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Comparison of efficacy and safety of the Dinoprostone Vaginal tape and Dinoprostone vaginal tablet for the induction of labor in para three and more women: A retrospective cohort Study

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Abstract

***Background*:** Prostaglandins have a central role in the cervical ripening and parturition, and have been widely used for induction of labor (IOL). This study aimed to compare the effectiveness and safety of Dinoprostone vaginal tape (Propess) over Dinoprostone vaginal tablets (Prostin) for IOL and find which has better outcome to be applied in clinical practice. ***Participants and Methods*:** A retrospective cohort study was conducted via reviewing of medical records of multipara women admitted to King Fahad Medical City, Riyadh between January-2021 and December-2022 for IOL by Propess or Prostin. ***Results*:** A total of 87 multipara women were included in the study; 39 (44.8%) were treated by Propess and 48 (55.2%) were treated by Prostin for IOL. Full dilatation of the cervix after induction of labour was reported among majority of women (94.2%): being 92.1% among women treated with Propess and 95.8% among those treated with Prostin, however, this difference was not statistically significant, p>0.05. Regarding mode of delivery, normal spontaneous vaginal delivery was reported among 84.9% of women; 86.8% among women treated with Propess and 83.3% among those treated with Prostin while emergency cesarean section delivery was reported among 10.5% of women; 7.9% among women treated with Propess and 12.5% among those treated with Prostin. However, these differences were not statistically significant, p>0.05. ***Conclusion*:** The success rate of IOL among multipara women was high; however, no difference was reported between Propess and Prostin as regards the effectiveness (maximum cervical dilatation) and safety (rate of emergency cesarean section).

Keywords: Propess, Prostin, Induction of labour, Muliparaous women, Efficacy, Safety.

INTRODUCTION

The aim of induction of labor is to initiate labor when maternal and fetal conditions necessitate delivery before the onset of spontaneous contractions [1]. The success of this obstetric practice is highly dependent upon the condition of the cervix, and it is well known that an unfavorable cervix is associated with failure of induction, operative vaginal delivery and cesarean section [1].

Prostaglandins have a central role in the physiological events of cervical ripening and parturition, and have been widely used for induction of labor [2]. These can be administered orally, vaginally, intracervically, endovenously and by extra- amniotic or intra-amniotic routes [3]. Dinoprostone is one of the synthetic prostaglandins most commonly used to achieve cervical ripening and labor induction, and can be administered as tablets, suppositories, gel (vaginal and intracervical) or as a controlled-release intravaginal pessary [3].

Epidemiological studies have shown that, after 41 weeks, the rate of fetal, maternal and neonatal complications increases [2]. Therefore, the management of post term pregnancies remains one of the most

common obstetric problems in practice. In order to prevent post- term and associated complications, routine induction before 42 weeks has been proposed [3].

The ideal method to induce labor should be safe, painless, inexpensive, comfortable and effective. However, such a perfect method does not currently exist [4]. Most of the available methods for induction of labor imitate the physiological sequence of effacement and dilation of the cervix, followed by contraction of the uterus, however, most of these methods achieve only part of the natural progression to labor and delivery [5].

Cervical ripening and the administration of oxytocin, misoprostol and dinoprostone are the most frequently used methods for labor induction [6]. Cervical ripening is a complex process that results in physical softening and distensibility of the cervix, ultimately leading to partial cervical effacement and dilatation [6].

Dinoprostone is a synthetic analogue of prostaglandin E2 (PGE2). It is commercially available in three forms a gel, a time- release vaginal insert, and a 20-mg suppository [7].

A 10-mg dinoprostone vaginal insert—Cervidil—also is approved for cervical ripening. This is a thin, flat, rectangular polymeric water held within a small, white, mesh polyester sac. The sac has a long attached tail to allow easy removal from the vagina. The insert provides slow release of medication—0.3 mg/hr. Cervidil is used as a single dose placed transversely in the posterior vaginal fornix. Lubricant is used sparingly, if at all, because it can coat the device and hinder dinoprostone release. Following insertion, the woman remains recumbent for at least 2 hours. The insert is removed after 12 hours or with labor onset and at least 30 minutes before the administration of oxytocin [6].

Prostin E2 Vaginal Tablets, each tablet contains 3 mg dinoprostone. It is a white, biconvex, oblong tablet, embossed with Upjohn 715 on one side and plain on the other. One tablet has to be inserted high into the posterior fornix. A second tablet may be inserted after six to eight hours if labour is not established. Maximum dose 6 mg [8].

Rationale of the Study

There is no study was done on multipara women to prove the efficacy and safety of Dinoprostone vaginal tape over Dinoprostone vaginal tablet.

Study Objective

To compare the effectiveness and safety of Dinoprostone vaginal tape over Dinoprostone vaginal tablets for induction of labor in multipara women and find which has better outcome to be applied in clinical practice.

PATIENTS AND METHODS

Study Design

A retrospective cohort study was conducted via reviewing of medical records of women admitted to King Fahad Medical City, Riyadh, Saudi Arabia between January 2021 to December 2022 for induction of labor.

Study Area and Setting

The study was conducted at Obstetrics and Gynecology department, King Fahad Medical City, Riyadh, Saudi Arabia

Target Population and Sampling

The study population was identified from the hospital clinical database and included all women induced by Dinoprostone vaginal tape and Dinoprostone vaginal tablet at King Fahad medical city, Riyadh, Saudi Arabia from January 2021 to December 2022.

Inclusion Criteria

- Para 3 and more
- Healthy fetuses
- Gestational age of >37weeks
- Bishop score < 6
- Single tone pregnancy
- Cephalic presentation

Exclusion Criteria

- Para 2 and less
- Gestational age of <37 weeks of gestation
- Fetuses with anomalies
- Previous 1 cesarean section
- Previous uterine surgery
- Multiple gestations
- Breech presentation
- Rupture of membrane before induction of labor
- Used of two forms of Dinoprostone in the first 24 hours of the induction course
- Any contraindications for vaginal delivery

Data Collection Method and Technique

Data were collected in a specific checklist from the database of patient who were admitted at King Fahad medical city and underwent induction of labor with Dinoprostone Vaginal tape and Dinoprostone vaginal Tablet from January 2021 to December 2022. Checklist included data regarding:

- Woman`s age (years)
- Gestational age (weeks)
- Obstetric history (Gravidity, parity and abortion)
- Maximum cervical dilatation in cm
- Induction of labour (Dinoprostone Vaginal tape, Dinoprostone vaginal tablet)
- Mode of delivery (Normal spontaneous vaginal, Ventous, Cesarean section “CS”)

Data Presentation & Analysis

Data were presented and analyzed using descriptive and analytic statistics methods by the aid of Statistical Package for Social Sciences (SPSS) program version 28. Categorical variables were described by frequency and percentage whereas continuous variables were described by arithmetic mean, median, range, interquartile range (IQR) and standard deviation (SD), depending on distribution of the variables. Bivariate analysis was done using chi-square test, independent two-sample t-test or Mann-Whitney test; depending on the variables` distribution. Statistical significance was determined at p-value<0.05.

Budget: All costs of this study were self-funded by the researcher.

Ethical Consideration

1. Ethical approval from Local Research and Ethical committee at King Fahad Medical city, Riyadh, Kingdom of Saudi Arabia was taken.
2. Administrative approval was taken from director of program of Obstetrics and Gynecology, Riyadh requesting her approval to conduct the study.
3. Assuring data confidentiality and, data collected from medical records were only used for scientific purposes.

RESULTS

A total of 87 multipara women were included in the study; 39 (44.8%) were treated by Dinoprostone Vaginal tape (Propess) and 48 (55.2%) were treated by Dinoprostone vaginal tablet (Prostin) for induction of labour. Their mean±SD age and BMI were 35.6±4 years and 31.3±6.1 Kg/m^2, respectively with no statistically significant difference between the compared groups. Their gestational age was slightly significantly higher in group of women treated with Prostin than those treated with Propess (38.9±1.3 vs. 38.2±1.9), p=0.048. Concerning reasons for induction of labour, the most frequently reported one was postdate (24.7%), followed by gestational diabetes mellitus/uncontrolled diabetes (18.8%), with no significant difference between he compared two groups. Their median (IQR) of gravidity and parity were 6 (4-7) and 4 (3-5). And the rate of abortion was 37.9%; without significant difference between the two groups. Table 1

Full dilatation of the cervix after induction of labour was reported among majority of women (94.2%): being 92.1% among women treated with Propess and 95.8% among those treated with Prostin, however, this difference was not statistically significant, p>0.05. Table 2.

Regarding mode of delivery, normal spontaneous vaginal delivery was reported among 84.9% of women; 86.8% among women treated with Propess and 83.3% among those treated with Prostin while emergency cesarean section delivery was reported among 10.5% of women; 7.9% among women treated with Propess and 12.5% among those treated with Prostin. However, these differences were not statistically significant, p>0.05. Table 3 Number of Prostin doses was not significantly associated with maximum dilatation of the cervix and mode of delivery as seen in Table 4.

Table 1: Comparison of efficacy of demographic and beeline characteristics of para three and more women treated with Dinoprostone Vaginal tape (Propess) or Dinoprostone vaginal tablet (Prostin) for the induction of labor

Variables	Propess N=39	Prostin N=48	Total N=87	P-value
Age in years Mean±SD	36.1±4.2	35.2±3.9	35.6±4.0	0.317*
Body mass index (Kg/m^2) Mean±SD	31.2±7.2	31.4±5.2	31.3±6.1	0.922*
Gestational age in weeks Mean±SD	38.2±1.9	38.9±1.3	38.6±1.6	0.048*
Indications for induction, n (%)	N=38	N=47	N=85	
Postdate	9 (23.7)	12 (25.5)	21 (24.7)	
Deep vein thrombosis	5 (13.2)	1 (2.1)	6 (7.1)	
GDM/uncontrolled diabetes	5 (13.2)	11 (23.4)	16 (18.8)	
Advanced maternal age	2 (5.3)	4 (8.5)	6 (7.1)	
Decrease fetal movement	5 (13.2)	2 (4.3)	7 (8.2)	
HTN/PIH	1 (2.6)	1 (2.1)	2 (2.4)	
History of IUFD	3 (7.9)	3 (6.4)	6 (7.1)	
SLE/Rheumatoid arthritis	3 (7.9)	1 (2.1)	4 (4.7)	
Pre=eclampsis	0 (0.0)	5 (10.6)	5 (5.9)	
Epilepsy	1 (2.6)	1 (2.1)	2 (2.4)	
ITP	0 (0.0)	3 (6.4)	3 (3.5)	
Cholestasis of pregnancy	0 (0.0)	2 (4.3)	2 (2.4)	

Others	4 (10.5)	1 (2.1)	5 (5.9)	0.080ᶞ
Gravidity, Median (IQR)	6 (6-7	5 (4-7)	6 (4-7)	0.266**
Parity, Median (IQR)	4 (3-5)	4 (3-4)	4 (3-5)	0.075**
Abortion, n (%)				
No	24 (61.5)	30 (62.5)	54 (62.1)	
Yes	15 (38.5)	18 (37.5)	33 (37.9)	0.927ᶞ

SD: Standard deviation
HTN: Hypertension
IUFD: Intrauterine fetal death
ITO: Idiopathic thrombocytopenic purpura
IQR: Interquartile range
*Independent two samples t-test
GDM: Gestational diabetes mellitus
PIH: Pregnancy induced hypertension
SLE: Systemic lupus erythrematosis
ᶞChi-square test
**Mann-Whitney test

Table 2: Comparison of efficacy (maximum cervical dilatation) between Dinoprostone Vaginal tape (Propess) and Dinoprostone vaginal tablet (Prostin) in para three and more women

Maximum cervical dilatation (cm)	Propess N=38	Prostin N=48	Total N=86	P-value*
2	1 (2.6)	1 (2.1)	2 (2.3)	
3	2 (5.3)	0 (0.0)	2 (2.3)	
4	0 (0.0)	1 (2.1)	1 (1.2)	
5 (fully)	35 (92.1)	46 (95.8)	81 (94.2)	0.337

*Chi-square test

Table 3: Comparison of safety (mode of delivery) between Dinoprostone Vaginal tape (Propess) and Dinoprostone vaginal tablet (Prostin) in para three and more women

Mode of delivery	Propess N=38	Prostin N=48	Total N=86	P-value*
Normal spontaneous vaginal	33 (86.8)	40 (83.3)	73 (84.9)	
Ventous	2 (5.3)	2 (4.2)	4 (4.7)	
Emergency cesarean section	3 (7.9)	6 (12.5)	9 (10.5)	0.773

*Chi-square test

Table 4: Association between number of Dinoprostone vaginal tablet (prostin) doses and its efficacy and safety in para three and more women

	Number of Prostin doses				P-value*
	One N=35 N (%)	Two N=8 N (%)	Three N=4 N (%)	Four N=1 N (%)	
Maximum cervical dilatation (cm)					
2	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	
4	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	
Five "Fully"	34 (94.1)	7 (87.5)	4 (100)	1 (100)	0.488
Mode of delivery					
Normal spontaneous vaginal	28 (80.0)	7 (87.5)	4 (100)	1 (100)	
Ventous	2 (5.7)	0 (0.0)	0 (0.0)	0 (0.0)	
Emergency cesarean section	5 (14.3)	1 (12.5)	0 (0.0)	0 (0.0)	0.946

*Chi-square test

List of Abbreviations

Abbreviation	Description
PGE2	Prostaglandin E2
CS	Cesarean section
SD	Standard deviation
IOL	Induction of labour
IQR	Interquartile range
SPSS	Statistical Package for Social Sciences

DISCUSSION

This study found no difference between Propess and Prostin in multipara women as regards the effectiveness (maximum cervical dilatation) and safety (rate of emergency cesarean section. Another similar study carried out among primipara reported comparable rates of cesarean deliveries in groups of women treated with either Propess or Prostine [9].

Although, not significant, the rate of spontaneous normal vaginal delivery was slightly higher in group of women treated with Propess for induction of labour than those treated with Prostine. Others reported the same in primipara women in Taiwan [9].

The success rates reported in this study were relatively high; being 86.8% with propess and 83.3% with prostin. However, relatively higher success rates were reported in another study conducted among primipara women; being 96.7% with Propess and 90% with Prostin.[9] Most of previous studies reported success rates ranged between 71% and 90.4% [10- 17].

Concerning the efficacy, fully cervical dilation was observed among 95.8% of women treated with Prostin compared to 92.1% among those treated with Propess, with no significant difference. In a study conducted among paipara women, the efficacy of Propess was better than that of Prostin in induction of labour [9].

A review study documented that Propess has an advantage over Prostin in induction of labout as it provides a sustained, steady, and controlled release of prostaglandins [18], while Prostin offers unpredictable and irregular release of prostaglandines as doses has often to be repeated every 4- 6 hours, especially [19].

A previous study included 33 women with controlled-release dinoprostone in a dose of 10 mg showed that the CS rate was 12% and vaginal delivery within 24 hours rate was 51.6%, with a medium time to delivery of 17.5 hours in primipara women [20], while another study documented that Propess was used for induction of labour in full-term pregnant women and 81.5% of them achieved successful vaginal delivery, with multiparity was the only significant predictor of successful vaginal delivery [21].

Up to our knowledge, this study is the first of its kind in Saudi Arabia to to compare the effectiveness and safety of proprss and prostine in IOL among multipara women. However, some limitations should be mentioned. First of all, the study was carried out in only one healthcare facility which affects the ability to generalize the results over population in other healthcare facilities. Second, its design as a retrospective cohort study depending for getting information on the accuracy of medical records is considered another limitation of the study. Finally, our results might be underpowered to detect a significant associations, because the relatively small sample size. Therefore, caution is warranted in interpreting our results.

CONCLUSION

In conclusion, the success rate of induction of labour among multipara women was high; however, no difference was reported between Propess and Prostin as regards the effectiveness (maximum cervical dilatation) and safety (rate of emergency cesarean section.

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