



Full length article

## Term induction of labour in nulliparous women: When to draw the line?


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## ARTICLE INFO

**Keywords:**

Induction of labour  
Cervical ripening  
Dinoprostone  
Prostaglandin  
Perinatal outcomes

## ABSTRACT

**Objective:** There exists uncertainty surrounding the most effective and efficient means of inducing labour, particularly in the setting of an unfavourable cervix. This study aims to determine the merit of repeating dinoprostone administration when a single application has failed to render the cervix favourable for amniotomy. **Study design:** Retrospective analysis of a consecutive cohort of nulliparous women who underwent term induction of labour in a tertiary referral centre in Ireland was conducted over a 12- month period (December 2019 to January 2021). The time-interval from dinoprostone administration to delivery and the incidence of complicated birth, associated with single and sequential dinoprostone dosing, were determined. Comparisons were made using the Chi-square test and logistic regression adjusting for gestational age delivery.

**Results:** 586 nulliparous women underwent term induction of labour during the study period. Administration of a single dose of dinoprostone or amniotomy alone were associated with the greatest prospect of an uncomplicated vaginal birth when compared to sequential dinoprostone dosing. Nonetheless, just one in four nulliparous women undergoing induction of labour experienced an unassisted and uncomplicated vaginal birth. The median [interquartile range] for time interval from induction to delivery or decision for caesarean delivery was 0.4 [0.3–0.6] days in those who underwent amniotomy alone, compared to 1.1 [0.7–1.5] days, 1.8 [1.4–2.2] days and 2.2 [2.0–2.6] days for those with 1, 2 or 3 doses of dinoprostone, respectively ( $p < 0.001$  between all groups; Figure 1)

**Conclusion:** These contemporaneous data indicate that in circumstances where more than a single dose of dinoprostone is required for cervical priming in a nulliparous woman, the incidence of an uncomplicated vaginal delivery decreased from more than half of women to less than one third. Over one third of women who were administered either a single dose of dinoprostone or more than one dose experienced an emergency intrapartum Caesarean delivery or a complicated vaginal birth. These findings are relevant to nulliparous women undergoing induction of labour in the setting of an unfavourable cervix and should be incorporated into shared decision-making consultations, particularly when repeat administration of dinoprostone is being considered.

### 1. Introduction

Shared decision- making and autonomy in childbirth represent integral dimensions of a quality modern health service. The benefits, risks and alternative treatment options must be accurately presented so that patients can understand the likely or potential outcomes of treatment [1]. In Ireland, the Health Service Executive National Consent Policy states that ‘the process of communication begins at the initial contact and continues through to the end of the service user’s involvement in the treatment process’ [2]. It is therefore imperative that patients are made

aware of the potential birth and neonatal outcomes when increasing doses of dinoprostone are required for cervical priming.

This study aims to determine the merit of repeating dinoprostone administration when a single application has failed to render the cervix favourable for amniotomy. In order to better facilitate informed decision making, we sought to examine the perinatal outcome of sequential dinoprostone dosing in order to accurately determine the prospect of achieving an uncomplicated vaginal delivery versus complicated vaginal delivery or caesarean section.

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## 2. Method

This is a retrospective analysis of a consecutive cohort of nulliparous women with a singleton cephalic pregnancy who underwent term induction of labour in a tertiary referral centre in Ireland over a 12-month period (December 2019 to January 2021). The electronic health record Maternal and Newborn Clinical Management System (MN-CMS) was used for data collection. All study subjects were nulliparous women who underwent induction of labour using dinoprostone (Prostin® vaginal gel or Propess® 10 mg vaginal delivery system) and women who underwent amniotomy without pre-induction cervical priming. Approval for the study was granted by the Institutional Research Ethics Committee.

One dose of dinoprostone was defined as either Prostin® 2 mg vaginal gel or Propess® 10 mg vaginal pessary delivery system. Two doses of dinoprostone was defined as either Propess® followed by Prostin® 1 mg or Prostin® 2 mg followed by Prostin® 1 mg. Three doses of dinoprostone was defined as either Propess® followed by two sequential doses of Prostin® 1 mg or Prostin® 2 mg followed by two sequential doses of Prostin® 1 mg. According to the World Health Organisation (WHO), there is no difference in rate of caesarean delivery when prostaglandin gel administration is compared to the pessary delivery system [3].

Time-interval from dinoprostone administration to delivery and the incidence of complicated vaginal birth or caesarean section, associated with single and sequential dinoprostone dosing, were determined.

Complicated vaginal birth was defined as the occurrence of shoulder dystocia, significant perineal trauma (high vaginal tear or obstetric anal sphincter injury), admission to the neonatal intensive care unit, postpartum haemorrhage greater than or equal to 1000 ml, sequential use of instruments to achieve delivery, manual removal of placenta or maternal admission to the High Dependency Unit. Caesarean delivery was sub-categorized as intrapartum caesarean section or prelabour caesarean section. Intrapartum caesarean section was defined as a caesarean section when the cervix was three or more centimetres dilated in association with regular painful uterine contractions. Caesarean section was considered 'prelabour' if cervical dilatation did not exceed 2 cm. The latter cohort included women who were commenced on an intravenous oxytocin infusion but did not progress into the active first stage of labour (3 cm or more) and included cases where artificial rupture of membranes was not undertaken, or the induction attempt was deemed to have 'failed'. Statistical comparisons are for one mode of delivery against all other modes of delivery, for any difference between the cervical priming groups. Comparisons were made using the Chi-square test and logistic regression, adjusting for gestational age at delivery.

## 3. Results

### 3.1. Demographic data

Five hundred and eighty six nulliparous women underwent term induction of labour during the study period. Sixty-five percent of the study cohort (381/586) received a single dose of dinoprostone for cervical priming. Twenty percent of the study cohort (119/586) received two doses of dinoprostone. Four percent of the study group (24/586) received three doses of dinoprostone. Eleven percent of subjects underwent amniotomy alone (62/586). Fig. 1 depicts the proportion of subjects who received Propess® versus Prostin® alone in each group.

Patient demographics and body mass index (BMI) are presented in Table 1. Indications for induction of labour are presented in Table 2. Gestational age ranged from 37 + 0 to 41 + 6. The median (interquartile range) gestational age was 40 + 1 (39 + 1 to 41 + 1).

Administration of a single dose of dinoprostone or amniotomy alone were associated with the greatest prospect of an uncomplicated vaginal birth when compared to sequential dinoprostone dosing. More than half of those who received a single dose of dinoprostone or amniotomy alone

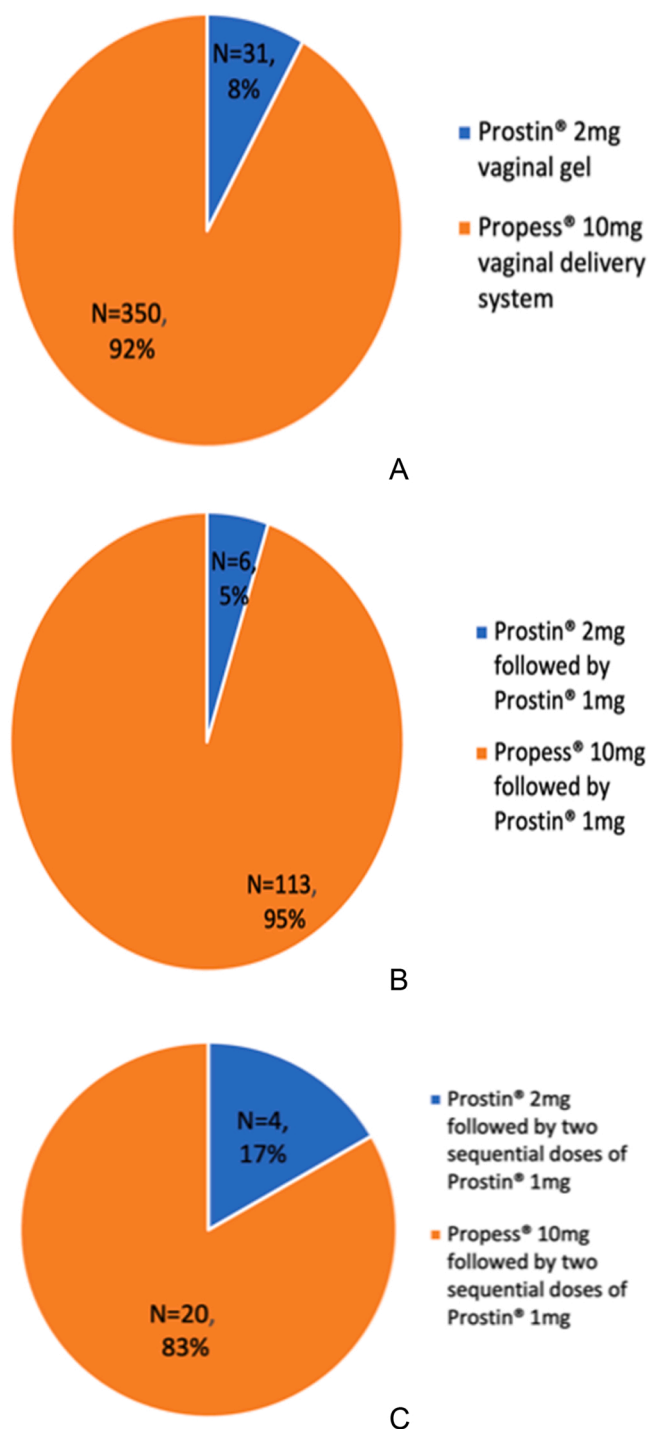


Fig. 1. Dinoprostone preparations.

achieved a spontaneous vaginal delivery (SVD) or uncomplicated operative vaginal delivery (OVD) ([single dose of dinoprostone achieving uncomplicated SVD or OVD = 52%, n = 199] [amniotomy alone achieving uncomplicated SVD or OVD = 58%, n = 36]), significantly higher than the rates of uncomplicated vaginal delivery amongst those who received two or more doses of dinoprostone. Mode of delivery for amniotomy alone, single and sequential dinoprostone dosing is presented in Table 3. Table 4.

### 3.2. Time from induction to delivery

The median [interquartile range] for time interval from induction to

**Table 1**  
Patient Characteristics (N = 586).

Characteristic	Category	n (%)
Age (years)	< 20	19 (3.2%)
	20–29	179 (30.5%)
	30–39	348 (59.4%)
	40 or more	40 (6.8%)
BMI (kg/m <sup>2</sup> )	< 18.5	19 (3.2%)
	18.5–24.9	256 (43.7%)
	25–29.9	179 (30.5%)
	30–39	121 (20.6%)
	40 or more	11 (1.9%)
Health insurance	Public	509 (86.9%)
	Private	77 (13.1%)
Epidural use <sup>a</sup> (n = 537)	Yes	472 (87%)
	No	73 (13%)

<sup>a</sup> Epidural Use (among women whose induction proceeded to rupture of membranes (either artificial or spontaneous))

**Table 2**  
Indication for Induction of Labour (N = 586).

Indication	n (%)	1 Dose (n = 381)	2 Doses (n = 119)	3 or more Doses (n = 24)	ARM (n = 62)
Postdates <sup>1</sup>	201 (34.3%)	141 (36.9%)	29 (24.4%)	7 (29.2%)	24 (38.7%)
Suspected fetal macrosomia	38 (6.5%)	21 (5.5%)	10 (8.4%)	1 (4.2%)	6 (9.7%)
Suspected SGA	56 (9.4%)	38 (9.9%)	11 (9.2%)	2 (8.3%)	5 (8.1%)
Oligohydramnios	23 (3.9%)	13 (3.4%)	6 (5%)	2 (8.3%)	2 (3.2%)
Reduced fetal movements	35 (6.0%)	23 (6%)	7 (5.9%)	2 (8.3%)	3 (4.8%)
Obstetric cholestasis	15 (2.6%)	6 (1.6%)	4 (3.4%)	1 (4.2%)	4 (6.5%)
Advanced maternal age	30 (5.1%)	21 (5.5%)	7 (5.9%)	0	2 (3.2%)
Hypertension (non- proteinuria)	50 (8.5%)	30 (7.9%)	14 (11.8%)	3 (12.5%)	3 (4.8%)
Pre-eclampsia	14 (2.4%)	9 (2.4%)	3 (2.5%)	2 (8.3%)	0
Gestational Diabetes	53 (9.0%)	34 (8.9%)	12 (10.1%)	2 (8.3%)	5 (8.1%)
Fetal Abnormality	3 (0.5%)	2 (0.5%)	0	1 (4.2%)	0
Maternal request/ No clinical indication	68 (11.6%)	43 (11.2%)	16 (13.4%)	1 (4.2%)	8 (12.9%)

<sup>a</sup> Postdates was defined as a gestational age of at least to 41<sup>+0</sup> weeks.

delivery or decision for caesarean delivery was 0.4 [0.3–0.6] days in those who underwent amniotomy alone, compared to 1.1 [0.7–1.5] days, 1.8 [1.4–2.2] days and 2.2 [2.0–2.6] days for those with 1, 2 or 3 doses of dinoprostone, respectively ( $p < 0.001$  between all groups; Fig. 1). Fig. 2.

#### 4. Discussion

The WHO has emphasised the importance of considering the individual wishes, preferences and cervical status of each woman when undertaking induction of labour[4]. In Ireland, the Health Products Regulatory Authority (HPRA) recommends that when administering Prostin® E2 Vaginal Gel, a maximum dose of 4 mg of dinoprostone be used in unfavourable primigravid patients and 3 mg in other patients [5]. The HPRA does not issue any guidance on the administration of alternate formulations of dinoprostone (such as Prostin®) after Propess® 10 mg has not rendered the cervix suitable for amniotomy, but the

regulatory authority explicitly cautions against repeat Propess® (10 mg) administration due to insufficient evidence of safety [6]. However, a randomised control trial is underway investigating the safety and effectiveness of a second administration of Propess® pessary[7]. The use of Prostin® vaginal gel following Propess® is unlicensed and the benefits and risks of pursuing cervical ripening must be considered and discussed with the patient.

With recent evidence demonstrating that induction of labour in low-risk nulliparous women at 39 weeks of gestation does not increase neonatal morbidity and is associated with a decreased requirement for caesarean delivery, the number of patients undergoing induction of labour is expected to rise [8]. It is important to continue to evaluate methods and interventions that are safe and effective at establishing induced labour.

As expected, the time- interval from induction to delivery or decision for caesarean delivery was shortest in those who underwent an amniotomy alone and was prolonged with each additional dose of dinoprostone. A shorter time- interval between induction and delivery is associated with increased patient satisfaction and decreased hospital costs[9]. Our findings are consistent with a systematic review which found that early amniotomy during induction of labour was associated with a shorter time to delivery without an increase in the rate of caesarean delivery[10].

The findings of this study offer valuable insights relating to the outcomes that can be anticipated with sequential administration of dinoprostone for pre-induction cervical priming in nulliparous women. In circumstances where more than a single dose of dinoprostone was required, the prospect of achieving an uncomplicated vaginal delivery was lower than those who underwent amniotomy alone or had one dose of dinoprostone and the incidence of undergoing a caesarean section was higher than the latter cohort. Of note, the percentage of uncomplicated operative vaginal deliveries was higher in the amniotomy only group compared to the other induction groups. It is important to consider this contemporaneous data when counselling patients on the likely outcomes of induction of labour. The National Institute for Health Care Excellence (NICE) states ‘that if the prospects for success are low, particularly if the response to early attempts to start labour are disappointing, it may be necessary to reconsider the wisdom of proceeding and perhaps to resort to caesarean delivery’[11], an approach supported by the findings of this study.

Shared decision-making is a key element of modern healthcare. It encompasses information sharing, communication, collaboration and relationship building in order to facilitate patient autonomy[12]. The benefits of a shared approach to decision-making include the empowerment of patients to secure a management decision that is right for them at the time. It is important to inform the patient of the potential benefits, risks and consequences of a proposed intervention through discussion and information sharing[13]. Furthermore, enhanced satisfaction has been demonstrated among women who are afforded comprehensive information in advance of the process of induction of labour[9,14].

These contemporaneous data, accrued from a large cohort of nulliparous women in a single tertiary referral centre, indicate that for every six women who require a single dose of dinoprostone for pre-induction cervical priming, three will have an uncomplicated vaginal birth (with approximately half of this group requiring operative assistance to complete delivery), a further one in six will undergo Caesarean delivery pre-labour and the remaining two women will experience either an intrapartum Caesarean delivery or complicated vaginal birth. Such data should be shared with women in order to secure a fully informed approach to decision-making and should be revised as clinical circumstances change. For example, if a second dose or a third dose of dinoprostone is required, two in six women will have an uncomplicated vaginal birth (half with operative assistance), two in six will undergo pre-labour Caesarean delivery following an unsuccessful attempt to establish in labour, and a further two in six will experience either an

**Table 3**  
Induction of labour and mode of delivery (N = 586).

Induction Type/ Mode of delivery	Number of Dinoprostone Doses <sup>a</sup>				Amniotomy only (N = 62)	P-value for Dinoprostone 1 dose vs 2 or more
	1 dose (N = 381)	2 doses (N = 119)	3 doses (N = 24)	Any dose (N = 524)		
Spontaneous Vaginal Delivery	115 (30%)	16 (13%)	6 (25%)	137(26%)	13 (21%)	< 0.001 <sup>b</sup>
Uncomplicated Operative Vaginal Delivery	84 (22%)	17 (14%)	2 (8%)	103(20%)	23 (37%)	0.025 <sup>b</sup>
Complicated Vaginal Delivery <sup>c</sup>	67 (18%)	8 (7%)	3 (13%)	78 (15%)	10 (16%)	0.005 <sup>b</sup>
Intrapartum Caesarean Delivery	81 (21%)	39 (33%)	5 (21%)	125 (24%)	14 (23%)	< 0.001 <sup>b</sup>
Prelabour Caesarean Delivery <sup>d</sup>	34 (9%)	39 (33%)	8 (33%)	81 (15%)	2 (3%)	< 0.001 <sup>b</sup>

<sup>a</sup> Number of Dinoprostone Doses: One dose of dinoprostone was defined as either Prostin® 2 mg vaginal gel or Propess® 10 mg vaginal pessary delivery system. Two doses of dinoprostone was defined as either Propess® followed by Prostin® 1 mg or Prostin® 2 mg followed by Prostin® 1 mg. Three doses of dinoprostone was defined as either Propess® followed by two sequential doses of Prostin® 1 mg or Prostin® 2 mg followed by two sequential doses of Prostin® 1 mg.

<sup>b</sup> Statistically significant after adjustment for gestational age at delivery (p < 0.05, logistic regression).

<sup>c</sup> Complicated Vaginal Delivery: Shoulder dystocia, significant perineal trauma, NICU admission, postpartum haemorrhage, sequential use of instrumentation or manual removal of placenta. Statistical comparisons are for one mode of delivery against all other modes of delivery, for any difference between the cervical priming groups.

<sup>d</sup> Prelabour Caesarean Section was defined as decision made for casearean section when the cervix was two centimetres dilated or less. This included women who were commenced on an intravenous oxytocin infusion but did not progress into the active first stage of labour (3 cm or more).

**Table 4**  
Induction of labour and mode of delivery simplified (N = 586).

Induction Type/ Mode of delivery	One Dose of Dinoprostone <sup>a</sup> or Amniotomy Only (n = 443)	2 or more doses of Dinoprostone <sup>b</sup> (n = 143)
Uncomplicated Vaginal Delivery	235 (53%)	41 (29%)
Intrapartum Caesarean Section or Complicated Vaginal Delivery <sup>c</sup>	173 (39%)	55 (38%)
Prelabour Caesarean Section	36 (8%)	47 (33%)

<sup>a</sup> One dose of dinoprostone: defined as either Prostin® 2 mg vaginal gel or Propess® 10 mg vaginal pessary delivery system.

<sup>b</sup> Two or more doses of dinoprostone: Two doses of dinoprostone were defined as either Propess® followed by Prostin® 1 mg or Prostin® 2 mg followed by Prostin® 1 mg. Three doses of dinoprostone was defined as either Propess® followed by two sequential doses of Prostin® 1 mg or Prostin® 2 mg followed by two sequential doses of Prostin® 1 mg.

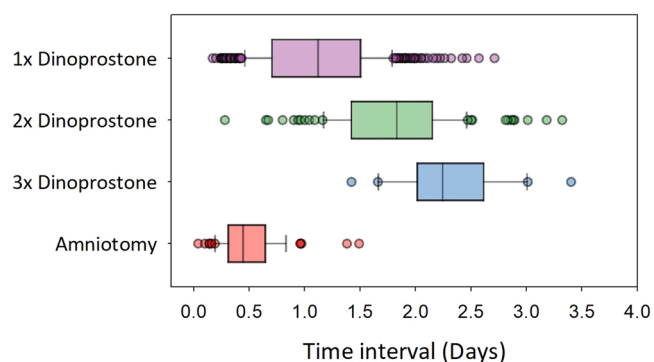
<sup>c</sup> Complicated Vaginal Delivery: Shoulder dystocia, significant perineal trauma, NICU admission, postpartum haemorrhage, sequential use of instrumentation or manual removal of placenta. Statistical comparisons are for one mode of delivery against all other modes of delivery, for any difference between the cervical priming groups.

demonstrated that attempting amniotomy when the Modified Bishop's score was < 7 did not increase the need for oxytocin, did not influence the likelihood of a vaginal birth and was not associated with a higher incidence of failed induction of labour. There were no statistically significant differences in any of the other secondary clinical outcome measures, however, the trends generally favoured the amniotomy group with fewer instrumental births, fewer caesarean deliveries, fewer failed inductions, less blood loss and less postpartum haemorrhage. The findings of this trial are aligned with our results in terms of shorter time interval. Similarly, no benefit to sequential dinoprostone dosing was demonstrated. However, there are notable differences between the studies, which renders comparison difficult. Firstly, this trial included all patients irrespective of parity whereas our study focused solely on nulliparous women. Furthermore, our study is a retrospective review in which the women who received two or more doses of dinoprostone were deemed not suitable for amniotomy by the attending clinician rather than being randomised into groups and receiving sequential doses until they achieved a Modified Bishop's Score of 7 even if an amniotomy was technically possible earlier.

Previous research has explored the development of nonograms for use in nulliparous women prior to embarking on induction of labour which aim to identify women at the highest risk for caesarean delivery after induction so that they can be offered an elective pre-labour caesarean section in order to avoid the additional risks of prolonged labour and intrapartum caesarean delivery [16]. Our study evaluates the likelihood of achieving an uncomplicated vaginal delivery with each further dose of dinoprostone required to achieve adequate cervical ripening and can be used in discussions with patients about the likely risks versus benefits of continuing the induction process when one dose of dinoprostone has not achieved adequate cervical ripening. Future research could aim to incorporate antenatal factors with response to dinoprostone during the induction process to be used in the individualised counselling of women.

The Bishop Score has been shown to be an unreliable method of predicting the outcome of induction of labour at term [17,18]. A systematic review which included 40 primary studies reporting on 13,757 women, found that for the prediction of caesarean delivery, the sensitivity-specificity combinations were 47%–75%, 61%–53% and 78%–44% for the Bishop scores of 4, 5, and 6, respectively. The need for repeat doses of dinoprostone and response to dinoprostone should be further explored as a more reliable predictor of perinatal outcome.

This study was conducted in a large, tertiary referral centre with over 8000 deliveries per annum. All study subject data were accrued from individual electronic patient records, and 100% ascertainment of outcome data was secured. Accuracy of study data was ensured by complete review of all contributing patient records, without reliance on



**Fig. 2.** Boxplots of time interval from start of induction to delivery or decision for caesarean delivery.

emergency intrapartum Caesarean delivery or a complicated vaginal birth.

A randomised controlled trial evaluated perinatal outcomes of early amniotomy after one dose of Prostin® vaginal gel versus repeat doses of Prostin® until Modified Bishop's score was  $\geq 7$  [15]. This trial

automatically generated data from the electronic healthcare data collection system (Maternal and Newborn Clinical Management System (MN-CMS) Cerner®).

This study has a number of limitations. Firstly, a limited number of patients were administered three doses of dinoprostone. As mentioned previously, the administration of Propress® followed by subsequent doses of Prostin® is unlicensed and therefore clinicians may be less likely to administer a further dose of dinoprostone if previous doses had little effect. Secondly, we categorised Propress® 10 mg vaginal system and Prostin® 2 mg vaginal gel in the same group. Although there is no difference in risk of caesarean section between prostaglandin gel or pessary [3] they are not interchangeable due to different dinoprostone doses. Furthermore, this is a retrospective study and was not adjusted for confounding fetal and maternal risk factors for adverse outcomes other than gestational age. However, indications for induction of labour were similar among all dosing groups.

Further studies are needed to: (i) further investigate delivery outcomes when sequential doses of dinoprostone are required to render the cervix favourable for amniotomy, (ii) to investigate the reasons behind higher rates of complicated deliveries with increasing requirements for dinoprostone administration and (iii) to determine the impact that knowledge of contemporaneous outcome data has on shared decision-making and on perinatal outcome.

## Conclusion

These contemporaneous data indicate that in circumstances where more than a single dose of dinoprostone is required for cervical priming in a nulliparous woman, the likelihood of achieving an uncomplicated vaginal delivery is significantly reduced. These findings are relevant to nulliparous women undergoing induction of labour in the setting of an unfavourable cervix and should be incorporated into shared decision-making consultations, particularly when repeat administration of dinoprostone is being considered.

## Declaration of Competing Interests

The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs)

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