Comparison of Foley catheter and dinoprostone for labor induction in nulliparous women with Bishop's score less than 5

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Abstract

Objectives: *To compare Dinoprostone to Foley catheter as a cervical ripening method in primigravidae with Bishop's score less than 5.*

Materials and Methods: *This study utilized a quasi-experimental research design to investigate the induction of labor in primigravidae with low Bishop's score. The research was conducted at the Department of Obstetrics and Gynecology, Hospital of the Hue University of Medicine and Pharmacy from July 2022 to December 2023.*

Results: *In comparison to the Foley group, Dinoprostone exhibited higher efficacy in cervical ripening (74.1% vs. 44.0%; p = 0.02). Dinoprostone was associated with a shorter time to delivery (13.92 hours vs. 29.67 hours; p < 0.05). The requirement for oxytocin augmentation was higher in the Foley group (72.0% vs. 7.4%, p < 0.05). The rate of vaginal delivery within 24 hours was higher in the Dinoprostone group (74.1% vs. 20.0%, p < 0.05). No differences were noted in the rates of overall vaginal delivery. Dinoprostone use was associated with a higher likelihood of uterine tachysystole (18.5% vs. 0.0%, p < 0.05), and the incidence of prelabor rupture of membranes during induction of labor was comparatively higher in this group (40.7% vs. 12.0%, p < 0.05).*

Conclusions: *Both labor induction methods, utilizing Foley and Dinoprostone in women with low Bishop scores (Bishop's score < 5), demonstrate comparable effectiveness. The duration from induction of labor to the completion of labor is lengthier, and the need for oxytocin augmentation is greater in the Foley group. However, complications such as tachysystole and prelabor rupture of membranes during labor induction are more prevalent in the Dinoprostone group. The observed complications do not differ b*etween the two groups.

Keywords: *Labor induction, cervical ripening, Foley, Dinoprostone.*

1. INTRODUCTION

Labor induction is a common obstetric procedure, occurring in 30% of pregnancy cases [1]. The success of labor induction depends on the condition of the cervix before induction, with a favorable state characterized by cervical effacement and softening. A tightly closed cervix, firm in density, increases the likelihood of failed labor induction, prolongs the duration of labor, and poses a greater risk of cesarean delivery. Although there are various methods employed for labor induction, there is limited consensus on which method is considered the most effective [2]. Initiating labor induction presents a significant challenge for primigravida individuals, and there is still no consensus on the optimal method for inducing labor in this group. The outcome of labor induction depends on the state of the cervix. Bishop score, a commonly employed and effective system, plays a crucial role in assessing and predicting the success of labor induction, while also aiding in the evaluation and prediction of labor progression [3]. In cases where Bishop score indicates an unfavourable cervix, it is advisable to initiate labor induction using a method that facilitates cervical ripening [2].

The labor induction process may include both chemical and mechanical approaches. Chemical methods involve the use of substances such as Prostaglandin E1, Prostaglandin E2, and oxytocin. Since 2012, the Ministry of Health in Vietnam has prohibited the use of Prostaglandin E1 (Misoprostol) for inducing labor in full-term pregnancies with live fetuses due to the associated risk of uterine rupture. Oxytocin induction is restricted to cases where the cervix is favorable, with Bishop's score of ≥ 6 [4]. Unlike oxytocin, Prostaglandin E2 is effective in inducing labor in cases of unfavorable cervix [2].

Mechanical techniques for labor induction includes procedures such as membrane sweeping, the use of hygroscopic cervical dilators like Laminaria, a single-balloon Foley catheter, and a double balloon Cook catheter. Membrane sweeping, involving cervix dilation, may lead to pain and bleeding [3]. While induction with Laminaria is effective, it heightens the risk of perinatal infection and is costly, currently unavailable in Vietnam. The balloon catheter method for labor induction has proven efficacy. Yet, the single-balloon Foley catheter is more commonly utilized than the double-balloon catheter (Cook's balloon) due to similar effectiveness, lower cost, and greater availability at various medical

facilities [5].

Moreover, the majority of these studies examine cohorts that include all pregnant individuals, with a scarcity of research specifically dedicated to the subset of primigravida with unfavorable cervical conditions. At present, there exists a paucity of studies that compare the efficacy of Foley catheters and Dinoprostone, particularly among nulliparous women with a low Bishop's score. Hence, aiming to make a substantive contribution to research in this field, we conducted a study titled "**Comparison of Foley catheter and Dinoprostone for labor induction in nulliparous women with Bishop's score less than 5**". The objective was to compare the effectiveness of labor induction with Foley catheter balloon and Dinoprostone in nulliparous women with Bishop's score < 5.

2. MATERIALS AND METHODS

This is a quasi-experimental research study on the induction of labor in women with low Bishop's score at the Department of Obstetrics and Gynecology, Hospital of the Hue University of Medicine and Pharmacy from July 2022 to December 2023.

Inclusion criteria

- Nulliparous women over 37 weeks' gestation with Bishop's score < 5.
- Indicated for induction of labour.
- Singleton pregnancy.
- Cephalic presentation.
- Intact membranes.
- Agreement to participate in the study.

Exclusion criteria

- Previous uterine scar.
- Severe chronic diseases of the mother such as heart failure, eclampsia, etc.…
- Placenta previa, Vasa previa, Umbilical cord presentation.
- Sexually transmitted diseases (genital herpes, genital warts,…).
- Have a history of allergy to Prostaglandin, Latex resin.

Select pregnant women who meet the inclusion criteria were included. History was taken in detail and clinical examination and prenatal care checkups were done. Determination of Bishop's score was performed. All women with a singleton pregnancy of 37 weeks or more with an indication for induction of labor and a Bishop score of less than 5 were advised to induce labor. Non-stress test and stress test were taken before the beginning of labour induction. Patients were randomly assigned to either the Foley catheter group (n=25) or the Dinoprostone group (n=27).

Foley catheter insertion: After ensuring an empty bladder, women were placed in lithotomy position. Disinfecting the vulva, the vagina, and the perineum. A no.16 Foley's catheter was inserted into the endocervical canal using heart-shaped forceps, then inflated the balloon with 60 ml saline and pulled down so that the balloon restsed on the internal cervical os. The balloon catheter position was then confirmed by ultrasound.

Dinoprostone vaginal slow-release system insertion: Dinoprostone vaginal slow-release system was inserted into the vagina using sterile gloves. The system was placed and set in a transverse position in the posterior fornix. Women remained lying down for 30 minutes after insertion.

Cardiotocography (CTG) is employed about an hour after the placement of Foley and Dinoprostone. Assess uterine contractions and fetal heart rate every hour. Monitor CTG and perform vaginal examination every 6 hours to promptly detect and manage any abnormalities or complications.

The Dinoprostone was left in place for a maximum time of 24 hours and the foley catheter was left in place for a maximum time of 12 hours or until it fell out. Upon removal of the devices, the cervix was reassessed, and Bishop score was recalculated.

A ripe cervix was defined as a Bishop score ≥ 7 according to Liran Hiersch [5].

Labor was monitored and augmented as needed with oxytocin under continuous fetal heart rate monitoring.

Outcome measures

The following data were collected: maternal age, gestational age at delivery, parity, maternal health conditions, mode of delivery, oxytocin use, used labor induction method, maternal safety outcomes (labor and birth complications, fever during labor time, tachysystole), and induction-delivery interval. All other outcomes were collected from patient records.

Statistical methods: Descriptive statistics were presented as mean ± standard deviation for continuous variables, while categorical variables were represented as numbers and percentages. To assess the relationship between the method of induction with demographical and clinical, either a Chi-square test or Fisher's exact test was conducted. An independent t-test was performed to compare the two groups in terms of continuous variables. A significance level of $P<0.05$ was applied to determine statistical significance.

3. RESULTS

A total of 52 women experienced labor induction during the study period. Out of these, 25 women were randomized to the Foley catheter group, while the remaining 27 women were randomized to Dinoprostone group.

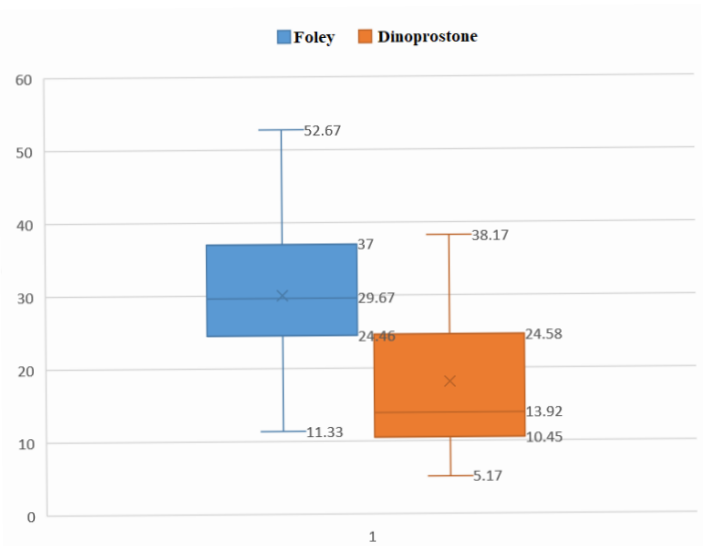
Table 1. Baseline characteristics by method used

Characteristics \ Method	Foley	Dinoprostone	p
Maternal age	26.0 ± 3.7	25.0 ± 3.9	0.33
BMI	22.3 ± 2.5	21.9 ± 2.8	0.61
Gestational age (weeks)	40.6 ± 0.3	40.4 ± 0.5	0.15
Bishop score before induction of labor	2.5 ± 0.9	2.7 ± 1.0	0.49

No statistically significant differences were noted in any of the baseline characteristics.

Table 2. Bishop's score after cervical ripening

Bishop's score after induction of labor \ Method	Foley		Dinoprostone		p
	n	%	n	%	
Ripe cervix	11	44.0	20	74.1	**0.02**
Unfavorable cervix	14	56.0	7	25.9	
Mean Bishop's scores	6.2 ± 1.5		7.3 ± 1.7		**0.02**



Dinoprostone demonstrates superior effectiveness in cervical ripening compared to Foley, with Bishop score of the Dinoprostone group higher following induction of labor than that of the Foley group.

Chart 1. Time from labor induction to delivery

Time from labor induction to delivery is shorter in the Dinoprostone group compared to the Foley group (13.92 hours versus 29.67 hours).

Table 3. Comparison of study outcomes between Dinoprostone and Foley catheter groups

Variables \ Method		Foley		Dinoprostone		p
		n	%	n	%	
Oxytocin requirement		18	72.0	2	7.4	**< 0.01**
Mode of Delivery	Vaginal delivery	8	32.0	15	55.6	0.09
	Cesarean section	17	68.0	12	44.4	
Vaginal delivery	Within 24 hours	5	20.0	20	74.1	**< 0.01**
	Over 24 hours	20	80.0	7	25.9	

The use of oxytocin is more prevalent in the Foley group compared to the Dinoprostone group.

The rate of vaginal delivery was similar between the two groups.

Additionally, the incidence of vaginal delivery within a 24-hour period was higher in the Dinoprostone group than in the Foley group.

Table 4. Maternal and newborn complications

Complications \ Method	Foley		Dinoprostone		p
	n	%	n	%	
Tachysystole	0	0.0	5	18.5	**0.02**
Prelabor Rupture of Membranes during induction of labor	3	12.0	11	40.7	**< 0.01**
Non-reassuring fetal heart rate tracing	3	12.5	5	18.5	0.51
Maternal fever during labour	1	4.0	1	3.7	-
1-Minute Apgar score <7	0	0.0	0	0.0	-
5-Minute Apgar score <7	0	0.0	0	0.0	-
NICU admission*	0	0.0	0	0.0	-
Others	0	0.0	1	3.7	-

NICU: neonatal intensive care unit

In the Dinoprostone group, the occurrence of tachysystole and prelabor rupture of membranes exceeds that observed in the Foley group. There was no significant difference in the incidence of abnormal fetal heart rates between the Foley and Dinoprostone groups. Fever during labor, along with other related complications, was rarely observed. No neonatal complications were documented.

4. DISCUSSSION

In our study, the average Bishop score before induction of labor was 2.5 ± 0.9 in the Foley group and 2.7 ± 1.0 in the Dinoprostone group. A study by Pham Chi Kong reported a Bishop's score of 2.7 ± 1.3 prior to induction of labor. [6]. In Le Bao Chau's investigation on induction of labor, the mean Bishop's score before induction of labor was 1.87 ± 0.71, which is consistent with our study [7].

Bishop score following induction of labor in our study was 6.2 ± 1.5 in the Foley group and 7.3 ± 1.7 in the Dinoprostone group, consistent with the results reported in Nguyen Thi Anh Phuong's study (6.5 ± 1.7) and Le Bao Chau's study [7], [8]. Bishop score following induction of labor with Dinoprostone in Pham Chi Kong's study was 8.6 ± 4.2, surpassing the results obtained in our investigation. This difference may stem from the author's assessment of cervical ripening 24 hours after initiation, whereas we conducted our evaluation at the conclusion of the designated time or upon removal of the induction device as specified, or when the labor induction device was expelled spontaneously [6]. In Daniel S. Lee's research involving 5807 women, it was discovered that women with a Bishop score exceeding 5 after induction of labor experienced a reduced risk of cesarean delivery (RR 0.55; 95% CI 0.46–0.66). The authors further concluded that, among women undergoing induction of labor, a favorable Bishop score before commencing oxytocin was linked to a decreased cesarean delivery rate in this particular population [9]. The percentage of women attaining a ripe cervix (Bishop score ≥ 7) following cervical ripening with Dinoprostone was 74.1%, surpassing the Foley group's rate of 56.0%, and this disparity was statistically significant. At present, there is limited research assessing the result of cervical ripening, with the majority focusing on the outcomes of labor induction. Therefore, we do not extensively discuss comparing our results in this regard with other studies.

The rate of vaginal delivery in our study was 32.0% in the Foley group and 55.6% in the Dinoprostone group, with no statistically significant difference between the two groups. The rate of vaginal delivery in our study is consistent with domestic studies. In comparison to international studies, the rate of vaginal delivery in our study is lower. For instance, the rate of vaginal delivery in Le Bao Chau's study was 56.4%, in Pham Chi Kong's study was 51.3%, and in Cromi's study, it was 66.7% and 69.7% for the Foley and prostaglandins groups, respectively [6], [7], [10]. The variance could be ascribed to variations in study design and diverse factors influencing the rates of vaginal delivery across regions, including maternal height, weight, and similar factors.

According to the results of our study, the time from induction of labor to delivery in the Dinoprostone group was shorter compared to the Foley group (13.92 hours versus 29.67 hours; p < 0.05). The time from induction of labor to delivery in the Foley group in our study is comparable to the findings in Nguyen Thi Anh Phuong's study (25.8 ± 10.7 hours) and Cromi's study (25.51 ± 8.85 hours) [8], [10]. Time from induction of labor to delivery in our study within the Dinoprostone group aligns with domestic studies, such as Nguyen Ba My Ngoc's research with 13.8 hours, and is shorter in comparison to international studies, such as Cromi's study (18.41 ± 9.5 hours) [10], [11].

For cases involving vaginal delivery, the rate of delivery within 24 hours was 20.0% in the Foley group

and 74.1% in the Dinoprostone group. This discrepancy is statistically significant. A 2021 study by Baumont and colleagues reported a delivery rate within 24 hours of 32.3% for the Foley group and 56.7% for the Dinoprostone group [12].

The observed variation may stem from differences in study design and other influential factors, such as a higher maternal BMI and lower gestational age in our study. However, similar to our findings, a higher proportion of deliveries within 24 hours was observed in the Dinoprostone group. The significance of achieving delivery within this timeframe is notable, as it aids in avoiding prolonged labor and fatigue while enhancing the success rate of the labor induction process. Lorie M. Harper's study suggested that prolonged labor is associated with prolonged second stage, fever during labor, elevated rates of shoulder dystocia, and specific adverse outcomes in newborns [13].

In our investigation, during the induction of labor, the incidence of tachysystole in the Dinoprostone group was 18.5%, significantly higher than the negligible rate observed in the Foley group (0.0%). Additionally, the occurrence of prelabor rupture of membranes during induction of labor was higher in the Dinoprostone group, reaching 40.7% compared to 12.5% in the Foley group. Pham Chi Kong's study reported a tachysystole occurrence rate of 17.9% [6]. In Rachel Blair's study, tachysystole was observed at a frequency of 9% and was absent in the Foley group [14]. The utilization of oxytocin to augment contractions following the induction of labor with Foley was 72.0%, significantly surpassing the Dinoprostone group at 7.4%. This discrepancy is statistically significant and is consistent with findings from both domestic and international studies. In Nguyen Ba My Ngoc's study, the respective rates for the Foley and Dinoprostone groups were 55.3% and 12.5%. A meta-analysis conducted by Hongye Wang in 2016 on the effectiveness of induction of labor using Foley and Dinoprostone revealed that induction of labor with Foley increased the risk of requiring oxytocin compared to the Dinoprostone group (RR 1.86; 95% CI 1.25 – 2.77) [11], [15]. This could be attributed to the different mechanisms of labor induction between the two methods. The Foley catheter primarily aims at cervical ripening, while Dinoprostone, in addition to cervical ripening, also triggers uterine contractions. This is also the reason explaining the higher frequency of tachysystole observed in the Dinoprostone group, a phenomenon rarely seen in the Foley catheter group.

Study limitations:

The enrollment of a relatively small number of women is a notable limitation. The study did not include a comparison of the costs associated with the two agents. Some records had missing information, resulting in incomplete comparisons. Specifically, variations in the time of entering the active labor phase made it challenging to precisely determine the time taken to achieve this phase. Consequently, it became impractical to compare the duration from the initiation of labor induction to the time of reaching the active phase of labor.

5. CONCLUSIONS

Both labor induction methods, utilizing Foley and Dinoprostone in women with low Bishop scores (Bishop's score < 5), demonstrate comparable effectiveness. The duration from induction of labor to the completion of labor is lengthier, and the need for oxytocin augmentation is greater in the Foley group. However, complications such as tachysystole and prelabor rupture of membranes during labor induction are more prevalent in the Dinoprostone group. The observed complications do not differ between the two groups.

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