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Original Research Article

Assessment of fetomaternal outcome following common induction methods (Foley's catheter, dinoprostone and misoprostol) for induction of labor in low risk women with term pregnancy

Manasa M. R.*, Sampath Kumar G., Aparna Nair

Department of Obstetrics and Gynecology, Vydhei Institute of Medical Science and Research Centre, Whitefield, Bengaluru, Karnataka, India

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***Correspondence:**
Dr. Manasa M. R.,
E-mail: manasameda93@gmail.com

ABSTRACT

Background: Various mechanical and pharmacological approaches available for induction of labor (IOL), have varying effectiveness. This study compared the efficacy of three common IOL methods: intracervical Foley catheter, dinoprostone, and misoprostol, in achieving timely and safe vaginal deliveries.
Methods: A 12 month (March 2022 to March 2023) prospective observational study at Vydehi Institute of Medical Science and Research Centre on 60 term pregnant women undergoing IOL compared induction-to-delivery interval, post-induction Bishop scores, mode of delivery, oxytocin requirements, maternal and fetal morbidities with Foley catheter, dinoprostone gel and misoprostol induction to determine the efficacy and safety of each method.
Results: The study revealed notable differences in the effectiveness of the induction methods. Dinoprostone demonstrated the shortest induction-to-delivery interval (8.13 hours) and the highest rate of vaginal deliveries (90%). Misoprostol, while slightly slower with a 12.35-hour interval, achieved 85% vaginal deliveries. While, Foley catheter group had the longest induction-to-delivery time (18.12 hours) and a lower rate of vaginal deliveries (70%). Additionally, oxytocin augmentation was required more in the Foley catheter group. Maternal and fetal complications were significantly lower in the dinoprostone and misoprostol groups, focussing their superior safety profiles.
Conclusions: Pharmacological methods proved more efficient than Foley catheter in reducing induction time, improving cervical ripening, and increasing the likelihood of successful vaginal deliveries. Dinoprostone, in particular, emerged as the most efficient method with the fewest complications. However, careful monitoring is necessary to mitigate potential risks like uterine hyperstimulation, especially with misoprostol.

Keywords: Dinoprostone, Foley catheter, Induction of labor, Misoprostol

INTRODUCTION

Induction of labor (IOL) is a widely performed obstetric intervention aimed at initiating uterine contractions before the spontaneous onset of labor to achieve vaginal delivery.[1-3] This procedure is often indicated when continuing the pregnancy poses higher risks to the mother or fetus, as in cases of post-term pregnancy, preeclampsia, or intrauterine growth restriction. According to a WHO global annual survey, the percentage of IOL ranges from 9.5% to 33.7% of all pregnancies.[4] In a multicentre prospective cohort study in India, it was found that 42.3% of women had induction of labor; in 27.3% of women, the labor was augmented, and 19.2% had both labor induction and augmentation.[5] The percentage of expectant mothers undergoing the induction of labor has been increasing recently.

The outcome of IOL largely depends on the cervix's readiness, which must undergo ripening-a process that includes softening, thinning, and dilation to prepare for labor. An unfavorable cervix, often reflected by a low Bishop's score, can result in longer labor durations, maternal exhaustion, increased infection risks such as chorioamnionitis, and higher cesarean section rates. Therefore, agents that promote cervical ripening are crucial for improving the success rates of labor induction.

Pharmacological agents are widely used to assist cervical ripening and stimulate uterine contractions. Dinoprostone gel (prostaglandin E2) is commonly used for this purpose and has shown effectiveness in inducing both cervical softening and contractions. However, it carries potential side effects, most notably uterine hyperstimulation, which may result in fetal distress. Another pharmacological option is misoprostol, a synthetic prostaglandin E1 analogue. Misoprostol is gaining popularity for its cost-effectiveness and ease of administration. It can be used vaginally, orally, or sublingually, making it versatile in various clinical settings. Studies have shown that misoprostol is effective for cervical ripening and induction of labor, but like dinoprostone, it carries a risk of uterine hyperstimulation, which necessitates careful monitoring during its use. Misoprostol is often used in lower doses to minimize these risks while still promoting labor progression.

Mechanical methods for cervical ripening, like the intracervical Foley's catheter, offer an alternative approach. This method works by physically dilating the cervix while also encouraging the release of natural prostaglandins from the body. The Foley catheter is particularly advantageous in resource-limited settings due to its cost-effectiveness and ease of use.[6-8] Unlike pharmacological agents, it does not require specialized storage and has a lower associated risk of uterine hyperstimulation.

Despite these benefits, the Foley catheter has seen less frequent use in favour of pharmacological methods, although recent studies suggest it can be just as effective in promoting successful labor outcomes. Evidence shows that both methods-pharmacological and mechanical-are effective, but their use depends on factors such as patient safety, resource availability, and the specific clinical scenario. Mechanical methods like the Foley catheter may also offer reduced complication risks, including a lower likelihood of cesarean delivery, making them an appealing option in certain cases.

Understanding the relative effectiveness of the intracervical Foley's catheter compared to dinoprostone gel and misoprostol in key areas such as cervical ripening, time to delivery, mode of delivery, and maternal and fetal outcomes can inform clinical decisions and optimize labor induction strategies. With the goal of improving maternal and neonatal health, choosing the most suitable induction method based on individual patient needs and clinical context is essential for minimizing complications and enhancing the overall success of labor induction.

METHODS

This prospective observational study was conducted on 60 term pregnant women with singleton pregnancies, cephalic presentations, a Bishop's score of <6, intact membranes, term pregnancies at Vydehi Institute of Medical Science and Research Centre, for a period of 12 months, i.e., March 2022 to March 2023.

Women with multiple pregnancies, malpresentations, premature rupture of membranes, scarred uterus, antepartum hemorrhage, or genital infections were excluded. The participants were divided into three groups: Group A (n=20), where induction was performed using an intracervical Foley catheter; Group B (n=20), where induction was performed using dinoprostone intracervical gel (0.5 mg); and Group C (n=20), where induction was performed using misoprostol (25 mcg).

Data collection involved obtaining detailed clinical histories, conducting physical and obstetric examinations, and monitoring fetal heart rate using cardiotocography (CTG). Per vaginal examinations were carried out every 6 hours for 24 hours post-induction. Maternal outcomes, such as the mode of delivery (vaginal, instrumental, or cesarean), and neonatal outcomes, including APGAR scores at 5 and 10 minutes, meconium-stained liquor, and NICU admissions, were recorded. The data were analyzed using SPSS version 24, with Chi-Square/Fisher's exact tests for qualitative data and t-tests/ANOVA for quantitative data, considering a p value <0.05 as statistically significant.

RESULTS

A total 60 cases admitted to low-risk labour room, Department of Obstetrics and Gynecology, Vydehi Institute of Medical Sciences and Research Centre, Bengaluru fulfilled the inclusion and exclusion criteria of the study.

The participants were divided into 3 groups based on the induction agent: Group A: 20 participants were induced labor using Foley's catheter; Group B: 20 participants were induced labor using Dinoprostone (0.5 mg); Group C: 20 participants were induced labor using Misoprostol (25 mcg).

The mean age was 26.51 years with a standard deviation of 3.397, indicating most participants were in their mid-twenties (Table 1).

Table 1: Mean age of study participants.

	Minimum	Maximum	Mean	SD
Age in years	20	33	26.51	3.397

Group A had 45% primiparous and 55% multiparous participants; Group B had 40% and 60%, respectively; and Group C had 50% for both. The p-value of 0.853 indicates no significant differences between groups (Table 2).

Percentage of subjects with pre induction modified BISHOPS scores of 2, 3, 4 and 5 in Group A was 15%, 55%, 25% and 5%. In Group B was 20%, 50%, 20%, and 10%, and in Group C was 10%, 70%, 15%, and 5%. The p-value of 0.731 indicates no significant differences between groups (Table 3).

Table 2: Distribution of study participants based on their parity.

Parity	Group A, N (%)	Group B N (%)	Group C, N (%)	P value
Primipara	9 (45)	8 (40)	10 (50)	0.853
Multipara	11 (55)	12 (60)	10 (50)	
Total	20 (100)	20 (100)	20 (100)	

Table 3: Distribution of study participants based on their modified Bishop's score before and after induction.

Pre-induction modified Bishop's score	Group A N (%)	Group B N (%)	Group C N (%)	P value
Before induction				
2	3 (15)	4 (20)	2 (10)	0.731
3	11 (55)	10 (50)	14 (70)	
4	5 (25)	4 (20)	3 (15)	
5	1 (5)	2 (10)	1 (5)	
Total	20 (100)	20 (100)	20 (100)	
After induction				
Less than or equal 6	1 (5)	0 (0)	1(5)	0.04
7	1 (5)	1(5)	1 (5)	
8	4 (20)	1 (5)	2 (10)	
9	6 (30)	3 (15)	5 (25)	
10	8 (40)	15 (75)	11(55)	
Total	20 (100)	20 (100)	20 (100)	
Mean change in the modified Bishop's scores before and after induction	3.59±1.11	8.12±1.81	6.85±1.58	0.001

Table 4: Comparison of mean induction to delivery interval (hours).

Mean induction to delivery interval (hours)	Group A (Mean±SD)	Group B (Mean±SD)	Group C (Mean±SD)	P value
	18.12±4.82	8.13±1.56	12.35±2.51	0.0001

Table 5: Distribution of study participants based on the mode of delivery.

Mode of delivery	Group A N (%)	Group B N (%)	Group C N (%)	P value
Normal vaginal delivery (NVD)	14 (70)	18 (90)	17 (85)	0.001
Instrumental vaginal delivery	4 (20)	1 (5)	2 (10)	
Lower segment caesarean section (LSCS)	2 (10)	1 (5)	1 (5)	
Total	20 (100)	20 (100)	20 (100)	

Percentage of subjects with post induction modified BISHOPS scores of ≤6, 7, 8, 9, 10 in Group A was 5%, 5%, 20%, 30% and 40% that in Group B was0 %, 5%, 5%, 15%, and 75% for scores and in Group C was 5%, 5%, 10%, 25%, and 55% respectively. The p-value of 0.04 indicates a statistical difference among the groups. Dinoprostone group had higher scores comparatively (Table 3).

Group A had a mean change of 3.59±1.11, Group B had 8.12±1.81, and Group C had 6.85±1.58 in modified Bishop's scores before and after induction. The p value of 0.001 indicates a significant statistical difference among the groups. Dinoprostone group more difference in the pre and post induction modified Bishop's scores comparatively (Table 3).

Group A had a mean induction to delivery interval of 18.12±4.82 hours, Group B had a significantly shorter

mean interval of 8.13±1.56 hours, and Group C had a mean interval of 12.35±2.51 hours. The p value of 0.0001 indicates a highly significant statistical difference in induction to delivery intervals among the groups (Table 4).

70% participants of Group A had normal vaginal deliveries (NVD), 20% had instrumental deliveries, and 10% had lower segment cesarean sections (LSCS). 90% participants of Group B had NVD, 5% had instrumental deliveries, and 5% had LSCS. 85% participants of Group C had NVD, 10% had instrumental deliveries, and 5% had LSCS. The p-value of 0.001 indicates a significant statistical difference among the groups. More participants in the Dinoprostone group had normal vaginal deliveries (Table 5).

In Group A, 75% participants had clear liquor, 10% had thick meconium stain, and 15% had thin meconium stain. Group B reported 95% participants with clear liquor, 0% with thick meconium and 5% with thin meconium stain. In Group C,90% participants had clear liquor, 5% had thick meconium stain, and 5% had thin meconium stain. The p-value of 0.001 indicates a significant statistical difference among the groups. More participants of dinoprostone group had clear liquid comparatively (Table 6).

Table 6: Distribution of study participants based on the colour of liquor.

Colour of liquor	Group A N (%)	Group B N (%)	Group C N (%)	P value
Clear	15 (75)	19 (95)	18 (90)	0.001
Thick meconium stain	2 (10)	0 (0)	1 (5)	
Thin meconium stain	3 (15)	1 (5)	1 (5)	
Total	20 (100)	20 (100)	20 (100)	

Table 7: Distribution of study participants based on oxytocin requirement.

Oxytocin requirement	Group A N (%)	Group B N (%)	Group C N (%)	P value
Yes	12 (60)	9 (45)	5 (25)	0.001
No	8 (40)	11 (55)	15 (75)	
Total	20 (100)	20 (100)	20 (100)	

60% participants of Group A, 45% of Group B and 25% of Group C required additional oxytocin. The p value of 0.001 indicates a significant statistical difference in oxytocin requirement among the groups. More participants of Foleys group required additional oxytocin supplementation (Table 7).

Maternal morbidity in Group A was 25%, Group B was 20% and Group C was 10%. The p value of 0.04 indicates a statistical difference in maternal morbidity among the groups. More participants of Foleys group had morbidities following delivery (Table 8).

Table 8: Distribution of study participants based on maternal morbidity.

Maternal morbidity	Group A N (%)	Group B N (%)	Group C N (%)	P value
Present	5 (25)	4 (20)	2 (10)	0.04
Absent	15 (75)	16 (80)	18 (90)	
Total	20 (100)	20 (100)	20 (100)	

Table 9: Distribution of study participants based on fetal morbidity.

Fetal morbidity	Group A N (%)	Group B N (%)	Group C N (%)	P value
Present	5 (25)	2 (10)	1 (5)	0.04
Absent	15 (75)	18 (90)	19 (95)	
Total	20 (100)	20 (100)	20 (100)	

Fetal morbidity in Group A was 25%, Group B was 10% and Group C was 5%. The p value of 0.04 indicates a significant statistical difference in fetal morbidity among the groups. More babies of participants in the Foleys group had morbidities (Table 9).

DISCUSSION

Labor induction is a critical component of modern obstetric practice, aimed at initiating labor in situations where it is deemed medically necessary or beneficial for maternal and fetal health. As the rate of labor induction has increased globally, understanding various induction methods and their implications on maternal and fetal outcomes has become essential for obstetric care providers. Induction agents can vary widely, with options including mechanical methods, such as the Foley catheter, and pharmacological agents, like prostaglandins (dinoprostone and misoprostol). Each method has distinct mechanisms of action, potential side effects, and efficacy in achieving successful vaginal delivery. This study focused on evaluating the outcomes of three different induction agents Foley's catheter, dinoprostone, and Misoprostol among a cohort of 60 participants admitted to a low-risk labor room at the Vydehi Institute of Medical Sciences and Research Centre. By examining parameters such as age, parity, Bishop's scores, induction to delivery intervals, modes of delivery, oxytocin requirements, and maternal and fetal morbidity, this research aimed to contribute valuable insights into optimizing induction practices and improving both maternal and neonatal outcomes.

The mean age of participants was 26.51 years, with a range from 20 to 33 years. This age distribution is consistent with previous studies reporting higher rates of obstetric interventions among women in their late twenties, highlighting the demographic often most affected by induction practices.

In terms of parity, there were no significant differences among the groups, with a predominance of multiparous women. This finding aligns with literature indicating that parity does not significantly influence induction outcomes (Yimer et al).[9] The pre-induction modified Bishop's scores also showed no significant differences among the groups (p=0.731). However, post-induction scores demonstrated significant differences (p=0.04), suggesting that the induction agents effectively improved cervical readiness, corroborating findings by Khan et al, who reported that misoprostol notably enhances Bishop scores compared to mechanical methods.[10]

The mean induction to delivery interval varied significantly among the groups, with Foley's catheter exhibiting the longest duration (18.12 hours), while dinoprostone (8.13 hours) and misoprostol (12.35 hours) had significantly shorter intervals. These results indicate that the choice of induction agent directly influences the time from induction to delivery. Previous studies support this, showing that prostaglandins, such as misoprostol, are associated with shorter induction times than mechanical methods (Perry et al).[11] However, the significantly shorter induction-to-delivery interval observed in the dinoprostone group underscores its efficacy and positions it as the preferred pharmacological induction agent.

Regarding the mode of delivery, a significant difference was observed, with the dinoprostone group achieving the highest rate of normal vaginal deliveries (85%) compared to the Foley's catheter group (70%). This indicates that the method of induction affects the likelihood of successful vaginal delivery, supporting findings from Barrilleaux PS, who documented that pharmacological induction methods, particularly prostaglandins like dinoprostone, improve vaginal delivery rates compared to mechanical methods.[12]

The study also assessed the color of the amniotic fluid, finding that significantly more participants in the dinoprostone and misoprostol groups had clear amniotic fluid compared to the Foley's catheter group (p=0.001). This suggests that the induction methods may influence fetal status at delivery.

The requirement for oxytocin varied significantly among the groups, with the Foley's catheter group showing the highest necessity (60%). This reduced need for oxytocin in the dinoprostone and misoprostol groups aligns with findings from Garg et al, who noted that both misoprostol and dinoprostone decrease the requirement for oxytocin during labor induction.[13] However, the results suggest that Dinoprostone may lead to a more efficient labor process with less intervention needed.

Lastly, maternal morbidity was significantly higher in the Foley's catheter group (25%) compared to the dinoprostone (20%) and misoprostol (10%) groups, with fetal morbidity also following a similar trend (p=0.04). These outcomes highlight that mechanical induction methods are often associated with increased complications.

This study gas few limitations. The study was conducted on a small population. The study was a single centred study.

CONCLUSION

In conclusion, the findings of this study emphasize the importance of selecting appropriate induction methods, as they significantly influence induction outcomes, delivery modes, and maternal-fetal morbidity. The results align with existing literature that supports pharmacological agents, particularly dinoprostone, as the most effective induction method compared to mechanical alternatives. This study advocates for the consideration of dinoprostone as the preferred agent in clinical practice, aiming for better maternal and fetal outcomes during labor induction.

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