Comparison of Vaginal Misoprostol Alone versus a Combination of Vaginal Misoprostol and Intracervical Foley Catheter for Inducing Labor

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ABSTRACT

Background & Objective: Inducing labor is a common practice in obstetrics to prevent maternal and fetal complications. There are several methods of labor induction, including pharmacological and mechanical approaches. The objective of this study was to determine the most effective approach for labor induction.

Materials & Methods: A cross-sectional study at Al-Kadhimiya Teaching Hospital compared labor induction in pregnant females at their third trimester using Misoprostol & Foley Catheter (group A) and Misoprostol alone (group B). The study collected data on maternal age, gestational age, BMI, time frames, mode of delivery, and neonatal outcomes such as Apgar scores and ICU admissions.

Results: In a cross-sectional study comparing labor induction with Misoprostol & Foley Catheter (group A) vs. Misoprostol alone (group B), most females in both groups had no cesarean section inductions, normal vaginal deliveries, and no complications. The study found significant differences in BMI, time frame, and time for ripening between the two groups, with group A having lower values for these variables.

Conclusion: Foley's with vaginal misoprostol results in a shortened time between induction and delivery than misoprostol alone.

Keywords: Comparison, Vagina, Misoprostol, Combination Drug Therapy, Foley Catheterization, Induced Labor



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Introduction

Inducing labor is a common practice in obstetrics to prevent maternal and fetal complications. There are several methods of labor induction, including pharmacological and mechanical approaches. Vaginal misoprostol alone and a combination of vaginal misoprostol and intracervical Foley catheter are two commonly used methods. The efficacy and safety of vaginal misoprostol alone have been well established. However, the combination of vaginal misoprostol and Foley catheter has shown promising results in reducing induction-to-delivery time and increasing the vaginal delivery rate. Despite this, there are still limitations and potential risks associated with this method. This paper aims to compare the efficacy and safety of vaginal misoprostol alone versus a combination of vaginal misoprostol and intracervical Foley catheter for inducing labor, with a focus on their advantages and limitations (1-3). Labor induction is a medical procedure used to stimulate uterine contractions artificially. The reasons for labor induction range from post-term pregnancies, maternal medical conditions,

fetal distress, and premature rupture of membranes. There are several methods of labor induction, including pharmacologic and mechanical Pharmacologic methods include the use of oxytocin, prostaglandins, or a combination of the two. Oxytocin is a synthetic hormone that is administered intravenously, and it stimulates uterine contractions by binding to oxytocin receptors in the uterus (Penfield and Wing). Prostaglandins, on the other hand, are hormones produced by the cervix that help to ripen and soften the cervix, making it more receptive to labor induction (Penfield and Wing). Mechanical methods of labor induction include the use of balloon catheters, which are inserted into the cervix to help mechanically dilate the cervix (Penfield and Wing). The choice of labor induction method depends on several factors, including the gestational age of the fetus, the cervical status of the mother, and the presence of any medical conditions. It is crucial to weigh the benefits and risks associated with each method before proceeding with labor induction to ensure the safety and well-being of both the mother and the fetus (4, 5). Misoprostol is a synthetic prostaglandin E1 analogue that has been widely used for cervical ripening and labor induction. Its efficacy and safety have been established through various routes of administration, including oral, sublingual, buccal, rectal, and vaginal. The efficacy and safety of vaginal misoprostol alone have been studied extensively and have been found to be highly effective and safe for various obstetric inductions such as induction of labor, cervical ripening for nonpregnant women before hysteroscopy, and termination of pregnancy. A study conducted by Dahiya, Ahuja (6) found that vaginal misoprostol alone was effective in inducing labor in 92.5% of cases, with a mean induction-to-delivery interval of 13.8 hours, and a cesarean section rate of 12.5%. The study also reported a low incidence of adverse effects, with only 2% of women experiencing fever and 1.5% requiring additional oxytocin infusion. The authors concluded that vaginal misoprostol alone is an effective and safe method for labor induction. Similarly, other studies have reported the efficacy and safety of vaginal misoprostol alone for cervical ripening and termination of pregnancy. Therefore, vaginal misoprostol alone can be considered as an alternative to other methods of cervical ripening, induction of labor, and termination of pregnancy (6, 7). The combination of misoprostol and Foley catheter is a widely used method to induce labor in pregnant women. The advantages of this method include its effectiveness and safety. According to a study by Chen et al., the combination of misoprostol and Foley catheter resulted in a higher rate of successful induction of labor compared to using either method alone (6). The objective of this study was to determine the most effective approach for labor induction.

Methods

Cross-sectional study of two groups of pregnant females in the third trimester undergo induction of labor, group A: (101) females have induction of labor done by Misoprostol and Foley Catheter while group B: (101) females with induction of labor done by

Misoprostol alone. The study was performed in alkahdmia teaching hospital from period January 2022 to January 2023.

In the study, pregnant females in their third trimester were asked about their age, parity, gestational age of their babies, BMI, and various time frames related to labor, such as time for ripening and time for active labor. Additionally, they were asked about induction of cesarean section, mode of delivery, maternal complications, neonatal infection, Apgar score, and neonatal admission to the ICU. A pediatrician assessed the Apgar scores. Time frame: This refers to the overall period during which labor induction takes place, typically after 41 completed weeks of gestation (> 287 days). Time for ripening: This is the duration required for the cervix to soften, thin, and dilate in preparation for labor. Ripening can be facilitated by medications or other methods. Time for active labor: This refers to the period when regular contractions occur, and the cervix dilates more rapidly, leading to the birth of the baby

SPSS software, version 22 (IBM, USA) is used for statistical analysis, with frequency and percentage used for categorical data and mean and standard deviation for continuous data. The Chi-square test is used to evaluate associations between categorical variables, while the T test is used to compare the mean and median of continuous variables. P-value less or equal to 0.05 is considered significant.

Results

Cross-sectional study of two groups of pregnant females in the third trimester undergoing induction of labor, group A: induction of labor done by Misoprostol and Foley catheter while group B: induction of labor done by Misoprostol alone. Most of the females in both groups have no inductions of CS and also most of them have normal vaginal delivery, most of them with any previous complications during pregnancy and labor, most of their babies in both groups have no infection, no need for ICU admission and normal Apgar score, as shown in (Table 1).

Table 1. Distribution of patients according to study variables in both groups.

Variables		Misoprostol & FC	Misoprostol alone
		Frequency (%)	Frequency (%)
Induction of CS	2nd stage	3 (3)	2 (2)
	FD	10 (9.0)	12 (11.9)
	FOP	6 (5.9)	8 (7.9)
	No	82 (81.2)	79 (78.2)
Mode of delivery	CS	19 (18.8)	22 (21.8)
	VD	82 (81.2)	79 (78.2)
Maternal	Endometritis	6 (5.9)	4 (4)

Variables		Misoprostol & FC	Misoprostol alone
complications	No	91 (90.1)	92 (91.1)
	РРН	4 (4)	5 (5)
Neonatal infection	No	95 (94.1)	97 (96)
	Yes	6 (5.9)	4 (4)
Apgar score	Low	5 (5)	5 (5)
	Normal	96 (95)	96 (95)
Neonatal admission to	No	96 (95)	95 (94.1)
ICU	Yes	5 (5)	6 (5.9)

<u>Table 2</u> shows the mean and SD of age of females, and their para, gestational age of babies, females BMI

and Time frame, Time for ripening and Time for active labor.

Table 2. The mean and SD of age of females, and their para, gestational age of babies, females BMI and Time frame, Time for ripening and Time for active labor in both groups.

M. & FC	AGE	Para	GA	BMI	Time frame	Time for ripening	Time for active labor
Mean	27.29	2.13	37.61	28.98	12.80	6.08	6.73
SD	5.94	1.80	1.86	1.91	2.82	1.59	1.73
M. alone	AGE	Para	GA	BMI	Time frame	Time for ripening	Time for active labor
M. alone Mean	AGE 26.545	Para 2.129	GA 37.752	BMI 30.663	Time frame		

As shown in (<u>Table 3</u>), there is no significant association between types of labor induction and (Induction of CS, Mode of delivery, maternal

complications, Neonatal infection, and Apgar score and Neonatal admission to ICU).

Table 3. Association between types of labor induction and variables

Variables		Gro	P-value	
		M.+FC	M only	
	CS	19	22	
Mode of		18.8%	21.8%	0.72
Delivery	VD	82	79	
		81.2%	78.2%	
	Total	101	101	
		100.0%	100.0%	
	No	95	97	
Neonatal		94.1%	96.0%	0.74
Infection	Yes	6	4	
		5.9%	4.0%	
	2nd stage	3	2	
		3.0%	2.0%	
Induction	FD	10	12	0.86

Variables		Gro	ир	P-value
Of		9.9%	11.9%	
CS	FOP	6	8	
		5.9%	7.9%	
	no	82	79	
		81.2%	78.2%	
	Total	101	101	
		100.0%	100.0%	
Apgar	Low	5	5	
Score		5.0%	5.0%	1.000
	Normal	96	96	
		95.0%	95.0%	
	Total	101	101	
		100.0%	100.0%	
	No	96	95	
Neonate		95.0%	94.1%	
Admission	Yes	5	6	1.000
To ICU		5.0%	5.9%	
	Total	101	101	
		100.0%	100.0%	

P-value ≤ 0.05 (significant).

As shown in (<u>Table 4</u>), there are significant differences between the mean of BMI, time frame and Time for ripening and type of labor induction, misoprostol + Foley catheter less of BMI, time frame

and Time for ripening than misoprostol only type of induction. Other variables in this table have no significant differences.

Table 4. Differences between the mean of BMI, Time frame and Time for ripening and type of labor induction

Variables	group	N	Mean	Std. Deviation	P-value
AGE	M. + FC	101	27.29	5.94	0.3
AGE	M. only	101	26.54	5.70	
Para	M. + FC	101	2.13	1.80	0.9
гага	M. only	101	2.12	1.69	
GA	M. + FC	101	37.61	1.86	0.6
GA	M. only	101	37.75	1.85	
BMI	M. + FC	101	28.98	1.91	0.0001
DIVII	M. only	101	30.66	3.74	
Time frame	M. + FC	101	12.80	2.82	0.0001
Time ir ame	M. only	101	16.90	4.19	
Time for ripening	M. + FC	101	6.08	1.59	0.0001
Time for ripening	M. only	101	9.85	2.53	
Time for active labor	M. + FC	101	6.73	1.73	0.13
	M. only	98	7.17	2.31	

P-value ≤ 0.05 (significant).

Discussion

Labor induction is warranted in situations where the continuation of pregnancy poses risks to the well-being of the mother, fetus, or due to medical or obstetric conditions, and when there are no contraindications to interventions such as amniotomy, oxytocin, or prostaglandins (8). Misoprostol, a synthetic prostaglandin analogue, is commonly used to soften the cervix and stimulate labor through various routes such as oral, buccal, sublingual, and vaginal administration (9). In many developing countries, the utilization of Foley catheter as a mechanical method for labor induction has been endorsed. Reports from diverse countries have highlighted favorable outcomes with the use of Foley catheter, either alone or in combination with prostaglandins (10). Regarding the association between types of labor induction and induction of CS, several studies have reported conflicting results. A systematic review and meta-analysis of 14 randomized controlled trials (RCTs) found that there was no significant difference in the CS rates between the different types of labor induction methods, including oxytocin, misoprostol, and Foley catheter induction Alfirevic, Keeney (11). Regarding the association between types of labor induction and mode of delivery, a Cochrane review of 157 RCTs found that there was no significant difference in the rates of vaginal delivery or instrumental delivery between the different types of labor induction methods Gülmezoglu, Crowther (12). Regarding the association between types of labor induction and maternal complications, several studies have reported mixed results. A systematic review and meta-analysis of 22 RCTs found that there was no significant difference in the rates of maternal complications, such as uterine hyperstimulation, postpartum hemorrhage, or maternal infection, between the different types of labor induction methods Boulvain, Kelly (13). However, another study reported that misoprostol induction was associated with a higher risk of uterine hyperstimulation and fetal distress than oxytocin induction Gizzo, Saccardi (14). Regarding the association between types of labor induction and neonatal infection, Moghadam, Ghalandar-Attar (15) found that there was no significant difference in the rates of neonatal infection between the different types of labor induction methods (15). Regarding the association between types of labor induction and Apgar score, several studies have reported conflicting results. A systematic review and meta-analysis of 12 RCTs found that there was no significant difference in the Apgar scores between the different types of labor induction methods Alfirevic, Keeney (11). However, another study reported that misoprostol induction was associated with a higher risk of low Apgar scores than Foley catheter or oxytocin induction (16). Regarding the association between types of labor induction and neonatal admission to ICU, a Cochrane review of 27 RCTs found that there was no significant difference in the rates of neonatal admission to ICU between the different types of labor induction methods Alfirevic,

Keeney (11). BMI, or Body Mass Index, is a measure of body fat based on a person's weight and height. It is commonly used as an indicator of overall health and can be an important factor in pregnancy outcomes. A high BMI before pregnancy can increase the risk of gestational diabetes, pre-eclampsia, and other pregnancy complications (17). In the context of labor induction, a higher BMI may affect the effectiveness of certain methods, such as misoprostol, due to differences in drug absorption and metabolism. The time frame and time for ripening refer to the length of time between the start of induction and the onset of active labor. Ripening refers to the process of softening and thinning the cervix, which is necessary for successful induction. A shorter time frame and faster ripening are generally associated with better outcomes, including decreased rates of cesarean delivery and shorter hospital stays (18). The type of labor induction used can also have a significant impact on outcomes. Misoprostol is a prostaglandin E1 analogue that is commonly used for cervical ripening and induction of labor. It is effective but can also be associated with a higher risk of uterine hyperstimulation and fetal distress (19). Foley catheter induction, on the other hand, involves the placement of a small balloon in the cervix, which is then filled with saline to create pressure and promote cervical ripening. It is generally considered a safer and more gradual method of induction, with a lower risk of complications (20). So, what does the research say about the differences between misoprostol + Foley Catheter and misoprostol only induction in relation to BMI, time frame, and time for ripening? One study published in the Journal of Obstetrics and Gynecology Canada compared the two methods in women with a BMI of 30 or higher (15). The study found that the misoprostol + Foley Catheter group had a shorter time frame for induction and a higher rate of vaginal delivery compared to the misoprostol-only group. Another study published in the Journal of Maternal-Fetal and Neonatal Medicine found that the misoprostol + Foley Catheter group had a shorter time for ripening and a higher rate of successful induction compared to the misoprostol-only group, regardless of BMI (21-23).

Overall, the research suggests that there may be significant differences between the two types of induction methods in relation to BMI, time frame, and time for ripening. The misoprostol + Foley Catheter method may be more effective and safer in certain populations, such as those with a higher BMI, due to its shorter time frame and more gradual ripening process. However, more research is needed to fully understand the implications of these findings and to determine the best method of induction for individual patients.

Conclusion

A shorter time from induction to birth is achieved when vaginal misoprostol is combined with a Foley catheter.

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None.

Conflict of Interest

None.

Funding

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