International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 5, May 2026 ijppr.humanjournals.com ISSN: 2349-7203

A Comparative Study on Safety, Efficacy, Fetal and Maternal Outcomes between Oral/Vaginal Misoprostol and Inj. Oxytocin in Induction of Labour

Punitha S.[1]; Sheeba D.[1]; Dr. Madhusudhan S. [2]

1 Department of Pharmacy, Annamalai University, Chidambaram. India.
2 Professor, Department of Pharmacy, Annamalai University, Chidambaram. India.

Received: 27 March 2026 Revised: 22 April 2026 Accepted: 28 April 2026

ABSTRACT:

Background:Labour induction is a routinely practiced obstetric procedure employed when continuing pregnancy may endanger maternal or fetal health. Among the various pharmacological agents used, misoprostol and oxytocin are the most common. Their comparative performance in terms of effectiveness and safety is still being explored.Objective:This study aimed to evaluate and compare the safety, efficacy, and outcomes for both mother and fetus between oral/vaginal misoprostol and intravenous oxytocin in women with an unfavorable cervix undergoing labour induction.Methods:A prospective observational study was carried out over a six-month period at the Department of Obstetrics and Gynaecology, Government Cuddalore Medical College and Hospital. Fifty pregnant women between 38 and 42 weeks of gestation were enrolled. Participants were allocated into two groups: Group A received misoprostol, while Group B was administered oxytocin. Key metrics included changes in Bishop score, mode and duration of delivery, fetal status (Apgar score, NICU admission), and maternal complications. Statistical analysis was performed using SPSS with appropriate tests based on data distribution.Results:Post-induction Bishop scores significantly improved in the misoprostol group ($p < 0.001$), indicating better cervical readiness. Additionally, the rate of successful vaginal deliveries within 24 hours was higher with misoprostol. Fetal outcomes did not differ significantly between groups. However, maternal response to misoprostol showed notable improvement ($p = 0.032$).Conclusion:Misoprostol proved to be a more efficient and equally safe alternative to oxytocin for labour induction in women with an unfavorable cervix. It enhanced cervical ripening, facilitated quicker labour, and resulted in better maternal outcomes.

Keywords: Safety, Efficacy, Fetal and Maternal Outcomes, Oral/Vaginal Misoprostol, Inj. Oxytocin, Induction of Labour

I.INTRODUCTION:

Induction of labour (IOL) is the artificial initiation of uterine contractions after fetal viability using medical or surgical methods to achieve vaginal delivery. It is a commonly performed obstetric intervention. The success of induction depends on gestational age, cervical favourability, and a Bishop score greater than six.

Physiology and Mechanism of Labour:

Labour begins with coordinated uterine contractions leading to cervical effacement, dilation, and descent of the fetus. The mechanism of labour involves engagement, descent, flexion, internal rotation, extension, restitution, external rotation, and expulsion, allowing the fetus to negotiate the maternal pelvis effectively.

Factors Initiating Labour:

The onset of labour is influenced by multiple interacting factors. Uterine stretching enhances myometrial excitability through gap junction formation and increased oxytocin receptor expression. Activation of the fetal hypothalamic-pituitary-adrenal axis increases cortisol production, promoting estrogen synthesis and reducing progesterone influence. Estrogen enhances uterine contractility by increasing oxytocin receptors and prostaglandin production. Prostaglandins and oxytocin play a central role in cervical ripening and sustaining uterine contractions, while neural and adrenergic mechanisms provide additional support.

Assessment Before Induction:

Accurate gestational dating is essential and is most reliably determined by first-trimester ultrasound or last menstrual period calculation. Cervical status is assessed using the Bishop score, which evaluates cervical position, consistency, dilation, effacement, and fetal station. A score of eight or more indicates a favourable cervix and a higher likelihood of successful induction.

Indications for Induction of Labour:

Induction is indicated in post-term pregnancy, premature rupture of membranes, hypertensive disorders of pregnancy, oligohydramnios, intrauterine growth restriction, and selected cases of multiple pregnancy to improve maternal and perinatal outcomes.

Complications of Induction:

Potential complications include uterine hyperstimulation leading to fetal distress, uterine rupture (especially in scarred uteri), infection, perineal trauma, and postpartum hemorrhage due to uterine atony.

Neonatal Outcome Assessment:

Neonatal condition is assessed using the Apgar score at one and five minutes after birth, evaluating appearance, pulse, grimace, activity, and respiration.

II. MATERIALS AND METHODS:

STUDY SITE:

The study will be conducted in department of obstetrics and gynaecology, Government Cuddalore Medical College and Hospital (RMMCH), Annamalai University, Annamalai nagar, Chidambaram.

STUDY DESIGN:

Prospective observational study.

STUDY PEROID:

The study will be conducted for a period of 6 months (November 2024-April 2025).

STUDY TOOLS:

Predesigned proforma (Data collection form).

SOURCES OF DOCUMENT:

Patient's case sheet (Inpatients).

SAMPLE SIZE:

The sample size of 50 term pregnant women with gestational week >38 will be allocated to either group A (Misoprostol) or group B (oxytocin) using a simple randomisation 1:1 ratio. This means 25 patients will be assigned to group A(misoprostol) and 25 patients will be assigned to group B(oxytocin). This allocation ensures equal distribution of participants between 2 groups, which allows for transparent comparison of safety and efficacy between oral/ vaginal misoprostol and Inj oxytocin.

III.SUBJECT RECRUITMENT:

TARGET POPULATION:

Patients with unfavourable cervix during labour in the gestationaperiod of 38 weeks to 42 weeks and those who are receiving oxytocin and misoprostol in the department of O&G at RMMCH, Chidambaram.

STUDY POPULATION:

The patients enrolled for the study will be selected based on inclusion and exclusion criteria.

SELECTION CRITERIA:

Inclusion criteria:

- Special group (pregnant women)
- Singleton pregnancy with vertex presentation
- Gestational period of 38 to 42 weeks or >36 weeks
- Inpatients
- Patients who are willing to participate

Exclusion criteria:

- Patients with premature rupture of membrane.
- Oigohydramnios , Polyhydramnios groups
- Multiple pregnancy
- Abnormal cephalic presentation
- Previous C- section delivery
- Patients with cardiac diseases and GDM.

IV.STUDY PROCEDURE:

- A single centre prospective observational study will be conducted in the department of O&G at Govt Cuddalore Medical College and Hospital, Chidambaram.
- Pregnant women with gestational period of 38 to 42 weeks and with unfavourable cervix of bishop score<5 will be selected for the study.
- Prior to starting of the study, written informed consent form and information sheet in English and vernacular language from patients will be obtained.
- Patient's demographic details were collected after taking informed consent form.
- Term pregnant women were divided into two groups- Group A and Group B.
- Group A will receive 20-25 microgram of misoprostol every 2 hrs max of 6 doses. Group B will receive 6 mIu/min every 30 mins and their outcomes were monitored.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 5, May 2026 ijppr.humanjournals.com ISSN: 2349-7203

- Mode of delivery, bishop score, induction to delivery time will be compared between two groups to find safe and effective drug for induction of labour in term pregnant women.

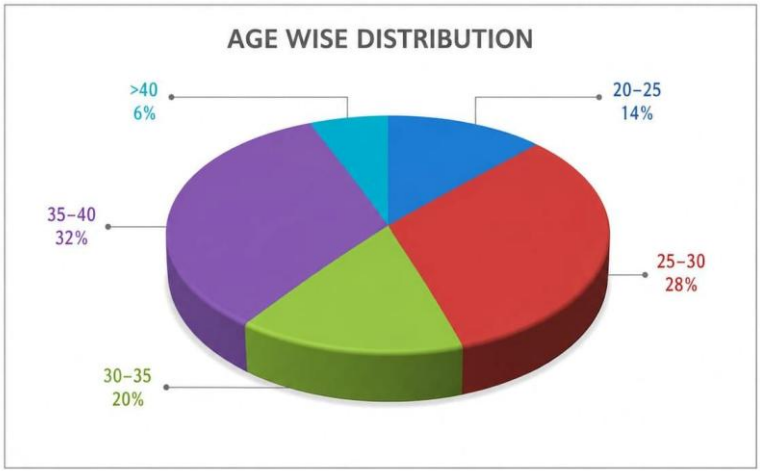
- All outcome measuring parameters were presented as Mean +- Standard deviation and were analyzed using the student t test. Statistical significance was taken.

V.OBSERVATION AND RESULTS:

AGE WISE DISTRIBUTION:

S.NO	AGE	NOOF PATIENTS	PERCENTAGE
01	20-25	5	10%
02	25-30	18	36%
03	30-35	3	6%
04	35-40	21	42%
05	>40	3	6%

AGE WISE DISTRIBUTION



This reflects a representative distribution, with the majority (78%) of patients between 25 and 40 years of age.

SUCCESS/ FAILURE OUTCOMES

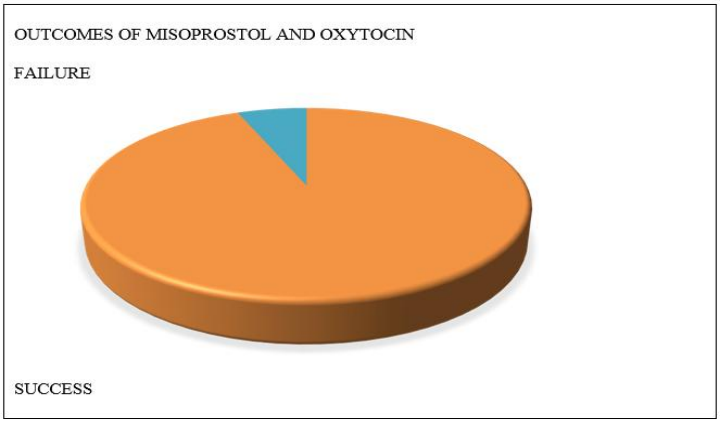
Table 1: Overall success rate induction of labor

TOTAL NO OF PATIENTS	50
PATIENTS WITH SUCCESS OUTCOME	46
PATIENTS WITH FAILURE OUTCOMES	4
PERCENTAGE OF SUCCESS	92%
PERCENTAGE OF FAILURES	8%

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 5, May 2026 ijppr.humanjournals.com ISSN: 2349-7203

SUCCESS/FAILURE OUTCOMES

Fig 1 : overall success rate of labor induction



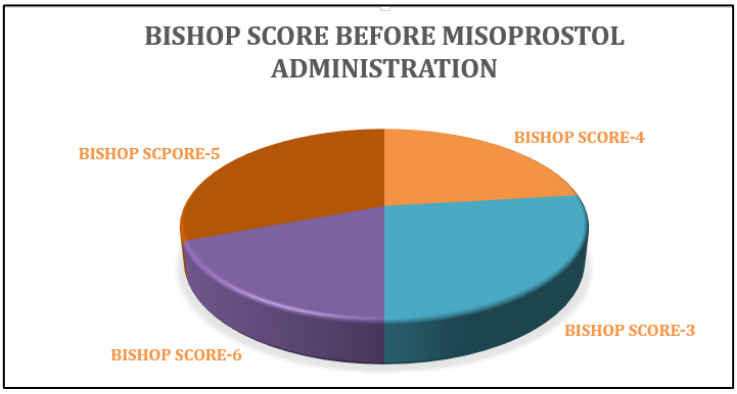
The overall success rate of induction in this study was high, at 92%.

BISHOP SCORE ANALYSIS

MISOPROSTOL- BEFORE ADMINISTRATION

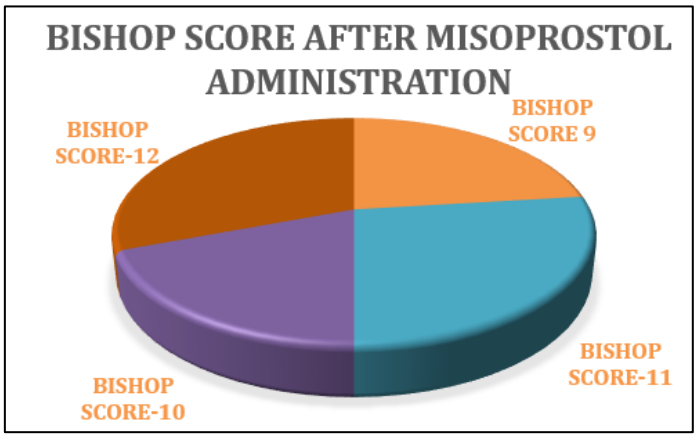
Table 2 Before misoprostol administration – Bishop score analysis

S.NO	BISHOP SCORE	NO.OF.PATIENTS	PERCENTAGE
1	4	8	32%
2	3	5	20%
3	6	4	16%
4	5	8	32%



MISOPROSTOL- AFTER ADMINISTRATION

S.NO	BISHOP SCORE	NO.OF.PATIENTS	PERCENTAGE
1	9	8	32%
2	11	5	20%
3	10	5	20%
4	12	7	28%

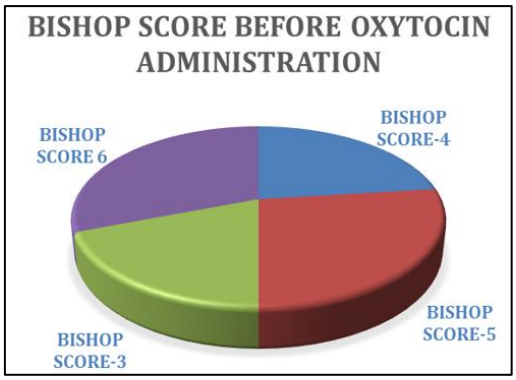


OBSERVATION:

There was a marked increase in bishop score post misoprostol with the majority of patients achieving scores of 9 or above, indicating improved cervical ripening and readiness of labor.

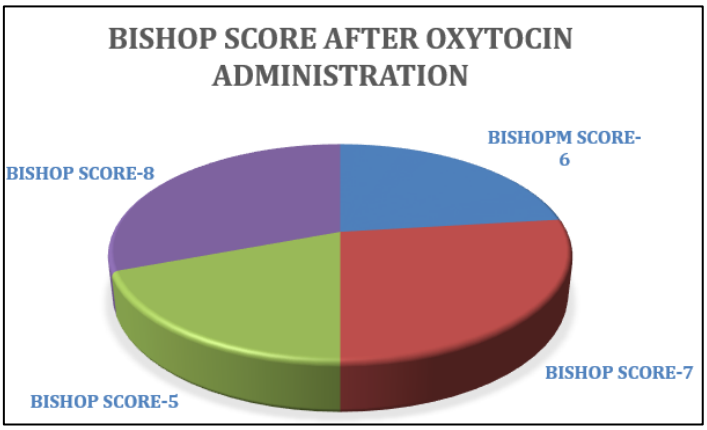
OXYTOCIN – BEFORE ADMINISTRATION

S.NO	BISHOP SCORE	NO.OF. PATIENTS	PERCENTAGE
1	4	9	36%
2	3	5	20%
3	5	4	16%
4	6	7	28%



OXYTOCIN – AFTER ADMINISTRATION

S.NO	BISHOP SCORE	NO.OF.PATIENTS	PERCENTAGE
1	6	8	32%
2	7	5	20%
3	5	6	24%
4	8	6	24%



Observation: In the oxytocin group, post-induction Bishop scores remained relatively lower, with only 24% of patients reaching a score of 8, indicating lesser cervical ripening efficacy compared to misoprostol.

BISHOP SCORE COMPARISON ON EFFECTIVENESS BETWEEN OXYTOCIN AND MISOPROSTOL:

TEST OF NORMALITY:

Test of normality- Effectiveness

	KOLMOGOROV SMIRNOV			SHAPIRO-WILK		
	statistic	Df	sig	statistic	Df	Sig
MISOPROSTOL	0.233	25	0.001	0.793	25	0.00
OXYTOCIN	0.208	25	0.007	0.809	25	0.00

NORMALITY TEST

Test statistics- Effectiveness

	DRUG ADMINISTRATION BISHOP SCORE BEFORE	BISHOP SCORE AFTER ADMINISTRATION DRUG
Mann-Whitney U	312.00	0.00
Wilcoxon W	637.00	325.00
Z	-.010	-6.221
Asymp Sig.(2-tailed)	0.992	0.000

Here p value is less than 0.05, so Mann-whitney U test have used.

Ranks

Result- effectiveness

	GROUP	N	MEAN RANK	SUM OF RANKS
Bishop score before administration	1	35	25.48	637.00
	2	25	25.52	638.00
	Total	50		
	38.00	950.00		
Bishop score after drug administration		13.00		325.00
Total		50		

• Shapiro-Wilk test results showed non-normal distributions for both Misoprostol and Oxytocin groups ($p < 0.05$), thus justifying the use of non-parametric tests.

Mann-Whitney U Test

• Before drug administration:

oU = 312.0, Z = -0.010, p = 0.992 → No significant difference in baseline scores.

• After drug administration:

oU = 0.000, Z = -6.221, $p < 0.001$ → Statistically significant difference between groups.

OBSERVATION: (Effectiveness)

While both groups started with similar Bishop scores, post-administration scores were significantly higher in the misoprostol group, indicating superior efficacy in cervical ripening. Thus, from the observations, Misoprostol is found to be more effective than oxytocin.

RESULT:

The findings clearly demonstrate that misoprostol is significantly more effective than oxytocin in inducing labor, as evidenced by higher post-induction Bishop scores and statistically significant outcomes in the Mann-Whitney U test.

Misoprostol not only resulted in better cervical ripening but also maintained favorable fetal outcomes, making it a superior choice for induction of labor in the studied population.

FETAL OUTCOMES:

Tests of Normality						
	Kolmogorov-Smirnova			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	Df	Sig.
Apgar Score at 1 min	.269	50	.000	.855	50	.000
Apgar Score at 5 min	.240	50	.000	.871	50	.000
Tachycardia (Fetal)	.535	50	.000	.303	50	.000
RDS	.539	50	.000	.255	50	.000
NICU Admission	.535	50	.000	.303	50	.000
Birth Weight (kg)	.056	50	.200*	.982	50	.657
Patient ID	.065	50	.200*	.956	50	.058

Chi square test- Fetal outcome – misoprostol

Chi-Square Tests					
	Value	Df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.000a	1	.157		
Continuity Correctionb	.000	1	1.000		
Likelihood Ratio	2.773	1	.096		
Fisher's Exact Test				1.000	.500

Although oxytocin showed a higher incidence of adverse outcomes compared to misoprostol, the differences were not statistically significant in this sample ($p > 0.05$).

The Pearson Chi-Square test yielded a value of 2.000 with a p-value of 0.157, indicating no statistically significant association between the type of drug used and the occurrence of adverse outcomes.

Chi square test - Fetal outcome - oxytocin

Chi-Square Tests					
	Value	Df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.000a	1	.157		
Continuity Correctionb	.000	1	1.000		
Likelihood Ratio	2.773	1	.096		
Fisher's Exact Test				1.000	.500

MATERNAL OUTCOMES:

T-Test: Chi-Square Tests					
	Value	Df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.000a	1	.157		
Continuity Correctionb	.000	1	1.000		
Likelihood Ratio	2.773	1	.096		
Fisher's Exact T				1.000	.500

PAIRED SAMPLE STATISTICS:

		Mean	N	Std deviation	Std error Mean
Pair 1	MPR Before	81.50	50	5.392	0.763
	MPR After	85.04	50	10.687	1.511
Pair 2	FPR Before	90.76	50	4.914	0.695
	FPR After	91.58	50	7.486	1.059

PAIRED SAMPLE CORRELATION:

	N		Correlation	Sig
Pair 1	MPR Before and after	50	0.125	0.388
Pair 2	FPR Before and after	50	-0.007	0.963

PAIRED DIFFERENCES:

	Mean		Std deviation	Std Error Mean	Lower (95%CI)	Upper (95%CI)	1	df	Sig-2tailed
Pair 1	MPR Before and after	-3.54	11.35	1.606	-6.76	-0.313	-2.20	49	0.032
Pair 2	FPR Before and After	-0.02	0.902	1.270	-3.73	1.733	-0.64	49	0.522

Based on the t-test results provided and assuming the following:

- MPR = Maternal Pulse Rate
- FPR = Fetal Pulse Rate
- The intervention or treatment compared is Oxytocin vs Misoprostol, and the

pulse rates are measured before and after administration

Maternal Pulse Rate (MPR)

- MPR increased significantly after treatment (mean rose from 81.50 to 85.04).
- The mean difference was -3.54 (i.e., MPR After > MPR Before).
- p-value = 0.032, indicating a statistically significant change.

Interpretation:

The maternal pulse rate significantly increased after administration of the uterotonic agent (either oxytocin or misoprostol). This suggests that one or both drugs have a measurable cardiovascular effect on the mother. Given that this is an overall analysis, the increase may be more prominent in the oxytocin group, which is known to have vasopressor effects.

Fetal Pulse Rate (FPR)

- FPR slightly increased from 90.76 to 91.58.
- The mean difference was -0.82, and the p-value = 0.522, which is not.

statistically significant.

•A chi-square test was conducted to compare maternal outcomes between the oxytocin and misoprostol groups. The Pearson chi-square value was 2.000 with a p-value of 0.157, indicating no statistically significant association.

Interpretation:

There was no significant change in fetal pulse rate following administration of oxytocin or misoprostol. This implies that neither drug had a measurable impact on fetal heart rate, at least in the short term or within the limits of this sample.

Comparing maternal outcome between oxytocin and misoprostol

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	2.000a	1	.157	
Continuity Correctionb	.000	1	1.000	
Likelihood Ratio	2.773	1	.096	
Fisher's Exact Test				1.000

There was no statistically significant difference in maternal outcomes between the oxytocin and misoprostol groups. The Pearson Chi-Square test yielded a value of 2.000 with a p-value of 0.157, suggesting that the variation observed may have occurred by chance.

VI.DISCUSSION AND CONCLUSION

This study compared vaginal misoprostol and intravenous oxytocin for induction of labor in women with common obstetric indications such as post-dated pregnancy, pregnancy-induced hypertension, PROM, and gestational diabetes. Most participants were aged 20–30 years, with comparable age and parity distribution between groups, ensuring reliable comparison. Misoprostol showed superior efficacy by producing greater improvement in Bishop score, shorter induction-to-delivery interval, and a higher rate of vaginal delivery within 24 hours, particularly in women with an initially unfavourable cervix. Both drugs were found to be safe, with minimal maternal or fetal complications and comparable neonatal outcomes, including good Apgar scores and low NICU admissions. Misoprostol offered additional practical advantages such as low cost, ease of administration, and suitability for low-resource settings. Although the study was limited by its single-center design, small sample size, and lack of blinding, the findings support misoprostol as an effective, safe, and practical alternative to oxytocin for labor induction. Larger multicenter studies are recommended to further validate these results and explore optimal dosing strategies.

VII.CONCLUSION

In conclusion, this study found that vaginal misoprostol is more effective than intravenous oxytocin for labor induction in women with an unfavourable cervix. Misoprostol led to faster labor progression, better cervical ripening, and higher chances of vaginal delivery within 24 hours. Both drugs were safe for mothers and babies when used appropriately, but misoprostol offered practical advantages in terms of cost, administration, and effectiveness.

Given these findings, MISOPROSTOL CAN BE CONSIDERED A RELIABLE AND EFFICIENT ALTERNATIVETO OXYTOCIN, especially in settings where IV administration is not feasible. Careful patient selection, adherence to recommended doses, and vigilant monitoring remain essential for ensuring the safety and success of labor induction with either drug.

VIII.BIBILIOGRAPHY:

1. ACOG (American College of Obstetricians and Gynecologists). (2021). Induction of Labor. Practice Bulletin No. 222.
2. American Journal of Obstetrics & Gynecology. 2018). Induction of labor using one dose vs multiple doses of misoprostol: a randomized controlled trial. American Journal of Obstetrics & Gynecology, 219(3), 275.e1–275.e9.
3. Barrett, J. F. R., et al. (2013). A randomized trial of planned cesarean or vaginal delivery for twin pregnancy. New England Journal of Medicine, 369(14), 1295–1305.
4. Bishop, E. H. (1964). Pelvic scoring for elective induction. Obstetrics & Gynecology, 24, 266–268.
5. Brosens, I., & Pijnenborg, R. (2011). Changes in the uterus and cervix during labor. In The Human Placenta: Development and Function.
6. Carroli, G., & Mignini, L. (2009). Episiotomy for vaginal birth. Cochrane Database of Systematic Reviews, (1), CD000081.
7. Caughey, A. B., Sundaram, V., Kaimal, A. J., et al. (2009). Maternal and Neonatal Outcomes of Elective Induction of Labor. AHRQ https://www.ncbi.nlm.nih.gov/books/NBK51960/
8. Cheung, C. W., Miu, W. M., & Pun, T. C. (2006). Oral misoprostol for induction of labor in prelabor rupture of membranes (PROM) at term: a randomized control trial. Acta Obstetricia et Gynecologica Scandinavica, 85(9), 1050–1055.
9. Cunningham, F. G., Leveno, K. J., Bloom, S. L., et al. (2022). Williams Obstetrics (26th ed.). McGraw-Hill.
10. Dutta, D. C., & Konar, H. (2021). Textbook of Obstetrics (9th ed.). Jaypee Brothers Medical Publishers.
11. Fareed, A., Faisal, J., Kanwal, S., Fatima, A., & Afridi, N. (2020). Comparison of Misoprostol and Oxytocin for Induction of Labor in Post-term pregnancy. Pakistan Journal of Medical and Health Sciences, 14(3), 1479–1481.
12. Fraser, D. M., & Cooper, M. A. (2014). Myles Textbook for Midwives (16th ed.). Elsevier Health Sciences.
13. Groom, K. M., et al. (2006). Oligohydramnios in uncomplicated term pregnancies: Outcomes after labor induction. BJOG, 113(6), 704–709.

14. Jackson, K. M., & Ecker, J. L. (2016). Cervical assessment and Bishop score in predicting induction success. Obstetrics & Gynecology Clinics of North America, 43(3), 429–437. https:// doi.org/ 10.1016/j.ogc.2016.04.006
15. Johnson, T. R. B., & Blackwell, S. C. (2020). Operative Obstetrics (4th ed.). McGraw Hill.
16. Kashanian, M., Eshraghi, N., Rahimi, M., Sheikhansari, N., & Javanmanesh, F. (2020). Efficacy comparison of titrated oral solution of misoprostol and intravenous oxytocin on labour induction in women with full-term pregnancy. Journal of Obstetrics and Gynaecology, 40(1), 20–24.

How to cite this article:
Punitha S et al. Ijppr.Human, 2026; Vol. 32 (5):327-338.

Conflict of Interest Statement: All authors have nothing else to disclose.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.