

Low-dose misoprostol solution for labour induction: A prospective study in Pakistani women from a single urban centre in Multan

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Abstract

Objective: To assess the safety and effectiveness of low-dose misoprostol administered in oral solution for induction of labour at term.

Method: The prospective, observational study was conducted from September 1, 2022, to September 1, 2023, at the Women Christian Hospital, Multan, and comprised women having a singleton pregnancy with a cephalic presentation and an unfavourable cervix. Misoprostol 200mcg was dissolved in 200mL of drinking water for the oral solution. Up to 12 doses of 25mcg were administered every two hours. Data was noted for induction-to-delivery interval, mode of delivery, and maternal and neonatal complications. Data was analysed using SPSS 25.

Results: Of the 230 women with mean age 27.7 ± 6.2 years, 109(47%) were primigravida, 84(37%) were multigravida and 37(16%) were grand multipara. Overall, 170(74%) achieved a successful vaginal delivery, while 60(26%) experienced a failed induction of labour, and required a caesarean section. Among those who had a successful vaginal delivery, 127(74.6%) delivered within 24 hours, and 143(84.1%) had favourable maternal outcomes with no complications.

Conclusion: Low-dose oral solution regimen for induction of labour was found to be low-risk and efficient, and it was less inclined to result in unfavourable outcomes.

Keywords: Labour induction, Misoprostol, Oral administration. (JPMA 76: 1633; 2026)

DOI: <https://doi.org/10.47391/JPMA.22302>

Introduction

Induction of labour (IOL) is an obstetrical intervention to initiate labour artificially. The World Health Organisation (WHO) endorses IOL at 41 weeks.¹ But many countries advocate IOL between 41 and 42 weeks to circumvent adverse perinatal outcomes of prolonged pregnancy.^{2,3} IOL is recommended when it is considered that the consequences for the foetus, the mother, or both will be more favourable compared to waiting for spontaneous onset of labour.⁴ It serves to mitigate pernicious perinatal outcomes, like caesarean section (CS), prolonged labour, postpartum haemorrhage (PPH), perineal trauma and stillbirth.^{5,6} With its incidence striking 20% of pregnancies, IOL is most common in cases where the cervix is considered unfavourable.⁷ There is a notable variation in IOL rates across the globe, which can be attributed to differences in guidelines and the absence of a unified consensus on the clinical practice standards for IOL.^{8,9} The epidemiology of labour induction in low- and middle-income countries (LMICs), like Pakistan, is not well described.¹⁰

Various pharmacological and non-pharmacological techniques are applied for IOL, including oxytocin,

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Submission completed: 01-12-2024 **1st Revision received:** 16-05-2025

Acceptance: 20-06-2026

Last Revision received: 19-06-2026

prostaglandin (PG) analogues and smooth muscle stimulants. Non-pharmacological methods involve cervical sweeping, hygroscopic cervical dilators, balloon catheters and artificial rupture of membranes.^{11,12} PGs, particularly prostaglandin E2 (PGE2 or dinoprostone), have been extensively used in practice for IOL, particularly when cervical favourability is deficient.¹³ Unfortunately, vaginal preparations of PGE2 are costly and prone to instability at ambient temperatures.¹⁴

Misoprostol, a synthetic PGE1 analogue initially manufactured for preventing stomach ulcers in 1973, has been used off-label in obstetrics and gynaecology since 1986. Usual indications include medical termination of pregnancy, managing incomplete abortion, IOL, cervical ripening before surgical procedures, and preventing/treating PPH. Its affordability, stability, lack of drug interactions and broad reproductive health applications led the WHO to include it in the model list of essential medicines in 2011. The International Federation of Gynaecology and Obstetrics (FIGO) also recommends its use for various indications in different doses in line with gestation and gynaecological conditions, suggesting dosages of 25-50mcg per vagina every four hours or 25-50mcg orally every two hours for IOL.¹⁵

While evidence confirms the safety, effectiveness and cost benefits of oral misoprostol for IOL,¹⁶⁻¹⁸ its unavailability in 25mcg or 50mcg tablet, especially in LMICs, like Pakistan, poses challenges and administering the prepared doses

suitable for IOL lacks precision. Despite this barrier, it is frequently used off-label for IOL by cutting a high-dose misoprostol tablet (200mcg) into smaller pieces, raising concerns regarding uterine hyper-stimulation and adverse foetal outcomes due to dosing inaccuracy. Accurate dosing of misoprostol is crucial to ensure both effectiveness and safety while minimising adverse events. Administering too high a dose can raise the risk of uterine hyper-stimulation, while too low a dose may result in unsuccessful induction.^{19,20}

In LMICs, the shortage of adequately trained personnel to administer PGs vaginally, coupled with the high cost and instability of these products at room temperature, present considerable challenges. These obstacles could be addressed by utilising oral misoprostol in the form of solution. This alternative approach would lead to decreased economic strain, reduced reliance on maintaining specific storage conditions, and diminished dependence on trained healthcare personnel.

Practitioners contemplating a switch from PGE₂ to oral misoprostol should weigh the benefits of low-dose oral misoprostol, including reduced CS rates, cost-effectiveness, heat stability and ease of administration, against the challenges stemming from the lack of a 25mcg oral formulation, like dosage inaccuracies, which could be addressed by preparing an oral solution. It is prepared by dissolving one tablet misoprostol 200mcg in 200mL of water and used as per the advised schedule.²¹ Another concern for practitioners is whether to administer misoprostol orally or vaginally for IOL. Given that safety should be paramount, the evidence favours oral regimens over vaginal ones, particularly in settings with a high risk of ascending infection and a shortage of trained personnel.²²

The current study was planned to assess the safety and effectiveness of low-dose misoprostol administered in oral solution for IOL at term.

Patients and Methods

The prospective, observational study was conducted from September 1, 2022, to September 1, 2023, at the Women Christian Hospital, Multan. Pregnant women requiring IOL for obstetric or medical indications, including post-dated pregnancy, pre-labour rupture of membranes, hypertensive disorders, gestational diabetes mellitus (GDM), recurrent pregnancy loss or other medical indications, were enrolled consecutively. Those included were women with singleton live pregnancy in the third trimester having a cephalic presentation with Bishop score <7.²³

Women with multiple pregnancies, preterm premature rupture of membrane (PROM), severe intrauterine growth restriction (IUGR) with abnormal Doppler studies, previous CS, intrauterine foetal demise, or known hypersensitivity to misoprostol or PG analogues were excluded.

Approval was obtained from the institutional ethics review committee, and written informed consent was obtained from all the participants.

The sample size was calculated using the OpenEpi sample size calculator, assuming a 95% confidence level, 5% margin of error, and an expected success rate of 80% for vaginal delivery based on previous studies.^{7,24}

Oral misoprostol protocol involved a 200µg misoprostol tablet that was dissolved in 200mL of drinking water to prepare an oral solution with a concentration of 1 µg/mL (Figure 1). The solution was prepared under sterile conditions, stored at room temperature, and discarded if unused within 24 hours (Figure 2). According to FIGO recommendations, misoprostol 25µg (25mL) was administered orally every two hours for a maximum of 12 doses.¹⁵

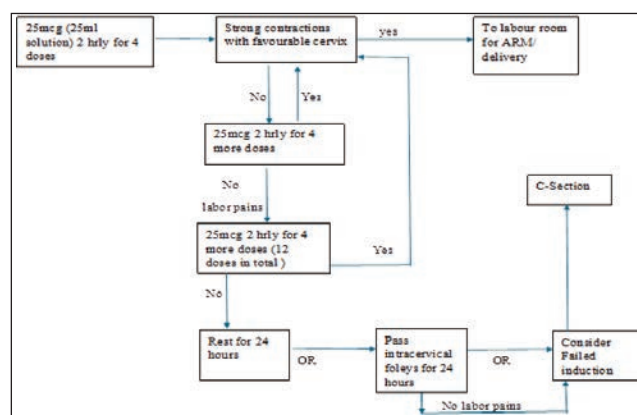


Figure-1: Oral misoprostol solution protocol.



Figure-2: Step by step guide to diluting misoprostol.^{21,24}

If the cervix remained unfavourable (Bishop score <4) and labour did not commence after the maximum dose, induction was either postponed, intracervical Foley catheterisation was considered where appropriate, or the induction was labelled as failed and CS delivery was performed.

Further misoprostol doses were withheld if uterine tachysystole (≥ 5 contractions in 10 minutes) or hypertonus (contraction lasting ≥ 2 minutes) occurred. Oxytocin was not administered during active labour and, if required, was initiated at least four hours after the last misoprostol dose.

Baseline vaginal examination was performed to assess the Bishop score. Maternal observations and uterine activity were assessed before each dose by abdominal palpation, and foetal heart rate was monitored using foetoscope or handheld Doppler at baseline and every 30 minutes following administration. Women in established labour were transferred to the labour ward, and amniotomy was performed only when clinically indicated. Labour progress was monitored using a partogram.

Bishop score assessment was performed by senior obstetric staff trained in standardised scoring to minimise inter-observer variability. Labour monitoring followed uniform departmental protocols.

Failed IOL was defined as failure to achieve vaginal delivery after one full course of misoprostol (12 doses). Failure of Foley catheter induction was defined as the inability to achieve vaginal delivery within 24 hours of insertion. Emergency CS was performed for failed induction or maternal or foetal indications.

The primary outcome was the proportion of women achieving vaginal delivery. Secondary outcomes included the induction-to-delivery interval (<24 hours), as well as the incidence of maternal complications, such as PPH (blood loss >500mL), uterine hyper-stimulation or rupture, antepartum haemorrhage, and third- or fourth-degree perineal tears. Perinatal outcomes included perinatal death, Appearance-Pulse-Grimace-Activity-Respiration (APGAR) score $25 \leq 7$ at 1 and 5 minutes, and admission to the neonatal intensive care unit (NICU).

Data was analysed using SPSS 25. Descriptive data was expressed as frequencies and percentages, or as mean $\pm$ standard deviation. Association between categorical variables and IOL outcomes were assessed using the chi-square test. $P < 0.05$ was considered statistically significant.

Results

Of the 2,480 women screened for eligibility, 230 (9.27%) were enrolled. The mean age of the participants was

27.7 ± 6.2 years. Most women were aged 26-35 years 121 (53%), followed by 16-25 years 90 (39%) and 36-45 years 19 (8%). Regarding parity, 109 (47%) subjects were primigravida, 84 (37%) were multigravida and 37 (16%) were grand multipara. The mean gestational age at induction was 38.5 ± 1.0 weeks. At induction, 92 (40%) women had a Bishop score <4, while 138 (60%) had the score ranging 4-6. Overall, 153 (67%) women delivered within 24 hours, whereas 77 (33%) delivered after 24 hours (Table 1).

The most common indications for induction were oligohydramnios and spontaneous rupture of membrane (SRM), each accounting for 37 (16%) cases, followed by post-dated pregnancy 32 (14%). Small for gestational age (SGA) and GDM were the indications in 29 (13%) cases each.

Overall, 8 (3%) women required intracervical Foley catheterisation; with 2 (25%) achieving vaginal delivery, and 6 (75%) subsequently undergoing CS.

Of the total, 170 (74%) women achieved vaginal delivery, while 60 (26%) underwent CS following failed IOL. Among those who delivered vaginally, 127 (83%) delivered within 24 hours. PPH occurred in 21 (9%) cases, and third- or fourth-degree perineal tears occurred in 9 (4%) (Table 2A).

Table-1: Demographic characteristics compared according to delivery category (n=230).

Characteristics	Successful IOL n (%)	Failed IOL n (%)	Total n (%)	p-value (<0.005)
Number	170 (74)	60 (26)	230 (100)	
Age (years)				
16 – 25	62 (69)	28 (31)	90 (100)	0.37
26 – 35	93 (77)	28 (23)	121 (100)	
36 – 45	15 (79)	4 (21)	19 (100)	
Parity				
Primigravida	69 (63)	40 (37)	109 (100)	0.002
Multigravida (2 to 4)	68 (81)	16 (19)	84 (100)	
Grand multipara (5 or >5)	33 (89)	4 (11)	37 (100)	
Indication for induction				
Oligohydramnios	32 (87)	5 (13)	37 (100)	0.137
SRM	23 (62)	14 (38)	37 (100)	
Post dates	22 (69)	10 (31)	32 (100)	
SGA	23 (79)	6 (21)	29 (100)	
GDM	18 (62)	11 (38)	29 (100)	
Previous 3 abortions	14 (74)	5 (26)	19 (100)	
Previous MSB	14 (78)	4 (22)	18 (100)	
PIH	10 (100)	0 (0)	10 (100)	
Others	14 (74)	5 (26)	19 (100)	
Bishop score				
<4	55 (60)	37 (40)	92 (100)	0.000
4-6	115 (83)	23 (17)	138 (100)	
The interval between the start of induction and delivery				
<24 hrs	127 (83)	26 (17)	153 (100)	0.000
>24 hrs	43 (56)	34 (44)	77 (100)	

Statistical test: Chi-square test; $p < 0.05$ considered statistically significant; IOL: Induction of labour, SRM: Spontaneous rupture of membranes, SGA: Small for gestational age, GDM: Gestational diabetes mellitus, MSB: Macerated stillbirth, PIH: Pregnancy-induced hypertension.

Table-2A: Comparison of maternal and perinatal outcomes between the groups.

Maternal outcomes	Successful IOL n (%)	Failed IOL n (%)	Total n (%)
Number	170 (74)	60 (26)	230 (100)
Maternal complications			
Nil	143(72)	57(29)	200(100)
PPH*	19(11)	2(9)	21(100)
3rd/4th perineal tear*	8(4)	0(0)	8(100)

*Postpartum haemorrhage was defined as blood loss >500ml following vaginal delivery; *3rd/4th degree perineal tear: Injury involving the anal sphincter complex, with or without rectal mucosal involvement; IOL: Induction of labour, PPH: Postpartum haemorrhage

Table-2B: Perinatal outcomes.

Apgar score (at 5min intervals after delivery)			
<7	5(56)	4(44)	9(100)
7 or >7	165(75)	56(25)	221(100)

SRM: Spontaneous rupture of membranes; SGA: Small for gestational age; GDM: Gestational diabetes mellitus; MSB: Macerated stillbirth; PIH: Pregnancy-induced hypertension; PPH: Postpartum haemorrhage; IOL: Induction of labour; FIGO: The International Federation of Gynaecology and Obstetrics.

No case of uterine hyper-stimulation, uterine rupture or maternal death was recorded.

Among the 60(26%) women who underwent CS, the primary indication was failure to progress in labour 48(80%). Parity was significantly associated with IOL outcome, with primigravida accounting for 40(67%), followed by multigravida 16(27%) and grand multipara 4(7%) ($p=0.002$).

Failed induction was more frequent among women with an initial Bishop score <4 37(62%) compared to those with Bishop score 4-6 23(38%) ($p<0.001$). Among women with a Bishop score of 4-6 who still required CS delivery, most were primigravida 14(61%).

The induction-to-delivery interval was significantly associated with IOL outcome. Of the 153(67%) women who delivered within 24 hours, 127(83%) had vaginal deliveries, whereas 26(17%) underwent CS ($p<0.001$).

Of the 60(26%) cases with failed IOL, 28(46.6%) each were aged 16-25 years and 26-35 years, while 4(6.6%) were aged 36-45 years. The most frequent indications among failed IOL cases were SRM 14(23%), GDM 11(18%) and post-dated pregnancy 10(17%).

All neonates were liveborn. A small proportion of newborns 9(4%) had APGAR score <7 at five minutes (Table 2B). No NICU admission or perinatal death was recorded.

Discussion

Oral misoprostol, administered either as a tablet or solution, has been widely evaluated for IOL in women with an unfavourable cervix. In the current prospective, observational study assessing low-dose oral misoprostol

solution, 74% of the women achieved vaginal delivery, while 26% experienced failed IOL. Among the 153 women who delivered within 24 hours, 83% had a successful vaginal birth. A significant association was observed between induction-delivery interval and successful vaginal delivery. Although direct comparisons cannot be made in the absence of a control group, the findings are broadly consistent with previously published studies.²⁴⁻²⁶ Most of the successful deliveries in the current study had no complications. Few experienced postpartum haemorrhage (9%) or perineal tears (4%), but none had severe outcomes. All babies were born alive, and no NICU admission or adverse perinatal outcome during the study period was noted. Faucett et al. also reported similar outcomes.²⁷ Published literature suggests that the oral route may be associated with a lower risk of severe adverse events, such as uterine hyper-stimulation and uterine rupture, compared to vaginal administration.²⁸ In the present cohort, maternal complications were infrequent, and no severe adverse maternal or neonatal outcome was observed.

Dobert et al. also compared oral misoprostol with vaginal insert, and showed significantly shortened interval from induction to delivery in vaginal insert cases, but at the expense of a higher CS rate and negative effects on neonatal outcomes.²⁹

The success of this regimen is attributed to the low dose of oral misoprostol commencing at 25mcg per dose two hourly up to 12 doses, provided there were no complications or till the labour commences. Similar results were shown by Bendix et al., who compared high- and low-dosage oral misoprostol protocols, and found that low-dosage regimens were associated with better obstetric outcomes, including higher rates of vaginal delivery. This suggests that careful titration of dosages can optimise IOL results.³⁰ The current findings are supported by a systematic review which found low-dose oral misoprostol (≤ 25 mcg) to be as effective and safe as vaginal PGE₂ with significantly fewer women requiring CS delivery.¹⁶

A randomised controlled trial (RCT) compared oral misoprostol (25µg every 2 hours) with oxytocin infusion. Results indicated that oral misoprostol was a viable IOL option, showing favourable outcomes compared to traditional methods.²³

Misoprostol is a crucial medicine in obstetrics and gynaecology, particularly in resource-limited countries, like Pakistan. The high cost of other PG preparations, like PGE₂, for IOL and the elevated maternal mortality rates make misoprostol an essential alternative. Economic evaluations have also shown that misoprostol is cost-effective for

IOL.^{16,17} A literature review of cost analysis indicated that preliminary outcomes suggested oral misoprostol tablets at 25mg per dose may improve outcomes in IOL and be cost-saving, highlighting its potential for labour induction.¹⁸

Despite the promising findings, the current study has some limitations. As a single-centre, prospective, observational study without a contemporaneous control group, the findings primarily describe clinical outcomes rather than establish comparative effectiveness or causality. Further, the calculated sample size was 246, but only 230 consecutive eligible participants were enrolled due to time-limited recruitment. This reduction in sample size may have affected the statistical power to detect uncommon adverse outcomes. Although efforts were made to ensure accurate preparation and dosing of the oral misoprostol solution, the lack of a standardised commercial formulation may have introduced variability in practice. Lastly, the absence of long-term neonatal follow-up limits conclusions about delayed perinatal outcomes.

RCTs comparing oral misoprostol solution with standard induction methods, such as vaginal dinoprostone or oxytocin, are required to confirm the current findings.³¹

Conclusion

Low-dose oral misoprostol solution was associated with favourable maternal and neonatal outcomes when used for labour induction.

Acknowledgement: We are grateful to Dr Hajra Adil, a public health expert, for assistance in writing the manuscript and critical appraisal of the study, and to Dr Michelle Walsh for administrative support.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

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Author Contribution:

WS: Concept, design, drafting and critical revision.

IK: Concept, critical revision and drafting.

SS & JK: Data collection, entry and interpretation.