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Efficacy and safety of dinoprostone versus Cook's balloon for cervical ripening: a retrospective study in a tertiary hospital in Portugal

Eficácia e segurança da dinoprostona *versus* balão de Cook para a maturação cervical: estudo retrospetivo de um hospital terciário em Portugal

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Abstract

Overview and Aims: Cervical ripening (CR) aims to prepare the cervix for labor induction whenever the cervix is unfavorable, in order to increase the likelihood of vaginal delivery (VD). This study included full-term pregnant women with Bishop score < 7, who received either Dinoprostone vaginal insert 10mg or cervical double balloon catheter (CDBC) for CR. The primary outcome of this study was the rate of VD. The secondary outcomes were the rate of cesarean due to non-reassuring fetal status (NRFS) and the maternal and neonatal outcomes.
Study Design: Retrospective cohort study.
Population: Inclusion criteria were singleton pregnancy with cephalic presentation at term, a Bishop score < 7, and intact membranes upon hospital admission. Among the 646 women enrolled, 366 received dinoprostone and 280 underwent CR with CDBC.
Methods: Data collected through computerized clinical processes between October 2021 and April 2024 were evaluated.
Results: VD was more common in the DP group and was associated with a lower time from the start of CR to labor. There were no statistically differences between the rate of cesarean due to NRFS observed between the groups but chorioamnionitis was more frequent in the CDBC group while tachysystole rate was lower. Neonatal outcomes, such as NICU admission rate and Apgar at 5th minute <7 rate were similar. There were no cases of uterine rupture or neonatal deaths described. In the subgroup of pregnancies complicated by fetal growth restriction (FGR), both methods showed similar vaginal rates, maternal and neonatal outcomes.
Conclusions: Dinoprostone appears to be more effective than CDBC for CR in full-term pregnancies, leading to higher rates of VD within shorter intervals. While tachysystole occurred more frequently with dinoprostone, this did not translate into higher rates of adverse maternal or neonatal outcomes. CDBC demonstrated particular utility in pregnancies complicated by FGR, where it achieved outcomes comparable to dinoprostone with reassuring safety profiles.

Keywords: Cervical ripening; Labor induction; Dinoprostone; Double balloon catheter.

Resumo

Introdução/objetivos: A indução do trabalho de parto requer, frequentemente, maturação cervical (MC) prévia, quando as características cervicais são inicialmente desfavoráveis, de forma a aumentar a probabilidade de parto vaginal (PV). Este estudo incluiu grávidas de termo com índice de Bishop < 7, submetidas a MC com dinoprostona 10 mg ou balão duplo

cervical (BDC). O principal objetivo do estudo foi avaliar a taxa de PV entre os grupos. Os objetivos secundários foram a taxa de cesarianas por estado fetal não tranquilizador (EFNT) e os desfechos maternos e neonatais.
Desenho do estudo: Estudo de coorte retrospetivo.
População: Foram incluídas grávidas com gestação única, feto em apresentação cefálica, de termo, índice de Bishop <7 e membranas íntegras à admissão. Das 646 mulheres incluídas no estudo, 366 utilizaram dinoprostona e 280 DBC.
Materiais e Métodos: Foram avaliados dados recolhidos através de processos clínicos informatizados entre outubro de 2021 e abril de 2024.
Resultados: O PV foi mais comum no grupo da dinoprostona e esteve associado a um menor tempo entre o início da MC e o parto. Não se verificaram diferenças nas taxa de cesarianas por EFNT entre os grupos. A corioamnionite ocorreu com maior frequência no grupo DBC, enquanto a taquissistolia foi menos frequente. No entanto, não houve diferenças nos desfechos neonatais, incluindo a taxa de admissão na unidade de cuidados intensivos neonatais e taxa de Apgar ao 5.º minuto <7 entre os dois grupos. Não se registaram casos de rotura uterina ou mortes neonatais. No subgrupo de gravidezes complicadas por restrição de crescimento fetal (RCF), ambos demonstraram taxas de PV e desfechos maternos e neonatais semelhantes.
Conclusões: A dinoprostona demonstrou ser um método de MC mais eficaz do que o BDC nas gravidezes de termo, uma vez que se associou a maior taxa de PV e menor tempo de indução. Embora a prevalência da taquissistolia tenha sido superior no grupo da dinoprostona, tal não se traduziu em diferenças significativas nas taxas de cesariana por EFNT entre os grupos ou a desfechos maternos/ neonatais adversos. O DBC demonstrou particular utilidade em gravidezes complicadas por RCF, onde obteve resultados comparáveis aos da dinoprostona, associado a um perfil de segurança favorável.

Palavras-chave: Maturação cervical; Indução do trabalho de parto; Dinoprostona; Balão de Cook.

INTRODUCTION

Induction of labor (IOL) is a common obstetric intervention employed when the benefits of delivering the fetus outweigh the risks associated with continuing the pregnancy[1,2], with its prevalence reaching up to 28% of term pregnancies in developed countries[3].

When IOL is indicated but the cervix is deemed unfavorable, cervical ripening (CR) is considered in order to increase the likelihood of achieving a vaginal delivery (VD) and reduce the need for surgical intervention[4,5].

Over recent decades, both pharmacological and mechanical methods have been developed to enhance CR, with the ultimate aim of reducing induction-to-delivery intervals, improving VD rates, and minimizing maternal-fetal complications.

Among pharmacological methods, dinoprostone, a synthetic prostaglandin E2 analogue, has been widely used due to its dual effect of promoting cervical softening and stimulating uterine contractions.

In contrast, mechanical approaches such as the cervical double-balloon catheter (CDBC), composed of a cervicovaginal balloon and a uterine balloon, act by exerting direct pressure on both the internal and the external os of the cervix, stimulating endogenous prostaglandin release.

Although earlier studies comparing these two methods have come to varying conclusions regarding the superiority of one over the other in terms of safety and ability to progress the patient to VD[6-9], more recent evidence indicates no significant differences between the approaches in either VD rates or cesarean section incidence[10-12]. Nevertheless, there appear to be circumstances in which mechanical methods may be preferable, as they have been associated with lower risk of uterine tachysystole, cesarean delivery or operative delivery for non-reassuring fetal status[13,14]. This might be particular important in pregnancies complicated by fetal growth restriction (FGR)[14,15]. As for neonatal outcomes, however, current evidence does not support a definitive conclusion regarding the superiority of either method[10,16].

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The primary outcome of this study was to evaluate the rate of vaginal delivery between the groups undergoing CR. The secondary outcomes included the rate of cesarean deliveries due to non-reassuring fetal status (NRFS); the maternal outcomes including chorioamnionitis rate, tachysystole and uterine rupture rate; and neonatal outcomes such as rate of Apgar score at 5th minute <7, mean 5-minute Apgar scores, Neonatal Intensive Care Unit (NICU) admission and neonatal deaths rate.

METHODS

Design

This retrospective study was carried out in the Department of Obstetrics of a tertiary hospital in Portugal. The study was approved by the local institutional Clinical Research and Ethics Committee (number 51/2024).

Patients

Pregnant women requiring labor induction from October 2021 to April 2024 were reviewed. Eligible participants to this study were women with a singleton term pregnancy (gestational age ≥ 37 weeks), vertex presentation, a Bishop index (BI) < 7, and intact membranes upon admission.

From an initial cohort of 1957 women admitted to our unit for labor induction, 1311 were excluded (Figure 1), resulting in a final sample of 646 women included in the analysis: 366 in the dinoprostone group and 280 in the CDBC group.

Two subgroup analyses were conducted: the first included pregnant women whose pregnancies were complicated by fetal growth restriction (FGR) (n = 78), defined by the Delphi consensus criteria[17], and the second included those induced due to a pregestational body mass index (BMI) > 35 kg/m² (n = 148).

Interventions

Before administering the cervical ripening agent, study subjects provided their informed consent.

CR was indicated for patients with a Bishop < 7 and was performed according to institutional protocol.

The CDBC balloons were each inflated with 80 mL of sterile saline and left in situ for 12 hours. Fetal cardiotocography (CTG) and ultrasonography to confirm cephalic presentation were performed before and after insertion. Following the 12-hour period, the balloons were deflated, and amniotomy with oxytocin infusion was commenced if regular uterine contractions were absent. Cesarean delivery (CD) was considered in case of failure of induction, defined as the absence of progression to active phase of labor despite adequate uterine contractions (2-4 contractions/10 minutes) for a period of 15 hour and rupture of membranes[18].

For pharmacological CR, a 10 mg dinoprostone vaginal insert was placed in the posterior vaginal fornix and maintained for up to 24 hours. CTG was performed 1, 3 and 6 hours after dinoprostone vaginal insert placement or sooner if maternal symptoms warranted. The insert was removed in the event of tachysystole (defined as ≥ 5 contractions in 10 minutes) or non-reassuring fetal status (NRFS), according to FIGO consensus guidelines on intrapartum fetal monitoring[19]. Cervical assessment was performed after 12 hours; if the Bishop index (BI) was ≥ 7, amniotomy and oxytocin were initiated. If the BI remained < 7, the insert was maintained until 24 hours. Should the cervix remain unfavorable at 24 hours, a second 10 mg dinoprostone insert was placed for an additional 24 hours. If the BI was still < 7 after the second application, CD was performed.

Outcomes

The primary outcome of this study was to evaluate the rate of VD between the groups undergoing CR. The secondary outcomes evaluated were the rate of CD for NRFS, maternal outcomes, such as uterine tachysystole (>5 contractions in 10 minutes for at least 30 minutes); clinical chorioamnionitis, defined as the presence of fever and at least 2 of the following criteria: maternal tachycardia (>100 beats/min), maternal leukocytosis (white blood cell count >15,000 cells/mm^3), fetal tachycardia (>160 beats/min), or purulent cervical discharge and uterine rupture rate. Neonatal outcomes, including NICU admission, mean 5-minute Apgar scores, rate of Apgar score 5th minute <7 and neonatal deaths rate were also accessed.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 25.0.

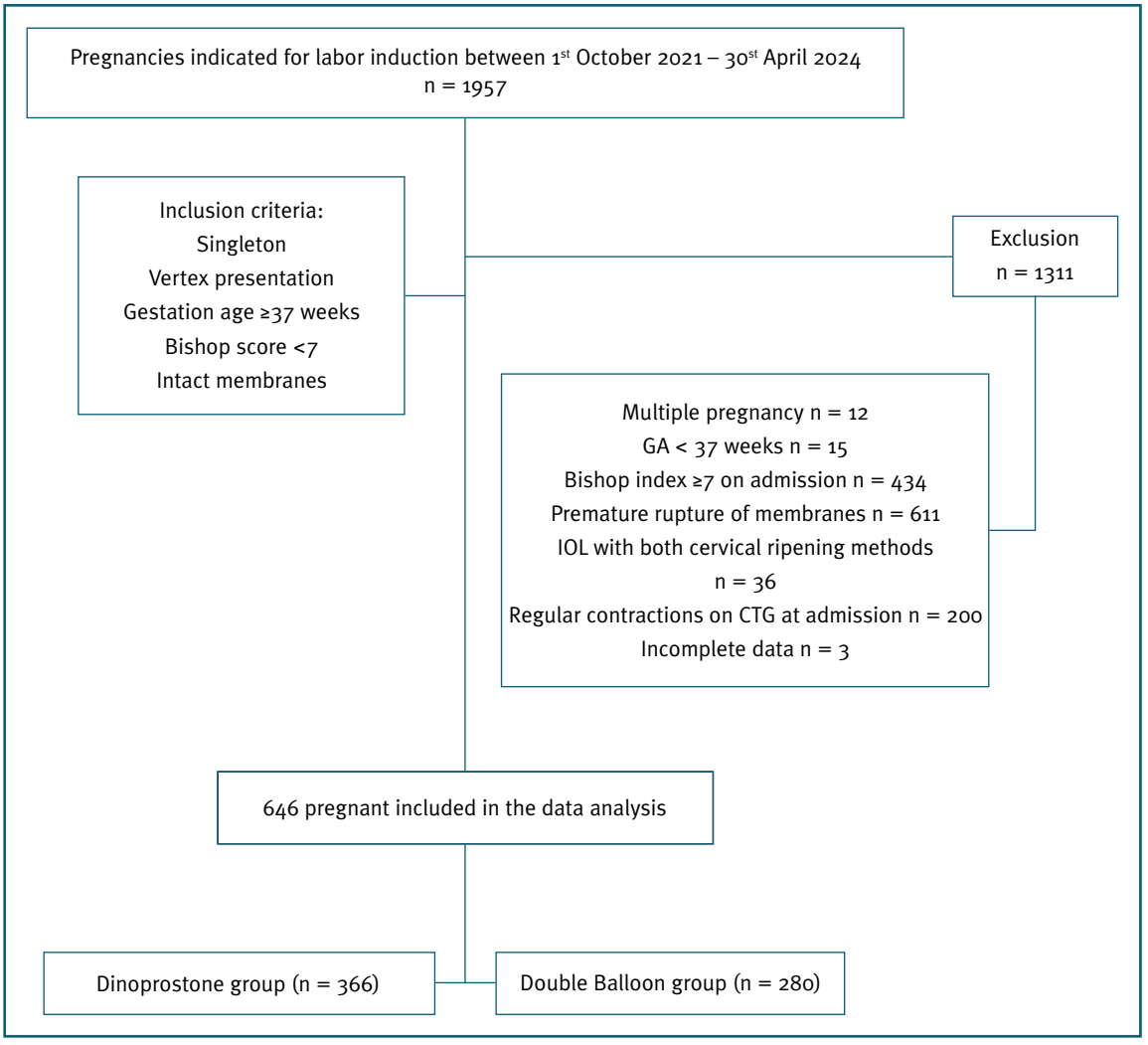

FIGURE 1. Patient selection flow chart.
CTG – cardiotocography; GA – gestacional age; IOL – induction of labor.

Categorical variables were presented as absolute and relative frequencies, and were analyzed using the Chi-square test or Fisher's exact test, as appropriate. Continuous variables were described using the mean and standard deviation (SD) when normally distributed, or by the median, minimum, and maximum values when they were not. To compare groups, the Student's t-test was used for variables with a normal distribution, and the Mann–Whitney U test for non-normally distributed variables.

To identify variables independently and significantly associated with mode of delivery, a multivariate logistic regression analysis was performed. Variables included in the model were those with a statistically significant association in the bivariate analysis and/or those previously described in the literature.

A p-value < 0.05 was considered statistically significant for all analyses.

RESULTS

This retrospective analysis included a total of 646 pregnant women who underwent CR, of whom 366 received dinoprostone and 280 CDBC. As presented in Table I, there were no significant differences in baseline

TABLE I. DISTRIBUTION OF CLINICAL-OBSTETRIC CHARACTERISTICS.

	Overall sample (N=646)	Dinoprostone group (N= 366)	Cervical ripening Balloon group (N=280)	p value
Age, mean (±SD)	31.4 (6.1)	31.7 (6.3)	(31.1) (5.8)	0.262
Age, n (%)				
<30 years old	244 (37.8)	132 (36.1)	112 (40.0)	
30-39 years old	341 (52.8)	194 (53.0)	147 (52.5)	0.268
≥40 years old	61 (9.4)	40 (10.9)	21 (7.5)	
Mean BMI (±SD)	31.1 (6.1)	30.9 (5.5)	31.3 (6.7)	0.369
BMI, n (%)				
<18.5	1 (0.2)	1 (0.3)	0 (0.0)	
18.5-24.9	76 (11.7)	43 (11.7)	33 (11.8)	
25-29.9	236 (36.5)	126 (34.5)	110 (39.3)	0.154
30-39.9	277 (42.9)	170 (46.4)	107 (38.2)	
≥ 40	56 (8.7)	26 (7.1)	30 (10.7)	
Parity status, n (%)				
Nulliparous women	391 (60.5)	212 (57.9)	179 (63.9)	
Primiparous women	202 (31.3)	118 (32.2)	84 (30.0)	0.139
Multiparous women	53 (8.2)	36 (9.9)	17 (6.1)	
Previous cesarean, n (%)	101 (15.6)	47 (12.8)	54 (19.3)	0.025
Mean gestation age at induction, weeks (SD)	40.0 (1.3)	40.1 (1.2)	39.8 (1.4)	0.003
Indication for induction of labor, n (%)				
Gestation age ≥41 weeks	341 (52.4)	206 (56.3)	135 (48.3)	0.094
Pregestational BMI ≥ 35	51 (7.9)	28 (7.6)	23 (8.2)	–
Hypertensive diseases	57 (9.1)	29 (7.9)	28 (10.1)	0.792
DM type 1/ Gestational diabetes with poor metabolic control	28 (4.3)	15 (4.1)	13 (4.6)	0.073
Intrahepatic cholestasis of pregnancy	9 (1.4)	6 (1.6)	3 (1.1)	0.736
Small for gestational age	12 (1.9)	8 (2.2)	4 (1.4)	0.739
Fetal growth restriction	78 (12.1)	30 (8.2)	48 (17.1)	0.480
Other	70 (10.9)	44 (12.1)	26 (9.2)	0.075
Analgesia during labor, n (%)	562 (87.1)	307 (83.8)	256 (91.4)	0.004
SGB status, n (%)				
Positive	37 (5.7)	17 (4.6)	20 (7.1)	0.176
Negative	609 (94.3)	349 (95.4)	260 (92.9)	

N – number of patients included in the study; BMI – Body mass index; DM – diabetes mellitus; SD – standart deviation; SGB – streptococcus group B status.

maternal characteristics between the two groups, including maternal age, BMI, and parity (all $p > 0.05$). However, a significantly higher proportion of women with a previous cesarean section underwent cervical ripening with the CDBC compared to the dinoprostone group (19.3% vs. 12.8%; $p = 0.025$). The mean gestational age at induction was slightly lower among women in the CDBC group (39.8 ± 1.4 weeks vs. 40.1 ± 1.2 weeks; $p = 0.003$), and the use of intrapartum analgesia was more frequent in this group (91.4% vs. 83.8%, $p = 0.004$).

Regarding perinatal outcomes (Table II), VD occurred significantly more often in the dinoprostone group than in the CDBC group (55.5% vs. 44.3%; $p = 0.017$). While the rate of CD was significantly higher in the CDBC group than the dinoprostone group (55.7% vs.

TABLE II. LABOR AND DELIVERY CHARACTERISTICS AND NEONATAL OUTCOMES.

	Overall sample (N = 646)	Dinoprostone (N = 366)	Cervical ripening balloon (N = 280)	p value
Mode of delivery, n (%)				
Vaginal delivery, total	327 (50.6)	203 (55.5)	124 (44.3)	
Instrumental delivery	144 (22.4)	92 (25.2)	53 (18.9)	0.017
Cesarean delivery	319 (49.4)	163 (44.5)	156 (55.7)	
Cesarean indication, n (%)				
NRFS	100 (31.2)	57 (34.8)	43 (27.4)	0.154
Failure in IOL	93 (29.2)	48 (29.5)	45 (28.7)	0.905
Failure in progress	126 (39.6)	58 (35.7)	68 (43.9)	0.154
Cesarean delivery by urgency, n (%)				
Emergent cesarean	21 (6.5)	17 (10.4)	4 (2.5)	0.004
Urgent cesarean	298 (93.5)	146 (89.6)	152 (97.5)	
Instrumental delivery indication n (%)				
NRFS	21 (14.4)	18 (19.4)	3 (5.7)	0.074
Failure to progress	112 (78.1)	67 (73.1)	46 (86.8)	
Poor maternal collaboration	11 (7.5)	7 (7.5)	4 (7.5)	
Time interval from cervical ripening to delivery,				
Mean, hours: minutes	28:34	26:21	31:26	<0.0001
n (%)				
≤12 hours	99 (15.3)	92 (25.1)	7 (2.5)	
>12 and ≤24 hours	161 (24.9)	88 (24.0)	73 (26.1)	<0.0001
>24 and ≤48 hours	309 (47.8)	138 (37.7)	171 (61.1)	
>48 hours	77 (11.9)	48 (13.1)	29 (10.3)	
Time interval from rupture of membranes time to delivery, Mean, hours: minutes	11:06	8:52	13:53	<0.0001
Chorioamnionitis, n (%)	68 (10.5)	28 (7.7)	40 (14.3)	0.006
Uterine tachysystole, n (%)	49 (7.6)	46 (12.6)	3 (1.1)	<0.0001
Uterine rupture, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
Mean neonatal birthweight in grams (SD)	3308 (509)	3358 (496)	3242 (519)	0.004
Mean 5-min Apgar	10	10	10	0.504
Apgar score 5th min <7, n (%)	2 (0.3)	1 (0.3)	1 (0.4)	–
NICU admission, n (%)	21 (3.3)	11 (3.0)	10 (3.6)	0.688
Neonatal deaths, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–

IOL – induction of labor; NICU – Neonatal intensive care unit; NRFS – non-reassuring fetal status; SD – standart deviation.

44.5%; p = 0.017), the indications for cesarean were not significantly different between the two groups, including the rate of cesarean due to NRFS (34.8% vs. 27.4%, p = 0,154).

The median time from the initiation of CR to delivery was significantly longer in the CDBC group (31 hours 26 minutes vs. 26 hours 21 minutes, p < 0.0001). Similarly, the mean duration from rupture of membranes to delivery was longer in the CDBC group compared to the dinoprostone group (13 hours 53 minutes vs. 8 hours 52 minutes, p < 0.0001). Nonetheless, in both groups, the majority of women delivered within 48 hours of induction (86.9% in the dinoprostone group vs. 89.6% in the CDBC group). From the 280 women who underwent CR with dinoprostone, 96 required a second DP vaginal insert.

TABLE III. DISTRIBUTION OF CLINICAL-OBSTETRIC CHARACTERISTICS – FGR SUBGROUP.

	Dinoprostone (N = 30)	Cervical ripening Balloon (N = 48)	p value
Age (years) (mean ± SD)	30.4±6.7	31.8±5.6	0.309
Age, n (%)			
<30	15 (50.0)	16 (33.3)	
30-39	12 (40.0)	28 (58.3)	–
≥40	3 (10.0)	4 (8.3)	
BMI (mean ± SD)	28.0±4.9	30.2±7.3	0.153
BMI, n (%)			
<18.5	0 (0)	0 (0)	
18.5-24.9	10 (33.3)	9 (18.7)	
25-29.9	11 (36.7)	21 (43.8)	–
30-39.9	8 (26.7)	12 (25.0)	
≥ 40	1 (3.3)	6 (12.5)	
Parity, n (%)			
Nulliparas	18 (60.0)	30 (62.5)	
Primiparas	8 (26.7)	14 (29.2)	–
Multiparas	4 (13.3)	4 (8.3)	
Mean gestation age at induction, weeks (SD)	38.3±1.4	38.4±1.6	0.788
Previous cesarean, n (%)	5 (16.7)	10 (20.8)	0.650

BMI – body mass index, SD – standard deviation.

The incidence of chorioamnionitis was significantly higher in the CDBC group (14.3% vs. 7.7%; p = 0.006), whereas the occurrence of uterine tachysystole was markedly higher among women receiving dinoprostone (12.6% vs. 1.1%; p < 0.0001). No case of uterine rupture was observed in any of the groups. Neonatal outcomes, including mean 5-minute Apgar scores, rate of Apgar score 5th minute <7 and NICU admission rates, did not differ between groups. However, mean neonatal birthweight was significantly greater in the dinoprostone group (3358 ± 496 g vs. 3242 ± 519 g; p = 0.004). Lastly, there were no cases of neonatal deaths described.

Two predefined subgroup analyses were also performed. The first included 78 cases complicated by FGR (Tables III and IV) submitted to CR. Within this subgroup, the rate of vaginal delivery were similar between the two CR methods (53,4% vs. 50.0%, p = 0.546). Regarding maternal outcomes, the only statistically significant difference observed was the rate of uterine tachysystole, which was higher in the dinoprostone group (13.3% vs. 0%, p = 0.019). There were no significant differences between groups in the mean induction-to-delivery interval or neonatal outcomes, including the mean Apgar score, Apgar at 5th min <7 rate, NICU admission or neonatal deaths.

The second subgroup comprised 148 women induced due to a pregestational BMI > 35 kg/m² (Table V). Baseline maternal characteristics did not differ significantly between the dinoprostone (n=76) and CDBC (n=72) groups. There were no statistically significant differences in vaginal delivery rate (50% vs. 41.7%, p = 0.529) or in cesarean delivery rates due to NRFS (25.6% vs. 11.9%, p = 0.112). Regarding maternal outcomes, the only deserving mention is uterine tachysystole, which occurred in 18.4% of cases managed with dinoprostone but was not observed in the CDBC group. The neonatal outcomes did not differ significantly between groups.

Lastly, the multivariate analysis performed found that women with history of previous CD were 81.4% less likely to have a VD compared to women without prior CD (odds ratio [OR] = 0.186; CI 95% (0.106-0.328), p < 0.0001). Multiparous women were found to be six times more likely to deliver vaginally than nulliparous women (OR = 6.029; CI 95% (2.843-12.784),

TABLE IV. LABOR AND DELIVERY CHARACTERISTICS AND NEONATAL OUTCOMES – FGR SUBGROUP.

	Dinoprostone (N = 30) n (%)	Cervical ripening balloon (N = 48) n (%)	p value
Mode of delivery, n (%)			
Vaginal delivery (total)	16 (53.4)	24 (50.0)	
Instrumental delivery	8 (26.7)	8 (16.7)	0.546
Cesarean delivery	14 (46.7)	24 (50.0)	
Indication for cesarean section, n (%)			
NRFS	4 (28.6)	8 (33.3)	0.637
Failure in IOL	6 (42.8)	7 (29.2)	0.126
Failure in progress	4 (28.6)	9 (37.5)	0.547
Cesarean delivery by urgency, n (%)			
Emergent cesarean	2 (14.3)	2 (8.0)	0.609
Urgent cesarean	12 (85.7)	22 (92.0)	
Operative delivery indication, n (%)			
NRFS	3 (37.5)	2 (25.0)	
Failure to progress	4 (59.3)	5 (62.5)	0.569
Poor maternal collaboration	1 (3.2)	1 (12.5)	
Time interval from cervical ripening to delivery,			
Mean, hours: minutes	29:46	31:49	0.585
n (%)			
≤12 hours	7 (23.3)	2 (4.2)	
>12 and ≤24 hours	7 (23.3)	10 (20.8)	0.037
>24 and ≤48 hour	11 (36.7)	30 (62.5)	
>48 hours	5 (16.7)	6 (12.5)	
Time interval from rupture of membranes to delivery,			
Mean, hours: minutes	8:19	11:23	0.123
Chorioamnionitis, n (%)	2 (6.7)	8 (16.7)	0.301
Uterine tachysystole, n (%)	4 (13.3)	0 (0)	0.019
Uterine rupture, n (%)	0 (0.0)	0 (.0)	–
Mean neonatal birthweight in grams (SD)	2401.3±269.1	2401.9±268.6	0.992
Mean 5-min Apgar	10	10	0.725
5-min Apgar score <7, n (%)	0 (0.0)	0 (0.0)	–
NICU admission, n (%)	3 (10.0)	4 (8.3)	1.000
Neonatal deaths, n (%)	0 (0.0)	0 (0.0)	–

IOL – induction of labor; NICU – Neonatal intensive care unit; NRFS – non-reassuring fetal status; SD – standart deviation.

$p < 0.0001$). Moreover, for every additional hour of labor induction, the likelihood of VD decreased by 2.6% (OR = 0.974, CI 95% (0.962-0.985), $p < 0.001$).

DISCUSSION

The dinoprostone vaginal insert and the CDBC are two widely used methods for CR in clinical practice. Our findings suggest that in term pregnancies, dinoprostone use was associated with a higher rate of VD within a shorter induction-to-delivery interval. However, the mechanical method demonstrated a more favorable safety profile, with significantly lower rates of tachysystole. Importantly, this increased uterine activity in the dinoprostone group did not translate into worse maternal or neonatal outcomes, nor into higher rates of cesarean delivery for non-reassuring fetal status.

TABLE V. LABOR AND DELIVERY CHARACTERISTICS AND NEONATAL OUTCOMES – PREGESTATIONAL BMI >35 SUBGROUP.

	Dinoprostone (N = 76) n (%)	Cervical ripening balloon (N = 72) n (%)	p value
Mode of delivery, n (%)			
Vaginal delivery (total)	38 (50.0)	30 (41.7)	
Instrumental delivery	13 (17.1)	12 (16.7)	0.529
Cesarean delivery	38 (50.0)	42 (58.3)	
Indication for cesarean section, n (%)			
NRFS	10 (26.3)	5 (11.9)	0.112
Failure in IOL	14 (36.8)	17 (40.5)	0.916
Failure in progress	14 (36.8)	20 (47.6)	0.123
Cesarean delivery by urgency, n (%)			
Emergent cesarean	2 (5.1)	1 (2.3)	0.602
Urgent cesarean	36 (94.9)	41 (97.7)	
Operative delivery indication, n (%)			
NRFS	4 (28.6)	1 (8.3)	
Failure to progress	8 (64.3)	10 (83.3)	–
Poor maternal collaboration	1 (7.1)	1 (8.3)	
Time interval from cervical ripening to delivery,			
Mean, hours: minutes	29:48	34:04	0.085
n (%)			
≤12 hours	15 (19.7)	1 (1.4)	
>12 and ≤24 hours	12 (15.8)	10 (13.9)	0.003
>24 and ≤48 hours	37 (48.7)	50 (69.4)	
>48 hours	12 (15.8)	11 (15.3)	
Time interval from rupture of membranes to delivery,			
Mean, hours: minutes	9:59	16:46	<0.0001
Chorioamnionitis, n (%)	9 (11.8)	12 (16.7)	0.401
Uterine tachysystole, n (%)	14 (18.4)	0 (0.0)	<0.0001
Uterine rupture, n (%)	0 (0.0)	0 (0.0)	–
Mean neonatal birthweight in grams (SD)	3513.0±477.8	3298.3±490.1	0.008
Mean 5-min Apgar	10	10	–
5-min Apgar score <7, n (%)	0 (0)	0 (0)	–
NICU admission, n (%)	0 (0)	1 (1.4)	0.486
Neonatal deaths, n (%)	0 (0.0)	0 (0.0)	–

IOL – induction of labor; NICU – Neonatal intensive care unit; NRFS – non-reassuring fetal status; SD – standard deviation.

In subgroups of pregnancies complicated by FGR or those with a pregestational BMI greater than 35, the effectiveness of CR was comparable between the two methods, with similar rates of VD and comparable time intervals from CR to delivery. In these populations, both approaches appeared to be safe, as no severe maternal or adverse neonatal outcomes were reported.

Several authors have published about this topic in the last decades, showing its relevance in modern Obstetrics. A metanalysis comparing this two methods, found no significant difference in VD and cesarean rates between dinoprostone and CDBC, whereas Suffecool et al. reported that more women delivered vaginally with double balloon catheter[10,20]. Overall, our findings were consistent with those reported by Yan *et. al*[16], as women in dinoprostone group had higher rates of VD (55% vs. 44.3%, p = 0.017) and lower rate of chorioamnionitis (7.7% vs. 14.3%, p = 0.006). Our

TABLE VI. VARIABLES INDEPENDENTLY RELATED TO VAGINAL DELIVERY.

Variables	B	S.E.	Wald	df	OR (95% CI)	p value
Previous cesarean	-1.679	0.288	33.925	1	0.186 (0.106 – 0.328)	<0.0001
Nulipara			36.974	2		<0.0001
Primipara	1.187	0.237	25.184	1	3.278 (2.062 – 5.212)	<0.0001
Multipara	1.797	0.384	21.945	1	6.029 (2.843 – 12.784)	<0.0001
Time interval from cervical ripening to delivery	-0.027	0.006	19.828	1	0.974 (0.962 – 0.985)	<0.0001

B – Beta coefficient; S.E. – Standard error; df – Degrees of freedom; CI – Confidence interval; Statistically significant at p<0.05.

institutional protocol includes amniotomy following balloon removal and, as expected, women in the CDBC group had a prolonged interval between membrane rupture and delivery. This extended duration may contribute to the increased incidence of chorioamnionitis.

Despite comparable baseline demographic characteristics between groups, it is worth mentioning that the CDBC cohort included a significantly higher proportion of women with a history of CD and a lower mean gestational age at induction – both factors known to adversely affect the likelihood of VD and thus might have a role dictating the mode of delivery[21].

The safety of CR methods is of paramount importance, as it ensures that induction achieves its goal without exposing mother or child to unnecessary harm. Dinoprostone, as a prostaglandin analogue, stimulates uterine contraction and might be associated with higher incidence of uterine tachysystole and subsequent fetal heart rate abnormalities, which may require urgent intervention, including cesarean delivery. CDBC, in the other hand, offers a mechanical alternative with a very low risk of uterine hyperstimulation. The group of Di Mascio et al.[14] reported a tachysystole incidence of 19.2% vs. 5.2%, p = 0.001 associated to dinoprostone. Our findings where consistent with the literature, with higher incidence of tachysystole rate observed in the dinoprostone group[7].

Sustained uterine hyperstimulation can compromise fetal well-being and increase the likelihood of medical interventions such as cesarean delivery. However, in our study, higher rates of tachysystole did not translate into increased cesarean sections rates for NRFS. Similarly, Diguisto et al. reported no significant difference in cesarean delivery for NRFS between the CDBC and dinoprostone groups (5.8% vs. 5.3%, p=0.70)[11].

There were no disparities or unfavorable neonatal outcomes observed in the two groups, underscoring the overall safety of both CR approaches.

In the subgroup of pregnancies complicated by FGR, both methods showed efficacy achieving VD (53.4% vs. 50.0%, p = 0.546). Concerning safety, uterine tachysystole occurred significantly more frequently among women who received dinoprostone (13.3% vs. 0%; p = 0.001). Despite this, no difference in cesarean rate for NRFS or neonatal outcomes between the two CR methods were observed. These findings are consistent with those presented by Duro-Gómez et al. in 2017[22], but contrast with those by Di Mascio et al.[14], who reported lower risk of cesarean delivery for non-reassuring fetal status and lower NICU admission rate with mechanical methods. In our study, both methods were equally effective in achieving VD, and no significant differences were found in cesarean indications between groups.

Several studies link maternal obesity to decreased likelihood of VD in women submitted to labor induction[23-26]. Our findings were consistent with the literature, as among women undergoing induction due to a pregestational BMI > 35, the rate of CD was higher compared to the overall cohort.

Nevertheless, in our study, both dinoprostone and CDBC were similarly effective in achieving VD in women with pregestational BMI > 35 and there were no significant differences in cesarean delivery rates for NRFS (25.6% vs. 11.9%, p = 0.112) between the two methods. Interestingly, while our results demonstrated no significant difference in induction-to-delivery interval between the two groups, they diverge from findings by Lauterbach et al.[24], who reported a shorter

time to delivery in obese women induced with CDBC. Differences from Lauterbach et al., who reported shorter induction times with CDBC, may be explained by differing BMI cutoffs across studies.

The multivariate analysis provided further insights into factors influencing delivery mode. A history of previous cesarean significantly reduced the likelihood of VD by 81.4%, while multiparity increased the odds of vaginal birth sixfold, findings that corroborate existing evidence[21,27].

CLINICAL IMPLICATIONS

These results may support the preferential use of dinoprostone in full-term pregnancies to increase the likelihood of vaginal delivery and reduce time to labor. However, in pregnancies complicated by fetal growth restriction, CDBC could be considered a safer and equally effective option. Tailoring the choice of cervical ripening method to the clinical context may optimize maternal and neonatal outcomes while minimizing complications.

STRENGTHS AND LIMITATIONS

The study addresses an important clinical question in obstetric practice in Portugal, where data on CR strategies remain limited, thereby contributing valuable insights to inform decision-making in similar settings. To our knowledge, this is the first study to compare these two CR methods within a Portuguese maternity setting. Moreover, the study, conducted at the only public hospital on Madeira Island – which accounts for approximately 85% of all deliveries in the region – likely reflects the characteristics of the broader Portuguese obstetric population. Additionally, the sample size is large and representative and thus enhancing the generalizability of the findings.

The retrospective nature of the study introduces inherent potential selection bias, as CR methods were not randomly assigned and may have been influenced by clinical or provider factors. Uniform adherence to institutional protocols cannot be guaranteed, and practice variations may have affected outcomes.

In addition, this is a single center study and was developed according to the institution protocol of induction of labor at that time.

The two methods compared differ fundamentally in mechanism – dinoprostone as a pharmacological agent versus the double-balloon catheter as a mechanical approach – making direct comparisons inherently limited. Finally, the sample size was not sufficient to evaluate rare but important adverse events such as uterine rupture. Larger, prospective multicenter trials are needed to validate these findings and better define the comparative safety and efficacy of these induction strategies.

CONCLUSION

Our results suggest that dinoprostone outperforms the cervical double-balloon catheter in terms of induction speed and VD rates in full term pregnant women with unfavorable local conditions with indication for CR and even if was associated with a higher rate of tachysystole, it did not show to have worse neonatal outcomes.

The double-balloon catheter remains a safe and valuable alternative, particularly in women where pharmacological agents might be of concern.

In pregnancies complicated by fetal growth restriction or pregnant women with pregestational BMI > 35, both methods showed to be equally efficient and safe methods.

Future research should focus on prospective, multicenter randomized trials to overcome the limitations of retrospective single-center studies and improve the generalizability of findings. In particular, evaluating combined approaches, such as the adjunctive use of prostaglandins with the double-balloon catheter, may help determine whether pharmacological support can further improve cervical ripening, delivery outcomes, and maternal safety. Comparative studies examining not only delivery success rates and safety profiles but also patient satisfaction, and cost-effectiveness will provide a more comprehensive understanding of optimal induction strategies.

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AUTHOR CONTRIBUTIONS

ITL: conceptualization, data collection and analysis, writing – original draft. FC: Writing –review & editing. FR: Supervision; Validation; MIB: data collection and analysis. Writing – review & editing. CS: Data collection and analysis. Writing – review & editing. SF: Data collection and analysis. CB: Supervision; Validation. All authors approved the final version to be published.

DECLARATION OF GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this work the authors used ChatGPT in order to improve language and readability of the manuscript. After using this tool, the authors reviewed and edited the content as needed and takes full responsibility for the content of the publication.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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DATA AVAILABILITY

The complete dataset and detailed specifications of the statistical analysis used in this study are available upon reasonable request from the corresponding author at inestabordaleal@hotmail.com. The study was approved by the Ethics Committee "Comissão de Ética para a Saúde do SESARAM, EPERAM", under protocol number 51/2024.

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