International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

To Compare the Outcome of Induction of Labour by Intracervical Foley's Catheter and Misoprostol Versus Misoprostol Alone

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OPEN ACCESS

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Received: 14-10-2025
Accepted: 16-11-2025
Available online: 26-11-2025

ABSTRACT

Background: Combining a mechanical method of induction of labour with pharmacological method may decrease the induction to delivery interval by achieving cervical ripening in lesser time.
Aims and objectives: Aim: To assess the comparative outcome of induction of labour by intracervical Foley's catheter and misoprostol versus misoprostol alone.
Primary Objective: •To identify the induction-delivery outcome with the use of 2 methods of induction, i.e., Foley's catheter-misoprostol combination and misoprostol alone.
•To find out the maternal and neonatal outcome with the use of Foley's catheter-misoprostol combination and misoprostol alone.
Secondary Objective: To study the rates of cesarean section in the two groups; Foley's catheter-misoprostol combination group and misoprostol alone group.
Materials and Methods: This Randomised Control Study was conducted in the patients undergoing induction of labour, in the department of obstetrics and gynaecology, CMC, Ludhiana. As per inclusion and exclusion criteria, 100 patients were randomised into two groups, by block randomization, 50 each. In one group, induction was carried out by use of intracervical foley's catheter and 25 mcg misoprostol vaginally, simultaneously and vaginal 25 mcg misoprostol alone in second group. This was followed by per vaginal misoprostol, 25 mcg every 4 hourly till the onset of moderate uterine contractions, in both the groups.
Results and Observations: In both the groups, a similar proportion of patients underwent a vaginal delivery after induction of labour (68% in foley's plus misoprostol group and 74% in misoprostol alone group). The mean time between the induction and delivery in patients of foley's plus misoprostol group was 13.17 ± 6.63 hours and in misoprostol alone group, it was 12.59 ± 5.14 hours, which was similar in both the groups. The rates of cesarean section in the two groups were comparable. (32% in Group A and 24% in Group B). There were no maternal or fetal complications found in the patients studied
Conclusion: none of the methods studied was superior to the other in terms of successful vaginal deliveries, induction to delivery interval, maternal or neonatal outcomes. The difference in the rates of cesarean section in both the groups was not statistically significant.

Keywords*: Foley's catheter, Induction of labour, Induction to delivery interval, Misoprostol.*

INTRODUCTION

Induction of labour is defined as the process of initiation of the uterine contractions by either mechanical, medical, or surgical methods, prior to their spontaneous onset, with an intent to achieve a vaginal delivery.(1) The available methods are non pharmacological, including mechanical methods and pharmacological, including prostaglandins, E1 and E2, oxytocin. Combining these two methods can reduce hazardous effects, like tachysystole (by reducing the doses of PGs required) and infection (a faster ripening leading to expulsion offoley's catheter)(2) The combination may help to achieve

a shorter induction to delivery interval.[3] Both dinoprostone and misoprostol are of comparable efficacy and are well tolerated in terms of safety.[4] The study was undertaken to compare a combined method of induction with single method.

AIMS AND OBJECTIVES

To assess the comparative outcome of induction of labour by intracervical Foley's catheter and misoprostol versus misoprostol alone.

Primary Objective: 1. To identify the induction-delivery outcome with the use of 2 methods of induction, i.e., Foley's catheter-misoprostol combination and misoprostol alone.

2. To find out the maternal and neonatal outcome with the use of Foley's catheter - misoprostol combination and misoprostol alone.

Secondary Objective: To study the rates of cesarean section in the two groups; Foley's catheter-misoprostol combination group and misoprostol alone group.

MATERIALS AND METHODS:

1. **PLACE OF STUDY-** The study was conducted in the department of Obstetrics and Gynaecology, Christian Medical College and Hospital, Ludhiana
2. **STUDY DESIGN-** Randomised Control Study, non-blinded.
3. **DURATION OF STUDY-** A period of 1 year, starting from 15 August 2022 to 14 August 2023.
4. **SAMPLE SIZE-** 100 patients, 50 in each group

INCLUSION CRITERIA:

- Participant age more than 18 years
- Single fetus
- 37 weeks and above period of gestation
- Vertex presentation
- Intact membranes
- Unfavorable cervix (Bishop score <6)
- Reassuring CTG

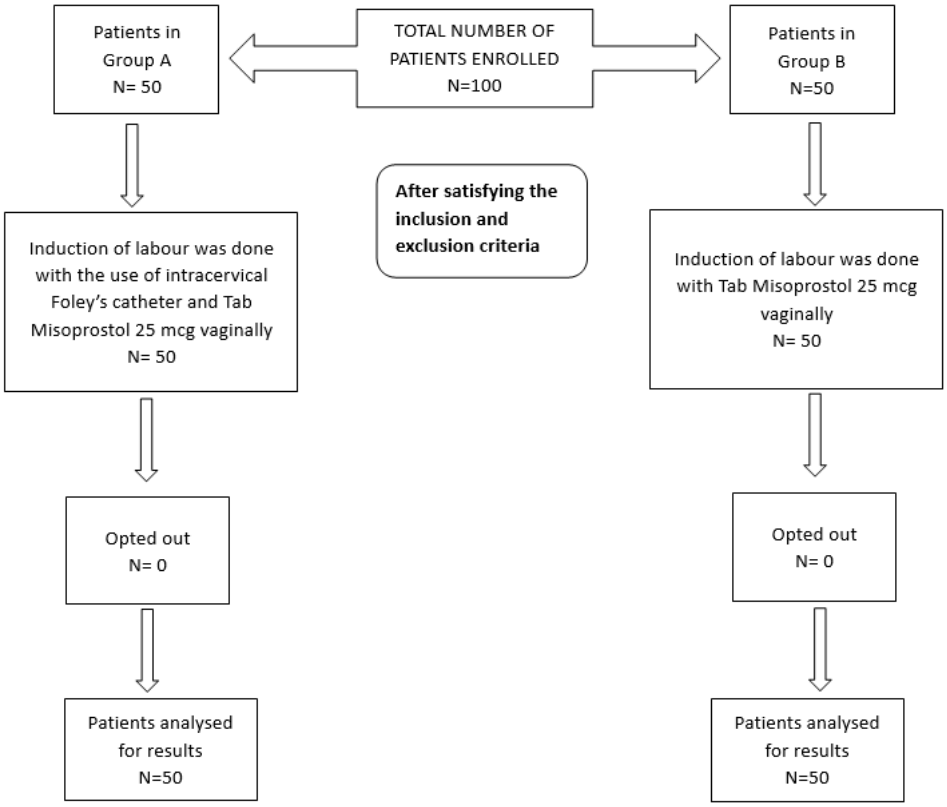
EXCLUSION CRITERIA:

- Women already in labour
- Multiple pregnancy
- Malpresentation
- Rupture of membranes
- Fetal Growth Restriction
- Previous cesarean delivery
- Any uterine surgery
- Malformed fetus
- Any contraindication to vaginal delivery

A detailed history and clinical examination of the patients presenting in the labour room at term was done. This was noted in a pre-designed proforma. A total of 100 patients undergoing induction of labour were enrolled into the study, 50 each in Group A and Group B. A written informed consent was obtained from the patients after explaining to them the nature of the study. Participants were selected by Block randomization method in which they were assigned a computer generated number from a table of random numbers. This table of random numbers was corresponding to two methods of induction of labour equally, i.e., Foley's catheter plus misoprostol and misoprostol alone. In Group A, a 16 Fr Foley's catheter was introduced into the cervix, beyond the level of internal os, by the use of sterile Cusco's speculum. All aseptic precautions were maintained. The bulb of the catheter was inflated with 60 ml of sterile water. The catheter was gently pulled until the bulb came to rest against the internal os of the cervix. The tail of the catheter was taped to the medial aspect of the thigh, under traction. Simultaneously, Tab. Misoprostol 25 microgram was inserted into the posterior fornix of the vagina. If the first attempt failed, a second attempt of insertion of Foley's catheter was made after 4 hours. The dose of Tab. Misoprostol 25 microgram was repeated 4 hourly until the onset of moderate uterine contractions (3 contractions in 10 minutes, each lasting for 35 seconds) or 4 cm dilatation of the cervix, or till the spontaneous expulsion of the foley's catheter. In Group B, Tab Misoprostol, 25 mcg was inserted into the posterior fornix of the vagina. This process was repeated every 4 hourly till the onset of moderate uterine contractions or till 4 cm of cervical dilatation. A maximum of 200 mcg or 8 doses of Tab Misoprostol was used. The progress of labour was monitored as per the standard protocols. In case of development of Tachysystole (more than 5 uterine contractions per 10 minutes, each contraction lasting for more than or equal to 40 seconds), the next dose of Tab Misoprostol was withheld. Since both the methods of induction of labour were specific and different in nature, the study was unblinded.

The results recorded were:
1. Time lapsed from start of induction to start of active labour.
2. Induction to delivery interval
3. Type of Delivery (vaginal delivery, LSCS)
4. Indication in case of LSCS
5. Presence of any complications (Post-partum hemorrhage/chorioamnionitis /puerperal sepsis.)
6. Neonatal outcome (APGAR score, Need for admission to NICU)

Time to time monitoring and documentation of the stages of labour was done in the patient's records and registers. It was made sure that the nature of the study remains unbiased and not observer dependent.



RESULTS AND OBSERVATIONS

A total of 100 patients were recruited in the study. These patients were randomised into 2 groups,with 50 patients in each group.Data was summarized using frequency distribution and descriptive analysis. The P value <0.05 was considered significant. Statistical analysis was performed using SPSS (Statistical Packages for Social Sciences, version 28.0).

Table 1: Demographic variables

VARIABLE	GROUP A	GROUP B	
Age (years)	**28.88 ± 3.83**	**29.58 ± 4.58**	
Nulliparous	**68%**	**56%**	
Multiparous	**32%**	**44%**	
Gestational Age (weeks)	**39.51 ± 0.91**	**39.45 ± 0.93.**	**Range: 37-40**
Indication of IOL			
1. Elective (at term, =40 weeks)	**54%**	**52%**	
2. Cholestasis of pregnancy	**20%**	**17%**	
3. Hypertensive disorders	**12%**	**10%**	
4. Post datism (>40 weeks)	**12%**	**08%**	
5. Gestational Diabetes Mellitus	**0%**	**16%**	

Most of the patients delivered with a maximum of two doses of Tab Misoprostol in both the groups. Only 4% patients of Group B required a maximum of 8 doses of Tab Misoprostol.

However, the statistical difference in the two groups for the number of doses of Tab Misoprostol was not significant. (p value = 0.126)

Though a greater percentage of patients in Group B required augmentation with oxytocin, as compared to those in Group A, (42% and 26% respectively) the difference was not statistically significant (p value= 0.091).

Compared to Group B, Group A had significantly lower proportion of patients requiring a dose of 2 units of inj. oxytocin. (p=0.024) (Table 2)

Table 2: Distribution of patients according to maximum dose of Oxytocin used

Dose of Oxytocin used	Group A(n=13)#		Group B(n=21)#		Total		P value
2 units	1	7.69%	10	47.62%	11	32.35%	0.024*
3 units	10	76.92%	6	28.57%	16	47.05%	0.012*
4 units	0	0%	4	19.05%	4	11.76%	0.144*
5 units	2	15.38%	1	4.76%	3	8.82%	0.544*
Total	13	100%	21	100%	34	100%	

* **Fisher's exact test**

 # = Number of patients in which oxytocin was used

Table 3:- Distribution of patients according to time lapsed from induction to start of active labour

Induction to active labour (in hours)	Group A (n=44)*		Group B (n=42)*		Total		P value
	N	%	N	%	N	%	
<6 hours	13	29.55%	10	23.81%	23	26.74%	0.548†
6to 8.9 hours	11	25%	11	26.19%	22	25.58%	0.899†
9 to 12 hours	11	25%	11	26.19%	22	25.58%	0.899†
>12 hours	9	20.45%	10	23.81%	19	22.09%	0.708†
Mean ± SD	9.39 ± 6.13		8.87 ± 4.83		9.14 ± 5.51		0.869§
Median(25th-75th percentile)	7.5 (5-12)		8.5 (6-12)		8 (5-12)		

§ **Mann Whitney test,** † **Chi square test**

***n= Number of patients who went into active labour**

The mean interval between the time of induction and the onset of active labour was 9.39 ± 6.13 hours in Group A, which was comparable to the mean time of 8.87 ± 4.83 hours in Group B. Though not statistically significant, but in our study, it was noted that more number of patients in the Group A went into active labour stage in less than 6 hours(Table 3)

Table 4: Distribution of patients according to induction and delivery interval, in cases of vaginal deliveries

Induction to delivery (in hours)	Group A(n=34)		Group B(n=38)		Total		P value
	N	%	N	%	N	%	
<12 hours	16	47.06%	15	39.47%	31	43.06%	0.516†
12 to <24 hours	15	44.12%	22	57.89%	37	51.39%	0.243†
>/= 24 hours	3	8.82%	1	2.63%	4	5.56%	0.338*
Mean ± SD	13.17 ± 6.63		12.59 ± 5.14		12.86 ± 5.86		0.95§
Median(25th-75th percentile)	12.5 (8.25-17.375)		13 (8.25-15.75)		13 (8-17)		

§ **Mann Whitney test,** * **Fisher's exact test,** † **Chi square test**

Among the patients who underwent a vaginal delivery, most of patients achieved a successful vaginal delivery in less than 12 hours in Group A (47.06%). The mean time between the induction and delivery in patients of Group A was 13.17 ± 6.63 hours and in Group B patients, it was 12.59 ± 5.14 hours, as observed in our study. Only a small proportion of women underwent a vaginal delivery after more than 24 hours of labour induction. This percentage was 8.82% in Group A, compared to only 2.63% in Group B. (Table 4)

In both the groups, a significant number of patients underwent a vaginal delivery after induction of labour (68% in Group A and 74% in Group B). Cesarean section was done in 32% of patients in Group A, as compared to 24% in Group B. The difference in the rates ofCesarean Section in both the groups was not statistically significant.

The indications for which LSCS was done included Meconium stained liquor, arrest of descent, non reassuring fetal heart rate and failed induction of labour. The most common indication of LSCS in the two groups of the study was meconium

stained liquor (56.25% in Group A and 41.66% in Group B) followed by Non Reassuring Fetal Heart Rate (25% in both the groups).

The patients who underwent induction of labour were compared for incidence of uterine tachysystole, atonic or traumatic PPH, chorioamnionitis and puerperial sepsis. However, it was observed in the study that IOL was not complicated by any of the above conditions.

Table 5:-Distribution of patients according to Neonatal Outcomes

Variables	Group A		Group B	
	N	%	N	%
Gestational age				
SGA	1	2%	2	4%
AGA	49	98%	48	96%
APGAR SCORE				
<7 at 1 min	1	2%	2	4%
>/=7 at 1 min	49	98%	48	96%
<7 at 5 mins	1	2%	1	2%
>/=7 at 5 mins	49	98%	49	98%
NICU Admission				
Yes	13	26%	8	16%
No	37	74%	42	84%
Ventilator Requirement				
Yes	1	2%	3	6%
No	49	98%	47	94%
Neonatal Mortality				
Yes	0	0%	1	2%
No	0	0%	49	98%
Birth Weight (Grams)	2941.28 ± 389.73		2970.78 ± 360.38	

It was observed that the mean birth weight was 2941.28 ± 389.73 grams in the Foley's catheter plus misoprostol group and 2970.78 ± 360.38 grams in the Misoprostol group, which was similar in both the groups.

In Group A, 2% patients had neonatal APGAR score of <7 and in Group B, 4% patients had neonates with APGAR score of <7. At 5 mins, both the groups had neonates with APGAR score of <7 in 2% patients.

NICU admission was needed in 26% patients of Group A and 16% patients of Group B. However, out of the 13 patients who needed NICU admission in Group A, only 1 required a ventilatory support. While in Group B, out of 8 NICU admissions, 3 babies were kept on ventilatory support. (Table 5)

DISCUSSION

Our study showed that the mean period of gestation in Group A was found to be 39.25 ± 0.89 weeks and in Group B, it was 39.11 ± 0.79 weeks. In the study by Nivedita A Kadu et.al. the mean age to induce labour in the Foley's plus Tab Misoprostol group was 39.26 ± 1.0 weeks and in Tab Misoprostol group, it was 39.28 ± 1.13 weeks of gestation.[5] These results were similar to those obtained in our study.

In our study, the most common indication for which induction of labour was done in ourstudy was term pregnancy, i.e. 40 completed weeks of gestation, followed by cholestasis of pregnancy. Some other indications were post datism (11%), hypertensive disorders of pregnancy (9%) and GDM (8%). These results were in comparison to the study done by Priyadarshini et.al and Santosh KP et.al. where the common indications to induce labour was pre eclampsia and post datism.[1][6] The mean time period between induction and the onset of active labour was 9.39 ± 6.13 hours in Group A, which was comparable to the mean time of 8.87 ± 4.83 hours in Group B in the present study. Also, when a Foley catheter was used in addition to misoprostol, the mean time between induction and active labour was much shorter (11.40 ± 5.91) than when misoprostol was used alone (20.00 ± 6.60), asquoted by Priyadarshini A and colleagues.[1]

In the present study as well as in the studies conducted by Priyadarshini A et.al. and Santosh KP et.al. the mean induction to delivery interval was comparable. It was 13.17 ± 6.63 hours and 12.59 ± 5.14 hours, respectively in both the groups in present study. In the study by Priyadarshini et.al., this interval was 19.65 ± 9.21 hours and 24.99 ± 12.76 hours, respectively.[1] The research by Santosh et.al observed the interval to be 14.58 ± 6.67 hours and 19.11±10.20 hours in the two groups.[6]

In the present study as well as in comparison to the other similar studies, there was no difference in the rates of caesarean section in both the groups. Among the patients who delivered vaginally, 68% patients were in Foley's plus misoprostol group and 74% were in Misoprostol alone group. The results were comparable to the study by Kadu NA et.al. with 62.2% patients delivering vaginally in Foley's plus misoprostol group and 60.8% patients delivering vaginally in misoprostol alone group.[5]

In the study by Priyadarshini et al, it was seen that the process of IOL was complicated by PPH and uterine tachysystole.(1) Similarly in the In the study by Kadu NA and colleagues, they noted the deliveries to be complicated by puerperal infections (27%) and atonic PPH (6.8%) [5] However, in our study, none of the above maternal complications were noted.

In the present study, it was observed that the mean birth weight was 2941.28 ± 389.73 grams in the Foley's catheter plus misoprostol group and 2970.78 ± 360.38 grams in the Misoprostol group. These results were similar to the outcomes by Kadu NA et. al. in which the mean birth weight of the neonates was 2.72 ± 0.16 kg and 2.76 ± 0.19 kg in the two groups, respectively.[5] In the present study, majority of the patients had neonates with APGAR score of >/=7. The results of our study were varying from those obtained by Santosh KP et.al. They noted that the neonates with mild birth asphyxia were 9.18% in Foley's plus misoprostol group and 12.12% in those induced with misoprostol group.[6] NICU admission was required in 26% patients of Group A and in 16% patients of Group B. According to Priyadarshini A et. al. the neonates who required NICU admission were 11% in foley's plus misoprostol group and 15% in the misoprostol alone group.(1)

CONCLUSION

Combined method of induction of labour with Foley's catheter plus misoprostol has comparable efficacy to the misoprostol alone method. Being a small study, no conclusive evidence could be established. However, in the Foley's catheter plus Misoprostol group, the time interval to be in active labour was short but due to lesser power of the study, it was not statistically significant. The difference in the rates of caesarean section in both the groups was not statistically significant.

Declaration:
Conflicts of interests: The authors declare no conflicts of interest.
Author contribution: All authors have contributed in the manuscript.
Author funding: Nill

REFERENCES

1. Priyadarshini A, Jaiswar SP, Singh A, Singh S. Comparative outcome of induced labor by intracervical Foley catheter with misoprostol versus misoprostol alone. J Comp Eff Res. 2019;8(1):55-9.
2. Garg R, Bagga R, Kumari A, Kalra J, Jain V, Saha SC, Kumar P. Comparison of intracervical Foley catheter combined with a single dose of vaginal misoprostol tablet or intracervical dinoprostone gel for cervical ripening: a randomized study. J Obstet Gynaecol. 2022 Feb 17;42(2):232-8.
3. Aregeb ZA, Albromboly W, Abdelhameid AA, Helal KF, Badr MS. Induction of Labor Using Vaginal Misoprostol Alone or Combined with Intracervical Foley Catheter. Egypt J Hosp Med. 2021 Oct 1;85(1):3125-9.
4. Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, et al. Low-dose oral misoprostol for induction of labour. Cochrane Database Syst Rev. 2021 Jun;6.
5. Kadu NA, Shiragur S. Comparison of Intracervical Foley's Catheter With Vaginal Misoprostol Versus Intravaginal Misoprostol Alone for Cervical Ripening and Induction of Labor. Cureus. 2023 Sep;15(9).
6. Santosh KP, Kaur A, Kaur M, Garg R. A comparative study of combination of intracervical Foley's catheter and intravaginal misoprostol versus intravaginal misoprostol alone for induction of labour. Indian J Obstet Gynecol Res. 2020 Dec 15;5(1):131-5.