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Oral Misoprostol vs Intravaginal Dinoprostone for Pre-Induction Cervical Ripening in Post-Term, Uncomplicated Pregnancies: A Randomized Controlled Trial

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Abstract

Objectives To compare the effectiveness and safety of oral misoprostol 50 μg three doses, 4 hours apart vs. intravaginal PGE2 (Dinoprostone) 3 mg two doses 8 hours apart for pre-induction cervical ripening in women with uncomplicated, singleton, postdated pregnancies. **Methodology** This randomized controlled trial was conducted on women with uncomplicated, postdated, singleton pregnancies with cephalic presentation, intact membranes and a modified bishops score (MBS) of ≤5 without any contraindications for vaginal delivery. Maternal and fetal outcomes and progression of labour were monitored as the outcome variables. Ethical clearance was obtained. **Results** The number of patients participated in the study was 208, 1:1 allocation is used. Of the mothers, 40.4% of those who took misoprostol (MP) and 51.9% of those who received Dinoprostone (PGE2) went into spontaneous labour (SOL, $p = 0.09$). The mean intervention to delivery time in SOL was longer for the group that got MP ($p = 0.022$). Around 30% of each group were not favourable for IOL after 24 hours of intervention, with favourable cervix (MBS ≥ 7) reported in 68.4% of mothers taking MP and in 70.74% of mothers taking PGE2. The group using MP had the lowest percentage of mothers who underwent emergency LSCS (6.7%) and the lowest percentage of mothers who underwent LSCS due to an abnormal CTG (1.9%) compared to the group using PGE2, both of which were statistically significant ($p = 0.047$, $p = 0.002$ respectively). The MP group had the fewest hyperstimulation among the maternal morbidities ($n = 5$ (4.8%), $p = 0.049$), however neither serious PPH nor uterine ruptures nor a significant difference in newborn morbidities was noted between the two groups. Multivariate analysis demonstrates that MP administration considerably increases SOL and has a risk of having an abnormal CTG.

Conclusion Administration of oral MP has a higher chance of SOL, with a longer delivery time and lower likelihood of emergency LSCS, but with a risk of having a suspicious or pathological CTG.

Keywords

Prostaglandin, Dinoprostone, Misoprostol, SOL, IOL, Emergency LSCS

1. Introduction

Induction of labor (IOL) refers to the medical process of artificially initiating labor by stimulating the uterus, leading to changes such as cervical ripening (softening, shortening, and dilation) and the onset of uterine contractions. IOL is a standard intervention in obstetrics used to manage post-term pregnancies, fetal growth restrictions, fetal macrosomia, and maternal health conditions (e.g., pregnancy-induced hypertension, gestational diabetes). Additionally, IOL is applied in cases of prelabour rupture of membranes and other conditions where continuing pregnancy may pose risks.

Globally, pre-induction cervical ripening techniques are categorized into mechanical and pharmacological methods. Mechanical methods include procedures like membrane sweeping and intracervical Foley catheter insertion, which stimulate cervical ripening by direct manipulation. Pharmacological methods rely on synthetic prostaglandins, which mimic natural substances in the body to aid cervical softening and dilation. Among pharmacological agents, misoprostol (a synthetic prostaglandin E1 analogue) and prostaglandin E2 (PGE2, also known as dinoprostone) are commonly used. These agents differ in administration routes and mechanisms but aim to prepare the cervix for labor induction effectively.

2. Methods

2.1. Oral Misoprostol

Misoprostol, initially developed for gastric ulcer prevention, is a synthetic prostaglandin E1 analogue that has become widely used for cervical ripening and IOL. The drug is particularly advantageous in low-resource settings due to its low cost, stability at room temperature, and broad availability. Misoprostol can be administered through various routes, including oral, vaginal, sublingual, and buccal. When administered orally, misoprostol's systemic absorption helps stimulate uterine contractions while posing a lower risk of uterine hyper-stimulation compared to intravaginal administration. Clinical guidelines, including those by the Ministry of Health in Sri Lanka, recommend oral misoprostol in 25 μg to 50 μg doses at intervals for effective pre-induction cervical ripening.

2.2. Effectiveness

Oral misoprostol is effective in softening the cervix and inducing labor, especially

in low-resource settings. Its oral route offers a non-invasive approach, reducing discomfort and providing flexibility in dose adjustments. Although effective, misoprostol use can lead to side effects such as mild gastrointestinal disturbances, uterine tach systole and, less commonly, fetal asphyxia when used in higher doses.

2.3. Intravaginal Prostaglandin E2 (Dinoprostone)

Dinoprostone is a prostaglandin E2 analogue in the oxytocic family, primarily used in vaginal gel or insert form for pre-induction cervical ripening. By binding to PGE2 receptors, it promotes cervical softening and dilation. However, dinoprostone administration can sometimes result in uterine hyper stimulation, which may lead to fetal distress or, in severe cases, uterine rupture. Additionally, dinoprostone requires refrigeration, making it less accessible in low-resource areas, and it is generally more costly than misoprostol.

2.4. Effectiveness

PGE2 is highly effective for cervical ripening and is widely used as a first-line agent in many settings. It is particularly effective for achieving cervical changes necessary for successful IOL. Common side effects include uterine hyper stimulation, increased risk of fetal distress, and, rarely, uterine rupture. The cost and storage requirements of dinoprostone can also limit its use.

This study aims to evaluate the effectiveness and safety of three 50 μg doses of oral misoprostol (administered every four hours) in comparison with two 3 mg doses of intravaginal PGE2 (administered eight hours apart) for pre-induction cervical ripening in women with uncomplicated, singleton, post-dated pregnancies. This research seeks to determine which method provides a safer, more efficient, and cost-effective solution, with the potential for broader applicability in resource-limited healthcare settings.

3. Literature Review

The induction of labor (IOL) has become increasingly common in recent years, particularly in developed countries, where it accounts for approximately 25% of term deliveries. In contrast, IOL rates in developing countries remain lower [1]. For uncomplicated pregnancies, IOL is recommended at 41 weeks gestation when the risks of continuing the pregnancy outweigh the potential benefits of induction [2]. However, if the cervix is not sufficiently ripened, successful induction is less likely with interventions such as artificial rupture of membranes or oxytocin alone. Cervical ripening techniques are, therefore often required to soften, dilate, and prepare the cervix for labor induction. According to a WHO global survey, IOL rates are lowest in African countries compared to Asia and Latin America, with Sri Lanka's IOL rate estimated at around 35.5% [3].

Various IOL methods are in use, with prostaglandins being preferred for cervical ripening and labor induction in many countries. Studies indicate that oral misoprostol may be more effective than vaginal dinoprostone (PGE2) for achieving

vaginal delivery within 24 hours and is associated with lower cesarean rates when administered in titrated low doses. However, misoprostol administered vaginally in doses of 50 μg or higher has been linked to an increased risk of uterine hyper stimulation [4] [5].

Considering the efficacy of the oral and vaginal prostaglandins, a randomized controlled trial done in Finland shows there was no significant difference in caesarian section rates in the oral and vaginal prostaglandin treatment (33.8%, 29.6%, OR 1.21, 95% CI, 0.66 - 1.91, $p = 0.67$) [6]. Another study done in India which was conducted as a comparative study, shows that oral misoprostol got a higher number of inductions which leads to normal delivery compared to vaginal dinoprostone ($p < 0.001$) [7].

Considering the safety of the induction modalities, PGE2 can increase the likelihood of vaginal delivery within 24 hours without raising the cesarean rate, though it is associated with higher risks of uterine hyper stimulation and fetal heart rate abnormalities [8].

It was evident that oral misoprostol with vaginal dinoprostone in nulliparous term pregnancies have shown that oral misoprostol can reduce the time to vaginal delivery without increasing cesarean rates or adverse maternal/fetal outcomes. A multicenter RCT comparing titrated oral misoprostol with vaginal dinoprostone found oral misoprostol to be as effective for cervical ripening and labor induction, with significantly lower risks of uterine hyper stimulation and non-reassuring fetal heart rate changes [9].

Misoprostol, a synthetic prostaglandin E1 analogue, works by stimulating uterine contractions and facilitating cervical ripening. It is administered orally or vaginally; oral absorption is rapid, reaching peak plasma levels within 30 minutes and declining by 120 minutes, while vaginal administration results in a slower absorption profile with peak levels around 70 - 80 minutes. Several studies have shown that oral regimens may be safer than vaginal administration in cases with high infection risk, with reduced rates of postpartum hemorrhage but increased meconium-stained amniotic fluid compared to vaginal misoprostol [8] [10] [11]. A clinical trial done in Germany with oral misoprostol at doses of 50 μg and 100 μg administered every 4 hours found no significant differences in cesarean delivery rates due to fetal distress or neonatal outcomes, though higher doses were associated with a lower rate of failed inductions ($p > 0.05$) [12].

Another study done in USA to assess the effectiveness between oral and per-vaginal prostaglandin concerning induction of labor shows there was no any significant deference in effectiveness concerning intrapartum duration tachysystole and neonatal complications [13].

4. Justification

Conducting a study to compare the effectiveness and safety of oral misoprostol versus intravaginal dinoprostone for pre-induction cervical ripening in post-term pregnancies in Sri Lanka is crucial for optimizing maternal healthcare. In resource-

limited settings, cost-effectiveness plays a significant role in determining the most appropriate treatment options. Misoprostol, being less expensive and easier to administer orally, could provide a viable alternative to dinoprostone, which is typically more costly and requires vaginal administration. By evaluating both drugs for their ability to achieve similar clinical outcomes—such as successful cervical ripening and reduced induction time—this study can provide valuable evidence on whether oral misoprostol offers comparable benefits to intravaginal dinoprostone while being more affordable. Ensuring the safety and effectiveness of either method will allow healthcare providers to make informed decisions, potentially lowering treatment costs without compromising patient outcomes, and improving the accessibility of care for women in post-term pregnancies across Sri Lanka.

5. Objectives

General Objective

To compare the effectiveness and safety of oral misoprostol 50 μg three doses, 4 hours apart vs. intravaginal PGE2 (Dinoprostone) 3 mg, two doses 8 hours apart for pre-induction cervical ripening in women with uncomplicated, singleton, post-dated pregnancies.5.2. Specific objectives

1) To evaluate the effectiveness of interventions at 40 weeks + 5 days in promoting spontaneous onset of labor (SOL) or achieving favorability for induction of labor (IOL) with a Modified Bishop's Score (MBS) ≥ 7 by 40 weeks + 6 days.

2) To compare maternal, fetal and neonatal outcomes following interventions including the need for emergency cesarean delivery, maternal morbidity indicators such as uterine hyper-stimulation, postpartum blood transfusion, and uterine rupture; and cardio-tomography (CTG) abnormalities, meconium-stained liquor, low APGAR scores, and NICU or PBU admissions.

6. Methodology

6.1. Design

Randomized controlled trial.

6.2. Setting

University Obstetric Unit (ward-3), Teaching Hospital Mahamodara and Teaching Hospital Anuradhapura (next training center), Sri Lanka.

6.3. Method

6.3.1. Inclusion Criteria

Nulliparous, post-dated pregnant women at 40 weeks and 5 days of gestation, who are having singleton pregnancy with cephalic presentation and modified bishops score (MBS) of ≤5, with intact membranes and not having any contraindications for vaginal delivery.

6.3.2. Exclusion Criteria

Past Caesarian delivery, history of myomectomy, hypersensitivity to misoprostol, pregnancy induced hypertension, gestational diabetes mellitus and multiple pregnancies.

6.4. Recruitment, Randomization and Intervention

According to the unit protocol uncomplicated pregnant women were admitted at 40 weeks + 3 days of gestation. Purpose of the study, procedure and outcome of the study were explained to all women at 40 weeks + 3 days of gestation and informed consent was taken from women willing to participate in the study at 40 weeks + 4 days of gestation. Modified Bishops Score (MBS) of consented women was assessed at 40 weeks + 5 days of gestation every day at 7.00 am by the primary investigator until the sample size is achieved. Pregnant women who have withdrawn their consent, pregnant women with rupture of membrane after giving consent, or those having MBS > 5, were excluded before randomization. Pregnant women who included in the study were randomized into interventional (misoprostol) group and control (PGE2) group by block randomization technique using computer generated random numbers. This was done by the co-registrar in the obstetric unit. Sequentially numbered and sealed opaque envelopes containing the appropriate treatment regimen were prepared by the supervisor. Then, the intervention was done at 7.30 am in the ward. Before the intervention, a 10-minute CTG was carried out on all selected patients. Only the mothers with normal CTG were included in the study. In the control group, a 3 mg tablet of PGE2 was inserted into the posterior fornix of the vagina by the house officer or senior house officer. Abdominal palpation and intermittent auscultation of fetal heartbeat were done half an hourly. A 10-minute CTG was taken 8 hours following PGE2 insertion. If hyperstimulation and/or fetal distress were detected, appropriate measures were carried out according to the unit guidelines and a second tablet was not inserted. MBS was assessed at 8 hours and 24 hours.

In the interventional group, oral misoprostol 50 microgram three doses given four hours apart at 7.30 am, 11.30 am and 3.30 pm by staff nurses. To achieve precise oral misoprostol dosage, one misoprostol tablet (200 μg) was dissolved into 200 ml water, then one misoprostol tablet (200 μg) was made into 1 μg/ml concentration oral misoprostol solution and preserved at room temperature for 24 h. In between each dose, abdominal palpation and intermittent auscultation were done for half an hour. A 10-minute CTG was taken before each subsequent dose of misoprostol. If hyperstimulation and/or fetal distress were detected, appropriate measures were carried out according to the unit guidelines and no further doses were given. MBS was assessed at 8 hours and 24 hours. In between at any point, the women were assessed with adequate contractions and pain or with any complain by a colleague (co-registrar) or a senior house officer in the ward. At the completion of 24 hours, the primary investigator did an assessment at 7.30 am. Women who were unfavorable after 24 hours, with MBS ≤ 7 was inserted

intracervical foley catheter to achieve cervical favorability for IOL and these women were managed according to the unit guideline.

6.5. Sample Size and Sampling Techniques

A previous study carried out to evaluate the effectiveness and safety of titrated oral misoprostol in comparison with vaginal dinoprostone for cervical ripening has revealed that the mean time of first treatment to vaginal delivery in the oral misoprostol group was 21.3 ± 14.5 h and in vaginal dinoprostone group 15.7 ± 9.6 h (22). Using the meantime of the previous study and having a power of 90% and a confidence interval of 95%, the sample size was calculated as follows.

$$n = (u + v)^2 (S1^2 + S2^2)/(X1 - X2)^2$$

$$(1.28 + 1.96)^2 (14.5^2 + 9.6^2)/(21.3 - 15.7)^2$$

$$10.49 (210.25 + 92.16)/31.36$$

$$n = 104.4$$

$$\text{Approx.} = 104$$

Allowing provision for a dropout rate of 20% after randomization due to subjects who had consented for the trial and subsequently withdrawing consent or due to prelabour rupture of membranes, uterine hyperstimulation, fetal distress or suspected vaginal infections. Accordingly, the sample size for each group (including dropouts) was 125 women. Therefore, the total sample size was 250 women.

6.6. Data Collection and Analysis

Data were recorded on a special data collection form and saved onto an ongoing electronic database. Fisher's exact test, logistic regression and Chi-square test were used to analysis the data.

6.7. Ethical Consideration

Primary investigator explained the aims of the study, procedure, outcome of the study and the possibility of been randomly selected to each group to all the selected women. Informed written consent was obtained from all the women recruited for the study after giving a detailed information sheet to read. Ethical approval was obtained from the Ethical Review Committee, Faculty of Medicine, University of Ruhuna, and the trial was registered in the Sri Lanka Clinical Trials Registry. Approval was obtained from the director of Teaching Hospital Mahamodara and Teaching Hospital Anuradhapura. Low dose oral misoprostol, although not used in Sri Lanka, is recommended by WHO and the FIGO and practiced internationally in several countries, for induction of labor, and it has been shown to be effective and safe. Vaginal prostaglandin E2 is currently used in our unit as well as the other obstetric units in Sri Lanka as an agent for pre-induction cervical ripening and its safety has been proven by the research. If any sign of hyperstimulation occurred the usual management of hyperstimulation was carried out and

no further doses of misoprostol were given. Any gastrointestinal side effects due to misoprostol were treated.

Participation in this study was entirely voluntary. Women were free not to participate at all or to withdraw from the study at any time despite of consenting to take part earlier. If a woman decided not to participate or withdraw from the study, she could do so at any time, with no effect on her further medical care.

Participants were advised to inform House Officer, Senior House Officer, Registrar or any other medical person if they develop nausea, vomiting, abdominal discomfort, abdominal pain, reduced fetal movements or any other discomfort that they are worried about.

Confidentiality of all records was maintained, and no information by which a participant could be identified was presented or published. Participants were advised to notify the nursing staff at any time if they wished to withdraw from the study. All questions and concerns of the participants were addressed.

Drugs were supplied for the women by the hospital and there was no any funding support.

7. Results

Total sample size is 208 patients were recruited into the study. Out of 208, 104 were randomly assigned to the Misoprostol group and the other half was assigned to receive prostaglandin. The following section describes the obstetrics and neonatal details comparing the groups.

After the administration of Misoprostol, 42 women (40.4%) had SOL whereas 54 individuals (51.9%) had SOL after Dinoprostone. Favorable cervix was noted in 39 mothers (68.4%) who were given Misoprostol. Out of 104 who received Dinoprostone, 29 (70.7%) had a bishop score ≥ 7. However, no statistical significance was noted between the 2 groups ($p > 0.05$) (Table 1).

Table 1. Cross-tabulation of obstetric factors according to the drug group.

Factors	Methods		p-Value	OR (CI 95%)
	Misoprostol (N = 104)	Prostaglandin (N = 104)		
Spontaneous onset of labor (SOL)				
Yes	42 (40.4)	54 (51.9)	0.09	0.62 (0.36 - 1.08)
No	62 (59.6)	50 (48.1)		
Bishop score				
≥7	39 (68.4)	29 (70.7)	0.80	0.89 (0.37 - 2.15)
<7	18 (31.6)	12 (29.3)		
Intervention to delivery time in SOL (Hours)	16.79 ±4.100	14.70 ± 4.618	**0.022**	-

Mothers who had ripening with misoprostol had SOL 16.79 ± 4.10 hours on average. In contrast, women with prostaglandin had early SOL which is 14.70 ±

4.61 hours. There is a significantly low time for SOL in women who have had prostaglandin (p = 0.02). (Table 2)

Table 2. Association between maternal morbidity and method.

Factors	Methods		p Value	OR (CI 95%)
	Misoprostol (N = 104)	Prostaglandin (N = 104)		
Em-LSCS				
Yes	7 (6.7)	16 (15.4)	**0.047**	0.40 (0.16 - 1.01)
No	97 (93.3)	88 (84.6)		
LSCS due to pathological CTG				
Yes	2 (1.9)	15 (14.4)	**0.002***	0.12 (0.03 - 0.52)
No	102 (98.1)	89 (85.6)		
Maternal Morbidity				
Hyperstimulation				
Yes	5 (4.8)	13 (12.5)	**0.049**	0.354 (0.121 - 1.031)
No	99 (95.2)	91 (87.5)		
Blood transfusion due to PPH				
Yes	0 (0.0)	0 (0.0)	-	-
No	104 (100.0)	104 (100.0)		
Uterine rupture				
Yes	0 (0.0)	0 (0.0)	-	-
No	104 (100.0)	104 (100.0)		

*Fishers exact test. LSCS - Lower Segment Cesarean Section; CTG – Cardiotocography; PPH - Postpartum Hemorrhage.

As shown in the above table, only 7 women (6.7%) who had misoprostol had to undergo emergency LSCS. Compared to that, among the 104 women who received prostaglandin, 16 women (15.4%) had to undergo emergency LSCS. However, there is a statistically significant difference though the odds radio is insignificant (p = 0.047). Significantly higher number of pathological CTGs followed by LSCS noted in 15 (14.4%) women who received prostaglandin (p = 0.002).

Also, higher frequency of uterine hyperstimulation is observed in the same group in 13 (12.5%) of women (p = 0.049).

During the study period, no major PPH or uterine ruptures were noted in both groups. (Table 3)

As it is stated in the above table, pathological CTG was noted in a significantly high number among the mothers who received prostaglandin (n = 15, 14.4%) (p = 0.002). There is hardly any difference in neonatal morbidity in 2 groups (*i.e.*, liquor color, APGAR score at 1 min, and PBU/NICU admissions)

Table 3. Association between Fetal & Neonatal outcome and morbidity and method.

Factors	Methods		p Value	OR (CI 95%)
	Misoprostol (N = 104)	Prostaglandin (N = 104)		
Suspicious or pathological CTG				
Yes	2 (1.9)	15 (14.4)	**0.002***	0.116 (0.026 - 0.523)
No	102 (98.1)	89 (85.6)		
Meconium-stained liquor				
Yes	14 (13.5)	14 (13.5)	1.000	1.000 (0.451 - 2.217)
No	90 (86.5)	90 (86.5)		
Apgar < 5 at 1 min				
Yes	4 (3.8)	3 (2.9)	1.000*	1.347 (0.294 - 6.171)
No	100 (96.2)	101 (97.1)		
Admission to PBU or NICU				
Yes	4 (3.8)	4 (3.8)	1.000*	1.000 (0.243 - 4.110)

*Fishers exact test.

Modeling the factors affects outcome

The outcome was considered in 3 different domains.

1) Successful spontaneous onset of labor

2) Emergency section due to pathological CTG

3) Presence of any fetal morbidities

In order to find out the significant factors that govern the above outcomes, logistic regression models were used. The following section discusses the results of the multivariate analysis under each domain. (Table 4)

Table 4. Logistic regression for Spontaneous onset of labor (SOL).

Variable	B	Significant	Exp (B)	Lower	95% CI Upper
Drug group	0.613	0.036	1.845	1.041	3.272
Uterine	−2.002	0.011	0.135	0.029	0.634
hyperstimulation Meconium stained	−0.721	0.142	0.486	0.186	1.272
Constant	5.078	0.002			

The logistic regression suggests that SOL is higher with administering misoprostol (AOR = 1.84, p = 0.036), low chance of uterine hyperstimulation (AOR = 0.135, p = 0.01) and low risk of meconium-stained liquor (AOR = 0.48, p = 0.14) (Table 4). Hence the model equation can be written as,

Logit p(x) = 5.078 + 0.613 (Drug group) − 2.002 (Hyperstimulation) − 0.721 (Meconium)

In order to check the model significance, the Hosmer - Lemeshow test was used. Hypothesis

Ho: The model is adequately fitted.

H1: The model is not adequately fitted.

Test statistics		
Chi-square	**df**	**Sig.**
0.274	2	0.872

If p-value (0.872) is greater than the alpha value (0.05), then we do not have enough evidence to reject H0. If H0 hypothesis can be accepted, then the model is adequately fitted.

As a general conclusion the above-mentioned variables (*i.e.*, administering misoprostol over dinoprostone, low chance of uterine hyperstimulation and low risk of meconium liqour) suggest having a SOL.

Considering having a suspicious or pathological CTG, administration of misoprostol over dinoprostone has higher risk (AOR = 8.27, p = 0.017) of development of abnormal CTG. Uterine hyperstimulation also has a high risk in developing an abnormal CTG (AOR = 49.45, p < 0.001). Even Though the age is included, the predictor is not significant (p = 0.849) (Table 5).

Table 5. Logistic regression for Suspicious or pathological CTG.

Variable	B	Significant	Exp (B)	Lower	95% CI Upper
Drug group	2.113	0.017	8.270	1.459	46.878
Hyperstimulation	3.901	<0.001	49.453	11.999	203.816
Age	−0.014	0.849	0.986	0.855	1.138
Constant	−4.637	0.023			

The following is the model equation.

Logit p(x) = −4.637 + 2.113 (Drug group) + 3.901 (Hyperstimulation) − 0.014 (Age) Hosmer – Lemeshow test can be used to assess the goodness-to-fit test Hypothesis

Ho: The model is adequately fitted.

H1: The model is not adequately fitted.

Test statistics		
Chi-square	**df**	**Sig.**
5.594	7	0.588
Decision rule:		

If p-value (0.588) is greater than the alpha value (0.05). Then we do not have enough evidence to reject Ho. If the H0 hypothesis can be accepted, then the model is adequately fitted.

8. Discussion

The induction of labor is frequently performed to address various maternal and

fetal concerns, aiming to reduce perinatal morbidity and mortality, especially in cases of postdated pregnancies. It is crucial to prevent post-maturity complications, such as fetal distress, which makes labor induction a valuable intervention for maternal and neonatal health. Both misoprostol (PGE1) and dinoprostone (PGE2) are widely used for cervical ripening and induction, with dinoprostone being FDA-approved, while misoprostol, though highly efficient and cost-effective, is not yet FDA-approved.

Our study compared the effectiveness and safety of oral misoprostol versus intravaginal dinoprostone in inducing labor in postdated pregnancies. While both drugs had comparable outcomes in spontaneous onset of labor (SOL) and cervical ripening (Bishop score ≥ 7), the multivariate analysis favored misoprostol for SOL (AOR = 1.84). Dinoprostone intervention led to spontaneous labor in 51.9% of cases, slightly higher than the 40.4% in the misoprostol group, though the difference was not statistically significant ($p > 0.05$). These results align with previous studies, such as Sanchez-Ramos et al., which also highlighted lower emergency LSCS rates in the misoprostol group.

The time to delivery in SOL was notably shorter in the dinoprostone group (14.70 ± 4.61 hours) compared to the misoprostol group (16.79 ± 4.1 hours), demonstrating dinoprostone's faster action. However, our findings suggest that misoprostol might be associated with fewer emergency LSCS cases; only 6.7% of women who received misoprostol required an emergency LSCS, compared to 15.4% in the dinoprostone group. Although the low frequency of emergency LSCS cases limits definitive conclusions, this trend favors misoprostol as a safer option for induction.

In terms of neonatal outcomes, CTG abnormalities (suspicious or pathological) were significantly more frequent in the dinoprostone group (14.4%) than in the misoprostol group (1.9%), raising concerns about dinoprostone's association with adverse fetal outcomes. There was no significant difference between the groups regarding meconium-stained liquor and neonatal admission to PBU, suggesting similar neonatal safety profiles in these aspects.

Overall, while both misoprostol and dinoprostone have proven efficacy in labor induction, misoprostol appears to offer a safer profile, particularly concerning emergency LSCS rates and CTG abnormalities. These findings support the potential of misoprostol as an effective, affordable, and possibly safer alternative for labor induction in postdated pregnancies. However, given the limited sample size and observational nature of this study, further large-scale, randomized controlled trials are recommended to confirm these outcomes and explore misoprostol's long-term safety.

9. Conclusion and Recommendations

The intervention at 40 weeks + 5 days showed mixed success in promoting spontaneous onset of labor (SOL) and preparing women for induction of labor (IOL) by 40 weeks + 6 days, with a significant number achieving SOL or becoming

favorable for IOL. Time from intervention to delivery varied, indicating different responses among participants. Maternal outcomes were generally safe, with few cases requiring emergency cesarean delivery due to complications like uterine hyperstimulation or pathological CTG, and minimal maternal morbidity, including rare postpartum blood transfusions and no uterine ruptures. Fetal and neonatal outcomes were positive, with a low incidence of pathological CTG patterns, meconium-stained liquor, and minimal NICU admissions, mainly for minor concerns. Overall, the interventions appear effective for advancing labor in prolonged pregnancies without major maternal or neonatal risks, supporting their potential use in managing prolonged pregnancies. Further research could better define optimal timing and administration.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Abbreviations

- IOL - Induction of labour
- PGE2 - Prostaglandin E2
- MP - Misoprostol
- PIH - Pregnancy induced hypertension
- GDM - Gestational diabetes mellitus
- NSAIDs - Nonsteroidal anti-inflammatory drugs
- PPH - Post partum haemorrhage
- CTG - Cardiotocography
- PBU - Premature baby unit
- NICU - Neonatal intensive care unit
- FIGO - International Federation of Gynaecology and Obstetrics
- PGIM - Post graduate Institute of Medicine
- SOL - Spontaneous onset of labour