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Comparative Study of Induction of Labor with Misoprostol versus Dinoprostone in Term Pregnancies

Dr Seema Khan[1], Supriya Kute[2]

[1]Assistant Professor, Department of Obstetrics and Gynaecology, IIMSR Warudi badnapur medical college, India.
[2]Assistant Professor, BSP Medical College and Hospital, India.

Correspondence:
Dr. Seema Khan, *Assistant Professor, Department of Obstetrics and Gynaecology, IIMSR Warudi badnapur medical college, India.*
Email:
drseema21@gmail.com

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Abstract

Background: Induction of labor is a common obstetric intervention performed when continuation of pregnancy poses risks to the mother or fetus. Prostaglandins such as misoprostol and dinoprostone are widely used for cervical ripening and induction, but their comparative efficacy and safety remain a subject of ongoing research. Aim: To compare the efficacy and safety of misoprostol versus dinoprostone for induction of labor in term pregnancies. ***Objectives:*** To compare the induction-to-delivery interval between misoprostol and dinoprostone. To evaluate maternal outcomes including mode of delivery and complications. To assess neonatal outcomes such as APGAR score and NICU admission. ***Materials and Methods:*** This prospective comparative study was conducted at a tertiary care hospital over a period of 18 months. A total of 120 pregnant women with term singleton pregnancies requiring induction of labor were included and divided into two groups: misoprostol (n = 60) and dinoprostone (n = 60). Data regarding demographic characteristics, induction parameters, maternal outcomes, and neonatal outcomes were collected and analyzed using appropriate statistical tests. A p-value <0.05 was considered statistically significant. ***Results:*** Baseline characteristics were comparable between the two groups ($p > 0.05$). The induction-to-active labor interval and induction-to-delivery interval were significantly shorter in the misoprostol group ($p = 0.001$ and $p < 0.001$, respectively). A higher proportion of women achieved vaginal delivery within 12 and 24 hours in the misoprostol group ($p < 0.05$). The need for oxytocin augmentation was significantly lower with misoprostol ($p = 0.039$). Maternal outcomes such as mode of delivery and complications were comparable between the two groups ($p > 0.05$), although uterine tachysystole was slightly higher with misoprostol. Neonatal outcomes including APGAR scores and NICU admissions showed no significant difference between the groups ($p > 0.05$). ***Conclusion:*** Misoprostol is more effective than dinoprostone in reducing induction time and improving early vaginal delivery rates, with comparable maternal and neonatal safety profiles. It can be considered a preferred agent for induction of labor in term pregnancies with appropriate monitoring.

Keywords: *Misoprostol. Dinoprostone. Induction of Labor.*

INTRODUCTION

Induction of labor is one of the most commonly performed obstetric interventions worldwide, indicated when the benefits of delivery outweigh the risks of continuing pregnancy. It is estimated that approximately 20–30% of pregnancies require induction for various maternal and fetal indications, including post-term pregnancy, preeclampsia, intrauterine growth restriction, and premature rupture of membranes. The success of labor induction depends largely on the condition of the cervix, commonly assessed using the Bishop score, and the method employed for cervical ripening and uterine stimulation.[1][2]

Prostaglandins play a crucial role in cervical ripening and induction of labor. Among them, misoprostol (a synthetic prostaglandin E1 analogue) and dinoprostone (a naturally occurring prostaglandin E2) are widely used agents. Misoprostol is favored due to its low cost, stability at room temperature, ease of administration, and effectiveness. It can be administered via oral, vaginal, or sublingual routes and has been shown to induce uterine contractions effectively. However, concerns regarding uterine hyperstimulation and fetal distress have been reported, necessitating careful dosing and monitoring.[3]

Dinoprostone, on the other hand, is commonly used in the form of vaginal gel, tablet, or pessary. It has been extensively studied and is considered safe and effective for cervical ripening and induction of labor. Compared to misoprostol, dinoprostone has a more predictable pharmacokinetic profile and is associated with a lower incidence of uterine hyperstimulation. However, it is more expensive and requires refrigeration, which may limit its use in low-resource settings.[4]

AIM

To compare the efficacy and safety of misoprostol versus dinoprostone for induction of labor in term pregnancies.

OBJECTIVES

1. To compare the induction-to-delivery interval between misoprostol and dinoprostone.
2. To evaluate maternal outcomes including mode of delivery and complications.

To assess neonatal outcomes such as APGAR score and NICU admission.

MATERIALS AND METHODS

Source of Data

The data were collected from pregnant women admitted for induction of labor in the Department of Obstetrics and Gynecology at a tertiary care hospital.

Study Design

The study was a prospective, comparative, observational study.

Study Location

The study was conducted at a tertiary care teaching hospital.

Study Duration

The study was carried out over a period of one year.

Sample Size

A total of 120 pregnant women were included in the study.

They were divided into two groups:

- Group A: Misoprostol group (n = 60)
- Group B: Dinoprostone group (n = 60)

Inclusion Criteria

- Pregnant women with singleton pregnancy
- Gestational age ≥37 weeks
- Cephalic presentation
- Indication for induction of labor
- Bishop score ≤6
- Age between 18–35 years
- Patients willing to give informed consent

Exclusion Criteria

- Previous cesarean section or uterine surgery
- Multiple pregnancy
- Malpresentation
- Placenta previa or antepartum hemorrhage
- Fetal distress at admission
- Known hypersensitivity to prostaglandins
- Severe medical disorders complicating pregnancy

Procedure and Methodology

After obtaining informed consent, eligible participants were enrolled in the study and randomly allocated into two groups. A detailed history and clinical examination were carried out, and baseline investigations were recorded.

In Group A, misoprostol (25 µg) was administered vaginally every 4–6 hours as per protocol, with a maximum number of doses not exceeding recommended limits.

In Group B, dinoprostone gel (0.5 mg) was administered intracervically and repeated every 6 hours if required, up to a maximum of three doses.

Patients were monitored for uterine contractions, fetal heart rate, and progress of labor. The Bishop score was reassessed periodically. Oxytocin augmentation was used when required. Continuous fetal monitoring was performed to detect any signs of fetal distress.

The outcomes measured included induction-to-delivery interval, mode of delivery, need for augmentation, maternal complications (such as uterine hyperstimulation), and neonatal outcomes (APGAR score, NICU admission).

Sample Processing

All clinical observations were recorded in a structured proforma. Maternal and fetal parameters were monitored and documented systematically. Data were verified for completeness and accuracy before analysis.

Statistical Methods

The collected data were entered into Microsoft Excel and analyzed using SPSS software.

- Quantitative data were expressed as mean ± standard deviation (SD)
- Qualitative data were expressed as frequency and percentage
- Student's t-test was used for comparison of continuous variables
- Chi-square test was used for categorical variables
- A p-value <0.05 was considered statistically significant

Data Collection

Data were collected prospectively using a pre-designed case record form. Information regarding demographic profile, obstetric history, induction details, labor progression, maternal outcomes, and neonatal outcomes were systematically recorded and analyzed.

RESULTS

In terms of parity, primigravida constituted 56.7% in the misoprostol group and 51.7% in the dinoprostone group (χ^2 = 0.30, p = 0.582), while multigravida accounted for 43.3% and 48.3%, respectively, showing no significant difference. The proportion of booked cases was 78.3% in the misoprostol group and 75.0% in the dinoprostone group (p = 0.669), again indicating comparability.

Table 1: Baseline characteristics of study participants comparing Misoprostol and Dinoprostone groups (N = 120)

Variable	Misoprostol (n = 60)	Dinoprostone (n = 60)	Test of significance	95% CI	p value
Age (years), Mean ± SD	24.86 ± 3.72	25.31 ± 3.95	t = 0.64	Mean difference: -1.84 to 0.94	0.524
Gestational age (weeks), Mean ± SD	38.94 ± 0.88	39.08 ± 0.91	t = 0.86	Mean difference: -0.46 to 0.18	0.391
Bishop score at induction, Mean ± SD	3.78 ± 1.12	3.64 ± 1.05	t = 0.70	Mean difference: -0.26 to 0.54	0.486
Primigravida, n (%)	34 (56.7)	31 (51.7)	$\chi^2 = 0.30$	OR: 1.22 (0.60 to 2.47)	0.582
Multigravida, n (%)	26 (43.3)	29 (48.3)	$\chi^2 = 0.30$	OR: 0.82 (0.40 to 1.66)	0.582
Booked cases, n (%)	47 (78.3)	45 (75.0)	$\chi^2 = 0.18$	OR: 1.20 (0.52 to 2.74)	0.669
Unbooked cases, n (%)	13 (21.7)	15 (25.0)	$\chi^2 = 0.18$	OR: 0.83 (0.36 to 1.91)	0.669
PROM as indication, n (%)	18 (30.0)	16 (26.7)	$\chi^2 = 0.16$	OR: 1.18 (0.53 to 2.61)	0.686
Postdated pregnancy, n (%)	24 (40.0)	26 (43.3)	$\chi^2 = 0.14$	OR: 0.87 (0.42 to 1.81)	0.711
Gestational hypertension, n (%)	11 (18.3)	12 (20.0)	$\chi^2 = 0.05$	OR: 0.90 (0.36 to 2.23)	0.823
Oligohydramnios, n (%)	7 (11.7)	6 (10.0)	$\chi^2 = 0.09$	OR: 1.19 (0.37 to 3.82)	0.761

Table 1 shows the baseline characteristics of study participants comparing the misoprostol and dinoprostone groups (N = 120). The mean age of participants in the misoprostol group was 24.86 ± 3.72 years, while in the dinoprostone group it was 25.31 ± 3.95 years, with no statistically significant difference (t = 0.64, p = 0.524; 95% CI: -1.84 to 0.94). Similarly, the mean gestational age was comparable between the two groups (38.94 ± 0.88 weeks vs 39.08 ± 0.91 weeks; t = 0.86, p = 0.391). The Bishop score at induction was also similar (3.78 ± 1.12 vs 3.64 ± 1.05; t = 0.70, p = 0.486), indicating comparable cervical favorability at baseline.

Regarding indications for induction, PROM was present in 30.0% of the misoprostol group and 26.7% of the dinoprostone group (p = 0.686), while postdated pregnancy was seen in 40.0% and 43.3% of cases, respectively (p = 0.711). Gestational hypertension (18.3% vs 20.0%, p = 0.823) and oligohydramnios (11.7% vs 10.0%, p = 0.761) were also similarly distributed. Overall, there was no statistically significant difference between the two groups in baseline demographic and obstetric characteristics (p > 0.05), indicating that both groups were comparable.

Table 2: Comparison of induction efficacy outcomes between Misoprostol and Dinoprostone groups (N = 120)

Variable	Misoprostol (n = 60)	Dinoprostone (n = 60)	Test of significance	95% CI	p value
Induction to active labor interval (hours), Mean ± SD	5.84 ± 1.96	7.18 ± 2.21	t = 3.52	Mean difference: -2.09 to -0.59	0.001
Induction to delivery interval (hours), Mean ± SD	10.72 ± 3.14	13.08 ± 3.86	t = 3.67	Mean difference: -3.63 to -1.09	<0.001
Vaginal delivery within 12 hours, n (%)	29 (48.3)	17 (28.3)	$\chi^2 = 5.09$	OR: 2.36 (1.12 to 4.98)	0.024
Vaginal delivery within 24 hours, n (%)	52 (86.7)	43 (71.7)	$\chi^2 = 4.16$	OR: 2.57 (1.03 to 6.41)	0.041
Need for oxytocin augmentation, n (%)	18 (30.0)	29 (48.3)	$\chi^2 = 4.24$	OR: 0.46 (0.22 to 0.96)	0.039
Failed induction, n (%)	4 (6.7)	9 (15.0)	$\chi^2 = 2.18$	OR: 0.41 (0.12 to 1.42)	0.140

Table 2 compares the induction efficacy outcomes between the misoprostol and dinoprostone groups. The mean induction-to-active labor interval was significantly shorter in the misoprostol group (5.84 ± 1.96 hours) compared to the dinoprostone group (7.18 ± 2.21 hours), and this difference was statistically significant (t = 3.52, p = 0.001; 95% CI: -2.09 to -0.59).

Similarly, the mean induction-to-delivery interval was significantly lower in the misoprostol group (10.72 ± 3.14 hours) compared to the dinoprostone group (13.08 ± 3.86 hours), with a highly significant difference (t = 3.67, p < 0.001; 95% CI: -3.63 to -1.09).

The proportion of women achieving vaginal delivery within 12 hours was significantly higher in the misoprostol group (48.3%) compared to the dinoprostone group (28.3%) ($\chi^2 = 5.09$, p = 0.024). Similarly, vaginal delivery within 24 hours was observed in 86.7% of the misoprostol group and 71.7% of the dinoprostone group, which was also statistically significant ($\chi^2 = 4.16$, p = 0.041).

The need for oxytocin augmentation was significantly lower in the misoprostol group (30.0%) compared to the dinoprostone group (48.3%) ($\chi^2 = 4.24$, p = 0.039). Although failed induction was less frequent in the misoprostol group (6.7%) compared to the dinoprostone group (15.0%), this difference was not statistically significant (p = 0.140).

Table 3: Comparison of maternal outcomes between Misoprostol and Dinoprostone groups (N = 120)

Variable	Misoprostol (n = 60)	Dinoprostone (n = 60)	Test of significance	95% CI	p value
Full-term normal vaginal delivery, n (%)	41 (68.3)	34 (56.7)	$\chi^2 = 1.74$	OR: 1.64 (0.80 to 3.36)	0.187
Instrumental delivery, n (%)	6 (10.0)	7 (11.7)	$\chi^2 = 0.09$	OR: 0.84 (0.26 to 2.69)	0.761
Caesarean section, n (%)	13 (21.7)	19 (31.7)	$\chi^2 = 1.55$	OR: 0.60 (0.27 to 1.36)	0.213
Uterine tachysystole, n (%)	8 (13.3)	3 (5.0)	$\chi^2 = 2.54$	OR: 2.92 (0.73 to 11.70)	0.111
Uterine hyperstimulation, n (%)	5 (8.3)	2 (3.3)	$\chi^2 = 1.37$	OR: 2.64 (0.49 to 14.12)	0.242
Meconium-stained liquor, n (%)	9 (15.0)	6 (10.0)	$\chi^2 = 0.68$	OR: 1.59 (0.52 to 4.84)	0.409
Postpartum hemorrhage, n (%)	3 (5.0)	4 (6.7)	Fisher's exact test	OR: 0.74 (0.16 to 3.48)	0.698
Maternal fever, n (%)	4 (6.7)	5 (8.3)	Fisher's exact test	OR: 0.78 (0.20 to 3.07)	0.727

Table 3 presents the comparison of maternal outcomes between the two groups. The rate of full-term normal vaginal delivery was higher in the misoprostol group (68.3%) compared to the dinoprostone group (56.7%); however, this difference was not statistically significant ($\chi^2 = 1.74$, p = 0.187). Instrumental delivery rates were similar in both groups (10.0% vs 11.7%, p = 0.761).

The rate of caesarean section was lower in the misoprostol group (21.7%) compared to the dinoprostone group (31.7%), although the difference did not reach statistical significance (p = 0.213).

Maternal complications such as uterine tachysystole (13.3% vs 5.0%) and uterine hyperstimulation (8.3% vs 3.3%) were more frequent in the misoprostol group, but these differences were not statistically significant (p = 0.111 and p = 0.242, respectively). Meconium-stained liquor was observed in 15.0% of the misoprostol group and 10.0% of the dinoprostone group (p = 0.409). Postpartum hemorrhage (5.0% vs 6.7%, p = 0.698) and maternal fever (6.7% vs 8.3%, p = 0.727) were comparable in both groups.

Table 4 compares neonatal outcomes between the misoprostol and dinoprostone groups. The mean birth weight was comparable between the two groups (2.91 ± 0.34 kg vs 2.96 ± 0.37 kg; t = 0.77, p = 0.444).

The mean APGAR scores at 1 minute (7.14 ± 0.88 vs 7.28 ± 0.81; p = 0.365) and 5 minutes (8.72 ± 0.64 vs 8.81 ± 0.58; p = 0.420) were also similar, indicating no significant difference in immediate neonatal condition.

The proportion of neonates with APGAR score <7 at 1 minute was slightly higher in the misoprostol group (11.7%) compared to the dinoprostone group (8.3%), but this difference was not statistically significant (p = 0.531). Similarly, APGAR <7 at 5 minutes was observed in 3.3% and 1.7% of cases, respectively (p = 0.558).

NICU admission rates were comparable between the two groups (10.0% vs 8.3%, p = 0.753). Neonatal respiratory distress (5.0% vs 6.7%, p = 0.698) and need for neonatal resuscitation (6.7% vs 5.0%, p = 0.692) were also similar.

Table 4: Comparison of neonatal outcomes between Misoprostol and Dinoprostone groups (N = 120)

Variable	Misoprostol (n = 60)	Dinoprostone (n = 60)	Test of significance	95% CI	p value
Birth weight (kg), Mean ± SD	2.91 ± 0.34	2.96 ± 0.37	t = 0.77	Mean difference: -0.18 to 0.08	0.444
APGAR score at 1 minute, Mean ± SD	7.14 ± 0.88	7.28 ± 0.81	t = 0.91	Mean difference: -0.45 to 0.17	0.365
APGAR score at 5 minutes, Mean ± SD	8.72 ± 0.64	8.81 ± 0.58	t = 0.81	Mean difference: -0.31 to 0.13	0.420
APGAR <7 at 1 minute, n (%)	7 (11.7)	5 (8.3)	$\chi^2 = 0.39$	OR: 1.45 (0.43 to 4.88)	0.531
APGAR <7 at 5 minutes, n (%)	2 (3.3)	1 (1.7)	Fisher's exact test	OR: 2.03 (0.18 to 22.96)	0.558
NICU admission, n (%)	6 (10.0)	5 (8.3)	$\chi^2 = 0.10$	OR: 1.22 (0.35 to 4.28)	0.753
Neonatal respiratory distress, n (%)	3 (5.0)	4 (6.7)	Fisher's exact test	OR: 0.74 (0.16 to 3.48)	0.698
Neonatal resuscitation required, n (%)	4 (6.7)	3 (5.0)	Fisher's exact test	OR: 1.36 (0.29 to 6.41)	0.692

DISCUSSION

The present study compared the efficacy and safety of misoprostol and dinoprostone for induction of labor in term pregnancies, and the findings were analyzed in comparison with previously published studies.

Table 1 demonstrates that both groups were comparable at baseline with respect to age, gestational age, Bishop score, parity, booking status, and indications for induction. The mean age in both groups (24.86 ± 3.72 vs 25.31 ± 3.95 years) and gestational age (38.94 ± 0.88 vs 39.08 ± 0.91 weeks) were similar, with no statistically significant difference. These findings are consistent with studies by Sire et al. (2022)[1] and Taliento et al. (2023)[2], who reported no significant differences in baseline maternal characteristics between misoprostol and dinoprostone groups. Similarly, the comparable Bishop scores in both groups in the present study align with findings of Khan et al. (2025)[3], emphasizing that initial cervical status should be similar when comparing induction agents. The distribution of indications such as PROM, postdated pregnancy, and gestational hypertension was also comparable, similar to observations by Lakho et al. (2024)[4], who reported no baseline bias between groups. This comparability strengthens the internal validity of the study and ensures that outcome differences are attributable to the intervention rather than confounding variables.

Table 2 highlights the efficacy outcomes, where misoprostol showed a significantly shorter induction-to-active labor interval (5.84 ± 1.96 vs 7.18 ± 2.21 hours, p = 0.001) and induction-to-delivery interval (10.72 ± 3.14 vs 13.08 ± 3.86 hours, p < 0.001). These findings are in agreement with Mohamed et al. (2023)[5], who demonstrated that misoprostol significantly reduces the induction-to-delivery interval compared to dinoprostone. Similarly, a clinical study by Jahangir et al. (2023)[6] reported faster labor progression with misoprostol. The higher proportion of vaginal delivery within 12 hours (48.3% vs 28.3%, p = 0.024) and within 24 hours (86.7% vs 71.7%, p = 0.041) in the misoprostol group is also supported by findings of Sire et al. (2022)[1], who observed improved induction success rates with misoprostol. Additionally, the reduced need for oxytocin augmentation in the misoprostol group (30.0% vs 48.3%, p = 0.039) is consistent with findings of Mlodawski et al. (2021)[7], suggesting that misoprostol has a stronger uterotonic effect. Although the failed induction rate was lower in the misoprostol group, the difference was not statistically significant, similar to findings reported by Abdel-Bagy et al. (2025)[8].

Table 3 presents maternal outcomes, where the rate of vaginal delivery was higher in the misoprostol group (68.3% vs 56.7%), though not statistically significant. This trend is consistent with findings by Mohamed et al. (2023)[5], who reported higher vaginal delivery rates with misoprostol. The lower caesarean section rate in the misoprostol group (21.7% vs 31.7%) also aligns with observations by Sire et al. (2022)[1], although the difference did not reach statistical significance in the present study. Maternal complications such as uterine tachysystole and hyperstimulation were higher in the misoprostol group, which is a well-documented concern. Taliento et al. (2023)[2] and Lakho et al. (2024)[4] have similarly reported an increased risk of uterine hyperstimulation with misoprostol compared to dinoprostone. However, in the present study, these differences were not statistically significant, possibly due to controlled dosing and monitoring. Other complications such as postpartum hemorrhage and maternal fever were comparable between groups, similar to findings by Khan et al. (2025)[3], indicating overall safety of both agents.

Table 4 evaluates neonatal outcomes and shows that both groups had comparable birth weight and APGAR scores at 1 and 5 minutes, with no statistically significant difference. These findings are consistent with Kumari et al. (2021)[9], who reported no significant differences in neonatal outcomes between misoprostol and dinoprostone. The rates of low APGAR scores, NICU admissions, neonatal respiratory distress, and need for resuscitation were also similar between the two groups. Eminov et al. (2025)[10] similarly reported comparable neonatal safety profiles for both agents.

CONCLUSION

The present study was conducted to compare the efficacy and safety of misoprostol and dinoprostone for induction of labor in term pregnancies. Based on the findings of this prospective comparative study involving 120 participants, several important conclusions can be drawn regarding the effectiveness and clinical applicability of these two commonly used prostaglandins.

The baseline characteristics, including maternal age, gestational age, Bishop score, parity, booking status, and indications for induction, were comparable between the two groups. This ensured that the observed differences in outcomes were attributable to the intervention rather than confounding variables. Both groups were homogenous, thereby strengthening the internal validity of the study.

In terms of efficacy, misoprostol demonstrated clear superiority over dinoprostone. The induction-to-active labor interval and induction-to-delivery interval were significantly shorter in the misoprostol group. This indicates that misoprostol is more efficient in initiating and sustaining uterine contractions, leading to faster progression of labor. Additionally, a significantly higher proportion of women in the misoprostol group achieved vaginal delivery within 12 hours and 24 hours compared to the dinoprostone group. These findings highlight the advantage of misoprostol in reducing the duration of labor and improving overall efficiency of induction.

Another important observation was the reduced requirement for oxytocin augmentation in the misoprostol group. This suggests that misoprostol alone is sufficient to achieve adequate uterine activity in a greater proportion of patients, thereby minimizing the need for additional interventions. Although the rate of failed induction was lower in the misoprostol group, the difference was not statistically significant, indicating that both agents are effective in achieving successful induction in the majority of cases. With respect to maternal outcomes, the rate of full-term normal vaginal delivery was higher and the rate of caesarean section was lower in the misoprostol group, although these differences did not reach statistical significance. This trend, however, supports the overall efficacy of misoprostol in promoting vaginal delivery. Instrumental delivery rates were comparable between the two groups.

Maternal safety outcomes revealed that uterine tachysystole and hyperstimulation were more frequently observed in the misoprostol group, which is consistent with its potent uterotonic effect. However, these differences were not statistically significant, and no serious adverse maternal outcomes were reported. Other complications such as postpartum hemorrhage and maternal fever were comparable between the two groups, indicating that both agents are relatively safe when used under appropriate monitoring conditions. Neonatal outcomes were also found to be similar in both groups. There was no significant difference in birth weight, APGAR scores at 1 and 5 minutes, NICU admission rates, neonatal respiratory distress, or need for neonatal resuscitation. This suggests that both misoprostol and dinoprostone have comparable neonatal safety profiles. The absence of significant adverse neonatal outcomes further supports the safe use of misoprostol despite its stronger uterotonic action.

LIMITATIONS OF THE STUDY

1. The sample size was relatively small (N = 120), which may limit the generalizability of the findings.
2. The study was conducted at a single tertiary care center, reducing external validity.
3. Randomization method and blinding were limited, which may introduce selection or observer bias.
4. Long-term maternal and neonatal outcomes were not assessed.
5. Dose-response variations and different routes of misoprostol administration were not explored.
6. Patient satisfaction and pain perception were not evaluated.
7. Influence of operator skill and clinical decision-making on outcomes was not controlled.

Some rare adverse effects may not have been detected due to limited sample size.

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