials and Methods: This was a case-control study conducted at the Department of Obstetrics and Gynaecology at Indira Gandhi Institute of Medical Sciences, Patna, Bihar (India), for a duration of 1.5 years. A total of 220 participants fulfilling the inclusion criteria were divided into 2 groups: Group A (Case) with Bishop's score <3 received 200 mg oral mifepristone and Group B (control) presented with spontaneous labour pain with cervical dilatation <3 cm. Change in Modified Bishop's score and serum Progesterone levels were assessed 48 hours after administering Mifepristone or at the onset of established labour in Group A. In Group B, Modified Bishop's score and serum progesterone measurement were done at the time of admission. Both groups were compared in terms of change in serum progesterone levels, number of patient's went into active labour, mode of deliveries, indications of LSCS, and neonatal outcomes.

Results: In the case group, mean Bishop Score significantly increased from 2.98 at the time of admission to 6.69 at 48 hours or onset of labor ($p < 0.001$), and the mean (SD) change in serum progesterone at 48 hours or onset of labor was -28.02 (22.90) ng/mL. There was a significant difference between the two groups in terms of serum progesterone level (48 hours/onset of labour) ($t = -3.946$, $p < 0.001$), with the mean serum progesterone level being highest in the control group. There was no significant difference between the 2 groups in terms of the number of patients who went into active labour, mode of deliveries, Indications of LSCS, and neonatal outcomes.

Conclusion: Mifepristone significantly enhances cervical ripening as evidenced by significant changes in Bishop scores, and lowers serum progesterone levels in a clinically relevant timeframe and shortened labor intervals without increasing maternal or neonatal risk. Hence, mifepristone is a valuable adjunct in obstetric practice, especially for women requiring cervical ripening and induction of labor..

Keywords: Mifepristone, Cervical Ripening, Induction of Labour, Modified Bishop's Score, Serum Progesterone

1. INTRODUCTION

Induction of labor is a vital intervention in obstetrics used to ensure timely and safe delivery. It is performed when the benefits of delivery outweigh the risks of continuing the pregnancy. Increasing high-risk pregnancies in our institute have

contributed to a rise in labor inductions. Indications for induction of labour are broadly categorized into obstetric indications (e.g., pre-labour rupture of membranes, post-term pregnancy, preeclampsia, fetal growth restriction) and medical conditions aggravated by pregnancy (notably hypertension and diabetes). Contraindications to induction include prior classical caesarean section, uterine surgery, abnormal fetal lie, cervical cancer, active HIV, placenta previa, and others [1]. Mifepristone, a progesterone receptor antagonist, has gained attention as a labor-inducing agent. It works by softening the cervix and promoting hormonal changes similar to those seen in spontaneous labor. Unlike other induction agents that require frequent vaginal administration, mifepristone is given one time orally and has better storage properties. Progesterone plays a key role in maintaining pregnancy, and its withdrawal, though not classical in humans, is believed to contribute to labor onset. Mifepristone mimics this withdrawal functionally. Functional progesterone withdrawal and partial progesterone level reduction leading to the onset of labour as a possibility is an active area of interest and is being researched [2]. Mifepristone is a notable pharmacological agent for labor induction due to its ability to influence hormonal pathways critical to pregnancy and labor onset. Mifepristone softens the cervix and increases uterine sensitivity to endogenous prostaglandins, thereby creating a favourable environment for the induction of labour [3]. It also shortens the time to labor compared to agents like dinoprostone and Foley's catheter [4,5]. It is also found to be safe for use in women with prior caesarean sections and can be used effectively in outpatient settings [6,7]

Aim of the study:

To evaluate the efficacy of oral mifepristone (200 mg) for the induction of labour by assessing changes in Modified Bishop's score and serum progesterone levels.

Primary Objectives:

- To assess the change in Modified Bishop's score and serum progesterone level 48 hours post Mifepristone administration or with the onset of labour.
- To compare serum progesterone levels between women with spontaneous onset of labour and those receiving oral 200 mg mifepristone for induction of labour.

Secondary Objectives:

- To analyze the Induction-to-Active Labour Interval in the mifepristone-induced group
- To analyze the Induction-to-Delivery Interval in the mifepristone-induced group.
- To determine the need for additional induction methods after 48 hours in the mifepristone group.
- To assess fetal outcomes, including APGAR scores and neonatal intensive care unit (NICU) admissions.

2. MATERIALS AND METHODS

This was a case-control study conducted in the Department of Obstetrics and Gynaecology at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India, over a period of 18 months from March 2023 to August 2024. This study was approved by the Institutional Ethics Committee (Letter no: 984/IEC/IGIMS/2023).

Sample size calculation

The required sample size per group was calculated to be 50, assuming a standard deviation of 1.33 in the case group and 0.97 in the control group, with a significance level of 5% and a power of 80%. However, a total of 220 participants were ultimately recruited, 110 in Group A, who received mifepristone, and 110 in Group B, who experienced spontaneous labour.

Inclusion Criteria:

Includes various maternal/fetal indications for induction of labor like: Preeclampsia/ Hypertensive disorders of pregnancy, Gestational diabetes mellitus, Post-dated pregnancy, Rh alloimmunization, Foetal death, Intrahepatic cholestasis of pregnancy, Foetal growth restriction, Gross fetal anomalies, oligohydramnios, Antepartum haemorrhage, Patients with heart disease (NYHA grade 1 & 2).

Exclusion Criteria:

Patient refusing induction, Active genital herpes, patients with absolute indication for caesarean section, contracted pelvis and cephalopelvic disproportion, prelabour rupture of membrane, twins, malpresentation, Patients with heart disease (NYHA grade 3 & 4), Pelvic tumours.

Study Participants

Group A (Case Group): Received 200 mg oral mifepristone for labor induction (with Bishop score <3).

Group B (Control Group): Presented with spontaneous labor pain (with cervical dilatation <3cm).

Data collection

Admission Assessment: Upon admission to the labour ward, written informed consent was obtained from all eligible participants. A comprehensive evaluation was conducted, including a detailed medical and obstetric history, general physical examination, routine clinical assessment, and obstetrical evaluation. All findings were systematically documented using a pre-designed, structured proforma for both study groups.

Case Group (Mifepristone Administration): Participants in the case group received a single oral dose of 200 mg mifepristone, with the exact date and time of administration duly recorded. The Modified Bishop's score was assessed prior to drug administration and re-evaluated either 48 hours later or at the onset of labour, whichever occurred earlier. If the Bishop's score remained ≤ 6 after 48 hours, labour induction was augmented with misoprostol. Participants whose Bishop's score failed to improve even after misoprostol administration were classified as having a failed induction.

Baseline serum progesterone levels were obtained via venous blood sampling prior to mifepristone administration. A follow-up sample was collected approximately 48 hours later or at the onset of established labour to assess post-treatment progesterone levels.

For participants who progressed to active labour, maternal vital signs and labour progression were continuously monitored using a standard partograph. Vaginal delivery was undertaken if labour progressed satisfactorily. Cesarean section was performed in cases of failed induction, non-progression of labour, or evidence of fetal distress.

Control Group (Spontaneous Labour): In the control group, the Modified Bishop's score was assessed at the time of admission and re-evaluated either at the onset of active labour or after 48 hours, whichever occurred first. A single blood sample for serum progesterone measurement was collected at admission. Monitoring of maternal vital signs, labour progression, and clinical decision-making regarding mode of delivery, including the need for cesarean section, was conducted using the same protocols and criteria as applied in the case group.

Modified Bishop's Score

PARAMETERS	SCORE			
	0	1	2	3
Cervical dilatation (cm)	<1	1-2	2-4	>4
Cervical length (cm)	4	2-4	1-2	<1
Cervical consistency	firm	medium	soft	-
Cervical position	posterior	mid	anterior	-
Station (cm about spine)	-3	-2	-1/0	+1/+2

If Bishop's score is more than or equal to 6, the likelihood of successful induction increases [1].

3. RESULTS

A total of 220 patients were recruited for the study. Of these, 110 were assigned to the case group, and 110 to the control group. In the case group, 3 patients refused induction, and in the control group, serum progesterone levels could not be evaluated in 33 patients due to technical issues. So, finally, analysis was done in 107 patients in the case group and 77 patients in the control group. No significant differences were observed in both groups in terms of baseline demographic characteristics like age, BMI, Gravida, Parity, and Gestational age. ($p > 0.05$)

Table 1: Change in Modified Bishop's score in patients receiving Mifepristone (Case Group)

Mean Bishop's score	
At the time of admission	2.98
After 48 hours/onset of labour	6.69
P value	<0.001

The mean Bishop Score significantly increased from 2.98 at the time of admission to 6.69 at 48 hours or onset of labor ($p < 0.001$).

Table 2: Change in Serum Progesterone level in patients receiving Mifepristone (Case Group)

Change in serum progesterone level (48 hours/ Onset of labour)	
Mean (SD)	-28.02 (22.90)
Median (IQR)	-24 (-38- -11)

In the Case group, the mean (SD) change in serum progesterone at 48 hours or the onset of labor was -28.02 (22.90) ng/mL. The median (IQR) change was -24 ng/mL (IQR: -38 to -11).

Table 3: Comparison of Serum Progesterone level (at 48 hours/ Onset of labour) between case and control in Bishop's score category ≤ 6 .

S. Progesterone (ng/ml) (at 48 hours/ Onset of labour)	Case Group (N=107)	Control Group (N=77)	t	P value
Mean (SD)	132.41 (34.00)	153.30(14.25)	-3.277	0.002
Median (IQR)	134 (112-154)	154 (145-161)		
Min-Max	34-225	122-187		

There was a significant difference in mean serum progesterone level between the two groups when compared in Bishop's score category ≤ 6 ($p=0.002$).

Table 4: Comparison of Serum Progesterone level (at 48 hours/ Onset of labour) between case and control in Bishop's score category > 6 .

S. Progesterone (ng/ml) (at 48 hours/ Onset of labour)	Case Group (N=107)	Control Group (N=77)	t-test	P value
Mean (SD)	142.16 (22.43)	145.67(17.08)	-0.682	0.501
Median (IQR)	139 (129-156)	149 (134-157.5)		
Min-Max	80-198	116-178		

There were no significant differences between the 2 groups in terms of Serum Progesterone level, when compared in Bishop's score category >6 ($t=-0.682$, $p=0.501$).

Table 5: Comparison of Serum Progesterone level between cases and controls at 48 hours/ Onset of labour

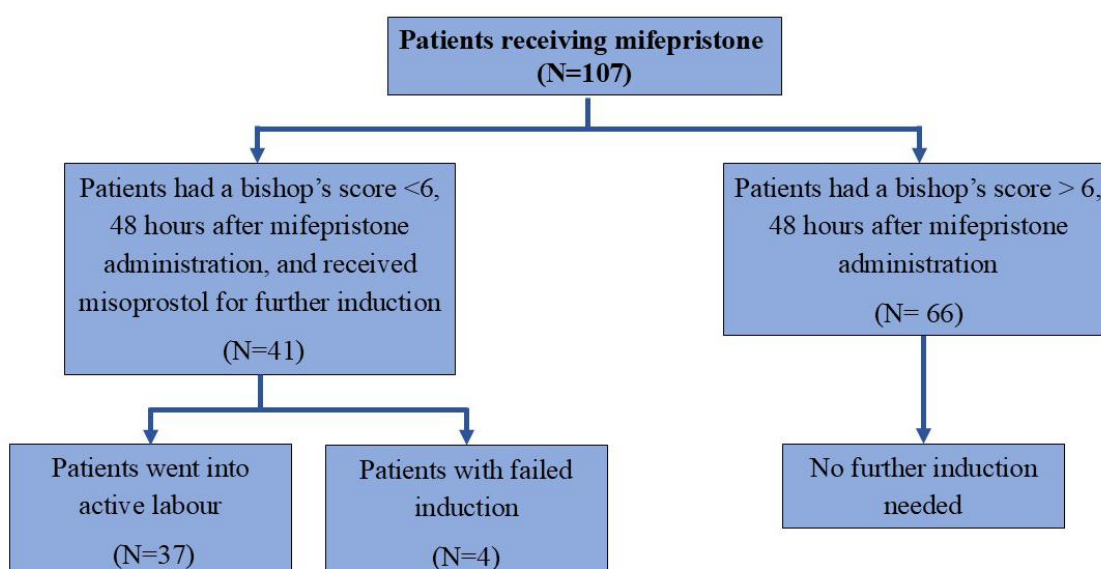
S. Progesterone (ng/ml) (at 48 hours/ Onset of labour)	Case Group (N=107)	Control Group (N=77)	t-test	P value
Mean (SD)	139.18	151.38	-3.946	<0.001
Median (IQR)	139	152		
Min-Max	34-225	116-187		

There was a significant difference between the two groups in terms of serum progesterone level (48 hours/onset of labour) ($t=-3.946$, $p<0.001$), with the mean serum progesterone level being highest in the control group.

Table 6: Comparison of the number of patients who went into active labour between cases and controls

Went into active labour	Cases (mifepristone given)	Control (mifepristone not given)	Chi-Squared test	
			χ^2	P value
Yes	N=94 (87.9%)	N=72(93.5%)	1.623	0.203
No	N=13(12.1%)	N=5(6.5%)		
Total	N=107(100%)	N=77(100%)		

There was no significant difference between the two groups in terms of patients who went into active labour ($\chi^2=1.623$, $p=0.203$)

Figure 1: Need for further induction with Misoprostol in the case group (patient receiving Mifepristone)**Table 7: Analysis of induction to delivery interval in the mifepristone-induced group**

Induction to vaginal delivery interval (in hours)	Mifepristone alone	Mifepristone + Misoprostol	P value
Mean (SD)	46.01(12.36)	56.94	<0.001
Median (IQR)	50 (40-55)	58	

Table 8: Comparison of Mode of delivery in cases and control group

Mode of delivery	Cases (Mifepristone given) N=107	Control (Mifepristone not given) N=77	Total	Chi-Squared Test	
				χ^2	P value
Vaginal	93 (86.9%)	68 (88.3%)	161 (87.5%)	0.080	0.778
LSCS	14 (13.1%)	9 (11.7%)	23 (12.5%)		
Total	107 (100%)	77 (100%)	184 (100%)		

No significant difference was found in terms of Mode of delivery between the groups ($\chi^2=0.080$, $p=0.778$).

Table 9: Comparison of Indications of LSCS between cases and control group

Indication of LSCS	Cases (Mifepristone given) N=107	Control (Mifepristone not given) N=77	Total	Fisher's Exact Test	
				χ^2	P value
Foetal distress	10 (71.4%)	8 (88.9%)	18 (78.3%)	0.080	0.778
NPOL/FOI	4 (28.6%) (FOI)	1 (11.1%) (NPOL)	5 (21.7%)		
Total	14 (100%)	9 (100%)	23(100%)		

No significant difference was found in terms of indication of LSCS in both the groups ($\chi^2=0.982$, $p=0.611$).

Table 10: Comparison of APGAR Scores between cases and control groups

APGAR	Case Group N=107	Control Group N=77	Wilcoxon-Mann-Whitney U Test	
			W	P value
Mean	8.69	8.78	3619.5	0.402
Median	9	9		
Min-Max	5-10	6-10		

There was no significant difference between the two groups in terms of APGAR Score ($w=3619.5$, $p=0.402$).

Table 11: Comparison of NICU admission between cases and control groups

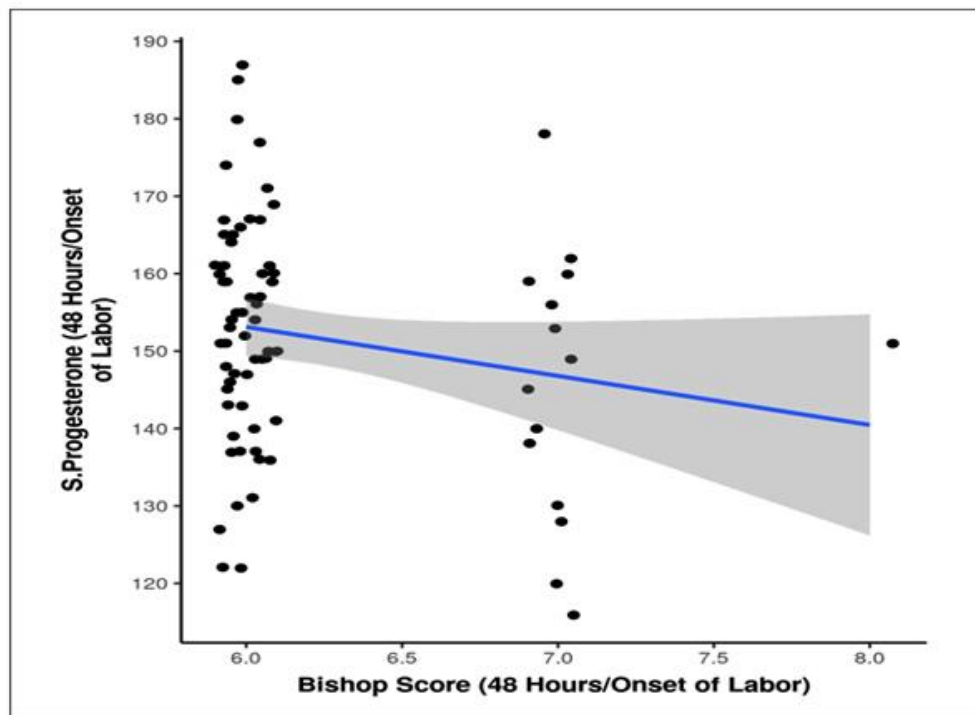
NICU admission	Case Group N=107	Control Group N=77	Total	Chi-Squared test	
				χ^2	P value

Yes	18 (16.82%)	9 (11.7%)	27 (14.67%)	0.206	0.650
No	89 (83.17%)	68 (88.3%)	157(85.32%)		
Total	107 (100%)	77 (100%)	184 (100%)		

NICU admission rate was not significant between the two groups ($\chi^2=0.206$, $p=0.650$).

Figure 2: Correlation between Modified Bishop's Score (48 Hours/Onset of Labor) and S. Progesterone level (48 Hours/Onset of Labor)

Does the serum progesterone level fall with increase in Bishop score?



The above scatterplot depicts the correlation between Bishop Score (48 Hours/Onset of Labor) and S. Progesterone (48 Hours/Onset of Labor). Individual points represent individual cases. The blue trend line represents the general trend of correlation between the two variables. The shaded grey area represents the 95% confidence interval of this trend line.

Correlation		Spearman Coefficient	Correlation	P Value
Bishop Score (48 Hours/Onset of Labor) Vs Progesterone (48 Hours/Onset of Labor)	S.	-0.17 (-0.38 to 0.04)	(95%CI:	0.133

Non-parametric tests (Spearman Correlation) were used to explore the correlation between the two variables, as at least one of the variables was not normally distributed. There was a weak negative correlation between Bishop Score (48 Hours/Onset of Labor) and S. Progesterone (48 Hours/Onset of Labor), and this correlation was not statistically significant ($\rho = -0.17$, $p = 0.133$). For every 1 unit increase in Bishop Score (48 Hours/Onset of Labor), the S. Progesterone (48 Hours/Onset of Labor) decreases by 6.33 ng/ml.

4. DISCUSSION

Mifepristone, a 19-norsteroid and potent progesterone receptor antagonist, has been under investigation for its role in cervical ripening and induction of labor for several decades. By antagonizing the effects of progesterone (known to maintain uterine quiescence), mifepristone is hypothesized to facilitate cervical softening and remodelling. Besides improvement in Bishop's score, it also sensitizes the uterus to prostaglandins and hence promotes cervical dilation and induces labour.

In this study, statistically significant improvement in Bishop score was observed in the case group (mean 2.98 vs. 6.69, $p < 0.001$). Our findings were similar to the study conducted by Thakur et al., who described the ability of mifepristone to significantly improve the bishop score before labor induction [8]. In their study, statistically significant improvement was seen in mean modified Bishop's score (1.87 at 0 hour and 6.92 at 48 hours after administration of Mifepristone) with p value < 0.05 . Similarly, in the study conducted by Pharande et al., a Significant increase in bishop score was observed in the test group, 24 hours following administration of mifepristone as compared to the placebo group ($p=0.013$) [9].

Serum Progesterone Over Time (Tables 3 and 4), at the time of admission, all groups had fairly comparable levels, but at 48 hours, the spontaneous group retained higher progesterone levels than those receiving mifepristone. This difference was significant in participants with a Bishop score < 6 , but not in those with a Bishop score > 6 , illustrating that baseline cervical status may also modulate the drug's hormonal impact.

Serum progesterone levels at 48 hours or the onset of labor were significantly lower in the mifepristone group compared to the control group (139.18 vs. 151.38 ng/mL, $p < 0.001$). The mean of the change in serum progesterone levels in the case group was -28.02. The lower serum progesterone levels observed in mifepristone recipients are physiologically consistent with the drug's mechanism of action. As a progesterone receptor antagonist, mifepristone blocks the action of endogenous progesterone, which may lead to a reduction in circulating progesterone levels through negative feedback mechanisms or alterations in progesterone metabolism.

Historically, progesterone has been recognized as essential for maintaining uterine quiescence and preventing the onset of labor [10]. Several authors, including Frydman and Fernandez, have noted that partial blockade of progesterone's uterine effects can initiate cervical softening [11]. While mifepristone primarily acts as a progesterone receptor antagonist and does not directly suppress progesterone synthesis, its action effectively reduces "functional" progesterone activity at the tissue level [12]. As a result, total circulating progesterone levels may not decline significantly in all individuals. However, our data demonstrate a measurable reduction in serum progesterone concentration following mifepristone administration, suggesting that the drug may also influence systemic hormone regulation, potentially through modulation of the hypothalamic-pituitary-adrenal (HPA) axis or by enhancing progesterone degradation pathways. An interesting outcome in our patients was that there was no statistically significant difference in the proportion of patients who "went into active labor" between the Cases (87.9%) and the control group (93.5%, $p = 0.203$).

Previous studies have reported mixed results regarding the ability of mifepristone to initiate or augment active labor. For instance, a systematic review by Stenlund et al found that mifepristone significantly increased the likelihood of spontaneous onset of active labor within 48 hours [13]. In contrast, a Cochrane review by Hapangama et al also observed a higher incidence of active labor at 48 hours among women treated with mifepristone, but concluded that the evidence was inconclusive and warranted further investigation [14].

Our study indicates that although the bishop's score and progesterone levels changed significantly in the mifepristone group, these physiological alterations did not necessarily result in a higher proportion of women reaching active labor compared to those who entered labor spontaneously.

Our results indicated that the induction-to-vaginal-delivery interval was significantly longer in the group requiring additional induction with misoprostol compared to the group that received only mifepristone, with mean durations of 56.94 hours and 46.01 hours, respectively.

A study by Li et al. showed a near 20% reduction in total induction-to-delivery time among women receiving mifepristone [15]. A prospective study by Buser et al. also supported that mifepristone, followed by oxytocin or prostaglandin, helped achieve shorter labor durations without increasing maternal or neonatal complications [16]. This showed that mifepristone modestly reduces overall labor duration.

In our study, there was an insignificant correlation between Bishop score at 48 hours and serum progesterone levels ($\rho = -0.17$, $p = 0.133$). These findings suggest that while mifepristone globally reduces progesterone levels, the direct linear linkage between the absolute progesterone concentration and labor progression parameters may be weaker than hypothesized.

The non-significant correlation in our results emphasizes that while mifepristone induces changes conducive to labor, the relationship between hormone measurements and mechanical cervical changes is likely multifactorial, influenced by local receptor density, maternal metabolism, and synergy with other labor mediators (e.g., prostaglandins, oxytocin, relaxin). In our study, there was no statistically significant difference in the mode of delivery between the Mifepristone group (86.9% vaginal delivery) and the spontaneous labour group (88.3% vaginal delivery; $p = 0.778$). The idea that mifepristone use might lower cesarean delivery rates by improving cervical ripeness has been tested in many studies. A Prospective cohort study conducted by Boipai et al. noted that when comparing mifepristone to placebo, there was a non-significant trend toward reduced cesarean deliveries [17]. In contrast, the study done by Gomathy et al, 38.4% of patients in Group I required a cesarean section, compared to only 10.2% in Group II [18]. Broader sample of our study, which included both primiparous and multiparous women, and the high overall vaginal delivery rates, might have diluted any potential difference between modes of delivery. Our data indicates that while mifepristone facilitates labor, it does not necessarily always guarantee a

reduction in cesarean births when compared to women undergoing spontaneous labor. We did not observe any significant difference in 5-minute APGAR scores or NICU admission rates between the Mifepristone and spontaneous labour groups (both $p > 0.05$). Multiple studies have confirmed the overall safety of mifepristone for fetal well-being. Baev et al. and Boipai documented no deleterious effects on APGAR scores or other neonatal indicators [17,19]. Our data are reassuring and support the existing consensus that mifepristone is generally safe for the neonate under standard induction protocols.

5. CONCLUSION

Our study supports the premise that mifepristone significantly enhances cervical ripening as evidenced by greater increases in Bishop scores, and lowers serum progesterone levels in a clinically relevant timeframe. These biochemical and clinical changes appear to translate into shortened labor intervals without increasing maternal or neonatal risk. While there were no major differences in delivery mode or neonatal outcomes, the consistent improvement in cervical conditions and labor progression suggests that mifepristone is a valuable adjunct in obstetric practice, especially for women requiring cervical ripening and induction of labor

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