

Induction of Labour, is the Second Propess® of any Benefit? A Comparative Study

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ABSTRACT

Objectives: Induction of labour world-wide has increased dramatically over the last decade. In 2019, third of women were induced, with a rate as high as 36% for nulliparous women. Prostaglandins, and in particular, dinoprostone vaginal delivery system (Propess®) has been widely used for cervical ripening and induction of labour. However, there is no consensus on the usage of second dosage of dinoprostone for women who do not respond after 24 hours of the first dose. The aim of the current study was to determine whether placement of second Propess®, if necessary, would increase the vaginal delivery rate in pregnant women, for whom first Propess® failed to induce cervical ripening.

Materials and Methods: This was a comparative study that included 821 women who had induction of labour by dinoprostone vaginal delivery system, at King's College Hospitals NHS Foundation Trust, United Kingdom. We used Kolmogorov-Smirnov test to examine the distribution of the included variables, with Mann-Whitney U test used to test the differences in the continuous variables and while chi-square test and Fisher's exact tests were used to test the differences in categorical values between the two groups.

Results: The association between placing second Propess® and obstetric outcomes showed that group who received single dose of dinoprostone was more likely to deliver vaginally.

Conclusion: Our study showed that the second dose of Propess® was associated with higher caesarean section rate and neonatal special care admission, though the difference was not statistically significant. Further multicentre randomised controlled studies with larger sample size are recommended.

Keywords: Propess, Vaginal Delivery Caesarean Section, Induction of Labour

Introduction

The process of induction of labour around the world, and particularly, in the United Kingdom has increased dramatically from 22% in the year to March 2011 to 33% in the year to March 2022 [1]. Many methods have been suggested for induction of labour, including pharmacologic agents (prostaglandins, oxytocin, mifepristone, hyaluronidase and nitric oxide donors) and mechanical methods (single- and double- balloon catheters, laminaria tent, membrane sweep and amniotomy).

Prostaglandins (PGs) [usually intravaginal dinoprostone (Propess®)] is one of the methods which has been widely used

for induction of labour by initiating cervical ripening [2]. Over the course of 24 hours, intravaginal dinoprostone releases 0.33 mg of PGE₂ per hour, totalling 10 mg. This will result in fewer vaginal assessments, medication insertions, with subsequent reduced risk of infection [3]. In addition, unlike prostaglandin E₂ gels or tablets (Prostine®), intravaginal dinoprostone can be easily withdrawn at any time if uterine hyper-stimulation (which may cause foetal implications) occurs. Inducing labour with PGs improves vaginal birth rates, decreases caesarean section rates, and lessens the requirement for epidural analgesia in the first 24 hours after giving birth. Moreover, the rate of maternal satisfaction is greater than when labour is induced using oxytocin (either alone or in combination with amniotomy) [4].

There is no real scientific evidence for the usefulness of using

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second dose dinoprostone in the process of induction of labour, and whether it has added any benefits or increase the success rate of vaginal delivery. According to the manufacturer's instructions, use of a single Propess® is recommended, and the active labour rate following a single Propess®, is 65% to 73%, with more than 80% of subsequent deliveries being vaginal [5]. However, as few studies have evaluated the efficacy and safety of applying a second vaginal pessary of dinoprostone, the aim of the current study was to compare the potential benefits and risks of using two doses of vaginal dinoprostone versus the use of a single dose, in the process of induction of labour, looking at both maternal and neonatal outcomes.

Materials and Methods

This is a retrospective comparative study that was conducted at King's College Hospitals NHS Foundation Trust, London, United Kingdom. The study was conducted across both sites of the Trust; Denmark Hill site and Orpington site, in the period of January 2017 to January 2020. The study included 821 patients who had induction of labour by vaginal dinoprostone 10mg pessary. Data of Induction of Labour were collected during routine clinical practice, and analysis of data was retrospective. Thus, our study did not require approval from the institutional review board. As per the Trust guidelines, the foetal heart rate was monitored within 2 hours from insertion and then every 6 hours afterwards. Additional monitoring was performed if the uterine contractions were reported.

Inclusion Criteria

Eligibility requirements

Intact membranes, term pregnancy (>37 weeks gestation), unfavourable cervical condition (Bishop score <6) and cephalic presentation of the foetus. Patients must be at least 18 years old and have been admitted for induction of labour.

Exclusion Criteria

The exclusion criteria are:

- Contraindications to the use of vaginal dinoprostone.
- Induction for intrauterine foetal demise, medical abortion, or the presence of a potentially fatal foetal pathology.
- A history of uterine scarring (due to myomectomy or caesarean section).
- Multiple pregnancy.
- If labour occurred in less than 24 hours from the time of insertion of first vaginal dinoprostone.
- If first vaginal dinoprostone is removed due to aberrant uterine contractility, abnormal foetal heart rate, or any adverse impact that occurs while the first vaginal dinoprostone is in place.
- Premature rupture of membranes.
- Large for gestational age presentation (> 97th percentile) or foetal intrauterine growth restriction (3rd percentile).

Sample Size

Initially, our sample consisted of a total of 821 patients who underwent induction of labour. Among them, 551 patients were excluded based on the predetermined criteria. Following this initial screening, 270 patients remained eligible for further consideration. However, 78 patients were subsequently excluded due to a lack of compatibility for matching. A final sample consists of 192 patients are considered for the analysis

of which 96 patients received single Propess® (controls) and 96 patients received second Propess® (cases). Detailed flow chart for inclusion and exclusion criteria is presented in Figure 1.

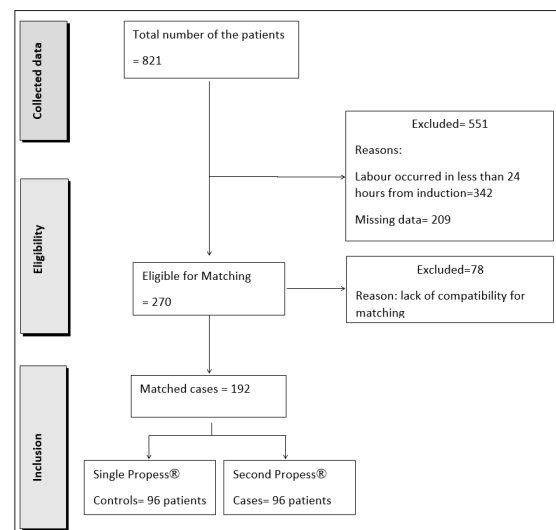


Figure 1: Flow Chart of the Study

Sample Size Considerations

The comparison of vaginal delivery rate using single and second doses of Propess® varied among different studies. We calculated the required sample size based on 0.05 significance level, two-sided alternative and 80% power. This calculation was performed in R v4.2.2 using library 'pwr' and the function 'pwr.2p.test' which yields an estimated sample size of a range 30-90 women. Accordingly, our sample size of 96 women per group would be more than sufficient to detect the effect of giving a second Propess on vaginal delivery.

Primary Outcome

The primary outcome is mode of delivery (vaginal delivery versus caesarean section), including the different indications for caesarean section.

Secondary Outcomes

Our secondary outcomes are divided into two categories.

Obstetric Outcomes

Including failed induction of labour (the inability to achieve the active phase of labour 24 hours after the second dosage of vaginal dinoprostone), total time of labour (from the first induction until the start of active phase of labour and from the onset of labour to the time of delivery), the development of chorioamnionitis, estimated blood loss and the need for surgical intervention in the theatre whether for instrumental vaginal delivery, third or fourth degree perineal tear, antepartum and/or postpartum haemorrhage, manual removal of the placenta, and any other maternal morbidity or mortality.

Neonatal Outcomes

Including the need for admission to the neonatal intensive care unit (NICU), and the presence of any perinatal morbidity and/or mortality.

Statistical Analysis

Given the retrospective nature of our study and the lack of randomisation between the two groups, we ensured comparability

by employing a matching approach based on key demographic and clinical variables known to impact the obstetric and neonatal outcomes. We used a sample of 821 women whose duration from first induction to onset of labour is more than 24 hours. Exact matching without replacement was conducted to achieve a balanced distribution across age (>30 years versus ≤30 years), parity (nulliparity versus multiparity), body mass index (BMI >25 versus ≤25), and gestational age (> 40 versus ≤ 40).

We used Kolmogorov- Smirnov test to examine the distribution of the included variables. Due to the violation of the normality assumption, the descriptive statistics of the continuous variables are expressed as medians and interquartile ranges and Mann-Whitney U test was used to test the differences between the two groups (Single propress versus a second propress).

The descriptive statistics for the categorical variables are expressed as percentages and frequencies, while chi-square test and Fisher's exact tests were used to test the differences between the two groups. Odds ratio, eta-squared, and Cramer's V measures accompanied by the confidence intervals were used to quantify the association between binary variables, between continuous and binary variables, and between categorical and binary variables respectively. Mann-Whitney U test, Fisher exact test and Chi-square tests are used to test the null hypothesis H0: No difference between placing single and second propress on the obstetric and Neonatal outcomes versus H1: there is difference between them. A value of $p < 0.05$ was considered statistically significant. Missing values were treated using pairwise deletion. The analysis was conducted using SPSS version 29.0.1.0 (171).

Results

The characteristics of the sample by each group are summarized in Table 1. The results of Kolmogorov-simranov test were insignificant for all continuous variables meaning that the variables deviate from normality. So, the descriptive statistics for age, body mass index (BMI), and gestational age are represented by median and inter-quartile range. The results shown in table 1 indicate no significant difference in the distribution of age, BMI, and gestational age between the two groups. Parity was

represented as a dichotomous variable and the proportions were identical among the two groups as a result of exact matching.

Table 1: Characteristics of the Sample

	Single Propress® (n= 96)	Second Propress® (n=96)	P
Age (years)	34 (IQR=8)	33 (IQR=8)	0.851 ^c
Parity			
Nulliparous	29.2% (28)	29.2% (28)	1.0 ^a , 1.0 ^b
Multiparous	70.8% (68)	70.8% (68)	
Body mass index	26.22 (IQR=7.4)	25.87(IQR=8.16)	0.960 ^c
Gestational age (week)	39(IQR=3)	39.5(IQR=3)	0.834 ^c

P: Significance of the difference between the single propress and second propress group, IQR: interquartile range, a= the p value is calculated based on Chi-squared test, b= the P value is calculated based on Fisher exact test, c= the P value is calculated based on Mann-Whitney U test.

The association between placing a second Propress® and obstetric outcomes showed that, albeit insignificant, the group who receive single propress is more likely to deliver vaginally (OR=1.398, CI=[0.724, 2.697]). For those who delivered by caesarean section; induction labour failure rate was higher in the single Propress® group, however, the caesarean section indication of arrest of cervical dilatation or failure of head to descend was higher in the second Propress® group (CV=0.133, CI=[0.088, 0.283]). The median duration from labour to delivery was higher by one hour when second propress is placed ($\eta^2=0.088$ CI=[0.005, 0.238]). Both chorioamnionitis (OR=0.539 CI=[0.215, 1.351]) and blood loss (OR=0.935 CI=[0.527, 1.659]) decreases with placing a second Propress®. With regards to neonatal outcome, results showed that placing a second Propress® results in neonatal intensive care unit admission more than when a single propress is used (OR=1.313 CI=[0.579, 2.976]), however the results of all tests are insignificant. (Table 2)

Table 2: Obstetric and Neonatal Outcomes

	Single Propress® (n=96)	Two doses Propress (n=96)	Effect size	P
Obstetric outcomes				
Mode of delivery				
Vaginal delivery % (n)	78.1% (75)	71.9% (69)	OR=1.398 CI= [0.724, 2.697]	0.317 ^a , 0.405 ^b
Caesarean % (n)	21.9% (21)	28.1% (27)		
Mode of delivery categories				
- Normal	42.7% (41)	44.2% (42)	CV=0.137 CI= [0.061, 0.301]	0.310 ^a , 3.14 ^b
- Forceps	19.8% (19)	10.5% (10)		
- Ventouse	15.6% (15)	16.8% (16)		
Caesarean % (n)	21.9% (21)	28.4% (27)		
Reason for Caesarean % (n)	(n=21)	(n=27)		
Arrest or failure to descend	9.5% (2)	18.52% (5)	CV=0.133 CI=[0.088, 0.283]	0.643 ^a , 0.685 ^b
Arrest or failure to dilate	23.8% (5)	29.36 (8)		
Pathological CTG	47.6% (10)	33.33% (9)		
Failed induction	19.1 % (4)	14.81% (4)		
Ut tachysystole with FHR involvement	0	3.7% (1)		

Duration from labour to delivery	7 (IQR=10)	8 (IQR=9)	$\eta^2=0.088$ CI=[0.005, 0.238]	0.122 ^c
No Chorioamnionitis % (n)	85.4% (14)	91.6% (87)	OR=0.539 CI=[0.215, 1.351]	0.182 ^a , 0.257 ^b
Blood loss < 500 ml % (n)	56.3% (54)	57.9% (55)	OR=0.935 CI=[0.527, 1.659]	0.818 ^a , 0.884 ^b
No need for theatre	64.6% (62)	61.1% (58)	OR=1.163 CI=[0.647, 2.093]	0.614 ^a , 0.655 ^b
Neonatal outcomes				
No need for neonatal intensive care unit % (n)	87.5% (84)	84.2% (80)	OR=1.313 CI=[0.579, 2.976]	0.514 ^a , 0.540 ^b

P: Significance of the difference between the single propress and Second propress group, OR= odds ratio, η^2 = eta-squared, CV= Cramer's V, CI= confidence interval, a= the p value is calculated based on Chi-squared test, b= the P value is calculated based on Fisher exact test, c= the P value is calculated based on Mann-Whitney U test.

In brief, although giving a second propress shows better outcomes with regards to induction failure rate, blood loss and chorioamnionitis, the confidence intervals of the effect sizes and the Chi-square, Fisher exact test and Mann-Whitney U test results show that these associations are not significant meaning that second Propess® is as effective as single Propess®. There was no maternal or foetal mortality in both groups. None of the mothers developed uterine rupture or needed admission to the Intensive Care Unit.

Discussion

The current study showed that the use of second dose of vaginal dinoprostone (Propess®) does not increase the success rate of vaginal delivery, and there is no statistical evidence to conclude that placing a second Propess® gives superior advantage than a single dosage. The main advantage of our study was the relatively large number of patients included in the study and the unawareness of the obstetricians of selected cases included in the study, hence minimizing any comparison or bias between the two groups. Another advantage is the matching of the two groups in relation to age, parity and Body Mass Index (BMI).

We included two groups of patients each 96 patients. One group had only single dosage of vaginal Propess® and the other one had two doses. Both groups included nulliparous as well as multiparous women. Our results showed that having single dosage was more likely to achieve vaginal delivery but the difference was not statistically significant. This finding is in agreement with the studies of Re-Dino multicenter trial and Karadag et al. [6,7].

Karadag et al, quoted vaginal delivery rate of 65% in the group who had single dosage of Propess® and 30.2% in the group who had two doses ($p=0.001$) [7]. In our study the success rate was 78.1% for the first group (who had single dosage) and 71.9 % of the second group (who had two doses) which is much higher success rate in both groups than in Karadag study. In the current study, the caesarean section rate was 28%, in women who received two dosages of dinoprostone compared to 13.3% in Karadag study. This could be attributed to the relatively large number of women in the current study compared to Karadag

study (96 vs 43). Additionally, the recruited participants in Karadag et al. study were mainly nulliparous while in our study, we included both nulliparous and multiparous patients but the majority were multiparous in both groups. However, the gestational age in Kardag study were lower than our study in the two-dosage group, which was 38.7 ± 2.9 while in our study it was 39.5 weeks, this difference is unlikely affect the neonatal unit admission, which was 14.5% in the current study, compared to 14% in Karadag study.

RE-DINO multi-centre randomised controlled trial in France, stated that a second dose of dinoprostone is unnecessary procedure, not useful for induction of labour, and does not increase the chance of successful vaginal delivery [6]. The caesarean section rate for arrest of cervical dilatation was higher in the two dosage Propess® group compared to the oxytocin group (52.6% vs 19%; $p=0.0262$). This is in agreement with our study, which showed that the caesarean section rate was higher in the two dosage group. However, the most common indication for caesarean section, in the current study, was pathological CTG (33.33% vs 47.6%, $p=0.643$) followed by arrest or failure of cervical dilatation. In addition, RE-DINO trial showed lower admission rate to the neonatal intensive care unit, in comparison to our study, (6.25% vs 14.5%) This might be attributed to the relatively larger sample size in the current study (192 case vs 160 case), in comparison to that in the RE-DINO study, which was stopped prematurely, before reaching the target sample size. The current study also showed that giving a second Propess® has a better outcome regarding induction failure rate, blood loss and chorioamnionitis but these associations are not significant.

Antonozzo et al. compared second dose of dinoprostone with oxytocin for patients who remain unfavourable after 24 hours of first dosage of dinoprostone [8]. His study found that a second vaginal administration of dinoprostone significantly enhanced the vaginal delivery rate (26/47, 55.3%) compared with oxytocin (16/47, 34.0%, $p=0.05$), with no increase in infant morbidity or mortality, however, the relative small number of participants in his study, (47 patients each group) increase the risk of false-negative results and limit the ability to detect true subtle effects. Whereas Petrovic Barbitch et al., 2013 did an observational study on 111 women who took two doses of propess for induction of labour. In more than half of the cases, the cervical ripening by two doses of Propess® was efficient and allows a vaginal delivery (53.1%). During their study, there was no increase in the maternal or neonatal morbidity. However, the majority of their patients were primigravida, which might explain the different outcome to our study.

The success of induction of labour process depends on several factors including parity, gestational age and BMI which were comparable between both groups. Our study showed that giving a second dose of Dinoprostone reduces induction failure rate, postpartum haemorrhage and the risk of chorioamnionitis but that reduction is not statistically significant.

Study Limitations

There were some limitations of our study. The majority of the patients in the current study were multiparous and there was no sub-group analysis to analyze the different modalities of induction of labour that were used after failed induction with Propess®.

Conclusion

Our study showed that the use of second dose of Propess® does not increase the vaginal delivery rate, but was associated with increased cesarean section rate and neonatal special care admission. It is also associated with reduced induction failure rate, postpartum haemorrhage and the risk of chorioamnionitis but this difference was not statistically insignificant. These findings will help to guide obstetricians and midwives to effectively counsel and manage women in the maternity units. Further large-scale single blinded randomized controlled studies are needed with relatively large number of patients and target sample size are needed.

Authors Contribution

M.M.H.: Conceptualization, data collection, writing – original draft, EE: Conceptualization, writing & editing, SJ & MA: Data collection, H.G.: Formal analysis. H.M.: Writing – review & editing.

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None

Disclosure of Interests

None

Ethical approval

Data of Induction of Labour were collected during routine clinical practice, and analysis of data was retrospective. Thus, our study did not require approval from the institutional review board.

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