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COMPARATIVE STUDY OF PER ORAL AND PER VAGINAL MISOPROSTOL FOR INDUCTION OF LABOR.

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Abstract

Background: Induction of labor (IOL) refers to the artificial initiation of uterine contractions before spontaneous onset of labor using mechanical or pharmacological methods, when continuing pregnancy poses greater maternal or fetal risk than delivery. It is a commonly performed obstetric intervention worldwide. Misoprostol, a prostaglandin E1 analogue, is widely used for cervical ripening and labor induction via oral and vaginal routes; however, the optimal route remains debated. ***Aim:*** To compare the safety, efficacy and maternal side effects of oral and vaginal misoprostol for induction of labor. ***Settings and Design:*** This interventional comparative study was conducted in the Department of Obstetrics and Gynecology at a tertiary care center over a period of 18 months. ***Material and Methods:*** A total of 400 pregnant women with singleton term pregnancies and unfavorable cervix (Bishop score <6) were randomly allocated into two groups: oral misoprostol (25 µg every 4 hours, maximum five doses) and vaginal misoprostol (25 µg every 4 hours, maximum five doses). Outcomes assessed included number of doses required, change in Bishop's score, induction-to-delivery interval, mode of delivery, need for oxytocin augmentation, uterine overactivity, FHR abnormalities and maternal side effects. ***Statistical Analysis:*** Data were analyzed using descriptive and inferential statistics. Continuous variables were compared using the Mann–Whitney U test, while categorical variables were analyzed using Chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant. ***Results:*** Vaginal misoprostol required significantly fewer doses for induction (p=0.001) and resulted in a greater improvement in Bishop score (p=0.001). The induction-to-active phase interval (7.10 ± 3.35 vs 9.02 ± 3.84 hours) and induction-to-delivery interval (11.50 ± 3.43 vs 13.32 ± 3.98 hours) were significantly shorter in the vaginal group (p=0.001). Mode of delivery and oxytocin requirement were comparable between groups. Maternal side effects were minimal and did not differ significantly. ***Conclusion:*** Both oral and vaginal misoprostol are safe and effective for induction of labor. Vaginal misoprostol demonstrates greater efficacy with faster labor progression and fewer doses Required, while maintaining a comparable safety profile.

Keywords: Induction of labor, oral misoprostol, vaginal misoprostol, Bishop's score.

INTRODUCTION

Induction of labor (IOL) refers to the artificial initiation of uterine contractions before spontaneous onset of labor using mechanical or pharmacological methods, when continuing pregnancy poses greater maternal or fetal risk than delivery..1 It is a frequently performed obstetric intervention, with rising global rates and an estimated prevalence of 20–30% in developed settings. Although beneficial, IOL is associated with risks such as failed induction, prolonged labor, uterine hyperstimulation, and increased cesarean delivery rates.2-3 The success of induction largely depends on cervical favorability, commonly assessed using the Bishop's score. An unfavorable cervix is associated with higher rates of induction failure, necessitating the use of cervical ripening methods, including pharmacological agents and mechanical techniques.4

Prostaglandins are the most widely used agents for cervical ripening. Misoprostol, a prostaglandin E_1 analogue, has gained popularity due to its low cost, stability, and ability to be administered via multiple routes. However, the optimal route of administration remains controversial, as vaginal misoprostol provides sustained uterotonic activity, whereas oral misoprostol offers greater convenience and acceptability.5

Despite recommendations supporting the use of low-dose regimens via both routes, evidence regarding their comparative efficacy and safety remains inconsistent.6Therefore, this study was undertaken to compare oral and vaginal misoprostol for induction of labor with respect to efficacy, safety, and maternal outcomes.

MATERIALS AND METHODS

This was an interventional comparative study conducted in the Department of Obstetrics and Gynaecology at Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar, from July 2024 to December 2025, after approval from the Institutional Ethics Committee. The aim of the study was to evaluate and compare safety, efficacy and maternal side effects of oral misoprostol with vaginal misoprostol for IOL. Pregnant women (booked or unbooked) admitted for induction and fulfilling the inclusion criteria were enrolled.

INCLUSION CRITERIA

1. Single fetus in cephalic presentation
2. Reassuring fetal heart rate (FHR)
3. Clinically adequate pelvis
4. Reactive Non Stress Test (NST)
5. Bishop score less than 6
6. Pregnancy with an indication of induction (maternal or fetal)

EXCLUSION CRITERIA

1. Malpresentation
2. Multiple pregnancy
3. Previous uterine scar like previous caesarean section, hysterotomy or myomectomy
4. Presence of uterine contractions >=3/10min
5. Contraindication to vaginal delivery.
6. Placenta Praevia
7. Drug allergy (allergy to prostaglandins)
8. Grand Multigravida
9. Active genital herpes

A total of 400 eligible participants were randomly allocate ed into two groups. Group, A (n=200) received oral misoprostol 25 µg every 4 hours (upto maximum of five doses), while Group B (n=200) received vaginal misoprostol 25 µg 25 µg every 4 hours (upto maximum of five doses), placed in the posterior fornix after moistening with saline.

A detailed clinical assessment was performed at baseline, including obstetric examination, Bishop's score evaluation, routine investigations, and fetal surveillance. Cervical status was reassessed every 4 hours, with minimal vaginal examinations to reduce infection risk. Fetal heart rate monitoring was performed before each dose, and induction was continued only if fetal status remained reassuring. Labor progress was monitored using a partograph once active labor commenced.

Induction was stopped upon onset of active labor (≥3 contractions/10 minutes or cervical dilatation >4 cm). Oxytocin augmentation was used when adequate contractions were not achieved after 4 hours of the last dose. Amniotomy was Performed at cervical dilatation >4 cm. Failure of induction was defined as no entry into active labor within 4 hours after the final dose. Safety of misoprostol for IOL was assessed by incidence of uterine hyperstimulation, tachysystole, hypertonus, and non-reassuring FHR patterns. Efficacy outcomes included change in Bishop score, induction-to-delivery interval, mode of delivery, number of doses required, and need for oxytocin augmentation. Maternal side effects such as nausea, vomiting, diarrhea, and fever were also recorded.

STATISTICAL ANALYSIS

Data was analyzed using descriptive and inferential statistics. Continuous variables were expressed as mean ± SD, while categorical variables were presented as frequencies and percentages. Normality was assessed using the Kolmogorov–Smirnov test. The Mann–Whitney U test (Z test) and Chi-square/Fisher's exact tests were used for comparisons. A p-value <0.05 was considered significant, and analysis was performed using SPSS version 26.0.

RESULTS

A total of 400 eligible participants were randomly allocated into two groups,200 in each**.**The mean demographic characteristics and indications for IOL were comparable in both the groups. Postdated pregnancy was the most common indication (20.0% in oral vs 26.0% in vaginal group), followed by pregnancy-induced hypertension (12.0% vs 18.0%),

gestational diabetes (11.5% vs 14.5%), and intrahepatic cholestasis (11.5% vs 12.5%). Other indications included intrauterine growth restriction (7.5% vs 8.5%), polyhydramnios (6.0% vs 8.0%), and oligohydramnios (4.0% vs 6.0%). Premature rupture of membranes was included only in the oral group (20.0%). Less frequent indications were intrauterine fetal demise (3.5% vs 4.5%), antepartum hemorrhage (3.0% vs 1.0%), and Rh-isoimmunization (1.0% in both groups).

Table 1 Number of doses of misoprostol required for IOL in both the groups

No. of Doses Required	Oral Group (n = 200)		Vaginal Group (n = 200)		Total	Chi-square Value	p-value
	No. of Cases	%	No. of Cases	%			
1	20	10.0	36	18.0	56		
2	60	30.0	92	46.0	152		
3	84	42.0	60	30.0	144	**27.651**	**0.001**
4	20	10.0	8	4.0	28		
5	16	8.0	4	2.0	20		
Total	**200**	**100.0**	**200**	**100.0**	**400**		

In the oral group, the majority of women required three doses (42.0%), followed by two doses (30.0%), whereas in the vaginal group, two doses were most common (46.0%), followed by three doses (30.0%). A higher proportion of women in the oral group required four or more doses compared to the vaginal group. The was statistically significant (p = 0.001).

Table 2 Oxytocin requirement for augmentation in both the groups

Oxytocin Requirement	Oral Group (n = 200)		Vaginal Group (n = 200)		Total	Chi-square Value	p-value
	No. of Cases	%	No. of Cases	%			
Required	80	40.0	92	46.0	172		
Not Required	120	60.0	108	54.0	228	**1.469**	**0.226**
Total	**200**	**100.0**	**200**	**100.0**	**400**		

Table 2 shows that in the oral group, 40.0% of women required oxytocin, compared to 46.0% in the vaginal group. This difference was **not statistically significant** (χ^2 = 1.469, p = 0.226).

Table 3 Mean preinduction and postindution Bishop's score in both the groups

Bishop's Score	Oral Group		Vaginal Group		Z Value	p-value
	Mean	SD	Mean	SD		
Pre-induction	3.48	0.94	3.40	0.92	0.805	0.422
Post-induction	8.69	1.47	9.72	1.63	-6.666	0.001

Table 3 demonstrates that baseline preinduction Bishop's scores were similar in both groups. However, mean post-induction scores were significantly higher in the vaginal group compared to the oral group (p=0.001).

Table 4 Mode of delivery and mean intervals in both the groups

Mean Interval	Oral Group		Vaginal Group		Z Value	p-value
	Mean (hrs)	SD	Mean (hrs)	SD		
Induction–Active Phase Interval	9.02	3.84	7.10	3.35	5.316	0.001
Induction–Delivery Interval	13.32	3.98	11.50	3.43	4.895	0.001

Table 4 demonstrates Vaginal delivery occurred in 57.5% of the oral group and 65.0% of the vaginal group, with similar rates of operative vaginal delivery (8.0% vs 9.0%). and caesarean section (34.5% vs 26.0%); however, the overall mode of delivery did not differ significantly between the groups (χ^2 = 3.494, p = 0.322).

The mean induction–active phase interval was significantly shorter in the vaginal group compared to the oral group (7.10 ± 3.35 vs 9.02 ± 3.84 hours), as was the induction– delivery interval (11.50 ± 3.43 vs 13.32 ± 3.98 hours; p = 0.001).

Table 5 Indication of LSCS in both the groups

Indication of LSCS	Oral Group (n = 200)		Vaginal Group (n = 200)		Chi-square Value	p-value
	No. of Cases	%	No. of Cases	%		
Failed Induction	3	1.50	2	1.00		
Failure to Progress	9	4.50	10	5.00		
Meconium-Stained Liquor (MSL)	13	6.50	24	12.00		
CTG Abnormality	20	10.00	27	13.50		
• Variable Deceleration	4	2.00	8	4.00		
• Late Deceleration	5	2.50	4	2.00		
• Bradycardia	7	3.50	8	4.00		
• Tachycardia	4	2.00	7	3.50		
Uterine Overactivity	7	3.50	6	3.00		
• Tachysystole	3	1.50	2	1.00		
• Hyperstimulation	2	1.00	1	0.50		
• Hypertonus	2	1.00	3	1.50	**2.2993**	**0.681**
Total LSCS	**52**	**26.00**	**69**	**34.50**		

Table 5 suggests that CTG abnormality was the most common indication, with similar rates across groups. Meconium-stained liquor was more frequent in the oral group, while other indications, including failure to progress and failed induction, were low and comparable. Overall, no significant difference was observed between groups (p=0.681).

Table 6 Maternal side effects in both the groups

Maternal Side Effect	Vaginal Group (n = 200)		Oral Group (n = 200)		Fisher's Exact Test	p-value
	No. of Cases	%	No. of Cases	%		
Nausea/Vomiting	23	11.5	18	9.0	0.678	0.410
Diarrhea	5	2.5	4	2.0	0.113	0.736
Chills	10	5.0	8	4.0	0.232	0.630
Fever	8	4.0	12	6.0	0.840	0.359

As depicted in table 6 maternal side effects were comparable between the two groups, with no statistically significant differences observed. Nausea and vomiting were slightly more frequent in the vaginal group (11.5%) than in the oral group (9.0%) (p = 0.410).Overall, all differences were statistically non-significant.

DISCUSSION

In our study, the indications for IOL were comparable between the oral and vaginal misoprostol groups, with postdated pregnancy being the most common indication (oral: 20.0% vs vaginal: 26.0%), followed by hypertensive disorders (12.0% vs 18.0%), GDM (11.5% vs 14.5%), and ICP (11.5% vs 12.5%). Less frequent indications included IUGR (7.5% vs 8.5%), oligohydramnios (4.0% vs 6.0%), and polyhydramnios (6.0% vs 8.0%). PROM was included only in the oral group (20.0%). Similar patterns were reported by Sarella and Uthrakumar et al.7, where PROM accounted for 25% and postdated pregnancy for 20% of cases, while hypertensive disorders constituted 30– 50%, comparable to our combined PIH proportion.

Vaginal misoprostol showed superior dose efficiency, with 64% requiring ≤2 doses compared to 40% in the oral group (p=0.001). This finding is consistent with Bhargava et al.8, Matega et al.9, and Rezaie et al.10, who also reported that approximately 55–60% of vaginal group patients required fewer doses, while around 60–65% of oral group patients required ≥3 doses.

Oxytocin augmentation was comparable between groups (oral: 40.0% vs vaginal: 46.0%, p=0.226), similar to Handal-Orefice et al.11 (39.6% vs 41.5%) and Mehta et al.12(42% vs 48%), indicating no significant difference in uterine response between routes.

Mode of delivery was also comparable, with vaginal delivery achieved in 57.5% (oral) vs 65.0% (vaginal), instrumental delivery in 8.0% vs 9.0%, and caesarean section in 34.5% vs 26.0% (p=0.322). Similar findings were reported by Handal-Orefice et al.11 (62% vs 64% vaginal delivery; 32% vs 21% LSCS) and Pandya et al.13 (59% vs 64%). Baseline Bishop's scores were similar (3.48 ± 0.94 vs 3.40 ± 0.92; p=0.422), while post-induction scores were significantly higher in the

vaginal group (9.72 ± 1.63 vs 8.69 ± 1.47; p=0.001), consistent with Khairnar et al.14, who also reported higher improvement in the vaginal group (9.5 ± 1.5 vs 8.4 ± 1.3).

The caesarean section rate was slightly higher in the oral group (34.5% vs 26.0%), though not significant. Fetal distress was the most common indication (MSL: 12.0% vs 6.5%; FHR abnormalities: 13.5% vs 10.0%), followed by failure to progress (5.0% vs 4.5%) and failed induction (1.0% vs 1.5%). Similar distributions were reported by Mehta et al.12, and Khairnar et al.14, where fetal distress contributed to approximately 12–20% of LSCS cases.Uterine overactivity was slightly higher in the vaginal group (3.5% vs 3.0%), consistent with findings of Handal-Orefice et al.11 and Adhikari et al.15, who also noted marginally higher hyperstimulation with vaginal administration without clinical significance.

Importantly, induction-to-active phase (7.10 ± 3.35 vs 9.02 ± 3.84 hours) and induction- to-delivery intervals (11.50 ± 3.43 vs 13.32 ± 3.98 hours) were significantly shorter in the vaginal group (p=0.001). Similar results were reported by Jindal et al. (2011) (10.2 vs 13.5 hours), Khairnar et al.14, Rezaie et al. 10 , and Matega et al.9 ,confirming faster labor progression with vaginal misoprostol.

Maternal side effects were low and comparable, with nausea/vomiting (11.5% vs 9.0%), fever (4.0% vs 6.0%), chills (5.0% vs 4.0%), and diarrhea (2.5% vs 2.0%), with no significant differences. Similar findings were reported by Mehta et al.12, Bhargava et al. 8, Sarella and Uthrakumar et al.7, and Young et al.16

Overall, our study demonstrates that both oral and vaginal misoprostol are safe and effective for induction of labor, with vaginal misoprostol showing advantages in dose efficiency, cervical ripening, and shorter labor duration, while maintaining comparable feto-maternal safety outcomes.

CONCLUSION

Based on the findings of our study, both oral and vaginal misoprostol are effective and safe methods for induction of labor (IOL). However, vaginal misoprostol demonstrated greater efficacy, as reflected by higher post-induction Bishop's scores, shorter induction-to-active phase and induction-to-delivery intervals, and a reduced number of doses required. Despite these differences in efficacy, maternal side effects and mode of delivery, were comparable between the two routes, indicating similar safety profiles. Although vaginal misoprostol showed a slightly higher tendency for uterine overactivity and oral misoprostol was associated with marginally more fetal heart rate abnormalities, these differences were not statistically significant, supporting the overall safety of both methods. Therefore, vaginal misoprostol may be considered a more effective option, particularly when rapid cervical ripening and shorter labor duration are desired, while oral misoprostol remains a safe and acceptable alternative, especially in situations where vaginal administration is less feasible or less acceptable. Further large-scale studies are recommended to refine optimal dosing regimens and validate these findings across diverse obstetric populations.

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