

**Comparative Study of Vaginal Misoprostol Alone Versus a Combination of Vaginal Misoprostol and Intracervical Foley Catheter for Inducing Labor**Shilpi Singh<sup>1</sup>, Anjani Kumari<sup>2</sup>, Pankhuri Jaiswal<sup>3</sup>, Seema<sup>4</sup><sup>1</sup>Senior Resident, Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Laheriasarai, Bihar<sup>2</sup>Senior Resident, Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Laheriasarai, Bihar<sup>3</sup>Senior Resident, Department of Obstetrics and Gynaecology, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, U.P<sup>4</sup>Professor and Head of Department, Department of Obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Laheriasarai, Bihar

Received: 25-03-2024 / Revised: 23-04-2024 / Accepted: 26-05-2024

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Conflict of interest: Nil

**Abstract:****Background:** In order to avoid difficulties for both the mother and the fetus, inducing labor is a standard treatment in obstetrics. Labor induction can be accomplished by a variety of techniques, such as mechanical and pharmacological procedures. The aim of the study was to identify the best method for inducing labor.**Methods:** A cross-sectional study conducted at the Department of Obstetrics and Gynecology, Darbhanga Medical College and Hospital, Laheriasarai, Bihar, compared the use of Misoprostol & Foley Catheter (group A) and Misoprostol alone (group B) for inducing labor in pregnant women in their third trimester. Data on mother age, gestational age, BMI, birth mode, duration of pregnancy, and newborn outcomes, including Apgar scores and ICU admissions, were gathered for the study.**Results:** In a study that compared the use of a Foley catheter plus misoprostol for labor induction (group A) to misoprostol alone (group B), the majority of women in both groups delivered their babies vaginally and without any problems or cesarean sections. The BMI, time frame, and ripening time were found to differ significantly between the two groups in the study; group A had lower values for these factors.**Conclusion:** Compared to misoprostol alone, foley's plus vaginal misoprostol produces a shorter period between induction and delivery.**Keywords:** Misoprostol, Foley Catheterization, Induced Labor.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

A series of uterine contractions known as labor cause the cervix to dilate and efface, and voluntary bearing down efforts result in the ejection of the conceived goods per vaginam.[1] In obstetrics, inducing labor is a routine practice. It is described as artificially inducing labor before its spontaneous beginning at a feasible gestational age in order to facilitate vaginal delivery in expectant mothers.[2] The purpose of inducing labor is to safely and promptly deliver the baby vaginally, avoid needless C-sections, and ensure a healthy outcome for the newborn.[3] The majority of the time, labor begins on its own, but for a variety of medical and obstetrical reasons, it must be induced when the advantages of extending the pregnancy outweigh those of inducing labor.[4] In industrialized nations, the percentage of labor induction has doubled and now makes up 25% of all deliveries.[5] There

are several ways to induce labor, including mechanical, surgical, pharmacological, and combination techniques. One of the most significant and traditional approaches to labor induction is the mechanical method.[2] Foley's catheter, a hygroscopic laminaria tent, and an additional amniotic saline infusion are all part of it. By separating the membrane from the lower uterine segment through mechanical means, lytic enzymes are released, which in turn promotes prostaglandin synthesis indirectly.[6] Prostaglandins (PG) E2 and E1, relaxin, oxytocin, and mifepristone are examples of pharmacological drugs. A synthetic version of prostaglandin E1 is called misoprostol.[7] It was initially created as a gastrocytoprotective agent. The sublingual, buccal, vaginal, and rectal routes are utilized to administer it. Cervical ripening and the rate of vaginal delivery within 24 hours are greatly enhanced

by the vaginal route. [8] It is frequently used for postpartum hemorrhage treatment and prophylaxis, as well as for the induction of labor. A useful technique for cervical ripening in unripe cervixes is the combination of prostaglandins and mechanical techniques. When used in tandem, mechanical devices can induce cervical dilatation while PG drugs soften and efface the cervix, potentially leading to a higher degree of cervix ripening and a successful induction of labor.

### Material and Methods

This cross-sectional study was carried out from May 2022 to January 2023 in the Department of Obstetrics and Gynecology at Darbhanga Medical College and Hospital in Laheriasarai, Bihar. The 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.

In the study, third-trimester pregnant females answered questionnaires on their age, parity, baby's gestational age, body mass index, and several labor-related timelines, like ripening and active labor times. They were also questioned about the route of birth, problems for the mother, infection in the newborn, Apgar score, and the admission of the newborn to the intensive care unit. A physician evaluated the Apgar ratings. Duration: This is the total time frame that labor induction occurs, usually

41 full weeks of gestation (more than 287 days). The amount of time needed for the cervix to soften, thin, and dilate in order to get ready for labor is known as the "ripening time." Other techniques or drugs may help with ripening. The time for "active labor" is when the cervix dilates more quickly and there are regular contractions, which eventually result in the birth of the baby [6].

Statistical analysis is performed using IBM version 22 of SPSS software, with mean and standard deviation being utilized for continuous data and frequency and % for categorical data. While the T test is used to compare the mean and median of continuous variables, the Chi-square test is used to assess connections between categorical variables. A significant P-value is one that is  $\leq 0.05$ .

### Results

A cross-sectional study was conducted on two groups of pregnant women who were in the third trimester and were being induced into labor. Group A received induction of labor with a Foley catheter and Misoprostol, while group B received induction of labor only with Misoprostol. As can be seen in Table 1, the majority of the females in both groups have not had any CS inductions and have had normal vaginal deliveries. The majority of them have had any prior labor and pregnancy complications. The majority of their babies in both groups have not had any infections and do not require ICU admission.

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

Variables		Misoprostol & FC	Misoprostol alone
		No. of cases (%)	No. of cases (%)
Induction of CS	2 <sup>nd</sup> 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 complications	Endometritis	6(5.9%)	4(4%)
	No	91(90.1%)	92(91.1%)
	PPH	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 ICU	No	96(95%)	95(94.1%)
	Yes	5(5%)	6(5.9%)

Table 2 shows the mean and standard deviation of female age, together with their para, baby's gestational age, female BMI, and the duration of ripening and 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
Mean	26.545	2.129	37.752	30.663	16.9010	9.8515	7.1735
SD	5.7053	1.6951	1.8569	3.7424	4.19167	2.53530	2.31100

Types of labor induction and (induction of CS, mode of delivery, maternal problems, neonatal infection, and Apgar score and neonatal admission to ICU) do not significantly correlate, as Table 3 illustrates.

**Table 3: Association between types of labor induction and variables**

Variables		Group		P-value
		M.+FC	M only	
Mode of Delivery	CS	19	22	0.72
		18.8%	21.8%	
	VD	82	79	
		81.2%	78.2%	
Total	101	101		
	100.0%	100.0%		
Neonatal Infection	No	95	97	0.74
		94.1%	96.0%	
	Yes	6	4	
		5.9%	4.0%	
Induction of CS	2ndstage	3	2	0.86
		3.0%	2.0%	
	FD	10	12	
		9.9%	11.9%	
	FOP	6	8	
		5.9%	7.9%	
	No	82	79	
		81.2%	78.2%	
Total	101	101		
	100.0%	100.0%		
Apgar Score	Low	5	5	1.000
		5.0%	5.0%	
	Normal	96	96	
		95.0%	95.0%	
	Total	101	101	
		100.0%	100.0%	
Neonate Admission to ICU	No	96	95	1.000
		95.0%	94.1%	
	Yes	5	6	
		5.0%	5.9%	
	Total	101	101	
		100.0%	100.0%	

P-value  $\leq$  0.05 (significant).

Table 4 illustrates that there are notable distinctions between the misoprostol + Foley catheter less of BMI, time frame, and time for ripening than the misoprostol only kind of induction in terms of mean BMI, time frame, and time for ripening. There are no notable changes between the other variables in this table.

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

Variables	Group	No.	Mean	Std. Deviation	P-value
	M.+FC	101	27.29	5.94	0.3
Age					
	M. only	101	26.54	5.70	

	M.+FC	101	2.13	1.80	0.9
Para					
	M. only	101	2.12	1.69	
	M.+FC	101	37.61	1.86	0.6
GA					
	M. only	101	37.75	1.85	
	M.+FC	101	28.98	1.91	0.0001
BMI					
	M. only	101	30.66	3.74	
	M.+FC	101	12.80	2.82	0.0001
Time frame					
	M. only	101	16.90	4.19	
	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	

## Discussion

When the mother's and the fetus' health is at risk, when there are no contraindications to procedures such as an amniotomy, oxytocin, or prostaglandins, or when there are medical or obstetric issues, labor induction is warranted [9]. Misoprostol is a prostaglandin analogue that is manufactured and usually used orally, buccally, sublingually, or vaginally to induce labor and soften the cervix [10].

The use of the Foley catheter as a mechanical technique for inducing labor has been approved in numerous developing nations. Positive results have been reported from a variety of nations when the Foley catheter is used, either by itself or in conjunction with prostaglandins [11]. Several research have revealed inconsistent results on the relationship between different labor induction methods and the induction of computer science. The various forms of labor induction techniques, such as oxytocin, misoprostol, and Foley catheter induction, did not significantly differ in the CS rates, according to a comprehensive review and meta-analysis of 14 RCTs. Keeney, Alfirevic [12]. A Cochrane review of 157 RCTs examined the relationship between labor induction methods and delivery mode and discovered no statistically significant difference in the rates of vaginal or instrumental delivery among the various labor induction techniques. Crowther, Gülmezoglu [13]. Numerous research have produced conflicting findings about the relationship between different labor induction techniques and difficulties for the mother. There was no discernible difference in the rates of maternal problems, such as uterine hyperstimulation, postpartum hemorrhage, or maternal infection, between the various labor induction techniques, according to a comprehensive review and meta-analysis of 22 RCTs. Kelly, Boulvain [14]. Nevertheless, compared to oxytocin induction, misoprostol induction was linked to a greater risk of uterine hyperstimulation

and fetal distress, according to another study Gizzo, Saccardi [15]. In reference to the relationship between labor induction methods and neonatal infection, Moghadam and Ghalandar-Attar [16] discovered that there was no statistically significant variation in the rates of neonatal infection across the various labor induction techniques [16].

Several research have produced contradictory findings about the relationship between the Apgar score and the various methods of labor induction. There was no discernible difference in the Apgar ratings across the various labor induction techniques, according to a systematic review and meta-analysis of 12 RCTs (Alfirevic, Keeney [12]). On the other hand, oxytocin or Foley catheter induction was linked to a lower risk of poor Apgar scores than misoprostol induction, according to a different study [17]. A Cochrane review of 27 RCTs examined the relationship between labor induction methods and neonatal admission to the intensive care unit (ICU) and discovered no statistically significant difference in the rates of neonatal admission to the ICU between the various labor induction methods Alfirevic, Keeney [12].

The Body Mass Index, or BMI, calculates a person's body fat percentage from their height and weight. It can have a significant impact on the outcome of a pregnancy and is frequently used as an indicator of general health. Prior to conception, a high body mass index can raise the risk of gestational diabetes, pre-eclampsia, and other pregnancy-related problems [18]. Due to variations in drug absorption and metabolism, a greater BMI may have an impact on the efficacy of some labor induction techniques, such as misoprostol. The period of time between the beginning of induction and the start of active labor is referred to as the time frame and time for ripening. The cervix must soften and narrow during the ripening process in order for induction to be successful. A shorter time frame

and faster ripening are generally associated with better outcomes, including decreased rates of cesarean delivery and shorter hospital stays [19]. The kind of labor induction that is employed can also significantly affect the results. An equivalent of prostaglandin E1, misoprostol is frequently used to induce labor and ripen the cervical mucosa. Although it works well, there is a chance that it will increase the risk of fetal distress and uterine hyperstimulation [20]. In contrast, Foley catheter induction creates pressure and encourages cervical ripening by inserting a tiny balloon into the cervix and filling it with saline. With a lesser likelihood of problems, it is typically regarded as a safer and more progressive technique of induction [21]. In terms of BMI, duration, and ripening time, what does the literature say about the distinctions between misoprostol + Foley Catheter vs misoprostol just induction? A study that was published in the *Journal of Obstetrics and Gynecology Canada* [16] examined the two approaches in females who had a body mass index (BMI) of 30 or above. According to the study, compared to the misoprostol-only group, the misoprostol + Foley Catheter group saw a shorter induction period and a greater vaginal delivery rate. In a different study, regardless of BMI [22–24], the misoprostol + Foley Catheter group saw a faster time for ripening and a higher rate of effective induction than the misoprostol-only group. This study was also published in the *Journal of Maternal-Fetal and Neonatal Medicine*.

### Conclusion

All things considered, the research points to possible notable distinctions between the two kinds of induction techniques for BMI, duration, and ripening time. Because of its shorter duration and more progressive ripening phase, the misoprostol + Foley Catheter technique may be safer and more effective in some populations, such as individuals with a higher body mass index. To completely comprehend the ramifications of these discoveries and to ascertain the most effective induction technique for a certain patient, additional study is necessary.

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