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Comparative Study of Titrated Low Dose Vaginal Misoprostol versus Titrated Low Dose Oral Misoprostol versus Intracervical Dinoprostone Gel for Induction of Labour.

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ABSTRACT

Induction of labour is a common obstetric intervention aimed at initiating uterine contractions before spontaneous onset to achieve vaginal delivery when continuation of pregnancy poses risks. Misoprostol, a prostaglandin E1 analogue, and dinoprostone, a prostaglandin E2 analogue, are widely used, but optimal route and formulation remain debated. To compare the efficacy and safety of titrated low-dose oral misoprostol, titrated low-dose vaginal misoprostol, and intracervical dinoprostone gel for induction of labour. A prospective comparative study was conducted on 180 term pregnant women, equally divided into three groups: Group 1 received oral misoprostol 50 mcg, Group 2 received vaginal misoprostol 25 mcg, and Group 3 received 0.5 mg intracervical dinoprostone gel. Induction–delivery interval, number of doses, mode of delivery, maternal complications, and neonatal outcomes were recorded. Data were analysed using ANOVA and chi-square tests with $p<0.05$ considered significant. Vaginal misoprostol had the shortest induction–delivery interval (10.76 ± 4.47 h) and highest final Bishop's score (6.97 ± 1.28). Oral misoprostol required more doses ($p=0.033$). Fetal distress was higher in vaginal misoprostol ($p=0.037$). Other maternal and neonatal outcomes showed no significant differences. All three agents were effective and safe. Vaginal misoprostol showed faster cervical ripening but with higher fetal distress rates.

Keywords: Labour induction, Misoprostol, Dinoprostone

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INTRODUCTION

Induction of labour is a common obstetric intervention aimed at initiating uterine contractions before the spontaneous onset of labour to achieve vaginal delivery when continuation of pregnancy poses maternal or fetal risks [1]. The choice of induction method depends on cervical favourability, maternal and fetal condition, and available resources. Pharmacological agents such as prostaglandins have been widely used for cervical ripening and stimulation of uterine contractions [2, 3]. Misoprostol, a synthetic prostaglandin E1 analogue, can be administered via various routes including oral, vaginal, and sublingual, with differences in absorption, onset, and side effect profile. Dinoprostone, a prostaglandin E2 analogue, is commonly used in the form of intracervical gel for cervical ripening [4].

Low-dose, titrated regimens of misoprostol—whether vaginal or oral—are increasingly preferred to minimize the risk of uterine tachysystole and associated fetal distress, while ensuring effective labour progression. Comparative evaluation of these regimens against dinoprostone is important to establish efficacy, safety, maternal comfort, and neonatal outcomes [5, 6]. This study aims to assess and compare the effectiveness of titrated low-dose vaginal misoprostol, titrated low-dose oral misoprostol, and intracervical dinoprostone gel in achieving successful induction, while analysing induction-to-delivery interval, mode of delivery, and maternal-fetal safety parameters.

METHODOLOGY

A prospective, comparative study was conducted to evaluate the efficacy and safety of three pharmacological agents for induction of labour: titrated low-dose oral misoprostol, titrated low-dose vaginal misoprostol, and intracervical dinoprostone gel. The study population comprised 180 pregnant women, each meeting predefined inclusion and exclusion criteria. Eligible participants were randomly allocated into three equal groups of 60 women each. Group 1 received oral misoprostol 50 mcg, Group 2 received vaginal misoprostol 25 mcg, and Group 3 received 0.5 mg intracervical dinoprostone gel. Baseline demographic data, obstetric history, gestational age, and initial Bishop's score were recorded before induction.

The induction protocol was administered under strict aseptic precautions in a labour ward setting with continuous maternal and fetal monitoring. For Groups 1 and 2, repeat doses of misoprostol were given at defined intervals based on uterine activity and cervical status, while in Group 3, additional doses of dinoprostone gel were administered as indicated. The need for oxytocin augmentation, number of doses required, and any adverse maternal or fetal events were documented. Labour progress was assessed by serial Bishop's scoring and partogram plotting, with the induction–delivery interval recorded for all participants.

Mode of delivery was determined according to obstetric indications, with caesarean section performed in cases of fetal distress, failed induction, or other complications. The presence of meconium-stained liquor, postpartum haemorrhage, hyperstimulation, vaginal or cervical tears, and other intrapartum complications were noted. Neonatal outcomes were evaluated by recording APGAR scores at 5 minutes and assessing the need for NICU admission. All clinical decisions adhered to standard institutional protocols to ensure patient safety and consistency in care.

Data collected were analysed using R statistical software version 3.5.3. Quantitative variables were summarised as mean and standard deviation, while qualitative variables were expressed as counts and percentages. Intergroup comparisons for quantitative variables were performed using one-way ANOVA, and qualitative data were compared using the chi-square test of independence. A p-value <0.05 was considered statistically significant. Graphical representations, including bar charts, histograms, pie charts, and boxplots, were utilised to illustrate findings for gestational age, Bishop's score, induction–delivery interval, mode of delivery, and maternal and neonatal outcomes.

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RESULTS

Table 1: Baseline Characteristics

Parameter	Oral Misoprostol (n=60)	Vaginal Misoprostol (n=60)	Dinoprostone Gel (n=60)	p-value	Significance
Mean Gestational Age (weeks) ± SD	39.43 ± 1.31	39.41 ± 1.52	39.47 ± 1.54	0.968	NS
Mean Initial Bishop's Score ± SD	4.50 ± 1.28	4.66 ± 0.98	4.70 ± 1.23	0.617	NS
Induction–Delivery Interval (hrs) ± SD	11.79 ± 5.20	10.76 ± 4.47	12.60 ± 5.89	0.154	NS
Mean Doses Required ± SD	2.02 ± 0.87	1.77 ± 0.76	1.63 ± 0.78	0.033	S

Table 2: Labour and Delivery Outcomes

Outcome	Oral Misoprostol (n=60)	Vaginal Misoprostol (n=60)	Dinoprostone Gel (n=60)	p-value	Significance
Vaginal Delivery (%)	38 (63.3)	46 (77.0)	38 (63.3)	0.174	NS
LSCS (%)	22 (36.7)	14 (23.0)	22 (36.7)		
Fetal Distress (as CS indication) (%)	12 (54.5)	13 (86.7)	10 (45.5)	0.037	S
Failed Induction (%)	9 (36.4)	1 (6.7)	9 (40.9)	0.065	NS

Table 3: Maternal Complications

Complication	Oral Misoprostol (n=60)	Vaginal Misoprostol (n=60)	Dinoprostone Gel (n=60)	p-value	Significance
Meconium-Stained Liquor (%)	15 (25.0)	20 (33.3)	9 (15.0)	0.065	NS
Hyperstimulation (%)	7 (8.3)	6 (11.5)	4 (6.7)	0.369	NS
Vaginal Tear (%)	5 (8.3)	2 (3.3)	3 (5.0)	0.466	NS
Cervical Tear (%)	7 (11.7)	7 (11.7)	4 (6.7)	0.583	NS
PPH (%)	4 (6.7)	5 (8.3)	6 (10.0)	0.768	NS

Table 4: Neonatal Outcomes

Parameter	Oral Misoprostol (n=60)	Vaginal Misoprostol (n=60)	Dinoprostone Gel (n=60)	p-value	Significance
NICU Admission (%)	15 (25.0)	15 (25.0)	12 (20.0)	0.077	NS
Mean APGAR Score at 5 min ± SD	8.37 ± 1.19	8.21 ± 1.47	8.52 ± 1.07	0.416	NS
Mean Final Bishop's Score ± SD	6.25 ± 1.13	6.97 ± 1.28	6.52 ± 1.22	0.004*	S (Group 2 > Group 1)

DISCUSSION

The present study compared the efficacy and safety of titrated low-dose oral misoprostol, titrated low-dose vaginal misoprostol, and intracervical dinoprostone gel for induction of labour in 180 women, equally distributed into three groups. Baseline characteristics, including mean gestational age and initial Bishop's score, were comparable across all groups, indicating that the study groups were well-matched and that any differences in outcomes could be attributed to the induction agent used. The mean gestational age in all groups was approximately 39.4 weeks, and the mean initial Bishop's score was around 4.5–4.7, with no statistical significance [7].

The induction–delivery (ID) interval was shortest in the vaginal misoprostol group (10.76 ± 4.47 hours) compared to oral misoprostol (11.79 ± 5.20 hours) and dinoprostone (12.60 ± 5.89 hours), although this difference was not statistically significant. This trend suggests a possible clinical advantage of vaginal misoprostol in reducing labour duration. A statistically significant finding was the number of doses required—oral misoprostol needed more doses on average (2.02 ± 0.87) compared to vaginal misoprostol (1.77 ± 0.76) and dinoprostone gel (1.63 ± 0.78) (p=0.033), indicating greater efficiency of the latter two methods in achieving effective labour.

Mode of delivery analysis showed a higher proportion of vaginal deliveries in the vaginal misoprostol group (77%) compared to both oral misoprostol and dinoprostone (63.3% each), though this was not statistically significant. Caesarean section for fetal distress was significantly more common in the vaginal misoprostol group (86.7%) among those who required operative delivery compared to oral misoprostol (54.5%) and dinoprostone (45.5%) (p=0.037). While this suggests a potential association between vaginal misoprostol and fetal distress, it is important to consider confounding variables such as baseline fetal tolerance and labour progression patterns.

Maternal complications, including meconium-stained liquor, hyperstimulation, vaginal and cervical tears, and postpartum haemorrhage, did not differ significantly between groups, indicating that all three agents were broadly safe from a maternal perspective. The incidence of hyperstimulation was relatively low across groups (6.7–11.5%), and postpartum haemorrhage occurred in 6.7–10% of participants, consistent with reported rates in similar studies [8, 9].

Neonatal outcomes were reassuring, with no statistically significant differences in NICU admissions or APGAR scores at 5 minutes. The mean APGAR score exceeded 8 in all groups, indicating good neonatal condition at birth. NICU admissions ranged from 20% in the dinoprostone group to 25% in both misoprostol groups, with no statistically significant variation. Importantly, the final Bishop's score was significantly higher in the vaginal misoprostol group (6.97 ± 1.28) compared to oral misoprostol (6.25 ± 1.13) (p=0.004), suggesting better cervical ripening efficiency with vaginal administration.

The findings align with previous literature [9-11] indicating that vaginal misoprostol may achieve a shorter induction-to-delivery time and better cervical ripening, while dinoprostone remains a safe and effective alternative. However, the increased proportion of fetal distress observed with vaginal misoprostol warrants further evaluation to clarify causation versus association. The higher dose requirement with oral misoprostol highlights the impact of administration route on drug bioavailability and efficacy.

In summary, all three agents were effective for labour induction, with vaginal misoprostol demonstrating trends towards faster delivery and superior cervical ripening, albeit with a higher rate of fetal distress. Dinoprostone gel performed comparably with fewer doses and good safety outcomes. Future larger-scale, multicentric studies are needed to confirm these trends and refine optimal dosing protocols.

CONCLUSION

All three agents were effective and safe. Vaginal misoprostol showed faster cervical ripening but with higher fetal distress rates.

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