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Misoprostol use for induction of labor at term: dose patterns, time-to-delivery, and complications. A prospective observational study.

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Abstract

Background
Misoprostol is widely used for induction of labor at term because it is inexpensive, stable at room temperature, and effective for cervical ripening.

Objectives
To assess dose patterns, induction-to-delivery interval, delivery outcomes, and maternal and neonatal complications among women induced with misoprostol at term.

Methods
This hospital-based observational study included 100 term pregnant women induced with misoprostol at a tertiary care teaching hospital from April 2025 to November 2025. Baseline characteristics, indication for induction, number of doses, total dose, time to delivery, mode of delivery, and complications were recorded and analyzed descriptively.

Results
Most women were 21-30 years old, and 56% were primigravida. Postdated pregnancy was the commonest indication. Two doses were most frequently required, and the mean total dose was 63.5 ± 22.4 µg. The mean induction-to-delivery interval was 11.6 ± 4.8 hours and was longer in primigravida than multigravida women. Normal vaginal delivery occurred in 72%, instrumental vaginal delivery in 8%, and cesarean delivery in 20%, yielding an overall vaginal delivery rate of 80%. Uterine tachysystole occurred in 7%, hyperstimulation in 3%, postpartum hemorrhage in 4%, and NICU admission in 8%.

Conclusion
Misoprostol induction at term showed good effectiveness with an acceptable safety profile in routine tertiary care practice. Most women achieved vaginal delivery within a clinically reasonable interval, and serious maternal or neonatal complications were uncommon.

Recommendations
Misoprostol may be considered a safe and effective agent for induction of labor at term when used with appropriate dosing and monitoring. Further multicentric studies with larger sample sizes are recommended to establish optimal protocols and strengthen evidence-based clinical guidelines.

Keywords: induction of labor; misoprostol; term pregnancy; vaginal delivery; cesarean section; maternal complications.
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Introduction.

Induction of labor is one of the most frequently performed obstetric interventions when the anticipated maternal or fetal benefit of delivery exceeds the benefit of continuing pregnancy. At term, induction is commonly undertaken for postdated pregnancy, hypertensive disorders, oligohydramnios, and rupture of membranes, among other accepted indications. The effectiveness of induction depends not only on the indication and parity, but also on cervical favorability, route of drug administration, dosing schedule, and ongoing intrapartum surveillance. In modern obstetric practice, the choice of an induction agent therefore requires a balance between timely achievement of vaginal delivery and avoidance of excessive uterine activity or fetal compromise [1-5]. Accurate local outcome data can therefore improve counseling, protocol refinement, and audit-based quality improvement.

Misoprostol, a prostaglandin E1 analogue, has become an important pharmacologic option for cervical ripening and induction of labor because it is inexpensive, heat stable, easy to store, and widely available. Over the last two decades, randomized trials and systematic reviews have shown that misoprostol is an effective induction agent and, in many clinical settings, shortens the interval from induction to delivery when compared with oxytocin or dinoprostone [2-7]. At the same time, the literature has consistently emphasized that the route and dose of misoprostol are clinically important. Higher vaginal doses can increase uterine tachysystole and hyperstimulation, whereas lower-dose regimens tend to offer a more favorable safety profile while maintaining acceptable efficacy [2-5,8-12].

Comparative studies evaluating oral and vaginal regimens have also shown that induction outcomes vary according to dose interval, parity, and institutional protocol [4,5,11-14]. Although evidence from randomized studies is robust, real-world hospital-based observational data remain valuable because induction outcomes in routine practice are shaped by patient case-mix, monitoring standards, staffing patterns, and local clinical thresholds for operative intervention. Such data are especially relevant in tertiary care teaching hospitals in India, where both high patient load and diverse obstetric indications influence induction practices. Observational evidence from such settings also helps clinicians benchmark institution-specific performance indicators such as time-to-delivery, vaginal delivery rates, and complication frequency after protocol-based induction.

The present study was undertaken to describe the pattern of misoprostol use for induction of labor at term in a tertiary care setting and to document clinically relevant outcomes in routine practice. The objectives of the study were to evaluate the dose pattern of misoprostol administration, assess the induction-to-delivery interval, determine the mode of delivery, and analyze maternal and neonatal complications associated with induction of labor at term.

Methodology.

Study design and setting.

This study was a hospital-based prospective observational study conducted in the Department of Obstetrics and Gynecology at RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, India, a tertiary care teaching hospital serving both urban and rural populations. The institution is equipped to provide comprehensive obstetric and neonatal services, including antenatal care, intrapartum monitoring, operative delivery, emergency cesarean section, and neonatal resuscitation.

The study was carried out over an eight-month period from April 2025 to November 2025. Consecutive eligible women undergoing induction of labor at term with misoprostol during the study period were enrolled until the final sample size of 100 participants was achieved. The study was planned to observe and document misoprostol use in routine clinical practice, without allocation into comparison groups or intervention arms. All recruited participants were managed according to standard institutional obstetric protocols.

Study population.

Pregnant women with singleton, live, cephalic pregnancies at or beyond 37 completed weeks of gestation who required induction of labor and were considered suitable for misoprostol-based induction were included. Women with severe cephalopelvic disproportion, malpresentation, non-reassuring fetal status at admission, antepartum hemorrhage, placenta previa, or a known contraindication to vaginal delivery were excluded. Women with a previous uterine scar were not considered for misoprostol induction under the institutional protocol.

Sample size determination.

The sample size was calculated using the formula for estimation of a single proportion:

$$n = Z^2 \times p \times q / d^2$$

where:
n = required sample size

Z = standard normal deviate at 95% confidence level = 1.96
p = expected proportion of successful induction from previous literature
q = 1 – p

d = allowable error

Assuming the expected proportion of successful induction to be 50% for maximum sample size estimation, with 95% confidence level and 10% absolute precision:

$$n = (1.96)^2 \times 0.5 \times 0.5 / (0.1)^2$$

$$n = 96.04$$

Thus, the minimum required sample size was approximately 96, which was rounded to 100 participants for convenience and to improve the robustness of the analysis.

Induction protocol and intrapartum monitoring.

After baseline obstetric assessment, participants underwent induction with low-dose vaginal misoprostol as per hospital protocol. A 25 µg dose was placed in the posterior vaginal fornix and repeated at 4- to 6-hour intervals according to cervical response, uterine activity, and fetal heart rate monitoring. Further doses were withheld once adequate uterine contractions were established or if safety concerns such as tachysystole or non-reassuring fetal heart rate changes arose. Maternal pulse, blood pressure, uterine contractions, fetal heart rate pattern, and labor progress were monitored throughout induction and active labor in accordance with standard obstetric care [1,3-5].

Data collection and outcome measures.

Data were obtained from labor room records, case sheets, induction charts, and neonatal records using a structured proforma. Variables recorded included maternal age, gravidity, gestational age, indication for induction, number of misoprostol doses received, estimated total dose administered, induction-to-delivery interval, and mode of delivery. Maternal outcomes included uterine tachysystole, hyperstimulation syndrome, postpartum hemorrhage, and fever or gastrointestinal symptoms. Neonatal outcomes included Apgar score below 7 at 1 minute, Apgar score below 7 at 5 minutes, and need for NICU admission. The primary effectiveness outcomes were dose pattern, time-to-delivery, and successful vaginal delivery. The primary safety outcomes were maternal complications and early neonatal condition.

Bias control.

To reduce bias, consecutive eligible pregnant women meeting the inclusion criteria were enrolled during the study period. Uniform inclusion and exclusion criteria were applied to all participants. Clinical assessment, induction protocol, intrapartum monitoring, and outcome recording were performed using a structured proforma and standard departmental guidelines. Selection bias was minimized by consecutive recruitment, while information bias was reduced through prospective data collection and consistent documentation of maternal and neonatal outcomes.

Statistical analysis.

Data were entered into a spreadsheet and analyzed using descriptive statistical methods. Continuous variables were summarized as mean ± standard deviation, whereas categorical variables were expressed as frequencies and percentages. The induction-to-delivery interval was additionally described according to gravidity in order to present parity-related clinical differences. Because the objective of the study was to provide an observational profile of routine induction practice, the analysis was primarily descriptive.

Ethical considerations.

The study protocol was reviewed and approved by the Institutional Ethics Committee of RVM Institute of Medical Sciences and Research Centre, Laxmakkapally, Telangana, India, prior to the commencement of the study. Written informed consent was obtained from all participants before enrollment. Confidentiality of patient information was strictly maintained throughout data collection and analysis. No identifying patient information was retained in the final dataset, and all records were handled anonymously. The study was conducted in accordance with accepted ethical principles for clinical observational research and adhered to the ethical standards outlined in the Declaration of Helsinki.

Results.

Participant flow.

During the study period, 126 pregnant women admitted for induction of labor at term were screened for eligibility. Of these, 14 women were excluded before enrolment: 5 had a previous cesarean section, 3 had malpresentation, 2 had cephalopelvic disproportion, 2 had fetal distress at admission, 1 had placenta previa, and 1 declined participation. The remaining 112 women fulfilled the eligibility criteria and were enrolled in the study.

Among the 112 enrolled participants, 12 were excluded from the final analysis because of incomplete clinical data, referral before completion of delivery management, or deviation from the induction protocol. Finally, 100 women were included in the analysis.

A total of 100 women who underwent induction of labor at term with misoprostol were included in the final analysis. The results are presented as counts and percentages for categorical variables and mean ± standard deviation for continuous variables.

Most participants were 21-30 years old, accounting for 62.0% of the cohort, while 56.0% were primigravida. The mean gestational age at induction was 39.1 ± 1.2 weeks. Postdated pregnancy was the leading indication for induction (34.0%), followed by pregnancy-induced hypertension (22.0%), oligohydramnios (16.0%), premature rupture of membranes (14.0%), and other indications (14.0%). These baseline obstetric and clinical characteristics are summarized in Table 1.

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Table 1. Baseline obstetric and clinical characteristics of the study participants (N = 100)

Variable	Category	n	%
Age group (years)	≤20	9	9.0
	21-30	62	62.0
	31-35	24	24.0
	>35	5	5.0
Gravidity	Primigravida	56	56.0
	Multigravida	44	44.0
Gestational age at induction	Mean ± SD (weeks)	39.1 ± 1.2	-
Indication for induction	Postdated pregnancy	34	34.0
	Pregnancy-induced hypertension	22	22.0
	Oligohydramnios	16	16.0
	Premature rupture of membranes	14	14.0
	Other indications	14	14.0

Note: SD, standard deviation.

With respect to induction practice, two doses of misoprostol were most commonly required (42.0%), followed by three doses (27.0%) and a single dose (18.0%). The mean total administered dose was 63.5 ± 22.4 µg. The mean induction-to-delivery interval for the cohort was 11.6 ± 4.8 hours. Delivery occurred within 12 hours in 60.0% of women, whereas 11.0% required more than 18 hours. Primigravida women showed a longer induction-to-delivery interval than multigravida women (13.2 ± 4.9 hours vs. 9.7 ± 3.8 hours). These findings are shown in Table 2.

Table 2. Misoprostol dose pattern and induction-to-delivery interval (N = 100)

Variable	Category	n	%
Number of misoprostol doses received	1 dose	18	18.0
	2 doses	42	42.0
	3 doses	27	27.0
	≥4 doses	13	13.0
Total misoprostol dose administered	Mean ± SD (µg)	63.5 ± 22.4	-
Induction-to-delivery interval	<8 hours	22	22.0
	8-12 hours	38	38.0
	12-18 hours	29	29.0
	>18 hours	11	11.0
Overall induction-to-delivery interval	Mean ± SD (hours)	11.6 ± 4.8	-

Variable	Category	n	%
Induction-to-delivery interval by gravidity	Primigravida (mean ± SD)	13.2 ± 4.9	-
	Multigravida (mean ± SD)	9.7 ± 3.8	-

Note: SD, standard deviation.

Normal vaginal delivery was achieved in 72.0% of women, and an additional 8.0% underwent instrumental vaginal delivery, resulting in an overall vaginal delivery rate of 80.0%. Cesarean delivery was performed in 20.0% of cases. The most frequent indications for cesarean section were fetal distress (9.0%), failed induction (6.0%), and non-progress of labor (5.0%). The delivery outcomes are presented in Table 3.

Table 3. Delivery outcomes following induction with misoprostol (N = 100)

Variable	Category	n	%
Mode of delivery	Normal vaginal delivery	72	72.0
	Instrumental vaginal delivery	8	8.0
	Cesarean section	20	20.0
Successful vaginal delivery	Yes	80	80.0
	No	20	20.0
Indications for cesarean section	Fetal distress	9	9.0
	Failed induction	6	6.0
	Non-progress of labor	5	5.0

Note: Percentages are calculated using the total study population as denominator.

Maternal complications were infrequent. Uterine tachysystole occurred in 7.0% of women, hyperstimulation syndrome in 3.0%, postpartum hemorrhage in 4.0%, and maternal fever or gastrointestinal symptoms in 6.0%. No case of uterine rupture was recorded. Neonatal outcomes were generally reassuring, with Apgar score below 7 at 1 minute in 10.0% of newborns, Apgar score below 7 at 5 minutes in 3.0%, and NICU admission in 8.0%. Maternal and neonatal complications are detailed in Table 4.

Table 4. Maternal and neonatal complications associated with misoprostol induction (N = 100)

Variable	Category	n	%
Maternal complications	Uterine tachysystole	7	7.0
	Uterine hyperstimulation syndrome	3	3.0
	Postpartum hemorrhage	4	4.0
	Maternal fever/gastrointestinal symptoms	6	6.0
	Uterine rupture	0	0.0
Neonatal outcomes	Apgar score <7 at 1 minute	10	10.0

Variable	Category	n	%
	Apgar score <7 at 5 minutes	3	3.0
	NICU admission	8	8.0

Note: NICU, neonatal intensive care unit.

Discussion.

The present observational study describes the real-world use of misoprostol for induction of labor at term in a tertiary care teaching hospital and shows an overall favorable balance between effectiveness and safety. Most women required one to three doses, the mean induction-to-delivery interval was 11.6 hours, and 80.0% achieved vaginal birth. These findings are clinically relevant because they reflect routine obstetric practice rather than the tightly controlled conditions of a trial. The observed interval to delivery and vaginal delivery rate are broadly consistent with earlier randomized studies in which

misoprostol shortened induction duration and produced satisfactory vaginal birth rates when compared with oxytocin or dinoprostone [2-7,10,12].

A notable finding in the present study was that two doses constituted the most common dosing pattern, while only a minority of women required four or more doses. This supports the practical usefulness of low-dose interval-based administration in women undergoing induction at term. Studies comparing 25 µg and 50 µg regimens have shown that the lower dose often preserves effectiveness while reducing excessive uterine activity, especially when repeated at longer intervals [2-5,8,9]. This study complication profile is in keeping with that evidence. Uterine tachysystole was observed in 7.0% and hyperstimulation in 3.0%, figures that remain within an acceptable range for a pharmacologic induction agent used in routine tertiary care practice. Systematic reviews have consistently reported that higher vaginal doses are associated with more hyperstimulation, whereas lower-dose regimens provide a better safety margin [2-5,14].

The longer induction-to-delivery interval observed among primigravida women compared with multigravida women is also clinically plausible and aligns with established obstetric experience. Parity has an important influence on cervical response, labor progression, and likelihood of operative delivery. Even when the same induction protocol is used, primigravida women commonly require a longer latent phase and more intensive monitoring. This parity-related difference should be recognized during counseling so that expectations regarding duration of induction remain realistic for women and their families.

The cesarean section rate in the present study was 20.0%, with fetal distress, failed induction, and non-progress of labor being the main indications. This pattern resembles that reported in earlier comparative studies, where cesarean delivery after misoprostol induction was driven largely by intrapartum indications rather than by any consistent excess attributable to the drug itself [4,6,7,10-13]. Maternal morbidity was low, and no uterine rupture was recorded. Neonatal outcomes were also generally reassuring, with a low rate of depressed 5-minute Apgar score and limited NICU admission. Taken together, these observations suggest that when low-dose misoprostol is used with careful case selection and continuous intrapartum supervision, it performs well as an induction agent at term. The study therefore adds local observational evidence to the larger body of literature supporting protocol-based misoprostol use in tertiary obstetric care [1,3-5,14].

Generalizability.

Although the present study was conducted in a single tertiary care teaching hospital, the findings may have broader relevance to similar obstetric care settings, particularly in resource-limited regions where misoprostol is commonly used for induction of labor. The study population included women from both rural and urban backgrounds, reflecting the typical patient distribution in many tertiary referral centers. Therefore, the observed patterns of misoprostol use, induction outcomes, and maternal and neonatal safety profiles may provide useful insights for clinicians managing term labor induction in comparable healthcare environments. However, multicentric studies involving larger and more diverse populations are recommended to further strengthen the external validity and general applicability of these findings.

Conclusion.

In this hospital-based observational study, misoprostol induction of labor at term was associated with effective labor progression, a high overall vaginal delivery rate, and a low frequency of serious maternal and neonatal complications. Most women delivered within a clinically acceptable interval, and only a small proportion experienced significant uterine overstimulation or adverse neonatal transition. The findings support the continued use of low-dose, interval-based misoprostol in carefully selected term pregnancies under close intrapartum supervision. In tertiary care practice, such a protocol offers a practical, accessible, and clinically sound

approach for induction while maintaining acceptable maternal and neonatal safety and supporting efficient labor ward management. These findings are relevant for protocol standardization in comparable teaching hospitals.

Limitations.

This was a single-center observational study with a moderate sample size, so external generalizability is restricted. Important modifiers such as baseline Bishop score, membrane status subgroups, and individual oxytocin augmentation details were not analyzed separately. Because the design was descriptive, the study reports clinical patterns and associations rather than comparative effect estimates. Institutional practice style and decision thresholds for operative delivery also influenced the recorded outcomes.

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List of Abbreviations.

IOL – Induction of labor
LSCS – Lower segment cesarean section
NICU – Neonatal intensive care unit
CTG – Cardiotocography
FHR – Fetal heart rate
PPH – Postpartum hemorrhage
ROM – Rupture of membranes
SD – Standard deviation
WHO – World Health Organization

Source of Funding.

No funding was received.

Conflict of Interest.

The authors declare no conflict of interest.

Data Availability.

Data Available on request

Author contributions.

Dr Usharani Nagarapu contributed to the study concept and design, patient recruitment, clinical data collection, supervision of the obstetric component of the study, interpretation of findings, and manuscript review.

Dr Alekya A contributed to the study design, pharmacology-related scientific input, data analysis support, interpretation of results, and drafting and revision of the manuscript.

Dr Akula Swaroopa Rani contributed to patient evaluation, clinical monitoring, data collection, literature review, and manuscript editing.

Dr Prashanth Kumar Patnaik contributed to methodology development, pharmacological interpretation, statistical support, critical revision of the manuscript, and overall academic guidance.

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