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Original Research Article

Assessing the safety and efficacy of dinoprostone vaginal insert in pregnancy

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ABSTRACT

Background: Induction of labor (IOL) is a procedure used to achieve vaginal birth when the hazards of extending the pregnancy for either the mother or the infant outweigh the dangers of delivery. It is often used in high-risk pregnancies, although it can also be useful in low-risk groups, as demonstrated by A Randomized Trial of Induction Versus Expectant Management (ARRIVE) study.
Methods: The cross-sectional study was conducted among 414 patients at Department of Obstetrics and Gynaecology tertiary care hospital. The study was conducted for one-year duration in pregnant women with maternal age >18 years, gestational week >37 weeks, and Bishop score <7 was included in the study with no signs of labor. Demographic details such as age, pregnancy history, and mode of delivery were recorded for comparison. Patients with no induction of labor were administered misoprostol and/or dinoprostone based on clinical conditions with further evaluation of maternal complications, delivery time, birthweight of the fetus, and fetal heart rate. Data were analyzed based on percentages and a chi-square test was used (p-value <0.05).
Results: The mode of delivery did not significantly affect delivery outcomes (p=0.354), with assisted delivery being the most common (35.41%). Indication for induction was found to be significant (p=0.034), with non-progress of labor being the most common indication (55.2%). Maternal complications were not significantly associated with delivery outcomes (p=0.390), with 60 (14.49%) patients experiencing complications. The use of misoprostol reported a significant difference between modes of delivery with 74.93% of vaginal delivery, 19.47% with lower segment cesarean section (LSCS), and 5.60% with assisted delivery (p value <0.03).
Conclusions: In low-risk pregnant women, the dinoprostone or misoprostol vaginal inserts are both safe and effective for inducing labor. Nulliparous individuals and those who did not get epidural analgesia during labor had a higher chance of caesarean section.

Keywords: Cross-sectional study, Dinoprostone, Maternal outcomes, Misoprostol, Pregnancy induction

INTRODUCTION

Induction of labor (IOL), which artificially initiates the process of effacement of the cervix, dilatation of the cervix, and uterine contractions as well as routinely results in successful vaginal delivery, is often considered when the prolonged pregnancy poses a risk of mortality or morbidity for the mother or offspring or at the request of the pregnant women at term.[1,2] For appropriate care and treatment, IOL has been used in modern obstetrics for mother and fetus safety.[3] Furthermore, according to the

Society for Mother-Fetal Medicine (SMFM) position on elective induction of labor in low-risk nulliparous women at term, IOL at 39 gestational weeks gives mother advantages without increased harmful newborn effects.[4] Recently, a Cochrane systematic review found that IOL was associated with fewer (all-cause) perinatal deaths (risk ratio [RR] 0.33, 95% confidence interval [CI] 0.14-0.78, from 20 trials involving 9960 infants) when compared to expectant management. The review by Middletown including 30 randomized trials (reporting 12,749 females) reported fewer perinatal deaths in the IOL method when compared with comparative management, and less incidence of stillbirths. The review also reported that births using IOL method reported lower rates of neonatal intensive care unit (ICU) admission with low APGAR (Appearance, Pulse, Grimace, Activity, and Respiration) scores <7 at five minutes in the induction group.[5]

To produce a successful IOL, cervical ripening is an important first step, followed by appropriate and forceful uterine contractions with a regular frequency which is one of the critical factors seen in preterm labor.[6,7] Based on the guidelines and treatment protocol, cervical ripening can be achieved by mechanical methods and pharmacological methods. Pharmacological agents such as prostaglandins, progesterone receptor antagonists, oxytocin, and nitric oxide are routinely used.[8-10]

The USFDA approved dinoprostone preparations for cervical ripening at term which is a PGE_2 naturally occurring biomolecule found in low concentration in tissues of the body as a local hormone.[11] Pregnant women have reported a continuous secretion of PGE_2 which plays an essential role in the initiation of labor.[12] A systematic review report by Hughes et al with 11 randomized controlled trials reported the effective use of dinoprostone vaginal inserts when compared with other vaginal inserts or cervical prostaglandins.[12]

However, there is still a debate on the beneficial use of dinoprostone and misoprostol concerning cervical ripening during pregnancy and labor. The current study aims to identify the effective use of misoprostol when compared with oxytocin by evaluating the induction during labor and maternal complications.

METHODS

The cross-sectional study was conducted at the Department of Obstetrics and Gynaecology at a tertiary care hospital. The study was conducted for a duration of one year (January 2022 to January 2023) with the approval of the ethics committee. A total of 414 pregnant women without labor were selected based on the inclusion and exclusion criteria and after obtaining informed consent.

Inclusion criteria

Maternal age >18 years, with a singleton pregnancy, patients who provided informed consent, pregnant women with gestational week >37 weeks, pregnant women with Bishop score <7, and no signs of labor and reassuring fetal heart rate pattern were included.

Exclusion criteria

Pregnant women with existing illness, increased risk of adverse pregnancy outcomes, comorbid conditions such as diabetes, hypertension, abnormal placenta (vaginal bleeding, placenta previa, placenta accreta, vasa previa or abnormal amniotic fluid volume), patients with planned C-sections or contraindicated for normal labor and pregnant women with an allergic history of dinoprostone were excluded.

Procedure

The study recruited low-risk women with a live singleton fetus in cephalic presentation and gestational age ranging from 36 weeks + 0 days to 37 weeks + 0 days. Inclusion criteria stipulated that these women had no contraindication to vaginal delivery and no planned caesarean delivery. Low-risk was defined as having no maternal illness, no placental or amniotic disorder, and no abnormal fetus. Women who conceived naturally had gestational age determined from menstrual history and fetal crown-to-rump length on ultrasound at 8 weeks + 0 days to 13 weeks + 6 days, while those who conceived through assisted reproductive technology had gestational age determined based on the date of embryo transfer or intrauterine insemination. The study screening process was conducted at 39 weeks + 0 days to 40 weeks + 6 days of gestation by research doctors.

Enrolled women received vaginal dinoprostone insert inserted by a research doctor with or without a speculum, with fetal heart rate monitoring 30 minutes before and 2 hours after placement, and every 6 hours thereafter during the study. The vaginal system was left in place for a maximum of 24 hours. A new system was inserted (for 24 hours) post-removal only if the initial inserted system was expelled without any cervical changes or contractions.

The examination was conducted in the event of extreme pain or ruptured membranes, with system removal or retention performed based on local protocols and individual indications. Labor, deliveries, and postpartum management were performed in accordance with local protocols.

Based on the modified protocol from the manufacturer's instructions, dinoprostone was discontinued in certain circumstances. Uterine tachysystole (five contractions in between 10 to 30 min period) non-reassuring fetal heart rate, intolerable uterine contractions, extended vaginal contraction (>12 hours), spontaneous rupture of the membrane were few situations that required discontinuation of dinoprostone.

If regular uterine contractions were not observed 1 hour after dinoprostone removal, intravenous oxytocin was administered to continue induction. The attending physician recorded all data, including BMI, age, parity, induction criteria, obstetrical history, Bishop score, the reason for dinoprostone removal, time of delivery, neonatal weight and induction comparison with various variables. Continuous fetal heart rate and uterine contraction patterns were closely monitored using central fetal monitoring.

The primary outcome of the study was defined as successful vaginal delivery following induction with a dinoprostone vaginal insert, with the duration between induction and delivery as the parameter. Adverse effects and neonatal outcomes were analyzed as secondary outcomes. The inclusion of data was done by presenting the mean and standard deviation (SD) for continuous variables and the number and percentage for categorical variables. Pearson's chi-square tests were used for categorical variables, and all statistical analyses were performed using SPSS version 28.0 and a P-value of <0.05 was considered statistically significant.

RESULTS

The baseline characteristics of 414 patients were described in Table 1, the mean age of patients was 26.03 (3.94%). Induction assessment revealed that the most common indication for induction was non-progress of labor (43.96%), followed by gestational hypertension (10.14%), and ruptured membrane without labor (4.36%). Of the deliveries, 62.07% were vaginal, 33.09% were by LSCS, and 4.83% were assisted. Oxytocin was the most commonly used method of induction (74.64%), followed by misoprostol (81.88%). Maternal complications occurred in 414 cases, with the most common being non-progress of labor (15.70%), birth trauma (9.18%), and arrest of descent (4.59%).

The data shown in Table 2 presents that the majority of patients, 81.40% (337), were less than or equal to 37 weeks gestation, while 18.60% (77) were between 37 and 40 weeks' gestation. Out of the 414 deliveries, 50 babies (12.08%) had a birth weight of less than or equal to 2.5 kg, which is considered low birth weight. The majority of babies, 177 (42.75%), had a birth weight between 2.5 kg to 3 kg, while 154 (37.20%) had a birth weight between 3.1 kg to 3.5 kg. Only 33 babies (7.97%) had a birth weight greater than 3.6 kg. In addition, out of 414 patients, 258 were primigravida (62.32%) and 156 were multigravida (37.68%).

The patients were divided into two groups based on their gestational age: <37 weeks and >37 weeks to <40 weeks. For the <37 weeks group, 5.04% of patients required assistance during delivery, 33.83% had LSCS and 61.13% had a vaginal delivery. For the >37 weeks to <40 weeks group, 3.89% required assistance, 29.88% had LSCS, and 66.23% had a vaginal delivery. The overall mode of delivery for the entire group was 4.83% assisted, 33.09% LSCS, and 62.08% vaginal delivery. A P-value of <0.694 was reported, which indicates that there was no statistically significant difference in the mode of delivery between the two gestational age groups (Table 3).

Table 1: Baseline characteristics of patients.

	Statistics (%)
No. of subjects	414
Age, years Mean (SD)	26.03 (3.94)
Indication for induction n (%)	
Non-progress of labor	182 (43.96)
Meconium stained	05 (1.21)
Cephalopelvic disproportion	15 (3.62)
Fetal distress	11 (2.66)
Diabetes	35 (8.45)
Gestational hypertension	42 (10.14)
Oligohydramnios	29 (7.00)
Post cesarean	28 (6.76)
Post dated	20 (4.83)
Post – term	10 (2.42)
Rh-Negative	19 (4.59)
Ruptured membrane without labor	18 (4.36)
Mode of delivery, n (%)	
Vaginal	257 (62.07)
LSCS	137 (33.09)
Assisted	20 (4.83)
Induction of labor	
Induction, n (%)	
Oxytocin	309 (74.64)
Misoprostol	339 (81.88)
LSCS hyperstimulation	10 (2.42)
Maternal complication	414
Non-progress of labor	65 (15.70)
Birth trauma	38 (9.18)
Arrest of descent	19 (4.59)
Hypo thyroidism	16 (3.86)
Meconium stained liquor	08 (1.93)
Cephalopelvic disproportion	04 (0.96)
Fetal bradycardia	10 (2.42)
Pre FTND	7 (1.69)

Table 3 demonstrates a higher percentage of patients who received oxytocin had a vaginal delivery compared to those who did not receive oxytocin (81.55% vs. 4.76%). On the other hand, a higher percentage of patients who did not receive oxytocin had an LSCS delivery compared to those who did receive oxytocin (92.38% vs. 12.94%). The association between the use of oxytocin and the mode of delivery was statistically significant (p-value <0.001). Overall, this suggests that the use of oxytocin may be associated with a higher likelihood of vaginal delivery and a lower likelihood of LSCS delivery. Out of 414 patients, 20 (4.83%) had Misoprostol induction, with 19 (5.60%) of those resulting in assisted delivery, 66 (19.47%) resulting in LSCS, and 254 (74.93%) resulting in vaginal delivery.

A significant difference was reported between the mode of delivery and misoprostol.

Table 2: Pregnancy characteristics and outcome.

Pregnancy characteristics	Number of patients	Percentage
Gestational age		
≤37 weeks	337	81.40
≥37 weeks to ≤40 weeks	77	18.60
Total	414	100.00
Baby of birth weight		
≤2.5 kg	50	12.08
≥2.5 kg year to ≤3 kg	177	42.75
≥3.1 kg to ≤3.5 kg	154	37.20
>3.6 kg	33	7.97
Total	414	100.00
Gravida		
Primi	258	62.32
Multi	156	37.68
Total	414	100.00

The data are presented as the number of patients (percentage)

The results show that among patients who were ≤20 years of age, none of them had an assisted delivery, while 13 (44.83%) had LSCS and 16 (55.17%) had a vaginal delivery. Among patients aged ≥21 to ≤35 years, 20 (5.33%) had an assisted delivery, 120 (32%) had an LSCS delivery, and 235 (62.67%) had a vaginal delivery. None of the patients aged over 36 years had an assisted delivery, 4 (40%) had an LSCS delivery, and 6 (60%) had a vaginal delivery. The p-value for this analysis was 0.431, indicating that there was no statistically significant association between maternal age and mode of delivery (Table 4).

Out of the total of 414 patients, 149 (35.99%) had an induction time of fewer than 12 hours, 145 (35.02%) had an induction time of 12 to 24 hours, and 120 (28.99%) had an induction time of more than 24 hours (Table 5).

For patients with gestational age <37 weeks, the percentage of patients with a time duration of induction <12 hours was 35.31%, while for 12-24 hours and >24 hours, it was 36.79% and 27.89%, respectively. The p-value for this group was 0.272, indicating that the differences in the time duration of induction were not statistically significant. Similarly, for patients with gestational age >37 weeks to <40 weeks, the percentage of patients with time duration of induction <12 hours was 38.96%, while for 12-24 hours and >24 hours, it was 27.27% and 33.76%, respectively. The total number of patients was 414, and the percentages for each time duration of induction were 35.99%, 35.02%, and 28.98% for <12 hours, 12-24 hours, and >24 hours, respectively (Table 6).

Table 3: Comparison of variables.

	Assisted (%)	LSCS (%)	Vaginal (%)	P-value
Gestational age				
<37 weeks	17 (5.04)	114 (33.83)	206 (61.13)	
>37 weeks to <40 weeks	03 (3.89)	23 (29.88)	51 (66.23)	<0.694
Total	20 (4.83)	137 (33.09)	257 (62.08)	
Oxytocin				
No	03 (2.86)	97 (92.38)	5 (4.76)	
Yes	17 (5.51)	40 (12.94)	252 (81.55)	<0.001*
Total	20 (4.83)	137 (33.09)	257 (62.08)	
Misoprostol				
No	01 (1.33)	71 (94.67)	03 (4)	
Yes	19 (5.60)	66 (19.47)	254 (74.93)	<0.003*
Total	20 (4.83)	137 (33.09)	257 (62.08)	

The data are represented as the number of patients (percentage) with the P-value

Table 4: Age and mode of delivery comparison.

Age	Assisted (%)	LSCS (%)	Vaginal (%)	P-value
≤20 year	0 (0)	13 (44.83)	16 (55.17)	
≥21 year to ≤35 year	20 (5.33)	120 (32)	235 (62.67)	<0.431
>36 year	0 (0)	04 (40)	06 (60)	
Total	20 (4.83)	137 (33.09)	257 (62.08)	

The data are represented as the number of patients (percentage) with the P-value

Among the patients who received oxytocin, 35.27% delivered within <12 hours, 34.62% delivered within 12-24 hours, and 30.09% delivered after >12 hours of induction. In the group who did not receive oxytocin, 38.09% delivered within <12 hours, 36.19% delivered within 12-24 hours, and 25.71% delivered after >12 hours

of induction. The p-value for the association between these variables is 0.688, which indicates that there is no significant association between the time duration of induction and oxytocin administration.

Table 5: Duration of induction.

Time duration of induction	Number of patients	Percentage
<12 hours	149	35.99
12 to 24 hours	145	35.02
>24 hours	120	28.99
Total	414	100.00

The data are represented as the number of patients (percentage)

A total of 35.69% of patients who received misoprostol gave birth in <12 hours, 35.98% gave birth in between 12-24 hours, and 28.31% gave birth after >12 hours. On the other hand, the group of patients who did not receive Misoprostol had 37.33% of births within <12 hours, 30.66% within 12-24 hours, and 32% after >12 hours. The p-value was found to be 0.660, indicating no significant difference between the two groups in terms of the time duration of induction. Inductions accomplished in <12 hours were aided 34.63% of the time, LSCS 36.49% of the time, and vaginal births 50% of the time. Inductions lasting for 12-24 hours were aided 35.41% of the time, LSCS 37.22% of the time, and vaginal births 5% of the time. Inductions lasting for more than 24 hours were aided in 29.96%, LSCS in 26.27%, and vaginal births in 35%. The p-value was 0.354, clearly suggesting no significant difference in the manner of delivery depending on induction time length.

Out of the total 414 patients, 149 (36%) had an induction for <12 hours, 145 (35%) had an induction for 12-24 hours, and 120 (29%) had an induction for >24 hours. The majority of patients were primi (first-time mothers) with 258 (62%) cases, while 156 (38%) were multi (multiparous). Multi gravida (more than two pregnancies lasting for >20 weeks) patients had a higher proportion of induction for less than 12 hours (43%), compared to primi gravida patients (32%). The difference in the proportion of induction time between the two groups was statistically significant (p=0.034). However, there was no significant difference in the mode of delivery by the time duration of induction (Table 6).

Table 6: Comparison of variables based on induction.

	<12 hours (%)	12 – 24 hours (%)	>12 hours (%)	P-value
Gestational age				
<37 weeks	119 (35.31)	124 (36.79)	94 (27.89)	
>37 weeks to <40 weeks	30 (38.96)	21 (27.27)	26 (33.76)	0.272
Total	149 (35.99)	145 (35.02)	120 (28.98)	
Oxytocin				
No	40 (38.09)	38 (36.19)	27 (25.71)	
Yes	109 (35.27)	107 (34.62)	93 (30.09)	0.688
Total	149 (35.97)	145 (35.02)	120 (28.98)	
Misoprostol				
No	28 (37.33)	23 (30.66)	24 (32)	
Yes	121 (35.69)	122 (35.98)	96 (28.31)	0.660
Total	149 (35.97)	145 (35.02)	120 (28.98)	
Mode of delivery				
Assisted	89 (34.63)	91 (35.41)	77 (29.96)	
LSCS	50 (36.49)	51 (37.22)	36 (26.27)	0.354
Vaginal	10 (50)	03 (5)	07 (35)	
Total	149 (35.97)	145 (35.02)	120 (28.98)	
Gravida				
Multi	67 (42.95)	47 (30.13)	42 (26.92)	
Primi	82 (31.78)	98 (37.98)	78 (30.23)	0.034
Total	149 (35.97)	145 (35.02)	120 (28.98)	

The data are represented as the number of patients (percentage) with the P-value

The different indications for induction were compared with the duration of the induction. The p-value was determined to test the statistical significance of the association between the indication for induction and the time interval between induction and delivery. The p-value of 0.340 indicates no significant association between the indication for induction and the time interval between induction and delivery (Table 7).

The non-progress of labor was the most common complication, with 19 cases observed in less than 12 hours, 29 cases observed in 12-24 hours, and 17 cases observed in more than 24 hours. However, there was no statistically

significant difference between the three-time intervals (p=0.575). Other complications observed include birth trauma, fetal bradycardia, and meconium-stained liquor. In total, there were 60 cases of maternal complications observed in less than 12 hours, 64 cases in 12-24 hours, and 43 cases in more than 24 hours (Table 8).

Table 7: Indication of induction compared with the duration of induction.

Indication for induction	<12 hours	12 – 24 hours	>12 hours	P-value
Cephalopelvic disproportion	06	05	04	
Diabetes	07	13	15	
Fetal distress	02	05	04	
Gestational hypertension	11	21	10	
Meconium stained	03	00	02	
Non-progress of labor	74	52	56	
Oligohydramnios	11	11	07	0.340
Post cesarean	12	09	07	
Post dated	09	07	04	
Post-term	03	03	04	
Rh-negative	05	10	04	
Ruptured membrane without labor	06	09	03	
Total	149	145	120	

The data are represented as the number of patients with the P-value

Table 8: Maternal complications comparison with the duration of induction.

Maternal complication	<12 hours	12 – 24 hours	>12 hours	P-value
Non-progress of labor	19	29	17	
Arrest of descent	08	04	07	
Birth trauma	15	15	08	
Cephalopelvic disproportion	02	00	02	
Fetal bradycardia	03	03	04	0.575
Hypo thyroidism	07	06	03	
Meconium-stained liquor	05	03	00	
Pre FTND	01	04	02	
Total	60	64	43	

The data are represented as the number of patients with the P-value

DISCUSSION

Induction of labor in low-risk pregnant women has been demonstrated to benefit both the neonate and the mother, hence labor induction in this category is gaining more popularity. Our study found that a vaginal dinoprostone insert was successful in inducing labor, with a 67.6% vaginal birth rate and a 32.4% cesarean section rate. The rate of c cesarean section was greater in this study than in previous trials of labor induction in low-risk pregnant women.[13]

The main outcome of IOL is to achieve cervical ripening and successful vaginal delivery. The current study reports the beneficial use of misoprostol in pregnant women during labor. Misoprostol use reported vaginal delivery in 254 patients accounting for 74.93% of the study population and 19.47% of patients underwent LSCS after misoprostol administration. A significant difference was also reported concerning to mode of delivery and misoprostol among patients. The effective use of misoprostol was also reported by several studies with positive outcomes in 71% to 90.4% of patients for a vaginal delivery rate which was similar to our findings.[14,15] Findings from the literature have suggested that misoprostol can be used effectively for the induction of labor. The use of misoprostol reported induction of labor in 339 patients overall comprising of 81.88% of the study population. Our study also compared the use of oxytocin which revealed a significant difference between the mode of delivery and induction.

The present study also found a significant difference between parity and induction of labor where 42.95% of multiparas pregnant women gave birth in <12 hours. However, primi gravida required majorly more duration with 37.98% of pregnant women delivering between 12-24 hours and 30.23% of women requiring >12 hours respectively. Similar to our findings, Tseng et al reported that multiparas women's use of dinoprostone and misoprostol required less delivery time, followed by successful vaginal delivery.[16] Our study did not report

significant differences between mode of delivery, misoprostol use, and gestational age. This was similar to the findings of Tseng et al, who also reported no significant correlation between other variables and induction. However, our study contributes to the existing literature in terms of sample size. Our study findings are based on a total of 414 patients undergoing pregnancy whereas, Tseng et al reported similar findings in a smaller sample size (n = 65).[16] Moreover, our study is of cross-sectional nature which provides a better understanding of the use of misoprostol or dinoprostone. The current study findings revealed that the use of misoprostol for induction of labor is one of the essential criteria without major complications when tested in a larger sample size. However, there is still a need for a comparative evaluation using randomized controlled trials.

The current study reports the successful use of misoprostol for induction of labor in 81.88% of the patients suggesting the effective use of prostaglandins vaginal delivery for better patient outcomes and preventing maternal complications. Several studies have favoured the use of PGE1 and few recommend the combination of drugs with either PGE2 or single use of mechanical or pharmacological therapy.[17] Non-progress of labor was also seen in our study comprising of 15.70% of patients, birth trauma (9.18%), and arrest of descent (4.59%) of patients.

The fetal results in our study appeared to be pretty satisfactory, suggesting that the use of dinoprostone slow-released vaginal insert for IOL can be feasible and safe for women in terms of pregnancy, regardless of which indications are used.

CONCLUSION

The use of PGE1 or PGE2 vaginal inserts can be beneficial in improving pregnancy outcomes and reducing the overall maternal complications by providing faster induction of labor without major side effects. For nulliparas women there is a need to conduct further studies concerning to various comorbid conditions and diseases.

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