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Maternal and Fetal Factors Affecting the Effectiveness of Vaginal Dinoprostone in Labor Induction

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Abstract

BACKGROUND/AIMS: Induction of labor is a common obstetric intervention used to encourage the onset of labor. The aim of the study was to evaluate the maternal and fetal factors that play a role in the efficacy of vaginal dinoprostone in labor induction.

MATERIALS AND METHODS: Our study included 780 patients who underwent pregnancy follow-up and delivery in our hospital between March 2018 and 2024. All data, including body mass index (BMI), age, parity, induction criteria, obstetric history, bishop score, time of delivery, newborn weight, and Apgar score, were entered by the delivery room physician. Data from 620 patients who had a successful delivery with vaginal dinoprostone application, and 160 patients who did not have a vaginal delivery were evaluated retrospectively.

RESULTS: The BMI value of women in group 2 at admission to the hospital was found to be significantly higher than that of women in group 1 ($p<0.001$). The Bishop score of women in group 1 at admission to the hospital was found to be significantly higher than that of women in group 2 ($p<0.001$). The nulliparity rate of women in group 2 was found to be significantly higher than that in group 1 ($p<0.001$). The uterocervical angle measurement of women in group 2 was found to be significantly lower than that in group 1 ($p<0.001$). The rate of newborns with 1st and 5th minute Apgar scores ≥8 in group 1 was found to be significantly higher than the rate in group 2 ($p=0.006$, $p=0.04$, respectively).

CONCLUSION: It was determined that parity was one of the important determinants in achieving vaginal delivery in pregnancies where dinoprostone vaginal insert was applied. It was determined that multiparous women benefited more from induction with dinoprostone. However, according to the results of our study, more research is needed to evaluate nulliparous pregnancies requiring induction.

Keywords: Dinoprostone, induction of labor, nulliparity, multiparity

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INTRODUCTION

Induction of labor (IOL) is a common obstetric intervention that uses artificial methods to stimulate the onset of labor by artificially initiating the process of cervical effacement, cervical dilation, and uterine contractions.[1] IOL is often considered when prolonged pregnancy poses a risk of death or morbidity for the mother or child or upon the request of pregnant women at term.[2] IOL is considered indicated when outcomes for the fetus, the mother, or both are better than expectant management, which means waiting for spontaneous onset of labor.[3] It is an increasingly common practice in modern obstetrics to provide better care for both the fetus and the mother.[4] For example, the rate of IOL more than doubled in 2006, reaching 22.5% of all births in the USA.[4] The American College of Obstetricians and Gynecologists (ACOG) has a comprehensive list of recommendations for the timing of delivery, including some of the common clinical scenarios listed for this purpose.[5] Also, ACOG recently endorsed elective IOL as a "reasonable" option following the publication of results from the Animal Research: Reporting of *In Vivo* Experiments (ARRIVE) (randomized trial of induction versus expectant management) study conducted by the Eunice Kennedy Shriver National Institute.[6] However, the Society for Maternal-Fetal Medicine statement suggested that inducing labor at 39 weeks' gestation in low-risk nulliparous women provides maternal benefits without an increase in adverse neonatal effects.[7] The New England Journal of Medicine published the ARRIVE study, which compared cesarean section (C/S) rates and perinatal outcomes in nulliparous pregnant women who underwent elective IOL at 39 weeks of gestation with expectant management. The results showed a significantly lower C/S rate in the induction group and no statistically significant difference in the incidence of adverse perinatal outcomes.[8] Another published study found that the likelihood of a C/S was reduced in nulliparous and multiparous women who were electively induced between 37 and 40 weeks of pregnancy.[9] It also found that women were not at increased risk of third or fourth degree tears or having an operative vaginal delivery, regardless of gestational age.[9] However, a Cochrane systematic review also showed that IOL is beneficial because it is associated with fewer perinatal deaths, and improved birth outcomes in women after delivery.[10] Cervical ripening is an important precursor to successful labor induction and is accompanied by adequate and strong uterine contractions at regular frequency.[11] There are two main options for cervical ripening: namely, mechanical and pharmacological methods.[12-16] Oxytocin may be one of the most popular pharmacologic agents for labor induction; however, it has minimal effects on cervical ripening.[17] Prostaglandin analogs, including dinoprostone, a synthetic preparation chemically identical to naturally occurring PGE2, and misoprostol, a synthetic PGE1 analog, not only have an effect on cervical ripening but also play an important role in the IOL.[18,19] Due to its benefits such as low price and easy storage (no refrigeration required), misoprostol may be the most commonly used pharmacological agent for labor induction worldwide.[20] However, Misoprostol is not licensed for labor induction, and has been widely used off-label (via oral or vaginal administration) worldwide for many years.[21] In contrast, a slow-release vaginal product used for dinoprostone administration contains 10 mg of dinoprostone dispersed throughout the matrix of a thin flat polymeric hydrogel drug delivery device designed to provide a controlled and constant release of dinoprostone from the reservoir at 0.3 mg/hr. The efficacy profile is faster and more variable in women without membrane rupture than in women with membrane rupture.[22] The main advantage of the dinoprostone slow-release vaginal insert is enabling rapid retrieval in the event of uterine tachysystole or abnormal fetal heart rate monitoring, and has a low side effect profile.[23] Our study aimed to evaluate the maternal and fetal factors that play a role in the effectiveness of vaginal dinoprostone in labor induction.

MATERIALS AND METHODS

The present study was conducted as a retrospective observational following the Principles of the Helsinki Declaration. Consent forms were obtained from all patients. The study received approval from Buca Seyfi Demirsoy Training and Research Hospital hospital's Ethics Committee (approval number: 2024/308, date: 26.06.2024). Our study included 780 patients whose pregnancy follow-ups and deliveries were performed in our hospital between March 2018 and 2024 a more recent past date. Data from 620 patients who had a successful delivery with vaginal dinoprostone application and 160 patients who could not have a vaginal delivery were evaluated retrospectively. Inclusion criteria were singleton pregnancy, vertex presentation, >36 weeks of gestation, Bishop score <7, absence of labor signs, and reassuring fetal heart rate. Gestational age was calculated using Naegele's rule and confirmed by early pregnancy ultrasound.[24] Exclusion criteria included abnormal placentation, antepartum bleeding, fetal malformation, history of C/S or uterine surgery, and other contraindications to vaginal delivery. Cervical dilatation, cervical effacement, cervical consistency, cervical position, and station of fetal presenting part were evaluated in calculating the Bishop score.[25] The American Diabetes Association Criteria were used to diagnose gestational diabetes mellitus (GDM).[26] GDM was diagnosed if fasting blood glucose was above any of the following criteria: 92 mg/dL; 1 hour: 180 mg/dL; 2 hours: 153 mg/dL. In pregnant women who have not previously been diagnosed with diabetes mellitus, a 75-g oral glucose tolerance test (OGTT) test is performed at 24-28 weeks, and plasma glucose is measured during fasting, 1st and 2nd hours. It is appropriate to perform OGTT in the morning after an overnight fast of at least 8 hours.[26] The American Diabetes Association Criteria were used to diagnose type-2 diabetes mellitus.[26] Diabetes is diagnosed if HbA1C is greater than or equal to 6.5%, fasting blood glucose is greater than or equal to 126 mg/dL, or two-hour blood glucose is >200 mg/dL.[26] Pregnancy-induced hypertension (PIH) was diagnosed in accordance with the most recent ACOG bulletin.[27] The combination of hypertension and proteinuria is used for the diagnosis of preeclampsia. Hypertension is defined as blood pressure levels of at least 140 mmHg for systolic or at least 90 mmHg for diastolic in measurements taken four hours or longer after the 20th week of pregnancy in a woman whose blood pressure values were previously normal. Severe hypertension is considered when blood pressure is at least 160 mmHg systolic or at least 110 mmHg diastolic. To diagnose preeclampsia, women with hypertension also require the presence of proteinuria, defined as at least 300 mg in a 24-hour urine collection. PIH is diagnosed in patients who meet hypertension criteria for preeclampsia without proteinuria or serious additional problems.[27] amniotic fluid index ≤5 is considered one of the most important criteria in the ultrasonographic diagnosis of oligohydramnios.[28] Routine fetal heart monitoring was performed for 2 hours, and treatment with the dinoprostone vaginal slow-release system (Propess®, Ferring, Controlled Therapeutics Ltd, UK) was started after the fetal heart rate was observed to be normal. Posterior fornix dinoprostone placement was performed and maintained for a maximum of 12 hours in pregnant women without contraindications, according to the manufacturer's instructions. All participants underwent continuous fetal monitoring. According to the modified protocol per

the manufacturer's recommendation, dinoprostone was removed in the presence of uterine tachysystole (defined as more than five contractions in 10 minutes in a 30-minute period), non-reassuring fetal heart rate, other non-specific adverse events (intolerable painful uterine contractions), persistence in the vagina for >12 hours, and spontaneous rupture of membranes. If regular uterine contractions were not noted 1 hour after removal of dinoprostone, intravenous oxytocin was additionally used to continue induction. All data, including BMI, age, parity, induction criteria, obstetric history, bishop score, reason for vaginal dinoprostone removal, time of delivery, neonatal weight, and Apgar score, were entered by the delivery room physician. The delivery room fetal monitoring device provided continuous close observation of fetal heart rate and uterine contraction patterns. Women with successful labor induction were divided into group 1, and those with unsuccessful labor induction into group 2.

Statistical Analysis

Statistical analysis was performed using SPSS version 22.0 (IBM-Inc.-Chicago-USA). The normality of the distribution was evaluated with the Kolmogorov-Smirnov test. Parameters that were not normally distributed were analyzed with the Mann-Whitney U test. Chi-square tests and Fisher's exact test were used in the analysis of categorical data. Parameters that were not normally distributed were presented as median (minimum-maximum). Number and percentage (%) were used to represent qualitative data. Results were evaluated at a 95% confidence interval. The p-value considered statistically significant was <0.05.

RESULTS

In our study, the mean age of the women in group 2 was found to be significantly higher than that of women in group 1 (p=0.001). The Bishop score at admission of women in group 1 was found to be significantly higher than that of women in group 2 (p<0.001). BMI scores of women in group 2 were found to be significantly higher than those of women in group 1 (p<0.001). The nulliparity rate of women in group 2 was found to be significantly higher than that of women in group 1 (p<0.001). The uterocervical angle measurement of women in group 2 was found to be significantly lower than that of women in group 1 (p<0.001). The time to delivery after insertion in group 2 women was found to be significantly higher than in group 1 women (p<0.001). The time to delivery after retrieval in the group 2 women was found to be significantly higher than in the group 1 women (p<0.001) (Table 1).

The rate of women with a 1-minute Apgar score ≥8 in group 1 was found to be significantly higher than that of women in group 2 (p=0.006). The rate of women with a 5-minute Apgar score ≥8 in group 1 was found to be significantly higher than that of women in group 2 (p=0.04), (Table 2).

DISCUSSION

The main purpose of the IOL is to ensure timely cervical ripening and successful vaginal birth. In our study, 79.4% of term pregnancies treated with dinoprostone slow-release vaginal insert for IOL had a successful vaginal delivery. This success rate was consistent with many other previous studies, with a successful vaginal delivery rate ranging from approximately 70% to 90% after using a dinoprostone slow-release vaginal insert for the IOL.[29-34] In the 2008 report of the Turkey Demographic and Health Survey (TDHS), the C/S rate was found to be 37%, and in the TDHS-2013 report, it was 48%.[35-37] These rates are significantly higher than the 15% rate given as an acceptable cesarean delivery rate by the World Health Organization.[38] In light of this information, the birth rate data in our study reveal that dinoprostone administration is an effective method for successful initiation of labor.

In our study, we demonstrated that parity is one of the most important determinants in achieving successful vaginal delivery in term pregnancies treated with dinoprostone slow-release vaginal insert for IOL. 96.7% of all multiparous women had a successful vaginal delivery, and in the nulliparous group, the rate of successful vaginal delivery after dinoprostone slow-release vaginal insert treatment, was determined to be 70.2%. However, there are different results in the literature regarding the success rates of deliveries after dinoprostone application in multiparous and nulliparous pregnant women.[39,40] In a

Table 1. Demographic-and clinical-characteristics of the groups

Variables	Group 1 n=620 79.4%	Group 2 n=160 20.6%	p-value
Maternal age (years)	30 (23-43)	31 (25-40)	0.001
Gestational age (weeks)	40 (38-41)	40 (38-41)	0.9
Bishop score at admission (n)	3 (1-4)	2 (1-4)	<0.001
Body mass index (kg/m^2)	28 (25-31)	30 (26-34)	<0.001
Parity			
Nulliparity	357 (57.6%)	151 (94.4%)	<0.001
Multiparity	263 (42.4%)	9 (5.6%)	
Indications for induction			
Elective	480 (77.4%)	113 (70.6%)	
Oligohydramnios	24 (3.9%)	5 (3.1%)	
Gestational diabetes mellitus	49 (7.9%)	15 (9.4%)	0.2
Type 2 diabetes mellitus	9 (1.5%)	5 (3.1%)	
Pregnancy induced hypertension	58 (9.4%)	22 (13.8%)	
Use of painless anesthesia	515 (83.2%)	141 (88.1%)	0.1
Uterocervical angle (°)	100 (60-140)	90 (60-130)	<0.001
Time to delivery after insertion (hours)	18 (7-29)	32 (21-45)	<0.001
Time to delivery after retrieval (hours)	11 (4-21)	14.5 (10-29)	<0.001

*Values are expressed as frequency or percentage. Values are expressed as median (minimum-maximum). The Mann-Whitney U test was conducted. The Chi-square test and Fisher's exact test were used.

Table 2. Fetal outcomes between the groups

Variables	Group 1 n=620 79.4%	Group 2 n=160 20.6%	p-value
Fetal weight (grams)	3,180 (2,340-4,310)	3,165 (2,330-4,290)	0.9
Apgar score (1-minute)			
≤7	180 (29%)	65 (40.6%)	0.006
≥8	440 (71%)	95 (59.4%)	
Apgar score (5-minute)			
≤7	18 (2.9%)	10 (6.3%)	0.04
≥8	602 (97.1%)	150 (93.8%)	

*Values are expressed as frequency or percentage. Values are expressed as median (minimum-maximum). The Mann-Whitney U test was used. Chi-square test and Fisher precision test were used.

retrospective study by Zhao et al.[41], results revealed that parity was the strongest predictor of successful vaginal delivery in term pregnancies when comparing the efficacy of dinoprostone slow-release vaginal insert between multiparous and nulliparous women. In the study by Huang et al.[42], parity was proven to be the main factor contributing to the time to vaginal delivery. A significant decrease in this time was observed in multiparous women compared to nulliparous women.

In the present study, the mean age was found to be significantly higher in the unsuccessful vaginal delivery group. In the study conducted by Pevzner et al.[43], it was revealed that a maternal age of <35 years significantly supports successful labor induction. Similarly, in the study conducted by Obut et al.[44], it was revealed that increasing maternal age reduces the probability of vaginal delivery. In the present study, no statistically significant relationship was found between gestational age, birth weight, IOL indication, and use of painless anesthesia parameters and successful vaginal delivery. Possible reasons could be the small sample size, as a limited sample size may prevent less important factors from reaching statistical significance. Only the most significant factor can be repeated in almost all studies.

In the literature, labor induction is shown to be more likely to be successful in women with lower BMI.[45,46] In our study, similar to the literature, BMI was found to be significantly lower in pregnant women who had successful vaginal births.

Higher bishop scores have traditionally been associated with higher vaginal birth success rates.[47,48] However, there are studies that question the reliability of Bishop scores in predicting birth outcomes.[49,50] In our study, bishop scores were found to be significantly higher in patients who had a successful vaginal delivery with vaginal dinoprostone administration, as supported by the results obtained in most randomized trials and clinical guidelines for labor induction.[51,52]

In our study, the 1st- and 5th-minute Apgar scores of patients who had a successful vaginal delivery were found to be significantly higher. In the literature, neonatal outcomes were found to be positive in pregnancies induced with dinoprostone.[41,53]

In our study, time to delivery after insertion (hours) and time to delivery after retrieval (hours) were found to be significantly lower in patients who had a successful vaginal delivery compared to patients who did not have a vaginal delivery. Similarly, in the literature, the time to delivery after insertion (hours) and time to delivery after retrieval (hours) were found to be lower in patients who had a successful delivery with dinoprostone compared to patients who underwent spontaneous delivery follow-up or C/S due to induction failure.

Whether epidural analgesia increases the risk of cesarean delivery and prolongs labor has been intensely debated during the last decade.[54] Unfortunately, good studies are few and most have had small sample sizes. Epidural analgesia was associated with slow progress of labor, which increased the rate of instrumental delivery. However, in our study, no relationship was found between the use of painless anesthesia and the success of vaginal delivery.

In our study, uterocervical angle measurement was found to be significantly higher in patients who had successful vaginal delivery compared to patients who did not have a vaginal delivery. However, in the study conducted by İleri et al.[55], no relationship was found between uterocervical angle and delivery success in pregnancies induced with dinoprostone. In the study conducted by Yang et al.[56], it was stated that the use of uterocervical angle measurement and bishop score could together help predict the success of labor induction. In another study in the literature, it was stated that the uterocervical angle could be used, in addition to cervical length measurement, to assess the risk of premature birth and term pregnancy when predicting delivery success.[57]

Our study showed that the success rate of vaginal delivery in nulliparous term pregnancies was only 70.2%, suggesting that other strategies may be considered instead of the dinoprostone slow-release vaginal insert for IOL for this group. In fact, many studies have supported the use of PGE1, and some have suggested the combination of mechanical and pharmacological methods or the use of mechanical or pharmacological agents alone, compared with PGE2.[58] A randomized controlled trial by Edwards et al. [59] compared the combined use of a dinoprostone slow-release vaginal insert and a Foley catheter with the use of a Foley catheter alone for cervical ripening and labor induction. This study supported the combined use of a dinoprostone slow-release vaginal insert and a Foley catheter for cervical ripening over the use of a foley catheter alone for IOL in nulliparous term pregnant women. The results showed that the combination strategy could shorten the time to vaginal delivery in nulliparous women but not in multiparous women.

Study Limitations

Our current study did not provide any recommendations on this issue due to its single-arm nature. The limitation of study is that it is retrospective in nature and a single-arm study.

CONCLUSION

Since multiparous women benefit the most from IOL using the dinoprostone slow-release vaginal insert, the two combinations mentioned above may be considered. However, based on the results of the current study, further research is needed to evaluate nulliparous term pregnancies requiring IOL.

MAIN POINTS

- The success rates of vaginal delivery after induction of labor (IOL) with dinoprostone in nulliparous term pregnancies are not satisfactory.

- In nulliparous term pregnancies, other strategies may be considered instead of dinoprostone slow-release vaginal insert for IOL.

- Multiparous women benefit the most from IOL using dinoprostone slow-release vaginal insert.

ETHICS

Ethics Committee Approval: The study received approval from Buca Seyfi Demirsoy Training and Research Hospital hospital's Ethics Committee (approval number: 2024/308, date: 26.06.2024).

Informed Consent: Consent forms were obtained from all patients.

Footnotes

Authorship Contributions

Surgical and Medical Practices: U.A., F.E., Concept: O.Y., C.A., Design: H.A.A., B.E., Data Collection and/or Processing: S.E., T.B.B., Analysis and/or Interpretation: H.A.A., C.A., Literature Search: U.A., S.E., B.E., Writing: O.Y., C.A., T.B.B., F.E.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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