Original Article

Comparison of Outcome of Foley Catheter versus Misoprostol for Induction of Labor at Term Pregnancy

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Abstract

Objective: To compare the mean induction-to-delivery interval of Foley catheter versus misoprostol for induction of labor (IOL) in singleton term pregnancies.

Methodology: This randomized controlled trial NCT07416487 (clinicaltrials.gov) was carried out at the Department of Obstetrics and Gynecology, Allama Iqbal Teaching Hospital, Dera Ghazi Khan, Pakistan, from February 2025 to July 2025. A total of 102 (51 in each group) pregnant females aged 18-40 years with a singleton term pregnancy, vertex presentation, intact membranes, and parity less than 4 undergoing induction of labour were included. Participants were allocated by lottery method with concealment to intravaginal misoprostol 25 µg every 4 hours up to four doses or an intracervical 16F Foley catheter inflated with 30 mL saline. Induction to delivery interval was recorded from the insertion of the Foley catheter or misoprostol until the delivery of the fetus (in hours).

Results: In a total of 102 women the mean age was 27.5±5.5 years, with ages ranging from 18 to 40 years. The mean gestational age at induction was 39.4±1.3 weeks. Parity distribution was nullipara in 31 (30.4%), primipara in 21 (20.6%), and multipara in 50 (49.0%) women. Indications for induction were chronic hypertension in 33 (32.4%) women, gestational diabetes in 42 (41.2%), and congenital anomaly in 27 (26.5%). Induction-to-delivery interval differed between the study groups as women in misoprostol group had a shorter mean induction-to-delivery interval compared with those allocated to Foley catheter at 14.6±1.8 hours versus 18.5±2.7 hours ($p<0.001$). With regards to different indications for induction, induction to delivery interval remained significantly shorter among women in misoprostol group.

Conclusion: Intravaginal misoprostol resulted in a shorter induction to delivery interval than the intracervical Foley catheter among women undergoing induction of labour for singleton term pregnancies.

Keywords: Fetus, gestational diabetes, misoprostol, parity, pregnancy.

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Introduction

Induction of labour (IOL) is described as the deliberate initiation of uterine contractions before the spontaneous onset of labour after fetal viability with aims of achieving progressive cervical effacement and dilatation, and ultimately vaginal delivery.[1] IOL is undertaken when continuing the pregnancy is judged to carry greater risk for the mother, the fetus, or both than planned delivery, and when outcomes are expected to be improved compared with expectant management.[2] Professional guidance provides detailed indications and suggested timing for delivery across a range of maternal and fetal conditions.[3] IOL has become a routine component of modern obstetric practice. In disorders that threaten maternal well-being such as hypertensive disease of pregnancy and its severe variants, timely delivery may be necessary to prevent progression to serious complications. Evidence also supports that appropriately selected induction can reduce maternal morbidity and improve neonatal outcomes.[4]

The frequency of induction has risen steadily worldwide over recent decades, reflecting shifts in clinical

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thresholds for intervention, increasing maternal age, and broader access to antenatal and intrapartum care. In many high-income settings, induction is performed in roughly 20-30% of term pregnancies.[5,6] In contrast, reported rates in developing countries are generally lower (6-15%) often attributed to constraints in health system capacity, limited availability of induction agents, and barriers to timely obstetric care.[7]

Multiple approaches are available for induction, broadly grouped into mechanical and pharmacological methods. Mechanical strategies include membrane sweeping, transcervical balloon catheter placement, and extra amniotic saline infusion, which aim to promote cervical ripening through local pressure and stimulation. Pharmacological options include prostaglandin preparations, oxytocin infusion, and misoprostol.[8,9] In obstetrics and gynaecology, misoprostol is widely used outside its original indication, including for medical termination in the second trimester, management of missed or incomplete miscarriage, and induction following intrauterine fetal demise.[10] When administered in low doses, misoprostol has demonstrated efficacy for cervical ripening and IOL at term.[11] Misoprostol offers several advantages, including multiple routes of administration (oral, sublingual, or vaginal), low cost, and dual action on cervical ripening and uterine contractions. However, different dose schedules, delivery methods, and research designs have produced conflicting results about its relative efficacy and safety in terms of PROM.[12] Mechanical approaches to induction, particularly transcervical balloon catheterisation with a Foley catheter, are often viewed as an attractive option because they are associated with a lower likelihood of excessive uterine activity than uterotonic drugs. By exerting direct pressure at the cervix and promoting gradual dilatation, the Foley catheter facilitates cervical ripening through a physical mechanism rather than stimulating myometrial contractions pharmacologically.[13] This characteristic can be clinically relevant in situations where uterine tachysystole would be especially undesirable, and it is one reason balloon methods are frequently considered in women with a prior uterine scar who are candidates for a trial of labour.[14]

Although Foley catheter and misoprostol have been compared previously, uncertainty remains regarding their relative efficiency because published studies have used heterogeneous dosing schedules, balloon volumes, oxytocin protocols, cervical eligibility criteria, and outcome definitions. Evidence from public sector hospitals in Pakistan, particularly from South Punjab, remains limited despite marked differences in patient characteristics, labour ward workload, monitoring capacity, and availability of induction resources compared with high income settings. The present randomized controlled trial provides a protocol based, direct comparison of low dose intravaginal misoprostol and intracervical Foley catheter in women with singleton term pregnancies, using induction to delivery interval as a clinically and operationally relevant outcome. It also examines whether the observed treatment effect remains consistent across maternal age, body mass index, parity, and indication for induction. These findings may support locally applicable induction protocols and assist clinicians in selecting an efficient method within resource constrained maternity units.

Methodology

This randomized controlled trial (NCT07416487 at: clinicaltrials.gov) was carried out at the Department of Obstetrics and Gynecology, Allama Iqbal Teaching Hospital, Dera Ghazi Khan, Pakistan, from February 2025 to July 2025, after obtaining approval from the institutional ethical review committee (No.PM.U-I/008/-036-/A.I.T Hosp, D.G.K dated: 21-01-2025). A sample size of 102 (51 in each group) was calculated using the OpenEpi sample size calculator, considering the expected mean IDI as 14.03±7.61 hours in the misoprostol group and 18.40±8.02 hours in the Foley catheter group[15], with a 95% confidence interval and 80% power. Inclusion criteria were females aged 18-40 years with a singleton term pregnancy (37-41) weeks, had labor induction, with parity <4, vertex presentation, and intact membranes. Females with a previous uterine surgery, non-reassuring cardiotocography, oligohydramnios, intrauterine growth restriction (IUGR), or abruptio placenta were excluded. Labor induction was defined as the artificial commencing of labor at 37-41 weeks prior to the spontaneous onset of labor. Females with one or more of the following indications, i.e., chronic hypertension (on history or previous medical record), gestational diabetes (fasting blood sugar level >100), and congenital fetal anomaly (on ultrasound scan), went through IOL. Non-probability consecutive sampling technique was adopted. Informed written consents were sought from patients or their guardians after briefing them about the purpose and safety aspects of the study.

At enrolment, relevant demographic and clinical information was recorded. Participants were randomly allocated in a 1 to 1 ratio to either the misoprostol or Foley catheter group using the lottery method, with allocation concealed until assignment. Women in the misoprostol group received 25 µg of intravaginal misoprostol at 4 hourly intervals, up to a maximum of four doses. In the Foley catheter group, a 16 F catheter was inserted intracervically, and the balloon was inflated with 30 mL of sterile normal saline and retained until spontaneous expulsion. Following cervical ripening and the onset of labour, uterine contractions and labour progression were monitored using a partogram. Oxytocin augmentation was initiated when uterine contractions were inadequate or labour progress was unsatisfactory, according to the institutional labour management protocol. Amniotomy was performed when clinically indicated and technically feasible. The same criteria for oxytocin augmentation and amniotomy were applied in both groups. The induction to delivery interval was recorded for each participant and was defined as the time, in hours, from administration of the first dose of misoprostol or insertion of the Foley catheter to delivery of the fetus. Figure-1 is showing CONSORT study flow diagram. All of the relevant data was collected on a specifically pre-designed proforma.

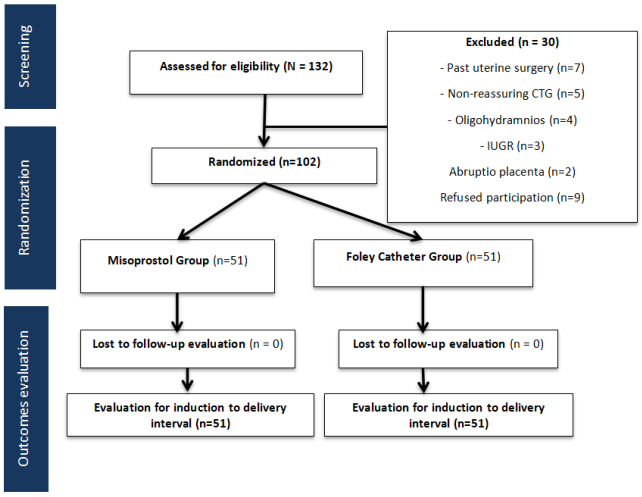


Figure 1. CONSORT flow diagram.

Statistical analysis was done using IBM-SPSS Statistics version 26.0. The qualitative data were shown in the form of frequency and percentage. For the quantitative data, means with standard deviations (SD) or medians with interquartile ranges (IQR) were computed after normality distribution of data was checked. Chi-square test or fisher's exact test was applied to compared baseline categorical characteristics between groups. The mean IDI between the two groups was compared using the independent t-test (as it was normally distributed). Effect modifiers like age, parity, BMI, and indication for IOL were controlled, making a stratified table, and independent sample t-test, or analysis of variance was employed to see the effect of effect modifiers on IDI. The marker for significance was set at a p-value <0.05.

Results

A total of 102 women were included in the study. The mean age and gestational age were 27.5 ± 5.5 years and 39.4 ± 1.3 weeks, respectively. Parity distribution was nulliparous in 31 (30.4%), primiparous in 21 (20.6%), and multiparous in 50 (49.0%) women. The indications for induction were chronic hypertension in 33 (32.4%) women, gestational diabetes in 42 (41.2%), and congenital anomalies in 27 (26.5%). The baseline characteristics of the women included in the study are presented in Table I.

Table I: Study characteristics of females undergoing induction of labor. (N=102)

Characteristics		N (%)
Age group (years)	18-29	53 (52.0%)
	30-40	49 (48.0%)
BMI (kg/m2)	20-25	28 (27.5%)
	25-30	32 (31.4%)
	30-35	42 (41.2%)
Parity	Nullipara	31 (30.4%0
	Primipara	21 (20.6%)
	Multipara	50 (49.0%)
Indication for induction	Chronic hypertension	33 (32.4%)
	Gestational diabetes	42 (41.2%)
	Congenital anomaly	27 (26.5%)

Age (p = 0.843), gestational age (p = 0.440), BMI (p = 0.438), parity (p = 0.763), and indication for induction (p = 0.975) were statistically similar between the study groups. The details are presented in Table II.

The induction-to-delivery interval (IDI) differed significantly between the groups (p < 0.001) (Figure 2). Women in the misoprostol group had a significantly shorter mean IDI than those in the Foley catheter group (14.6 ± 1.8 hours vs. 18.5 ± 2.7 hours, p < 0.001).

In the post-stratification analysis, the mean IDI remained shorter with misoprostol than with the Foley catheter across all categories of age, BMI, parity, and indication for induction. Additional analyses were performed separately within each treatment group. In the misoprostol group, IDI did not differ significantly according to age group (p = 0.447), BMI category (p = 0.803), parity (p = 0.792), or indication for induction (p

= 0.593). Similarly, within-group analyses in the Foley catheter group showed no significant differences according to age group (p = 0.699), BMI category (p = 0.882), parity (p = 0.514), or indication for induction (p = 0.706), as shown in Table III.

Table II: Study characteristics of females undergoing induction of labor. (N=102)

Characteristics		Groups		P-value
		Misoprostol (n=51)	Foley Catheter (n=51)	
Age group (years)	18-29	26 (51.0%)	27 (52.9%)	0.843
	30-40	25 (49.0%)	24 (47.1%)	
Gestational age (weeks) Mean±SD		39.5±1.4	39.3±1.2	0.440
BMI (kg/m^2)	20-25	13 (25.5%)	15 (29.4%)	0.438
	25-30	19 (37.3%)	13 (25.5%)	
	30-35	19 (37.3%)	23 (45.1%)	
Parity	Nullipara	16 (31.4%)	15 (29.4%)	0.763
	Primipara	9 (17.6%)	12 (23.5%)	
	Multipara	26 (51.0%)	24 (47.1%)	
Indication for induction	Chronic hypertension	16 (31.4%)	17 (33.3%)	0.975
	Gestational diabetes	20 (39.2%)	22 (43.1%)	
	Congenital anomaly	15 (29.4%)	12 (23.5%)	

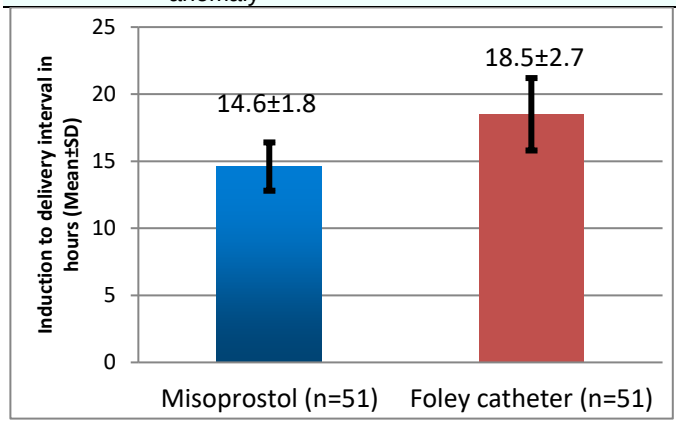


Figure 2. Induction-to-delivery interval (hours) between the study groups. (N=102)

Discussion

This randomized controlled trial found that intravaginal misoprostol shortened the IDI compared with an intracervical Foley catheter (p<0.001). The difference remained significant across every examined category of maternal age, BMI, parity, and indication for induction. Within each intervention group, induction to delivery interval did not vary significantly across these maternal and obstetric characteristics. These patterns may indicate that the induction method was the main measured factor associated with duration of induction in this selected term pregnancy population. The main findings of this study are supported by another study where the mean IDI was significantly shorter with misoprostol than with Foley catheter at 10.2±2.4 hours versus 11.6±2.0 hours (p=0.007).[16] These results are exhibiting that low dose vaginal misoprostol can achieve delivery earlier than Foley catheter when used as an independent cervical ripening method. Another study reported a mean induction to delivery interval of 14.0±7.6 hours with 25 µg vaginal misoprostol and 18.4±8.0 hours with transcervical Foley catheter (p<0.01).[16] Vaginal delivery was achieved in 76.7% and 56.8% of women, respectively. A randomized study comparing oral misoprostol alone with concurrent oral misoprostol and Foley catheter revealed that the combined method reduced the mean IDI from 21.9±2.5 hours to 16.9±3.8 hours (p=0.001).[17] These findings do not contradict the present results because the Foley catheter group in the current trial did not receive misoprostol concurrently. Instead, they indicate that the mechanical method may become more efficient when combined with a uterotonic agent that promotes both cervical ripening and uterine contractions.

Maternal age did not significantly affect IDI within the misoprostol group (p=0.447), or within the Foley

Table III: Stratified and within group analyses of induction to delivery interval. (N=102)

Characteristic	Category	Misoprostol, Mean±SD	Within misoprostol P-value	Foley catheter, Mean±SD	Within Foley p value	Between group P-value
Age group, years	18–29	14.5±1.6	0.447	18.6±2.8	0.699	<0.001
	30–40	14.9±2.1		18.3±2.7		<0.001
BMI, kg/m2	20–25	14.3±1.7	0.803	18.3±3.0	0.882	<0.001
	25–30	14.7±1.96		18.8±3.2		<0.001
	30–35	14.7±1.9		18.4±2.4		<0.001
Parity	Nullipara	14.4±1.9	0.792	18.9±2.9	0.514	<0.001
	Primipara	14.7±2.4		18.9±2.7		<0.001
	Multipara	14.8±1.6		18.0±2.7		<0.001
Indication for induction	Chronic hypertension	14.8±1.5	0.593	18.6±2.4	0.706	<0.001
	Gestational diabetes	14.3±1.8		18.1±2.6		<0.001
	Congenital anomaly	14.9±2.3		18.9±3.6		<0.001

Independent samples t test was used for comparisons between the two treatment groups within each stratum and for the two age categories within each treatment group. One way analysis of variance was used to compare BMI, parity, and indication categories separately within each treatment group.

catheter group (p=0.699). A study evaluating maternal age and BMI during induction with oral misoprostol found no significant difference in induction outcomes between women < 35 years and those aged 35 years or older.[18] This supports the observation that age alone may have limited influence when women have otherwise uncomplicated term pregnancies and receive a standardized induction regimen. A study reported that women aged 35 years or older had greater odds of induction failure at OR 13.9 (p<0.001), and required longer intervals to reach 6 cm cervical dilatation and delivery.[19] The difference from the current trial may be related to the restriction of that study to nulliparous women with ruptured membranes. The present trial included nulliparous, primiparous, and multiparous women with intact membranes and divided age at 30 years rather than specifically isolating advanced maternal age. The current age categories may therefore have reduced the ability to detect an age-related difference.

Indication for induction was not significantly associated with the interval within either intervention group. The treatment difference remained present among women induced for chronic hypertension, gestational diabetes, and congenital anomaly. A recent cohort evaluating misoprostol induction found that gestational diabetes was not independently associated with vaginal delivery within 24 hours after adjustment, with an adjusted OR of 0.73 and 95% CI 0.39 to 1.40.[20] In that analysis, BMI, nulliparity, and birth weight were more influential than gestational diabetes. This supports the interpretation that the response to induction may depend more strongly on cervical readiness, parity, fetal size, and the induction protocol than on the medical indication considered in isolation.[21]

The clinical importance of reducing the IDI extends beyond statistical significance. A reduction of several hours may decrease labour ward occupancy, repeated examinations, duration of fetal surveillance, maternal discomfort, and pressure on staff in high volume maternity units.[22,23] Misoprostol is inexpensive, easy to store, and does not require procedural catheter placement. A systematic review and network meta-analysis of low dose vaginal misoprostol supported its effectiveness in reducing the interval to delivery.[24] Selection of an induction method may still account for the greater potential for excessive uterine activity with prostaglandin-based methods and the need for appropriate maternal and fetal monitoring.

The randomized design, equal allocation, comparable baseline characteristics, and uniform augmentation criteria strengthen the interpretation of the primary finding. Several limitations should be considered. Baseline Bishop score was not reported, despite its recognized relationship with cervical response and induction duration. Future trials should record each component of the Bishop score and use stratified randomization according to cervical favourability. Oxytocin and amniotomy were applied according to the same institutional protocol, but their frequency, timing, and dose were not reported separately. The single centre setting and limited subgroup sizes restrict generalizability and reduce statistical power for within group comparisons.

Conclusion

Intravaginal misoprostol resulted in a shorter induction-to-delivery interval than the intracervical Foley catheter among women undergoing induction of labour for singleton term pregnancies. The selection of the induction method should be guided by contraindications, monitoring capacity, staff skill mix, and a balanced appraisal of efficiency and safety outcomes. Future research should priorities multicentre intention-to-treat trials that incorporate baseline cervical assessment, standardized co-interventions, and a prespecified set of maternal and neonatal outcomes to inform context-specific induction guidelines.

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