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Comparison of labor duration of induced labor with dinoprostone insert vs spontaneous labor

Katarzyna A. Skibinska[1], Magdalena Kolak[1], Agnieszka Micek[2], Hubert Huras[1], Andrzej Jaworowski[1]

[1]Jagiellonian University Medical College, Department of Obstetrics and Perinatology, Cracow, Poland
[2]Statistical Laboratory, Institute of Nursing and Midwifery, Jagiellonian University Medical College, Cracow, Poland

ABSTRACT

Objectives: Labor induction is one of the most common procedures in modern obstetrics. One in five pregnant women and 30–40% of women delivering vaginally undergo this procedure. If the cervical status is unfavorable, a ripening process is used prior to induction to shorten the duration of oxytocin administration and maximize the possibility of vaginal birth. The aim of this study was to compare the duration of labor induced with dinoprostone vaginal insert to spontaneous labor.

Material and methods: It was a retrospective study conducted between May 2019 and February 2021 in the tertiary reference center, the Obstetrics and Perinatology Department of the Jagiellonian University Hospital in Krakow. The research group involved 182 patients in singleton pregnancy at term, qualified for cervical ripening procedure. The control group consisted of 178 patients that were delivering spontaneously and admitted to the delivery ward in the first stage of labor. Statistical analysis was performed to compare the duration of labor between groups. To find factors affecting the procedure we compared different models consisting of maternal and fetal characteristics.

Results: Successful vaginal delivery in the dinoprostone group was achieved in the group of 88% of patients. There was no significant difference in labor duration between the groups: 315 minutes in the study group and 300 min in the control group. Only being primipara was a factor related to longer labor in both groups.

Conclusions: Pre-induction with dinoprostone insert and additional foley catheter, if indicated, does not make labor longer in comparison with spontaneous labor.

Keywords: labor; induced; dinoprostone; cervical ripening; pregnancy

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INTRODUCTION

Labor induction is a procedure of artificial stimulation of childbirth before the natural, spontaneous onset of labor. It is one of the most common procedures in modern obstetrics. Currently, one in five pregnant women and 30–40% of women delivering vaginally undergo this procedure [1]. The reasons for the induction include reduction of the perinatal mortality and morbidity of the fetus and newborn as well as the reduction of maternal complications. However, as with every medical intervention, labor induction is associated with a risk of complications. The decision to induce labor should always be justified on medical grounds and preceded by obtaining written informed consent from the pregnant woman [2]. When labor is induced, cervical status has an impact on the duration of induction and the likelihood of vaginal birth. If the cervical status is unfavorable, a ripening process is generally used prior to induction to shorten the duration of oxytocin administration and maximize the possibility of vaginal birth. There are two major modalities for cervical ripening: mechanical interventions, such as insertion of a balloon catheter or hygroscopic cervical dilators, and the application of pharmacologic agents, such as prostaglandins.

Prostaglandins stimulate collagenase activity, synthesis of glycosaminoglycans, elastase and hyaluronic acid in the cervix. They sensitize also the myometrium to the action of oxytocin and directly induce contractions of the uterus [3]. Dinoprostone vaginal insert (Cervidil®; Propess®) is a retrievable vaginal pessary containing 10 mg of dinoprostone [prostaglandin E2 (PGE2)] in

Corresponding author:
Katarzyna A. Skibinska
Jagiellonian University Medical College, Department of Obstetrics and Perinatology, 23 Kopernika St, 31-501 Cracow, Poland
e-mail: skibinska.katarzyna.anna@gmail.com

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a controlled-release drug delivery device. The initiation (or continuation) of cervical ripening in patients prior to labor induction is approved in Poland and in many countries worldwide. The effectiveness of dinoprostone vaginal insert has been demonstrated in multiple of randomized clinical trials in women at term. The demonstrated effectiveness and safety of the system, simple application, and efficient dose control, suggest that a dinoprostone vaginal insert is a valuable option for cervical ripening in patients with an unfavorable cervix [3, 4].

Objectives

The aim of this study was to compare the labor duration of induced labor with the use of a dinoprostone vaginal insert to the spontaneous labor.

MATERIAL AND METHODS

Data collection and study sample

It was a retrospective study conducted between May 2019 and February 2021 in the tertiary reference center, the Obstetrics and Perinatology Department of the Jagiellonian University Hospital in Krakow. The research group involved 182 patients in singleton pregnancy at term, qualified for cervical ripening procedure according to Polish Gynecological Society indications with unfavorable cervix. The indications include hypertension, gestational or pregestational diabetes mellitus, cholestasis and fetal growth restriction as well as gestational age of 41 + 0. Although the gestational age for the procedure differs regarding a particular indication, the gestational age was at least 37 + 0 weeks. Our facility uses the following regime for labor induction. For an unprepared cervix (Bishop score < 6 points), a dinoprostone vaginal insert is used (Cervidil®). After 24 hours (when the 1st labor stage does not occur and the cervical dilation is < 3 cm), mechanical methods for labor induction are introduced, namely, Foley catheter, with filling of 60–120 mL for 24 hours. The intravenous oxytocin infusion is initiated when the balloon falls out and there is no contractile function or is removed after 24 hours.

The control group consisted of 178 patients that was delivering spontaneously and admitted to the delivery ward in the first stage of labor. The labor onset was defined as regular uterine contractions, at least one in 10 minutes that cause progressive dilation and effacement of the cervix. Labor duration was counted for successful vaginal delivery patients, that is 120 of the study group and 149 patients in the control group.

The medical data was taken from electronic medical history. The study received consent from the Ethics Committee No. 1072.6120.291.2021.

Statistical analysis

To compare the duration of labor between groups and to find factors affecting it, we compared the models preferring those with lower AICc (the second-order Akaike Information Criterium) as giving greater support for data relative to the others. AICc is analogous of classical AIC and its use is recommended when the sample size n is relatively smaller than the number of estimated parameters K, namely $n/K < 4$ [5]. The dependent variable in all analyses was the duration of the vaginal labor treated as continuous or dichotomized. Four variables: the main explanatory (Cervidil induction) and three others which can potentially influence the duration of labor (woman's age at birth together with being multiparous or primiparous and gestational age) were regarded as 'basic' predictors and were retained in all constructed models. We used an approach focusing on searching the most parsimonious models based on subsets of 'basic' predictors and some other covariates potentially influencing tested association. We considered nine features characterizing both mother and child, namely: parity (multiparous or primiparous), baseline characteristic (woman's age at birth (continuous), body mass index (BMI) before pregnancy (continuous), variables relating to a woman's pregnancy (pregnancy duration, change weight during pregnancy (continuous), child's birth weight (< 2500, 2500–4000, ≥ 4000 g) and interventions (Cervidil preinduction (yes/no), Foley catheter (yes/no). Linear regression was applied to estimate coefficients of change in the duration of labor associated with switching from the reference category to others or per unit increase in a covariate. Analogically, logistic regression was engaged to compare the chances of a longer duration of labor with a cut-off point of 450 minutes used as a threshold. The odds ratios (ORs) with 95% confidence intervals (Cis) were calculated with the classical method of logistic regression or Firth's bias reduction method (in the case of zero cells) by applying the Wald test. The comparison of alternative models with different subsets of predictors was done with the MuMIn package. The difference in AICc (Δ) between the two competing models reflects the extent of their equivalence. The value of $\Delta \leq 4$ indicates that both models are plausible, and when $\Delta \geq 14$ there is little evidence in the data for model with greater AICc [5, 6]. All analyses were conducted in R software version 4.0.4.

RESULTS

A total of 6,300 childbirths took place in 2019–2021 at the Department of Obstetrics and Perinatology, UH, of which 3,400 were by Caesarean section. In the analyzed period, 300 pregnant women were qualified for labor induction, of whom 182 met the inclusion criteria and were included in the analysis. The control group included

Table 1. The comparison of characteristics of patients in the study and the control group (only successful vaginal labors)

Variable	Inducted labor N = 120	Spontaneous labor n = 149	p
Mothers characteristics			
BMI at baseline [kg/m^2], Q2 (Q1; Q3)	23.8 (20.9; 25.7)	21.9 (20.5; 23.9)	0.006$^{\#}$
Age [years], Mean (SD)	30.8 (4.8)	31.4 (4.2)	0.288
Change in body weight [kg], Mean (SD)	14.0 (6.0)	13.2 (4.8)	0.233
Labor characteristics			
Gestational age [days], Q2 (Q1; Q3)	277.0 (273.0; 286.0)	276.0 (270.0; 281.0)	0.047$^{\#}$
Length of vaginal delivery [min], Q2 (Q1; Q3)	315.0 (195.0; 450.0)	300.0 (205.0; 450.0)	0.569
Neonatal characteristic			
Birth weight [g], Mean (SD)	3 421.4 (427.6)	3 441.6 (433.0)	0.702
Apgar < 7, 1 min	3 (2.5)	0 (0.0)	0.175
Apgar < 7, 5 min	1 (0.8)	0 (0.0)	0.913
Apgar < 7, 10 min	1 (0.8)	0 (0.0)	0.910
Apgar < 8, 1 min	3 (2.5)	0 (0.0)	0.175
Apgar < 8, 5 min	1 (0.8)	0 (0.0)	0.913
Apgar < 8, 10 min	1 (0.8)	1 (0.7)	1.000
Apgar < 9, 1 min	5 (4.2)	2 (1.3)	0.289
Apgar < 9, 5 min	4 (3.3)	3 (2.0)	0.771
Apgar < 9, 10 min	3 (2.5)	4 (2.7)	1.000
Apgar < 10, 1 min	6 (5.0)	9 (6.0)	0.918
Apgar < 10, 5 min	5 (4.2)	7 (4.7)	1.000
Apgar < 10, 10 min	4 (3.4)	8 (5.4)	0.622

p value based on Student's t-test except of denoted by $^{\#}$ based on Mann-Whitney U test

178 patients admitted at the first stage of labor. Successful vaginal delivery occurred in 120 patients of the study group and in 149 of the control group on which this study was focused on. The rest of the patients in both groups had a caesarean section.

Among the study group, hypertension was diagnosed in 25% of patients (pregnancy-induced and chronic inclusively), diabetes mellitus in 38% of cases (pregestational and gestational inclusively), cholestasis in 1% and fetal growth restriction in 4% of patients. 13% of patients were qualified for the induction of labor because they achieved 41 weeks of gestational age. Some of the patients suffered from more than one disorder or abnormality related to pregnancy. A Foley catheter was used in 24 patients as an additional method to ripen an unfavorable cervix. 88% of inducted labor women had successful vaginal labor within 24 hours.

The characterization of each of the groups was presented in Table 1. Statistically significant difference regarded two following features — BMI before pregnancy and gestational age. Otherwise, BMI of both groups was defined as normal weight in both groups (Me (Q1–Q3): 23.8 (20.9; 25.7) vs 21.9 (20.5; 23.9), p = 0.006). The median gestational age differed only by one day. These differences, even if statistically significant, were not of clinical importance.

The Chi-square test had been used to check which variables had a significant difference between both groups that could affect the labor duration. Merely, being primigravida made labor duration longer (Tab. 2).

Another different model was compared. The model with the lowest AICc value is the best-supported one among those compared. The difference in AICc values between model i and the best model is Δi, number of estimated parameters is K, w — Akaike weight. The best model was primipara model, then model primipara with preinduction with Cervidil — AICc 3495.55 (Tab. 3).

DISCUSSION

The main goal of this study was to compare the time of induced labor to the spontaneous one. As it was mentioned in the introduction, the procedure of labor induction is nowadays one of the most commonly performed in the obstetrics, thus needed to improve safety for the mother and the child [1, 2]. Many studies compare the efficiency and safety of pharmacological and mechanical methods of labor induction. Patients with unfavorable cervixes are candidates for the procedure of cervical ripening. Compared with the use of oxytocin infusion alone, cervical ripening probably increases the chances of achieving vaginal birth

Table 2. Tested variables

Variable	Categories	Inducted vaginal delivery n = 120	Spontaneous vaginal delivery n = 149	p value
Primigravida	No	58 (48.3)	94 (63.1)	
	Yes	62 (51.7)	55 (36.9)	0.021
BMI	< 18.5	5 (4.2)	5 (3.4)	
	18.5–25	76 (63.3)	124 (83.2)	0.001
	25-30	31 (25.8)	13 (8.7)	
	≥ 30	8 (6.7)	7 (4.7)	
Primipara	No	52 (43.3)	77 (51.7)	
	Yes	68 (56.7)	72 (48.3)	0.215
Birth weight	< 2500	106 (88.3)	133 (89.3)	
	2500–4000	5 (4.2)	1 (0.7)	0.126
	≥ 4000	9 (7.5)	15 (10.1)	

BMI — body mass index; p value based on Chi-square test of independence

Table 3. Model comparison results based on second-order Akaike Information Criterium (AICc) values

Model	AICc	Δ	K	w
Primipara[#]	3494.45	0.00	3	0.32
Primipara + preinduction with Cervidil	3495.55	1.10	4	0.18
Primipara + gestational age	3496.08	1.63	4	0.14
Primipara + mother's age	3496.46	2.01	4	0.12
Primipara + preinduction with Cervidil + gestational age	3497.09	2.64	5	0.09
Primipara + preinduction with Cervidil + mother's age	3497.59	3.13	5	0.07
Primipara + gestational age + mother's age	3498.05	3.60	5	0.05
Basic[##]	3499.1	4.64	6	0.03
Full model	3507.61	13.15	12	0.00
Mother's age	3537.81	43.36	3	0.00
Preinduction with Cervidil + mother's age	3539.61	45.16	4	0.00
Gestational age + mother's age	3539.87	45.42	4	0.00
Preinduction with Cervidil + gestational age + mother's age	3541.68	47.23	5	0.00
Null model	3543.32	48.87	2	0.00
Preinduction with Cervidil	3545.26	50.81	3	0.00
Gestational age	3545.27	50.82	3	0.00
Preinduction with Cervidil + gestational age	3547.21	52.76	4	0.00

[1]Basic = Preinduction in Cervidil (yes/no) + woman's age at birth (continuous) + primipara (yes/no) + gestational age; [#]Best model; [##]Full model with all considered variables

within 24 hours and does not increase, but may decrease, the risk for cesarean section [7, 8]. There is no single, best practice for the choice of agent adopted for cervical ripening: both mechanical and pharmacologic agents are acceptable options unless the patient has a contraindication to the use of a specific procedure. A 2016 Cochrane meta-analysis comparing misoprostol, dinoprostone, and the balloon catheter for cervical ripening concluded that no method was clearly superior in terms of diminishing the over-24-hour vaginal birth or tachysystole with adverse FHR changes along with cesarean birth [9]. Another 2019 meta-analyses showed that choosing mechanical methods of cervical ripening is less satisfactory for women [10]. Many patients feel anxious about labor induction that it may last longer or will be more painful than spontaneous vaginal one [11], but after the delivery, most women report little overall effect on satisfaction with induced labor compared with a spontaneous one but feel an increased sense of control [12]. There are multiple studies and meta-analyses regarding the efficiency of labor induction. Most authors compare the percentage of successful

labor within 24- or 48-hours' time and time intervals of induction to labor activated by different agents [9]. This study aimed to compare the duration time of induced labor with dinoprostone insert with spontaneous labor and to identify factors that influence that time. We found that there is no significant difference in labor duration between the groups in comparison to the active phase of labor (the first and the second stage of labor): 315 minutes in the study group and 300 min in the control group. A similar duration time, 4 hours of the first stage of labor, was observed in Zielinska K. et al. study [13] and in Gornisiewicz T. study [14] (5.4 h of first stage of labor in dinoprostone group). In 2019 Wei Y. study [15] on 1,400 term pregnancies also showed no difference between time intervals of the first and second stage of labor in comparison to the one induced with dinoprostone and oxytocin in late-term pregnancies. (Latent phase: 3.75 h vs 3.68, active phase: 1.71 h vs 1.82 h, second stage: 0.45 h vs 0.53 h). However, for patients with a Bishop's score between 4–6, the duration of the active phase was significantly reduced in the subgroup who were given dinoprostone [15]. Similarly, Poma S. at al. [16] observed shorter time of induced labor compared to spontaneous one. Successful vaginal delivery in the dinoprostone group was achieved in our study in 88% of patients. That is a higher rate than expected according to other studies like in the MVI and EXPEDITE trials comparing dinoprostone and misoprostol vaginal inserts (72,9% and 71,6%) [17, 18]. There was no substantial difference in Apgar score between the analyzed groups. Other studies confirm that there are also no significant concerns regarding the safety of the dinoprostone for neonates [4, 19]. A variety of maternal and fetal factors have been suggested to predict labor induction success. Certain characteristics of the woman like parity, age, weight, height and body mass index, and of the fetus (including birth weight and gestational age) are associated with the duration of stages of labor and success of labor induction; with parous, young women who are taller and of lower weight have a higher rate of induction success. Fetuses with a lower birth weight or increased gestational age are also associated with increased induction success [20, 21]. Our research shows that pre-induction with pharmacological and additionally mechanical method if indicated, does not make labor longer in comparison with spontaneous labor. Only being primipara was a factor related to longer labor in both groups. Our findings are similar to the trends described in Poma et. al study that has proven shorter duration of the first stage of labor among patients qualified to use dinoprostone as a pre-induction method and with effective epidural labor analgesia in comparison to spontaneous labor [16]. Furthermore, the Cochrane systematic review including over 21,000 patients has showed that overall length of labor was shorter for women undergoing induction compared with the expectant management [22]. Pre-pregnancy BMI is important factor that makes an impact on labor duration and must be mentioned. Obesity increases the risk of prolonged spontaneous or induced labor duration and cesarean section rates [23]. Despite of significantly higher BMI of the study group, still both groups are characterized as normal weight. BMI is not a considered feature to have an impact on the labor duration or to disturb the research scores. Higher BMI among patients demanding labor induction is consistent with mentioned systematic review and meta-analysis which has proven that obesity women are less likely to go into labor spontaneously [22].

This study had some limitations as it was retrospective, not controlled and dependent on the quality and availability of data present in the medical records. It also had a small study sample. The strength is a different statistic approach that finds the best model of predicting factors for labor duration.

CONCLUSIONS

The aim of this study was to compare the duration time of induced labor to spontaneous one. Pre-induction with dinoprostone insert and additional foley catheter, if indicated, does not make labor longer in comparison with spontaneous labor. Statistical model showed that only being primipara was a factor related to longer childbirth. There are also no significant concerns regarding the safety of the dinoprostone for neonates based on Apgar score.

Article Information and declarations

Conflict of interest

All authors declare no conflict of interest.

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