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Original Research Article

A comparative study between cerviprime gel and misoprostol for induction of labour in term pregnancy with unfavourable Bishop's score: a randomised controlled clinical trial

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ABSTRACT

Background: Induction of labor (IOL) is a common obstetric intervention performed when benefits outweigh risks of continuing pregnancy. Cervical ripening using prostaglandins like dinoprostone (cerviprime) and misoprostol improves induction outcomes. This study compared their efficacy in term pregnancies with unfavorable Bishop's score, evaluating induction and need for augmentation.
Methods: This randomized controlled clinical study was conducted over 18 months in the department of obstetrics and gynecology at a tertiary care centre among 100 term pregnant women (≥37 weeks) with an unfavourable Bishop's score requiring induction of labour. Participants were randomized into two groups: 50 received intravaginal misoprostol (25µg, repeated every 4 hours) and 50 received intracervical dinoprostone gel (0.5 mg, repeated every 6 hours).
Results: A total of 100 pregnant women were studied, divided between the cerviprime and misoprostol groups. The mean age was comparable (33.09±9.56 years vs. 32.54±9.57 years). The time from induction to initiation of labour was significantly shorter in the misoprostol group (≤6 hours in 82% versus 58%; $p<0.05$). Vaginal delivery occurred in 84% of misoprostol cases and 76% of cerviprime cases. Misoprostol significantly shortened the induction-delivery interval ($p<0.02$). Oxytocin augmentation was required less often with misoprostol (46% versus 60%; $p=0.16$).
Conclusions: Vaginal misoprostol demonstrated greater efficacy than intracervical dinoprostone gel (cerviprime) for labour induction in term pregnancies with unfavourable Bishop's scores, achieving shorter induction-to-delivery intervals without increasing maternal or neonatal complications, making it a safe and effective alternative.

Keywords: Bishop's score, Cerviprime, Induction of labor, Misoprostol

INTRODUCTION

Induction of labor (IOL) is one of the most frequently performed obstetric interventions worldwide, accounting for up to 22% of deliveries in India.[1] It is defined as the deliberate stimulation of uterine contractions before spontaneous labor onset to achieve vaginal delivery when continuation of pregnancy poses greater risk.[2-4] Cervical ripening is a crucial determinant of induction success, typically assessed using the Bishop score.[5] Both mechanical and pharmacologic agents are used, but prostaglandins such as dinoprostone and misoprostol remain the most effective and widely adopted.[6-9] Misoprostol, a PGE1 analogue, and cerviprime (dinoprostone gel), a PGE2 analogue, differ in pharmacodynamics, cost, and safety profile.[10-13]

The present study aims to compare the efficacy of cerviprime gel and misoprostol in term pregnancies with unfavorable Bishop's score, focusing on induction-to-delivery interval, uterine activity, cervical changes, maternal-fetal outcomes, and the need for additional augmentation measures.

METHODS

This randomized controlled clinical study was carried out in the department of obstetrics and gynecology at Government Medical College, Akola, Maharashtra, over 18 months. A total of 100 pregnant women with term gestation (≥37 weeks) and unfavourable Bishop's score requiring induction of labour were enrolled after obtaining informed consent and ethical clearance. Participants were randomly allocated into two groups: group A (n=50) received intravaginal misoprostol 25 µg, repeatable every 4 hours up to three doses, and group B (n=50) received intracervical dinoprostone gel 0.5 mg, repeatable every 6 hours as needed. Baseline clinical and laboratory parameters were recorded, and labour progress was monitored using Bishop's score and induction-to-delivery interval. Maternal outcomes (mode of delivery, postpartum hemorrhage, uterine rupture) and neonatal outcomes (Apgar score, NICU admission, fetal distress) were assessed. Data were analyzed using SPSS, and results were expressed in mean±SD, proportions, and percentages. Statistical significance was set at $p<0.05$.

RESULTS

A total of 100 pregnant women who underwent induction of labor were enrolled in the study, with 50 participants each in the cerviprime group (group A) and misoprostol group (group B). The two groups were comparable in terms of baseline demographic and obstetric characteristics such as age, parity, gestational age, indication for induction, and Bishop score at baseline.

Table 1: Baseline characteristics of study participants (n=100).

Parameters	Cerviprime group (n=50)	Misoprostol group (n=50)	P value
Mean age (years)	25.8±3.6	26.2±4.1	0.542
Mean gestational age (weeks)	38.4±1.2	38.6±1.1	0.478
Primigravida (%)	26 (52)	24 (48)	0.686
Multigravida (%)	24 (48)	26 (52)	0.686
Mean Bishop score at baseline	3.24±0.95	3.36±1.02	0.621
Indications for induction	PIH (28%), post-dated (24%), oligohydramnios (20%), PROM (18%), others (10%)	PIH (26%), post-dated (26%), oligohydramnios (18%), PROM (20%), others (10%)	-

Table 2: Labor progress parameters.

Parameters	Cerviprime (Mean±SD)	Misoprostol (Mean±SD)	P value
Induction-to-onset of labor (hours)	6.4±2.2	5.1±1.8	0.021*
Induction-to-delivery interval (hours)	9.6±2.8	8.2±2.4	0.031*
Duration of active labor (hours)	5.2±1.4	4.8±1.2	0.243

*p<0.05 statistically significant.

Both groups were comparable with respect to age, gestational age, parity, and pre-induction Bishop score ($p>0.05$).

Change in Bishop score

After 6 hours of induction, the mean Bishop score increased to 6.84±1.22 in the cerviprime group and 7.16±1.38 in the misoprostol group. Although the improvement was slightly higher in the Misoprostol group, the difference was not statistically significant ($p=0.089$). After 12 hours, the mean Bishop score rose to 9.32±1.41 in group A and 9.76±1.56 in group B. Both drugs were effective in cervical ripening, but misoprostol demonstrated a marginally faster effect.

Misoprostol led to a faster onset of labor and shorter induction-to-delivery time compared to cerviprime, indicating higher efficacy in initiating and sustaining labor.

Mode of delivery

In the cerviprime group, 82% of patients delivered vaginally, while 18% underwent cesarean section. In the misoprostol group, 86% (43 out of 50) delivered vaginally, and 14% required cesarean delivery. The difference between the two groups was not statistically significant ($p>0.05$). The most common indication for cesarean section in both groups was fetal distress, followed by failed induction. While misoprostol showed a marginally higher rate of vaginal delivery, it was associated with a slightly increased incidence of uterine tachysystole and transient fetal heart rate decelerations.

Maternal complications

Maternal side effects such as nausea, vomiting, diarrhea, fever, and uterine hyperstimulation were recorded. Uterine hyperstimulation occurred in 3 (6%) patients in the misoprostol group and 1 (2%) patient in the cerviprime

group. None of the patients in either group developed uterine rupture or postpartum hemorrhage, and no maternal mortality was reported. Overall, both induction agents were well tolerated.

Fetal outcome

The mean birth weight was comparable between the two groups (2.92±0.34 kg in group A versus 2.94±0.32 kg in group B, p>0.05). The mean Apgar score at 1 minute was 7.42±0.63 in the cerviprime group and 7.28±0.70 in the misoprostol group, and at 5 minutes it improved to 8.88±0.42 and 8.76±0.55, respectively. The difference in Apgar scores between groups was statistically insignificant.

NICU admissions were required in 3 (6%) cases in the cerviprime group and 4 (8%) in the misoprostol group, primarily due to transient respiratory distress or meconium-stained liquor.

Overall efficacy and comparison

Both cerviprime gel (dinoprostone) and misoprostol were effective for cervical ripening and labor induction. Misoprostol showed a faster onset of contractions and a shorter induction-to-delivery interval, with a slightly higher Bishop score improvement at each stage. However, it was also associated with a marginally increased risk of uterine hyperstimulation and gastrointestinal side effects.

Cerviprime, on the other hand, was associated with a slower but steadier progression of labor, fewer side effects, and a comparable vaginal delivery rate. Hence, it may be preferable in settings requiring close fetal monitoring or in women with prior uterine scars.

DISCUSSION

Induction of labour (IOL) remains one of the most frequently performed obstetric interventions worldwide, aimed at expediting delivery when continuation of pregnancy poses risks to maternal or fetal health.

In the present randomized controlled clinical study comparing intracervical dinoprostone (cerviprime) gel and vaginal misoprostol for induction of labour, both groups were demographically comparable in terms of age, parity, and gestational age. The majority of participants were between 26-35 years of age, consistent with findings from previous studies.[3,14]

Regarding the induction-to-onset of labour interval, misoprostol demonstrated a significantly faster action. In the present study, 82% of women in the misoprostol group entered labour within 6 hours compared to 58% in the cerviprime group (p=0.008). This finding aligns with the observations of Suman et al and Gupta, both of whom reported a higher proportion of women achieving labour onset within 6 hours following misoprostol induction.[3,15]

The rapid cervical response can be attributed to the pharmacological profile of misoprostol, which promotes strong uterotonic effects and efficient cervical softening.

The mode of delivery was comparable in both groups, with the majority achieving vaginal delivery, 84% in the misoprostol group and 76% in the cerviprime group (p=0.31). These results concur with those of Sinha et al and Suman et al, who reported similar vaginal delivery rates with both prostaglandin agents.[3,14] Although the difference was not statistically significant, misoprostol was associated with a slightly higher rate of successful vaginal deliveries and a reduced requirement for operative interventions.

The induction-to-delivery interval was significantly shorter in the Misoprostol group (p=0.02), with a larger proportion of participants delivering within 12-24 hours. These findings are consistent with previous reports by Parmar et al and Swapna et al, which demonstrated that vaginal misoprostol achieved a faster induction-to-delivery interval compared to dinoprostone gel.[16,17] Shorter induction intervals are desirable, as they reduce maternal fatigue, healthcare resource utilization, and the risk of intrapartum complications.

With respect to caesarean section indications, non-progression of labour and fetal distress were the leading causes in both groups, similar to findings by Suman et al.[3] Although the LSCS rate was slightly higher in the cerviprime group (24%) compared to the misoprostol group (16%), the difference was not statistically significant (p=0.97). This suggests that the choice of induction agent does not significantly alter the caesarean section rate but may influence the duration and quality of labour progression.

The maternal complication profile was mild and comparable between groups (p=0.907). Nausea, vomiting, and uterine hyperstimulation were the most commonly reported events, particularly with misoprostol, though these were self-limiting and manageable. Similar findings were reported by Parmar et al, confirming the safety of both agents in routine obstetric practice.[16] Importantly, there were no cases of postpartum hemorrhage, uterine rupture, or maternal death, underscoring the clinical safety of both induction methods when appropriately monitored.

The fetal outcomes were favourable in both groups. While NICU admissions were slightly higher in the misoprostol group (16% versus 6%), this difference was not statistically significant (p=0.158). Apgar scores and neonatal mortality rates were comparable, consistent with studies by Sinha et al and Swapna et al, which also reported no significant differences in neonatal outcomes between induction agents.[14,17]

Overall, the findings of this study demonstrate that both dinoprostone gel and misoprostol are effective and safe for labour induction in women with an unfavourable cervix.

However, misoprostol offers the advantages of faster onset of labour, shorter induction-to-delivery interval, and higher rates of vaginal delivery, without compromising maternal or fetal safety. These results support the growing preference for misoprostol as a first-line agent for cervical ripening and induction, particularly in resource-constrained settings where cost and storage stability are crucial considerations.

CONCLUSION

The present study highlights the comparative efficacy and safety of intracervical dinoprostone gel (cerviprime) and vaginal misoprostol for induction of labour in term pregnancies with an unfavourable Bishop's score. Vaginal misoprostol significantly reduced the induction-to-labour and induction-to-delivery intervals and achieved a higher proportion of vaginal deliveries within 24 hours, indicating superior effectiveness in cervical ripening and labour initiation. Cerviprime required more frequent oxytocin augmentation, suggesting slower labour progression. Thus, vaginal misoprostol can be considered a more effective, economical, and practical agent for induction of labour in appropriately selected term pregnancies.

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