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Oral Versus Vaginal Misoprostol for Labor Induction: A Prospective Comparative Study of Maternal and Neonatal Outcomes

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Abstract

Background: Labour induction is increasingly common, and misoprostol is widely used due to its efficacy, affordability, and stability. The optimal administration route remains debated, particularly regarding efficacy and safety.

Objective: To compare the efficacy and safety of low-dose oral versus vaginal misoprostol for labor induction and evaluate associated maternal and neonatal outcomes.

Methods: Pregnant women requiring labor induction were prospectively allocated to receive either oral misoprostol (25 μg every 2 hours) or vaginal misoprostol (25 μg every 4 hours), up to eight doses. The primary outcomes were mode of delivery and number of doses required for vaginal delivery. The secondary outcomes included maternal and neonatal outcomes.

Results: Vaginal misoprostol increased vaginal delivery rates (94% *vs.* 81%, $P<0.05$) and reduced cesarean sections (6% *vs.* 19%) compared with oral administration. Fewer doses were required (2.81 ± 0.91 *vs.* 4.46 ± 1.45, $P<0.0001$). Maternal adverse events were lower (6% *vs.* 19%, $P=0.010$), with uterine hyperstimulation and rupture observed only in the oral group. Neonatal outcomes favored vaginal administration, with higher Apgar scores and fewer neonatal intensive care unit admissions (26.2% *vs.* 45.2%, $P<0.05$), while meconium-stained liquor was similar between groups.

Conclusion: Low-dose vaginal misoprostol was associated with improved labor induction outcomes compared with oral administration, including a higher rate of vaginal delivery, fewer required doses, improved maternal and neonatal outcomes. However, given the non-randomized design and baseline imbalances between the groups, these findings should be interpreted with caution and confirmed by randomized controlled trials.

Keywords: Misoprostol; Labor Induction; Vaginal Administration; Maternal Outcome; Neonatal Outcome

Introduction

Induction Of Labor (IOL) refers to the deliberate initiation of uterine contractions after fetal viability and prior to the spontaneous onset of labor, with the aim of achieving vaginal delivery when the benefits of termination of pregnancy outweigh the risks of its continuation [1]. IOL can be accomplished through two principal approaches: mechanical methods, such as balloon catheters, and pharmacological methods, including prostaglandins, with considerable variation in clinical protocols across different settings [2-6]. Among pharmacological agents, misoprostol (a prostaglandin E1 analogue) and dinoprostone (prostaglandin E2) are widely utilized in varying doses and routes of administration.

This agent offers several advantages over other prostaglandins, including lower cost, stability at room temperature, ease of administration via multiple routes (oral, vaginal, and sublingual), high efficacy and an acceptable safety profile [7-10]. These features make it particularly suitable for use in resource-limited and low-income settings.

The success of labor induction is influenced by multiple maternal and fetal factors. These include the pre-induction Bishop score, parity, history of prior vaginal delivery, maternal Body Mass Index (BMI), gestational age, hypertensive disorders of pregnancy, estimated fetal weight, fetal heart rate patterns, membrane status prior to induction, and maternal age. Additional factors such as place of residence, Intra-Uterine Growth Restriction (IUGR), Intra-Uterine Fetal Death (IUFD), placental abruption, fetal congenital anomalies, and the specific indication and method of induction have also been shown to impact outcomes [11-15].

Numerous individual studies across diverse populations, as well as meta-analyses, have evaluated the efficacy and safety of misoprostol administered via different routes and dosing regimens for labor induction. However, findings have been inconsistent, particularly regarding the comparative effectiveness and safety of oral versus vaginal administration [16-33].

Importantly, there is a lack of data addressing this issue in the Yemeni population, highlighting the need for locally relevant data.

The present study aimed to compare the efficacy and safety of low-dose misoprostol (25 μg) administered orally versus vaginally for labor induction. Additionally, it evaluated associated maternal and neonatal outcomes, providing insights into optimal dosing strategies and route selection in a resource-limited clinical setting.

Materials and Methods

Study design and setting

This study was designed as a prospective comparative study rather than a randomized controlled trial, conducted between February 2022 and February 2023 between at the Obstetrics Emergency Department of Republican General Teaching Hospital in Taizz Governorate, Republic of Yemen. The hospital is affiliated with the Ministry of Health and serves as a major referral center.

Study population and sample size

A total of 168 pregnant women requiring labor nduction and meeting the eligibility criteria were enrolled after obtaining written informed consent. All participants were adequately informed about the nature and objectives of the study prior to inclusion. A consecutive sampling technique was used to recruit eligible participants during the study period.

Inclusion criteria

Women aged ≥19 years with singleton live fetuses in cephalic presentation, gestational age ≥37 weeks, estimated fetal weight ≤4 kg, Bishop score ≤5, intact uterus, absence of regular uterine contractions, reassuring fetal heart rate pattern, and a valid medical or obstetric indication for labor induction.

Exclusion criteria

Women with a history of previous cesarean section or uterine surgery, multiple pregnancy, malpresentation, established uterine contractions (≥3 contractions per 10 minutes), placenta previa, Cephalon-Pelvic Disproportion (CPD), genital tract anomalies, chronic medical diseases, gestational diabetes mellitus, severe maternal conditions contraindicating vaginal delivery, contraindications to prostaglandins, fetal distress at admission, or suspected fetal anomalies were excluded.

Indications for labor induction included post-term pregnancy (≥42 weeks), Premature Rupture Of Membrane (PROM), Intra-Uterine Growth Restriction (IUGR), decreased fetal movements, and preeclampsia.

Data Collection Procedures

Data were collected using a structured, pretested, interviewer-administered questionnaire. Information obtained included sociodemographic characteristics and obstetric history, such as maternal age, gravidity, parity, history of abortion, interpregnancy interval, previous preterm delivery, prior successful induction of labor, gestational age at induction, and indication for induction.

All participants underwent a comprehensive clinical assessment. General and systemic examinations were followed by obstetric abdominal examination to assess fundal height, fetal lie, presentation, position, attitude, and uterine activity. Fetal heart rate was evaluated for rate, rhythm, and regularity. A vaginal examination was performed to assess cervical dilatation, effacement, consistency, position, fetal head station, and membrane status, which were used to calculate the Bishop score.

In cases of suspected PROM, a nitrazine (vaginal *pH*) test was used to detect changes in vaginal pH due to amniotic fluid leakage [34]. Baseline laboratory investigations and ultrasonography were performed for all participants.

Induction protocol

Participants were assigned to receive either oral or vaginal misoprostol using a predefined allocation approach guided by routine clinical practice. No formal randomization or allocation concealment was used. The baseline maternal and obstetric characteristics were similar between the two groups, with no statistically significant differences, which helps reduce the likelihood of selection bias.

In the oral group, misoprostol was given at a dose of 25 μg every 2 hours, up to a maximum of eight doses. In the vaginal group, 25 μg of misoprostol was administered every 4 hours, also up to a maximum of eight doses, with careful maternal and fetal monitoring.

Monitoring and labor management

All participants were managed according to standardized clinical protocols. Prior to each dose, maternal vital signs were checked, abdominal and vaginal examinations were performed and the Bishop score was reassessed. Fetal heart rate was continuously monitored throughout the course of labor.

Further doses of misoprostol were withheld once effective uterine contractions were established, the cervix became favorable, or active labor had begun. Treatment was also discontinued in the event of uterine tachysystole, hyperstimulation, fetal distress, or any maternal complications. Uterine tachysystole was defined as more than five contractions in 10 minutes over a 30-minute period.

Oxytocin augmentation was initiated at least 4 hours after the last dose of misoprostol if uterine contractions remained inadequate. Cesarean delivery was considered in cases where active labor was not achieved within 4 hours after the last dose, in the presence of persistently unfavorable cervical conditions, or if fetal distress occurred at any stage of labor.

Outcome measures

Primary outcomes:

- Mode of delivery (vaginal delivery or cesarean section).
- Number of misoprostol doses required to achieve vaginal delivery.

• Requirement for oxytocin augmentation.

Secondary outcomes:

• Maternal outcomes: postpartum hemorrhage, uterine hyperstimulation, uterine rupture, pyrexia, nausea, vomiting, diarrhea, and maternal mortality.

• Neonatal outcomes: meconium-stained amniotic fluid, Neonatal Intensive Care Unit (NICU) admission, Apgar score <7 at 1, 5, and 10 minutes, and neonatal mortality.

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) software (version 21, IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The Mann–Whitney U test was used for comparison of continuous variables, and the Chi-square (χ^2) test was applied for categorical variables. A two-tailed P value of <0.05 was considered statistically significant.

Results

A total of 168 pregnant women who underwent labor induction were included in the analysis. Of these, 79 (47.0%) were aged <30 years and 89 (53.0%) were aged ≥30 years, with a mean age of 29.51 ± 6.47 years (range: 19–41 years). Most participants were at term gestation (92.9%), while a smaller proportion were post-term (5.9%) or preterm (1.2%). In terms of parity, 57.7% were multiparous, 16.1% primiparous, and 26.2% nulliparous.

Test of normality

Assessment of data distribution using the Kolmogorov–Smirnov and Shapiro–Wilk tests showed that continuous variables were not normally distributed (*P*<0.05) (Table 1). Therefore, non-parametric tests were used for subsequent analyses.

Baseline obstetric characteristics

Baseline characteristics were broadly similar between the oral and vaginal misoprostol groups with respect to gestational age, blood pressure, gravidity, and history of abortion (*P*>0.05). However, significant differences were observed in maternal age and parity. Women in the vaginal misoprostol group were older on average

Table 1: Normality testing.

Continuous variables	Kolmogorov-Smirnov			Shapiro-Wilk		
	Statistic	df	*p*-values	Statistic	df	*p*-values
Age (year)	.126	168	.000	.937	168	.000
Gravidity	.148	168	.000	.907	168	.000
Parity	.159	168	.000	.891	168	.000
Abortion	.480	168	.000	.504	168	.000
SBP[a]	.189	168	.000	.886	168	.000
DBP[b]	.252	168	.000	.859	168	.000
GA	.239	168	.000	.820	168	.000
No. Of dose	.216	168	.000	.910	168	.000
Apgar1	.365	168	.000	.646	168	.000
Apgar5	.357	168	.000	.582	168	.000
Apgar10	.438	168	.000	.449	168	.000
Birth weight (kg)	.255	168	.000	.841	168	.000

[a]Systolic blood pressure; [b]Diastolic blood pressure.

Table 2: Baseline obstetric characteristics.

Obstetrics characteristics	Oral group N= 84	Vaginal group N= 84	*P* value
Maternal age (years)	28.48±6.29	30.55±6.53	0.037
Maternal age groups:			
≤25 years	29(34.5%)	22(26.2%)	-
> 25 to ≤30 years	22(26.2%)	21(25.0%)	0.397
>30 years	33(39.3%)	41(48.8%)	-
Gestational age (weeks)	38.76±2.089	38.83±1.57	0.803
SBP	111.40±15.43	113.69±16.41	0.400
DBP	74.4±11.12	76.9±12.8	0.195
Gravidity	2.88±1.67	3.2±1.62	0.199
Parity	1.6±1.36	2.0±1.42	0.047
Abortion	0.32±0.62	0.21±0.54	0.184

Table 3: Indications for induction of labor.

Indications	Oral group N= 84	Vaginal group N= 84	*P* value
Post term pregnancy	5(6.0%)	6(7.1%)	0.755
PROM[a]	18(21.4%)	24(28.6%)	0.285
IUGR[b]	6(7.1%)	5(6%)	0.755
Decrease fetal movement	21(22%)	18(21.4%)	0.584
Preeclampsia	12(14.3%)	16(19.0%)	0.408

[a]Premature rupture of membrane; [b]Intrauterine growth restriction.

than those in the oral group (*P*=0.037), although no significant difference was found when age was analyzed by categorical age groups (*P*=0.397). In addition, parity was significantly higher in the vaginal group (*P*=0.047). As both maternal age and parity may influence labor induction outcomes, these baseline differences should be considered when interpreting the comparative results between the two groups (Table 2).

Indications for induction of labor

The indications for induction were similarly distributed between the two groups, with no statistically significant differences observed (*P*>0.05).

In the oral group, decreased fetal movement was the most common indication (25.0%), followed by PROM (21.4%) and preeclampsia (14.3%), IUGR (7.1%), and post-term pregnancy (6.0%).

In the vaginal group, IUGR was the most frequent indication (28.6%), followed by decreased fetal movement (22.6%) and preeclampsia (19.0%), post-term pregnancy (7.1%), and PROM (6.0%) (Table 3).

Primary outcomes

The number of misoprostol doses required to achieve vaginal delivery was significantly higher in the oral group compared with the vaginal group (*P*<0.0001).

The vaginal group also showed a higher rate of normal vaginal delivery (94.0% *vs.* 81.0%) and a lower rate of cesarean section (6.0% *vs.* 19.0%) (*P*=0.010) (Table 4). No participants in either group required oxytocin augmentation.

Secondary outcomes

Maternal Outcomes: Uterine hyperstimulation and uterine rupture were observed only in the oral group, although the number

Table 4: Primary outcomes.

Primary outcomes	Oral group N= 84	Vaginal group N= 84	*P* value
No. of misoprostol doses	4.46±1.45	2.81± 0.91	0.000
Mode of delivery			
Normal vaginal delivery	68(81.0%)	79(94.0%)	0.010
Cesarean section	16(19.0%)	5(6.0%)	-
Oxytocin required			
Yes	0(0.0%)	0(0.0%)	-
No	84(100%)	84(100%)	-

Table 5: Secondary outcomes.

Secondary outcomes	Oral group N= 84	Vaginal group N= 84	*P* value
Maternal outcomes			
Uterine hyperstimulation	6(7.1%)	0(0.0%)	--
Uterine rupture	2(2.4%)	0(0.0%)	--
Pyrexia	1(1.2%)	1(1.2%)	--
Postpartum hemorrhage	7(8.3%)	4(4.8%)	0.349
Composite maternal outcomes	16(19.0%)	5(6.0%)	0.01
Neonatal outcomes			
Birth weight (kg)	2.74±0.28	2.78±0.25	0.391
Apgar score at 1 min	7.33±1.62	8.01±0.81	0
Apgar score at 5 min	7.81±1.54	8.42±0.75	0
Apgar score at 10 min	8.42±1.64	8.88±0.59	0.042
Apgar score <7at 1 min	13(15.5%)	4(4.8%)	0.021
Apgar score<7 at 5 min	11(13.1%)	3(3.6%)	0.026
Apgar score <7at 10 min	8(9.5%)	1(1.2%)	0.016
Meconium stained liquor	18(21.4%)	11(13.1%)	0.153
NICU[a] Admission	38(45.2%)	22(26.2%)	0.01
Perinatal death	2(2.4%)	0(0.0%)	--
Composite neonatal outcomes	38(45.2%)	22(26.2%)	0.01

[a]Neonatal intensive care unit admissions

of cases was small (7.1% and 2.4%, respectively) only. Pyrexia was rare and comparable in both groups (1.2%). Postpartum hemorrhage occurred more frequently in the oral group (8.3% *vs*. 4.8%), although this difference was not statistically significant (*P*=0.349).

Overall, composite maternal adverse outcomes were significantly higher in the oral group (19.0% *vs*. 6.0%, *P*=0.010). No cases of gastrointestinal side effects or maternal mortality were reported (Table 5).

Neonatal Outcomes: Mean birth weight was comparable between the two groups (*P*>0.05). Apgar scores at 1, 5, and 10 minutes were significantly higher in the vaginal group (*P*<0.05). Similarly, low Apgar scores (<7) were more frequent in the oral group at all time points (*P*<0.05). Although meconium-stained amniotic fluid was more common in the oral group (21.4% *vs*. 13.1%), the difference was not statistically significant (*P*=0.153). NICU admissions were significantly higher in the oral group (45.2% *vs*. 26.2%, *P*=0.010), and perinatal mortality occurred only in the oral group (2.4%).

Overall, composite adverse neonatal outcomes were more common in the oral group compared to the vaginal group (45.2% *vs*. 26.2%, *P*=0.010) (Table 5).

Discussion

The global rate of labor induction has increased substantially over recent decades, reflecting evolving obstetric practices and expanding clinical indications. Despite the availability of multiple induction methods, prostaglandins remain the cornerstone of cervical ripening and labor induction [35-37].

Among these, misoprostol - a synthetic prostaglandin E1 analogue - has emerged as a preferred agent due to its effectiveness, affordability, stability at room temperature, and versatility in routes of administration. Since its inclusion in the World Health Organization (WHO) Model List of Essential Medicines in 2005, it has become particularly valuable in low-resource settings.

Pharmacologically, misoprostol is rapidly de-esterified in the liver to its active metabolite, misoprostol acid, which enhances uterine contractility and facilitates cervical ripening through collagen degradation and reduction in cervical resistance [9, 38]. Its clinical effects are highly dependent on the route, dose, and dosing interval. Oral administration is associated with rapid absorption and higher peak plasma levels, whereas vaginal administration results in slower absorption, prolonged bioavailability, and sustained uterine activity, potentially translating into greater clinical effectiveness.

In the present study, low-dose oral misoprostol (25 μg every 2 hours) was compared with vaginal misoprostol (25 μg every 4 hours) in a prospective design. The findings suggest that vaginal misoprostol may be associated with higher rates of normal vaginal delivery and lower rates of cesarean section compared with oral administration. In addition, fewer doses were generally required to achieve successful vaginal delivery in the vaginal group. These results are broadly consistent with previous studies reporting improved efficacy with vaginal administration [25, 26]. Studies using higher oral doses (50 μg) have also demonstrated comparable or superior outcomes with vaginal regimens [27-29].

The apparent advantage of vaginal misoprostol could be explained by its pharmacokinetic profile, characterized by higher bioavailability and prolonged serum levels, resulting in sustained uterine stimulation. In contrast, oral misoprostol, despite its rapid onset, undergoes faster clearance, which may necessitate more frequent dosing and could lead to comparatively reduced efficacy. However, some studies have reported similar or slightly better outcomes with oral misoprostol [30-32]. These discrepancies may be attributed to variations in dosing protocols, cumulative doses, baseline cervical status, parity distribution, and other clinical factors.

Regarding the requirement for oxytocin, it was not necessary in either group, suggesting that administered low-dose misoprostol alone may suffice for effective labor induction in many cases.

Maternal outcomes

Vaginal misoprostol was associated with a lower incidence of composite maternal adverse outcomes compared to oral administration. Uterine hyperstimulation and uterine rupture were observed only in the oral group, although the latter was rare and did not reach statistical significance. Postpartum hemorrhage and pyrexia were comparable between the groups, and no cases of maternal mortality or gastrointestinal side effects were reported.

These findings align with prior studies indicating a lower incidence of uterine contractile abnormalities with low-dose vaginal misoprostol [21, 33]. Nevertheless, some studies have reported higher rates of hyperstimulation with vaginal administration [20, 24-26], suggesting that variability in dosing protocols, cumulative dose, and patient characteristics may influence maternal safety outcomes.

Neonatal outcomes

Neonatal outcomes were more favorable in the vaginal group, with significantly higher mean Apgar scores at 1, 5, and 10 minutes, as well as lower rates of low Apgar scores (<7), NICU admissions, and composite adverse neonatal outcomes. Although the incidence of meconium-stained amniotic fluid was higher in the oral group, the difference was not statistically significant. Perinatal mortality occurred only in the oral group, though the small sample size limits definitive conclusions.

These findings are broadly in agreement with prior studies reporting improved or similar neonatal outcomes with vaginal misoprostol [20, 25, 32, 33]. However, other studies have reported no significant differences or less favorable outcomes with vaginal administration [21-23, 30]. Variability across studies may reflect differences in study design, dosing regimens, fetal monitoring practices, and clinical settings.

The observed advantage of vaginal misoprostol may be further supported by pharmacokinetic evidence. Vaginal administration has been reported to result in approximately threefold higher bioavailability compared with oral administration, along with prolonged serum drug levels and sustained uterine activity [39, 40]. This enhanced exposure may contribute to more effective cervical ripening and labor progression. Current evidence indicates that a regimen of 25 μg vaginal misoprostol administered every 4 hours represents an effective and widely accepted approach for labor induction, although findings should be interpreted with caution given variations in study design and population characteristics.

Strengths and Limitations

This study has several notable strengths. It utilized a low-dose misoprostol regimen (25 μg) consistent with current safety recommendations, thereby minimizing the risk of adverse effects. It also provides a direct comparison between two commonly used routes of administration, enhancing clinical relevance, and includes both maternal and neonatal outcomes for a comprehensive assessment of safety and effectiveness. Additionally, it adds to the existing body of evidence by evaluating a low-dose vaginal misoprostol regimen (25 μg every 4 hours) compared with a comparable oral regimen (every 2 hours), providing further insight into dosing strategies.

Despite these strengths, several limitations should be acknowledged. The relatively small sample size may limit the generalizability, while the single-center design may reduce external validity. The absence of blinding introduces the potential for performance and assessment bias. Furthermore, the lack of randomization and allocation concealment may introduce selection bias and limit causal inference. Variability in individual response to misoprostol - particularly with vaginal absorption - was not controlled, and potential confounding factors, including parity, baseline Bishop score, and indication for induction, may have influenced the observed outcomes. Therefore, further well-designed multicenter randomized controlled trials with standardized protocols are needed to confirm these findings.

Conclusion

In this prospective non-randomized study, low-dose vaginal misoprostol (25 µg every 4 hours) was associated with higher vaginal delivery rates, lower drug requirements, improved maternal and neonatal outcomes compared with a comparable oral regimen. These findings provide additional evidence from a Yemeni population, where data on labor induction methods remain limited. However, the results should be interpreted cautiously, as baseline differences between the groups may have influenced the observed outcomes. Further adequately powered randomized controlled trials are needed to confirm these findings.

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Author Contributions

Elham Hamid Ismail Kaid: Conceptualization, Methodology, Investigation.

Mustafa Abdo Saif Dehwah: Data curation, formal analysis, Writing – original draft.

Sinaa Qasim Bagash Ahmed Alabsi: Methodology, Supervision, Writing – review & editing.

All authors contributed to data interpretation, critically revised the manuscript, approved the final version, and agree to be accountable for all aspects of the work.

Conflict of Interest

The authors declare no conflicts of interest. This manuscript is original, has not been published previously, and is not under consideration elsewhere.

Informed Consent

Written informed consent was obtained from all participants prior to enrollment.

Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki (2013 revision) and approved by the Institutional Review Board (IRB) of Republican General Teaching Hospital, Taiz University (Approval No: 7RGT2021; Date: 15/12/2021). Written informed consent was obtained from all participants prior to enrollment. Confidentiality and anonymity of patient data were strictly maintained throughout the study in accordance with ethical research standards.

Data Availability Statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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