



Comparison of Intracervical Foley Catheter Balloon and Dinoprostone Insertion in Late Term Pregnancy

ABSTRACT

Objectives: This study proposes to elucidate the efficacy and side effects of Foley catheter balloon and dinoprostone in late-term pregnancy (LTP).

Methods: A total of 70 women were included in this study. Patients were classified into two groups based on cervical ripening methods as Group 1, Foley balloon catheter (n=40), and Group 2, dinoprostone (n=30).

Results: The rate of cesarean section was higher in the Foley catheter group ($p<0.05$). The most common indication for cesarean section in the Foley catheter group was non-progressive labor. There were no significant differences in the other variables.

Conclusion: The intracervical Foley catheter balloon was found to be associated with an increased risk of cesarean delivery without inducing excess maternal or neonatal morbidity.

Keywords: Cervical ripening, dinoprostone, foley balloon catheter, late term pregnancy

Late-term pregnancy (LTP) is defined as pregnancy at or beyond 41 gestational weeks. Indeed, spontaneous onset of labor does not progress in approximately 20% of pregnancies, and unfortunately, LTP is associated with increased perinatal mortality and morbidity (1,2). That is why induction of labor (IOL) is a common obstetric procedure, accounting for approximately 20% to 30% of all deliveries (3). Favorable cervical status is pivotal for assessing successful labor induction (4). There are two known methods for cervical ripening, namely mechanical and pharmacological methods (5). Mechanical methods are the oldest approaches, such as amniotic membrane stripping, balloon catheters, and osmotic dilators. Dinoprostone and synthetic misoprostol form the pharmacological methods (6). The Foley catheter balloon softens the cervix and stimulates endogenous prostaglandin release. Dinoprostone is a vaginal pessary containing 10 mg of controlled-release prostaglandin E2 (PGE2) for cervical ripening (7).

The most efficient method for cervical ripening has not yet been determined. Published data on the efficacy of induction and maternal and perinatal side effects of Foley catheter balloon and dinoprostone are also conflicting (8). Therefore, this study proposes to elucidate the efficacy and side effects of Foley catheter balloon and dinoprostone in LTP.

METHODS

This retrospective study was performed at Ankara Etlik City Hospital, with a total of 70 women. The study was approved by the Ethics Committee of Etlik City Hospital (AEŞH-BADEK-2024-005). Women who had a singleton vertex presentation with a gestational age ≥ 41 weeks, confirmed by first-trimester ultrasonography, intact membranes, reactive non-stress test, unfavorable cervix (Bishop's score < 6), and aged 18–45 years were included. Exclusion criteria were the history of previous uterine surgery, systemic diseases, and contraindications to vaginal delivery. Patients were classified into two groups based on cervical ripening methods as Group 1, Foley balloon catheter (n=40), and Group 2, dinoprostone (n=30).

Under all aseptic conditions, a 16-F/18-F Foley catheter was inserted into the endocervical canal, then the balloon was filled with 30 mL of sterile water. The external end of the

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Table 1. Demographic and clinical characteristics

Variables	Foley Catheter (n=40)	Dinoprostone (n=30)	p value
Age (years)	26.47±5.18	25.66±4.85	0.51**
Gravida	1 (1-6)	1 (1-5)	0.91**
Parity	0 (0-3)	0 (0-3)	0.30**
BMI (kg/m ²)	30.12±4.35	28.76±3.41	0.16*
Latent phase (hours)	12.12±5.61	11.53±5.51	0.64**
Active phase (hours)	3.97±4.11	3.73±3.39	0.99**
Second phase (min)	4.87±6.25	6.50±6.17	0.27**
Mode of delivery (n, %)			0.045***
Vaginal birth	16 (%40)	19 (%63,3)	
Cesarean section	24 (%60)	11 (%36,7)	
Postpartum 6. hour Hb level	0.95±0.71	0.73±0.55	0.27**
Postpartum hemorrhage (cc)	64.50±19.20	63.33±18.44	0.65**
APGAR 1. min	9 (6-9)	9 (7-9)	0.61**
APGAR 5. min	10 (8-10)	10 (9-10)	0.87**

* T-test, ** Mann Whitney, *** Ki Kare (χ^2) test. p value <0.05 was considered as statistically significant BMI: body mass index, Hb: hemoglobin kg/m²: kilogram/ square meters, min: minutes

catheter was fixed to the patient's thigh and kept for a maximum of 12/24 hours. The vaginal dinoprostone (Propress®, Ferring) was inserted into the posterior fornix of the cervix and sustained for a maximum of 12 hours.

After removal of cervical ripening methods, in patients with inadequate uterine contractions, intravenous oxytocin was started at 2 mIU/min and increased every 15–20 minutes in both groups until sufficient uterine activity (3–5 uterine contractions in 10 minutes) was obtained. Continuous fetal monitoring was performed in all patients.

Demographic and laboratory data, mode of delivery, duration of labor, and maternal and perinatal complications were recorded.

Statistical Analysis

Statistical analyses were performed using the statistical packages for SPSS 20.0 for Windows (SPSS Inc., Chicago, IL, USA). Independent sample t-test and Mann-Whitney test were used to compare continuous variables between the two groups. Associations between continuous variables were examined with Spearman/Pearson correlation analysis. Chi-square (χ^2) test was preferred to examine the categorical and continuous variables. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 70 patients were included in this study. Demographic and clinical characteristics of the patients are given in Table 1. We found no significant differences in age, gravida, parity, body mass index (BMI), duration of labor, 6-hour postpartum hemoglobin, postpartum hemorrhage, and Apgar scores between the groups. The rate of cesarean section was higher in the Foley catheter group ($p < 0.05$). The most common indication for cesarean section in the Foley catheter group was non-progressive labor. No neonatal intensive care unit admission or perineal tear was observed in either group.

DISCUSSION

Cervical ripening is an essential step for vaginal delivery. Although several studies have been conducted to evaluate the efficacy and safety of ripening methods, there is no clear consensus. The present study showed that the rate of cesarean section was higher in the Foley catheter group, whereas the duration of labor and maternal and perinatal side effects were similar.

In agreement with the present study, Zhu et al. (9) reported that induction-to-delivery (I-D) interval, Apgar score, and maternal and perinatal side effects were similar between Foley catheter balloon and dinoprostone groups. In contrast with our findings, they did not show a significant difference between the groups regarding the cesarean delivery rate. In concordance with the current study, Jozwiak et al. (10) found an increased cesarean delivery rate with the use of the Foley catheter balloon.

Based on a literature review, there is conflicting evidence regarding the induction-to-delivery interval. In line with the present study, Jozwiak et al. (10) revealed that the I-D interval was similar in both groups, whereas Ghanaie et al. (11) found that the dinoprostone insert was associated with a shorter I-D interval. Contrarily, Deshmukh et al. (12) showed that a shorter I-D interval was related to the use of the Foley catheter balloon.

The most pivotal factors in choosing cervical ripening methods are efficacy and safety. Published data on efficacy and maternofetal morbidity showed similarity between the groups, in agreement with the findings of the present study (13,14).

CONCLUSION

In conclusion, the intracervical Foley catheter balloon was found to be associated with an increased risk of cesarean delivery without inducing excess maternal or neonatal morbidity. Larger studies are needed to confirm our results.

Ethics Committee Approval: This study was approved by the Ethics Committee of Etlık City Hospital (No: AEŞH-BADEK-2024-005, Date: 10/01/2024).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

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