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Mode of delivery after labor induction with vaginal dinoprostone versus oral misoprostol for women with unfavorable cervix at term.

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ABSTRACT

Objective: to compare the delivery mode after labor induction with 10 mg vaginal dinoprostone insert *versus* oral misoprostol 50µg/4 hours for women with an unfavorable cervix.

Material and methods: This is a retrospective observational study comparing the before/after introduction of oral misoprostol for labor induction, conducted at the Saint-Étienne University Hospital on a cohort of 396 women with a Bishop score <6. One hundred and twelve women (28.3%) were treated with a 10 mg vaginal dinoprostone insert *versus* 284 (71.7%) with oral misoprostol 50µg/4 hours. The primary outcome was the cesarean section rate.

Results: Labor induction with vaginal dinoprostone was independently associated with an increased rate of cesarean sections compared to oral misoprostol (aOR=2.44; CI95% from 1.35 to 4.40; p=0.003). The use of vaginal dinoprostone increased the induction rate during more than 48 hours (18.8% *versus* 9.9%; p=0.02), and the occurrence of fetal heart rate changes (34.8% *versus* 21.1%; p=0.005). The maternofetal morbidity was similar.

Conclusion: Labor induction with vaginal dinoprostone was independently associated with an increased rate of cesarean sections compared to oral misoprostol in women with an unfavorable cervix.

INTRODUCTION

The induction of labor (IOL) is the initiation of regular and efficient uterine contractions in a pregnant woman who is not in spontaneous labor, but for whom a maternal or fetal indication requires imminent birth. The IOL is only considered if it provides more benefits than simple monitoring while awaiting spontaneous labor (1,2). IOL is a common obstetric intervention, with an estimated rate of 25,8% in France in 2021 (3,4).

The IOL success mainly depends on cervical ripening (5,6). The Bishop score is a standardized evaluation to assess the physical characteristics of the cervix by vaginal examination to define its maturity. A cervix is considered favorable if the Bishop score ≥ 6 . The definition of IOL failure corresponds commonly to the realization of a cesarean section for mechanical dystocia. For unfavorable cervix (Bishop < 6), mechanical methods such as supracervical balloon or pharmacological methods like prostaglandins can be used. Prostaglandins are hormones naturally produced during labor that relax the cervix and facilitate uterine contractions.

Dinoprostone is a prostaglandin E2 contained in a vaginal insert of 10mg inserte for up to 24 hours (7). Misoprostol is an oral prostaglandin E1 with a posology of 50 μg per 4 hours; the maximum daily dose is 200 μg (8). Prostaglandins are the most frequently used molecule for cervical ripening, with a national rate in 2021 of 48.7% and 17.2% , for dinoprostone and misoprolol respectively (9). Few studies have compared the efficacy and safety of vaginal dinoprostone versus oral misoprostol (10,11). The main objective of this study was to compare the delivery mode of women with unfavorable cervix with an IOL by vaginal dinoprostone *versus* oral misoprostol. The secondary objectives were to compare the maternal and fetal morbidity between these two methods of induction.

MATERIAL AND METHODS

Study design

This is a retrospective monocentric cohort study performed on a cohort of women admitted for IOL in the department of Obstetrics and Gynecology department of Saint-Étienne University Hospital, France. We registered all patients induced by vaginal dinoprostone insert from 11 July 2019 to 11 July 2020, and those induced by oral misoprostol from 12 July 2020 to 1 July 2021. Oral misoprostol was used from September 2019 in the department. We have chosen a period after the transition phase to improve this method for this group. Initially, oral misoprostol was little offered and used. Gradually, oral misoprostol was offered and chosen by women until it was almost exclusively used. The choice of the IOL method was left to the women.

Inclusion criteria were: IOL for a maternal or fetal medical indication, cephalic presentation of the fetus, and no cesarean section scar. The exclusion criteria were: multiple pregnancy, gestational age < 37 weeks, and Bishop score ≥ 6 .

The Bishop score was evaluated by the midwife; the IOL method was chosen by the obstetrician and the woman. If prostaglandin induction was considered, the absence of contraindications (previous uterine scar, spontaneous labor, combination with oxytocin, fetal heart rate (FHR) abnormalities, pulmonary, hepatic or renal diseases, or known hypersensitivity to prostaglandins) was checked.

According to the method chosen, the administration modalities were the insertion of a vaginal insert of dinoprostone 10mg in the posterior vaginal fornix remained for a maximum of 24 hours, or the oral administration of two misoprostol 25 μ g tablets to be repeated every 4 hours, up to a limit of eight tablets per day.

During cervical ripening, three to four cardiotocography per 24 hours were made in the absence of clinical signs and in the absence of FHR changes such as persistent decelerations,

tachycardia or decreased short-term variability defined by the CNGOF and FIGO 2015 classifications (12). The IOL was stopped in case of uterine hyperstimulation (i.e. more than 5 contractions per 10 minutes for at least 20 minutes or a contraction lasting 2 minutes or more), FHR changes, adverse effects of prostaglandins (nausea, emesis, hypotension, headache, etc.) or at the time of active labor. Active labor was defined by the occurrence of at least three regular and effective uterine contractions per 10 minutes, and concomitant cervical dilatation starting from 6 cm. In the absence of active labor after 24 hours, the cervix was reevaluated: if it was still unfavorable, the use of a second method for induction was considered (balloon catheters, vaginal gel, or second misoprostol procedure); if the cervix was favorable, oxytocin was administered or artificial rupture of the membranes was performed (13). The IOL failure was defined as the non-entry in the active phase of labor that required a cesarean section.

Data collection

Data were collected from the Easily (HOPSIS Society, FR) database used at the University Hospital of Saint-Étienne. Personal characteristics, obstetrical history, follow-up and synthesis of the pregnancy, partogram, delivery mode, and intervention notes if a cesarean section or instrumental birth support were recorded for each patient.

Outcomes

The primary outcome was the cesarean section rate. The secondary outcomes were (1) labor duration (intervention to active phase of labor i.e. cervical dilation ≥ 6 cm and to delivery); (2) labor complications such as uterine hyperstimulation and FHR changes; (3) maternal and fetal morbidity: postpartum hemorrhage and obstetric anal sphincter lesions for the mother, arterial pH and an APGAR score at 5 minutes of life for the child.

Statistical analysis

Statistical analysis was performed using XLSTAT (ADDINSOFT society, FR). Qualitative data were described by absolute and relative frequencies (expressed in %). Quantitative variables were described by mean and standard deviation. The qualitative variables were compared by the Chi-square test or by Fisher's exact test if the numbers were insufficient. The quantitative variables were compared by the Student's t-test or, in the case of a non-normally distributed variable, by the Wilcoxon-Mann-Whitney test. The normality of each variable was checked beforehand by a Shapiro-Wilk test.

We also estimated the relative risks (risk ratio) and their 95% confidence intervals for the association between the cesarean section and the method of induction. This association was then examined using multivariable logistic regression analysis to adjust for potential confounding by relevant maternal and fetal characteristics. Only those variables with a crude association of $P < 0.2$ were included. The interest variables were parity, maternal body mass index, using of a second method of induction, Bishop score, and birthweight. A p-value < 0.05 was considered statistically significant.

Ethics

The study received a favorable opinion from the Committee for Research Ethics in Obstetrics and Gynaecology (CEROG 2021-OBST-1002). Loyal and clear information was provided on the modalities and risks of induction, and oral consent was obtained from each parturient.

RESULTS

A total of 396 women were included in the study; of these 112 (28.3%) received vaginal dinoprostone and 284 (71.7%) received oral misoprostol (**Figure 1**).

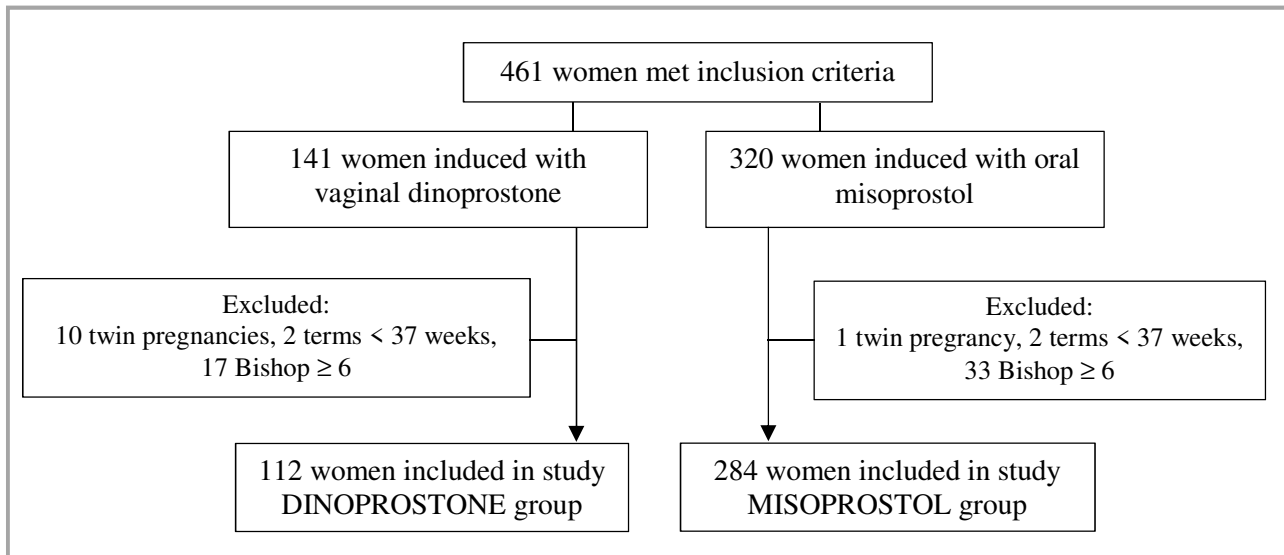


Figure 1. Flow chart

The characteristics of included women are shown in **Table 1**. They were similar in the two groups, except for parity and Bishop score. Women who received dinoprostone were more often nulliparous (62.5% *versus* 48.6%; $p=0.01$) and their BISHOP score was lower (2.9 *versus* 3.3; $p=0.02$), compared with women treated with misoprostol. The vaginal insert of dinoprostone was placed for an average of 7.11 hours, and was removed after 24 hours for 31.3% of women. Women induced with oral misoprostol received an average of 5.5 tablets: 116 (40.8%) patients had received eight tablets, while 61 (21.5%) took only two tablets. A second method of induction was required for 21.4% and 15.1% of the patients from the dinoprostone and the misoprostol group, respectively.

Table 1: Characteristics of included women

	Dinoprostone (n = 112)	Misoprostol (n = 284)	p value
Age, years (SD)	30.2 +/- 4.9	30.6 +/- 5.6	0.5
BMI, kg/m² (SD)	25.6 +/- 6.5	26.4 +/- 6.3	0.14
Nulliparous, n(%)	70 (62.5)	138 (48.6)	0.01
Gestational age, weeks (SD)	39.3 +/- 1.4	39.4 +/- 1.3	0.51
Pregnancy complications, n(%)	56 (50)	146 (51.4)	0.80
Indications for labor induction, n(%)			
- Post-dates	10 (8.9)	38 (13.4)	
- Rupture of membranes	28 (25)	67 (23.6)	0.63
- Fetal macrosomia +/- GD	41 (36.6)	105 (37)	
- Others	33 (29.5)	73 (25.7)	
Bishop score (SD)	2.9 +/- 1.5	3.3 +/- 1.5	0.02
Use of secondary methods, n(%)	24 (21.4)	43 (15.1)	0.13
Oxytocin stimulation, n(%)	59 (52.7)	133 (46.8)	0.29
Birthweight, kg (SD)	3.25 +/-0.44	3.31 +/- 0.44	0.10

Abbreviations: BMI, body mass index; GD, gestational diabetes.

The cesarean section rate was significantly more frequent in the dinoprostone group (33/112, 29.5%) compared to the misoprostol group (36/284, 12.7%) ($p < 0.001$) (**Table 2**). Indications for cesarean section were not similar: the occurrence of fetal heart rate abnormalities involving an alteration of the fetal health was the most frequent factor in both groups, but was more significant when dinoprostone was used ($p = 0.004$); failed IOL with vaginal dinoprostone and oral misoprostol were respectively 36.4% and 30.6% of the motives for cesarean section ($p = 0.009$). Instrumental vaginal delivery was less than 20% in both groups.

Table 2: Primary and secondary outcomes.

Induction	Dinoprostone (n = 112)	Misoprostol (n = 284)	p value
Cesarean section, n(%)	33 (29.5)	36 (12.7)	<0.0001
Cesarean section indication, n(%)			
- FHR changes	13 (39.4)	11 (30.6)	0.004
- Failure of induction	12 (36.4)	11 (30.6)	0.009
- Others	8 (24.2)	14 (38.8)	0.39
Instrumental vaginal delivery, n(%)	20 (17.8)	54 (19)	0.51
Labor duration, hours (SD)			
- Induction to active phase	17.9 +/- 11	16.7 +/- 10.1	0.446
- Induction to delivery	20.1 +/- 9.8	19.8 +/- 10.2	0.65
- Duration > 48h	21 (18.8)	28 (9.9)	0.02
Labour complications, n(%)			
- Uterine hyperstimulation	11 (9.8)	25 (8.8)	0.75
- FHR changes	39 (34.8)	60 (21.1)	0.005
Maternal complications, n(%)			
- Postpartum hemorrhage	24 (21.4)	39 (13.7)	0.06
- 3rd and 4th degree tear	2 (1.8)	1 (0.4)	0.14
Neonatal complications, n(%)			
- Umbilical artery pH < 7,1	1 (0.9)	8 (2.8)	0.23
- APGAR score < 7 at 5	0	6 (2.1)	0.12

The confounding demographic variables were integrated into the multivariate analysis (**Table 3**). This multivariate analysis showed that the IOL method, parity, and Bishop score were independently associated with the mode of delivery. The cesarean section rate was five times higher for nulliparous after induction compared to multiparous women. The other variables were not associated with the occurrence of a cesarean section. Compared with misoprostol (reference), and following multivariate analysis, dinoprostone was independently associated with a 2.44 increase in the risk of cesarean section (aOR=2.44; CI95% [1.35 ;4.40]; p=0.003).

Delivery occurred after an average of 20.1 hours of labor in the dinoprostone group, and 19.8 hours in the misoprostol group. However, the induction rate during more than 48 hours until birth was significantly higher in the dinoprostone group (18.8% versus 9.9%, $p = 0.02$). During labor, FHR changes were more frequent in the dinoprostone group (34.8%) compared to the misoprostol group (21.1%; $p = 0.005$). Uterine hyperstimulation and materno-fetal morbidity were similar between the two groups.

Table 3: Logistic regression adjusted odds ratio of cesarean section rates

	OR	95% CI	<i>p value</i>	aOR*	95% CI aOR	<i>p value</i> aOR
Method of IOL^(a)	2.88	[1.69 ;4.92]	<0.0001	2.44	[1.35 ;4.40]	0.003
Parity^(b)	0.22	[0.12 ;0.42]	<0.0001	0.21	[0.11 ;0.41]	<0.0001
BISHOP score	0.75	[0.63 ;0.9]	0.001	0.75	[0.62 ;0.92]	0.005
BMI	1.02	[0.98 ;1.06]	0.35	1.03	[0.98 ;1.07]	0.26
Use of secondary methods ^(c)	2.21	[1.2 ;4.07]	0.01	1.49	[0.73 ;3.02]	0.27
Birthweight	1.10	[0.61 ;2.0]	0.75	1.51	[0.78 ;2.92]	0.22

*Multivariate analysis adjusted for the method of induction, BMI, BISHOP score, use of a second method of induction and birthweight. The dependent variable was the cesarean section rate.; Abbreviations: IOL, induction of labor; OR, odds ratio; aOR, adjusted odds ratio; IC, confidence interval.

^(a) « dinoprostone » group versus « misoprostol » group used as reference

^(b) « multiparous » group versus « nulliparous » group used as reference

^(c) « use of secondary methods » group versus « single method » group used as reference

DISCUSSION

Misoprostol for IOL in women with unfavorable cervix was independently associated with a decreased risk for cesarean section compared to vaginal dinoprostone, without increasing maternofetal morbidity.

Recent epidemiological studies show that IOL involves one-quarter of women in France. This number has been increasing in the last few years, as is the cesarean section rate (21.4% in 2016 *versus* 20.3% in 2021)(4). Prostaglandins have proven their efficacy in developing the rate of vaginal delivery when compared with the use of amniotomy or oxytocin alone in women with an unfavorable cervix; but they are associated with increased rates of failure of induction and cesarean section in comparison with spontaneous labor (2). Until recently, dinoprostone was the most commonly used molecule to induce labor. In 2018 oral misoprostol became available for French medical induction. Contrary to dinoprostone, oral misoprostol is a thermally stable molecule and allows a non-invasive administration (8). However, in case of uterine hyperstimulation or FHR changes, its diffusion cannot be controlled whereas the dinoprostone insert can be easily removed.

Assessment of cervical maturity appears to be the most predictive factor of the probability of vaginal delivery after labor induction. The study by Vrouenraets *et al.* (6) found that a BISHOP ≤ 5 was a consistent risk factor for cesarean delivery (aOR=2.32; 95% CI 1.53-3.41), but that other factors should be considered, such as parity, BMI, and high birthweight (5,14). We performed a logistic regression to adjust for these potentially confounding variables.

On average, 5.5 tablets of misoprostol were needed to initiate active labor. Eriksson *et al.* (15) compared oral versus vaginal misoprostol inductions and found an average dose of 7.2 tablets but with a different administration protocol (one 25 μ g tablet every two hours).

In 2014, a Cochrane systematic review (16) evaluated oral misoprostol in labor induction. Eleven studies, including 3592 women, compared the rate of cesarean section as the primary outcome with oral misoprostol compared to vaginal dinoprostone: it was significantly higher in the dinoprostone group (26% versus 21%, RR 0.88, 95% CI 0.78 to 0.99). These results were supported by another Cochrane systematic review in 2021, especially with low doses of oral misoprostol. The use of oral misoprostol probably resulted in fewer cesarean sections compared with the other method (RR 0.84, 95% CI 0.78. to 0.90) (17). Our study had similar findings: the cesarean section frequency was significantly increased using dinoprostone, but the proportion of induction lasting more than 48 hours until birth was prevalent. In our study, the groups were similar on uterine hyperstimulation but different in FHR changes, which is precisely the main indication for cesarean section. This is in concordance with the data of the Cochrane review, even if the authors chose not to separate these two outcomes, uterine hyperstimulation with FHR changes, and uterine hyperstimulation without FHR changes. However, this Cochrane Review included 13 trials conducted in different healthcare systems in several countries, with a large choice of dosages. We also found no subgroup analysis for unfavorable cervix.

Dodd *et al.* (18) also compared the use of oral misoprostol 20µg every two hours, and dinoprostone 1 or 2 mg in a vaginal gel. No difference was observed in the cesarean section rate or in the duration of labor. Similarly, three recent studies (10,11,19) evaluated materno-fetal outcomes after IOL with oral misoprostol versus vaginal dinoprostone. The rates of natural delivery were similar between the groups, which is not in line with our results or those of other studies. Rouzi *et al.* concluded that the rate of vaginal deliveries in the first twenty-four hours after induction was superior with misoprostol for nulliparous compared to dinoprostone. For them the materno-fetal morbidity was significantly higher with dinoprostone (20,21).

The IOL duration is an important point to consider in the choice of method because it generates other complications such as prolonged rupture of membranes, infections, postpartum hemorrhage, or failed induction. The rate of instrumental vaginal delivery was quite similar between the two groups, which is consistent with the literature.

Regarding complications, the use of either method of induction was not associated with a higher frequency of uterine hyperstimulation. Several studies, such as that from Maggi *et al.* (22), show more uterine hyperstimulation with the use of vaginal misoprostol compared with the dinoprostone insert. FHR changes were significantly more frequent in the dinoprostone group, which was not objectified in the Cochrane meta-analysis (17). Post-partum hemorrhage was 1.5 times more frequent when the IOL was performed with dinoprostone versus misoprostol. Neonatal outcomes measured by arterial pH and APGAR score at 5 minutes were similar between the two groups, as in the literature.

This study was subject to methodological limitations as it was a retrospective and monocentric study, with two unbalanced groups. It was performed during a specific period corresponding to our practice changes in the department. The therapeutic used was at the obstetrician's and women's discretion. We collected data from the records retrospectively; there was no strict protocol for both methods because the induction was not prospectively studied. Indeed, this may be considered a selection bias.

The induction of labor is standardized, and the strength of our study is that we compared two different molecules, with two different methods of administration, but on a large and homogeneous cohort with defined management. Our data were based on the daily practice of a level III maternity hospital with the same protocols currently in place. Moreover, the use of computerized tools allowed better completeness of the data collection and limited the confounding bias inherent to retrospective analysis. Many studies have been done to compare

dinoprostone and misoprostol, but with a vaginal administration for these two prostaglandins; few studies comparing them with different routes of administration have been performed.

CONCLUSION

The use of oral misoprostol for IOL in women with unfavorable cervix was independently associated with a decreased risk of cesarean section compared with vaginal dinoprostone. Moreover, women treated with oral misoprostol presented less induction during more than 48 hours, and fewer FHR changes during labor compared with vaginal dinoprostone. A randomized trial is needed to confirm these results.

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