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Original Research

Safety and Efficacy of Combined Oral Misoprostol and Foley Catheter Treatment in Comparison with Oral Misoprostol Alone for Labor Induction: A Randomized Clinical Trial study

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ABSTRACT

Background: In the context of a rising trend in labor induction cases, limited research has explored the efficacy of the simultaneous use of misoprostol and Foley catheter methods. This clinical trial investigates the efficacy and safety of combining these labor induction techniques compared to the use of oral misoprostol alone. **Methods**: This randomized, open-label clinical trial was conducted on pregnant women candidates for induction of labor due to various medical indications referred to Shariati Hospital, Tehran. The oral misoprostol plus Foley catheter group received 50 mg of oral misoprostol every 4 hours, along with the insertion of a Foley catheter into the cervix under sterile conditions. The comparison group received only oral misoprostol. The Bishop scores in this study were measured prior to induction, and at 6 hours and 12 hours after the initiation of the intervention by a single specialist. Statistical comparisons included the number of deliveries within 24 hours, Bishop score, oxytocin dosage, and maternal and fetal complications. **Results**: The two groups were homogeneous in regard to age (27.11 ± 3.88 *vs.* 26.46 ± 4.95, P=0.26), gestational week (P = 0.44), and BMI (P = 0.88). The combination of the Foley catheter and oral misoprostol group showed significantly higher Bishop scores at 6 hours (P < 0.001) and 12 hours (P = 0.02). The oral misoprostol alone group exhibited a significantly higher rate of cases failing to deliver within 24 hours of induction compared to the combination treatment group (73.4% *vs.* 11.6%, P < 0.001). Furthermore, the oral misoprostol alone group demonstrated significantly higher incidences of adverse outcomes, including uterine tachysystole (17.6% *vs.* 3.85%, P < 0.001), NICU hospitalization (8% *vs.* 1.54%, P = 0.015), abnormal Apgar score at five minutes (4.8% *vs.* 0%, P=0.01), and meconium presence (7.2% *vs.* 1.54%, P = 0.03). **Conclusion**: This study suggests that the combined method for labor induction is more appropriate due to its quicker and more impactful results, along with lower complication rates.

Key words: Labor induction, Misoprostol, Foley catheter, Clinical trial

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INTRODUCTION

Induction of labor involves the initiation of uterine contractions to facilitate the completion of labor before spontaneous contractions begin. In recent years, there has been a significant surge in the frequency of induced labor, with rates in the United States escalating from 9.5% in 1990 to 27.1% in 2018[1]. Indications for induction include post-term pregnancy, premature rupture of membranes (PROM), conditions associated with high blood pressure like pre-eclampsia and eclampsia, diabetes, chorioamnionitis, and pregnancies involving twins, with post-term pregnancy being one of the most common indications[2].

Despite its widespread use, induction of labor carries certain risks, including an elevated risk of infection, hyperstimulation, fetal distress, uterine rupture, and an increased risk of cesarean section[3–5]. For women with an unfavorable cervix, the induction process often begins with cervical ripening. Various methods exist for inducing labor and ripening, categorized into non-drug methods such as amniotomy and Foley catheter, and drug methods such as the use of prostaglandins. Prostaglandins stand out as one of the most extensively employed pharmaceuticals for labor induction, particularly in regions with favorable conditions. They can be administered orally, intravenously, or topically in the vagina or cervix[6]. Previous studies have demonstrated that misoprostol (PGE1) is more effective than prostaglandins E2 (PGE2) and oxytocin[7].

Due to the lower incidence of uterine hyperstimulation and fetal complications, prescribing misoprostol in oral form is preferred over vaginal administration. Its availability and cost-effectiveness are among other significant advantages of misoprostol[8]. The incidence of side effects with misoprostol varies depending on the method of administration, ranging

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from 8% (vaginal method) to 22% (oral method) and 34% (sublingual method). It proves effective in regions with more limited resources. The purpose of using the Foley catheter is to prepare the cervix (ripening) through mechanical dilation of the cervical canal and an increase in the endogenous secretion of prostaglandins[9]. Previous studies have consistently reported equal efficacy and fewer occurrences of hyperstimulation, uterine, and fetal complications following the use of the Foley catheter compared to other methods of labor induction[10,11]. It appears that the use of the Foley catheter does not elevate the risk of infection[12].

The optimal method for inducing labor is currently a topic lacking consensus. Considering the distinct mechanisms of action for each of the pharmacological and mechanical methods of labor induction, there is potential for a synergistic effect when these methods are used in combination. However, concerns exist regarding potential adverse effects on both the mother and the neonate[13,14]. Due to limited treatment options and relatively few studies addressing the efficacy and safety of simultaneous use, especially with the oral form of misoprostol, there is a need for further investigation[13]. Therefore, we have decided to conduct a clinical trial study to assess the effectiveness and side effects of combining these two labor induction methods. This study aims to compare the outcomes with the use of oral misoprostol alone in a group of Iranian women with different indications.

METHODS

The present study is a clinical trial conducted on pregnant women with a gestational age of 37 weeks or more who were candidates for induction of labor due to various medical indications. The trial compared the effectiveness and safety of two methods of labor induction: the combination of mechanical (Foley catheter) and pharmacological (misoprostol) methods versus the use of misoprostol alone. The study was conducted in the Obstetrics and Gynecology Department of Shariati Hospital in Tehran during the first three months of 2022.

Sample size determination was based on the results of a study by Hossein *et al.*[13], where the rates of failed induction within the first 24 hours were 11.8% for the combination of oral misoprostol plus Foley catheter group and 28.7% for the oral misoprostol group. Considering an 85% power of the test, a type I error level of 0.05, and an estimated attrition rate of 15%, the sample size for each study arm was calculated to be 132 participants.

The inclusion criteria were as follows: the need for labor induction as determined by a physician, maternal age of 18 years or older, gestational age of 37 weeks or more, singleton pregnancy, and a Bishop score of less than 6. Women with contraindications to labor induction, such as cephalopelvic disproportion, placenta previa, previous uterine surgery, multiple pregnancies, and medical conditions contraindicating vaginal delivery, were excluded from the study. In this study, eligible women were randomly allocated to two groups: one receiving oral misoprostol and the other receiving a combination of oral misoprostol and a Foley catheter, following detailed explanations about the study procedures and obtaining written consent from the participants. It's important to note that blinding was not implemented due to the nature of the study design.

Upon entry into the study, eligible participants underwent a comprehensive clinical examination conducted by a gynecologist and their assistant. All relevant demographic information, medical history, details of the pregnancy, and cervical scores were thoroughly documented in specialized forms.

The pregnant women in the combination of oral misoprostol with Foley catheter group were administered oral misoprostol tablets at a dosage of 50 mg every 4 hours, with a maximum of three doses a day. Prior to each dose, the fetal and uterine conditions were assessed, and upon confirmation, the specialist doctor would prescribe the next dose. Subsequently, a sterile Foley catheter of suitable size was inserted into the cervix and secured after evaluating the condition of the cervix and the fetus. The Foley catheter balloon was filled with 30 ml of distilled water or normal saline and fixed to the patient's thigh. In the control group, patients received only the prescribed misoprostol pill, following the same procedure. The Bishop scores in this study were measured prior to induction, and 6 and 12 hours after the initiation of the intervention by a single specialist, which helps to maintain consistency and reduce variability in the scoring process.

If labor did not commence within 24 hours after the intervention in both groups, the induction process was deemed unsuccessful. The decision to continue the treatment process depended on the specialist doctor's opinion. Various parameters, including the number of childbirths within 24 hours after the intervention, the time interval from the beginning of the intervention to delivery, the frequency of cesarean sections, cases of no change in the cervix in the first 24 hours, the dose of oxytocin received, and maternal and fetal complications (such as uterine systolic

tachycardia, hypertonic uterine contractions, uterine rupture, postpartum hemorrhage, infection, asphyxia, Apgar score less than 7), and NICU hospitalization, were statistically compared between both groups.

In the statistical analysis, a t-test was employed to compare the time interval between induction and delivery across the two groups. Additionally, a chi-square test was utilized to compare the outcomes after delivery between the two groups. The significance level for establishing relationships was set at less than 0.05. Data analysis was performed using SPSS version 24 software.

RESULTS

A total of 295 participants were initially assessed for eligibility. Among them, 27 patients did not meet the inclusion criteria, and an additional 8 patients declined to participate. Subsequently, 260 participants were randomly allocated to either the combination treatment or misoprostol alone, with 130 patients assigned to each group. Notably, 3 patients in the misoprostol alone group did not receive their allocated treatment, and 2 patients discontinued the intervention. The discontinuation of the intervention in two cases was due to the preferences expressed by the patients or their partners. In the final analysis, 130 patients from the combination treatment group and 125 patients from the misoprostol alone treatment group were included.

In **Table 1**, we conducted a comparison of the baseline characteristics of patients within the two investigated treatment groups. As shown, the two groups were homogeneous in regards to age (27.11 ± 3.88 *vs.* 26.46 ± 4.95, P = 0.26), gestational week (P = 0.44), and BMI (P = 0.88). In both groups, post-term was the main cause of labor induction. However, there was not a significant difference between the two groups in this regard (P = 0.99).

Table 2 compares key variables between the oral misoprostol alone group and the combination of Foley's catheter and oral misoprostol group. The oral misoprostol alone group exhibited significantly higher values in the time from intervention to delivery (P < 0.001), required time to start the active phase (P < 0.001), time needed to initiate labor (P < 0.001), and oxytocin dose (P = 0.001). On the other hand, the combination of Foley's catheter and oral misoprostol group showed significantly higher Bishop scores at 6 hours (P < 0.001) and 12 hours (P = 0.02). There were no significant differences observed between the two groups concerning delivery type (P = 0.26), post-delivery bleeding (P = 0.47), and Apgar score at one minute (P = 0.23). However, a notable discrepancy emerged in the proportion of cases failing to deliver within 24 hours of induction, with the oral misoprostol alone group exhibiting a significantly higher rate compared to the combination treatment group (88.46% *vs.* 25.6%, P < 0.001). Furthermore, the oral misoprostol alone group demonstrated significantly higher incidences of adverse outcomes, including uterine tachysystole (17.6% *vs.* 3.85%, P < 0.001), NICU hospitalization (8% *vs.* 1.54%, P = 0.015), abnormal Apgar score at five minutes (4.8% *vs.* 0%, P = 0.01), and meconium presence (7.2% *vs.* 1.54%, P = 0.03), as detailed in **Table 3**.

DISCUSSION

The current clinical trial was conducted to assess and compare the efficacy and safety of two methods for labor induction, including the combination of misoprostol and Foley catheter methods, versus the use of oral misoprostol alone in women receiving care in the maternity ward. We found that the combination of the Foley catheter and oral misoprostol group showed significantly higher Bishop scores at 6 hours and 12 hours. In contrast, the group receiving oral misoprostol alone demonstrated a significantly higher rate of failing to deliver within 24 hours of induction, and adverse outcomes encompassed uterine tachysystole, NICU hospitalization, abnormal Apgar scores at five minutes, and the presence of meconium.

Regarding the duration from the onset of intervention to birth, our study revealed a noteworthy reduction of approximately 8 hours in the combined group. In contrast to our findings, Lanka and colleagues[15] did not observe a significant difference between the two groups. Conversely, Aduloju *et al.*[16] and Nasioudis *et al.*[17] reported consistent findings, indicating a shorter duration in the combined group. This variance could be attributed to differences in study populations, methodologies, or individual patient responses.

In our study, the rate of Bishop score increase was higher in the combined group. This was evident at both 6 and 12 hours post-intervention. Consistent with this, Aduloju *et al.*[16] reported a similar trend, emphasizing the superiority of the combined treatment in advancing cervical ripening. Moreover, the combined group reached the active phase 6 hours earlier. This finding aligns with the increased Bishop score and supports the notion that combined misoprostol treatment accelerates labor progression.

We found that the combined group required a lower oxytocin dose. This aligns with the observed efficiency of the combined treatment, as also noted by

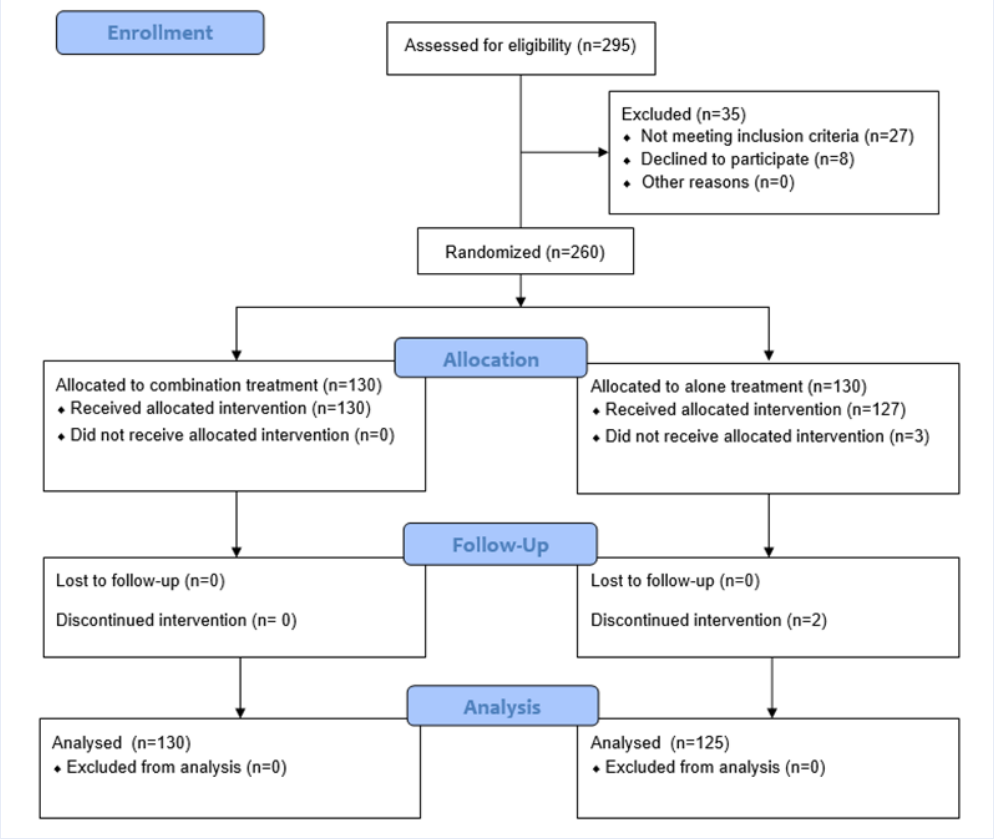

Figure 1: **The process of selecting and allocating the patients in the investigated treatment groups.**

Table 1: **Comparison of the baseline characteristics of patients in the two investigated groups**

Variable		Foley's catheter and oral misoprostol	Oral misoprostol alone	P-Value
Age (year)		27.11 ± 3.88	26.46 ± 4.95	0.26
Gestational age at delivery (week)		40.03 ± 4.12	39.63 ± 3.77	0.44
BMI (kg/m^2)	< 25	65 (50)	62 (49.6)	0.88
	25 - 30	44 (33.85)	40 (32.0)	
	> 30	21(16.15)	23 (18.4)	
Labor induction cause	Post term	31 (23.85)	30 (24.0)	0.99
	High BP	22 (16.92)	23 (18.4)	
	LP	22 (16.92)	21 (16.8)	
	Preeclampsia	17 (13.08)	15 (12.0)	
	GDM	15 (11.54)	14 (11.2)	
	Vaginal bleeding	11 (8.46)	11 (8.8)	
	Decreased fetal movement	12 (9.23)	11 (8.8)	

Table 2: Comparison of the primary outcome between two investigated group

Variable	Foley's catheter and oral misoprostol	Oral misoprostol alone	P-Value
Time from the intervention to delivery (h)	18.01 ± 7.66	26 ±6.93	< 0.001
Bishop score prior induction	1.76 ± 0.91	1.54 ± 1.15	0.1
Bishop score in 6 hours	2.32 ± 1.63	1.63 ± 0.51	< 0.001
Bishop score in 12 hours	5.72 ± 2.37	2.94 ± 1.29	0.02
Required time to start the active phase (h)	12.62 ± 9.40	18.69 ± 8.53	< 0.001
Time needed to initiate labor time (h)	16.91 ± 9.95	24.30 ± 5.33	< 0.001
Oxytocin dose	10.37 ± 4.83	11.61 ± 3.94	0.001

Table 3: Comparison of the primary outcome between two investigated group

Variable		Foley's catheter and oral misoprostol	Oral misoprostol alone	P-Value
Delivery type	Natural	110 (84.62)	91 (79.13)	0.26
	Cesarean	20 (15.38)	24 (20.87)	
Delivery time	<24 hours	115 (88.46)	32 (25.6)	<0.001
	> 24 hours	15 (11.54)	93 (74.4)	
Uterine Tachysystole	Yes	5 (3.85)	22 (17.6)	<0.001
	No	125 (96.15)	103 (82.4)	
Bleeding after delivery	Yes	15 (11.54)	11 (8.80)	0.47
	No	115 (88.46)	114 (91.20)	
NICU hospitalization	Yes	2 (1.54)	10 (8.0)	0.015
	No	128 (98.46)	115 (92.0)	
Apgar minute 1	Abnormal	2 (1.54)	5 (4.0)	0.23
	Normal	128 (98.46)	120 (96.0)	
Apgar minute 5	Abnormal	0	6 (4.8)	0.01
	Normal	130 (100)	119 (95.2)	
Meconium presence	Yes	2 (1.54)	9 (7.2)	0.03
	No	128 (98.46)	116 (92.8)	

Aduloju *et al.* [16]. The reduced need for oxytocin could be associated with the synergistic effects of misoprostol and the Foley catheter, enhancing uterine contractions.

Regarding the frequency of maternal complications, the lower incidence of tachysystole in the combined group suggests potential advantages in terms of safety. However, the comparable risk of hemorrhage warrants careful consideration. A lower incidence of uterine tachysystole in the combination group may be due to the lower doses of misoprostol that are required when combination methods are used [17]. Contrary to our findings in the two conducted studies in Africa, NICU admission was significantly higher in the combined group [16,18]. In the Jain et al. study, the only significant difference between the two groups was found in postpartum hemorrhage and 5-minute Apgar score <7, which was significantly more frequent in the misoprostol alone group [19]. Comparing our findings with other studies [20,21], discrepancies in outcomes may be attributed to differences in study design, participant demographics, or variations in intervention protocols. The heterogeneity of patient populations and diverse clinical settings may contribute to

divergent results.

However, the present study had some limitations. First, the study was conducted solely at Shariati Hospital in Tehran, which may limit the generalizability of the findings to a broader population. Different healthcare settings and patient demographics could influence the outcomes. Secondly, the lack of blinding introduces the potential for bias in outcome assessments and could impact the overall internal validity of the study. Finally, unanticipated dropouts or withdrawals during the study could influence the final sample size and, consequently, the statistical power.

CONCLUSION

In conclusion, for labor induction, the combined treatment emerges as more appropriate due to its quicker and more impactful results, along with lower complication rates. However, ongoing research and standardization of protocols are imperative to ensure consistent and optimal outcomes across diverse patient populations.

ABBREVIATIONS

BMI - Body Mass Index, **NICU** - Neonatal Intensive Care Unit, **PGE1** - Prostaglandin, **E1PGE2** - Prostaglandin E2, **PROM** - Premature Rupture of Membranes, **SPSS** - Statistical Package for the Social Sciences

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AUTHOR'S CONTRIBUTIONS

All authors equally contributed to this work, read and approved the final manuscript.

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AVAILABILITY OF DATA AND MATERIALS

Data and materials used and/or analyzed during the current study are available from the corresponding author on reasonable request.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Deputy of Research and Technology of Tehran University of Medical Sciences approved the study (Ethic code: IR.TUMS.MEDICINE.REC.1400.764).

CONSENT FOR PUBLICATION

Not applicable.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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