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Effectiveness and outcome of Dinoprostone (Propess®) for cervical ripping: A retrospective study

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Abstract

Background: There are different pharmacological and mechanical types of cervical dilators have been approved to ripen unfavorable cervix. The dinoprostone slow release Prostaglandin E2 (PGE2) (Propess®) is available as vaginal pessary for cervical ripening, which releases 10 mg of dinoprostone over 24 hours. The effect of PGE2 has been investigated and there are many studies in the literature comparing the efficacy of the different formulations available in the market. In our study, we evaluated PGE2 slow release on ripping cervix on different patient varieties and we evaluated the maternal outcome secondary to induction of labor by (Propess®).

Material and methods: This retrospective Cohort study included 187 patients whom were induced for labor at term with intact amniotic membrane from first of January till 31 December 2018. The induction was by (Propess®).

Result: *The* Propess® *was effective on ripping cervix within 24 hours with high* response rate 77.9% on Para (P) ≤2. *The* Propess® *was effective on cervical* ripping in *71% of normal body* mass index (BMI) *and show less response on high BMI. No increased risk of caesarean section on* patients with *different amniotic fluid index*. The vaginal *delivery* rate was 81.1% of the normal amniotic fluid index, 88.2% of oligohydramnios *patients*. We had 82.1%*of intrauterine fetal growth restriction patients achieved vaginal delivery.*

Conclusion: *The* Propess® is an effective method for cervical ripening, but less effective on high parity and high body mass index. No increase of fetal distress and caesarean section on oligohydramnios or intrauterine growth restriction in compare to normal fetus.

Introduction

Induction of labor has become more common worldwide medical intervention during the last years [1]. Between 1990 and 2012, the overall number of labor induction more than doubled in the United States, increasing from 9.5 in 1990 to a 23.8 percent in 2010, before it is decreasing to 23.3 % in 2012 [2]. Induction of labor before it became spontaneous is indicated when the maternal/fetal risks increasing with continuing of the pregnancy while it will be decrease by the termination of pregnancy and delivery [3]. There are different pharmacological and mechanical types of cervical dilators have been approved to ripen unfavorable cervix [4]. Prostaglandins are the most medical substance that affect in cervical ripening by increasing inflammatory mediators in the cervix and inducing cervical changes. Prostaglandin E1 (PGE1) and prostaglandin E2 (PGE2) have different effects on these processes and on myometrium contractility [5]. The PGE2 (Propess®) is available as vaginal pessary for cervical ripening, which releases 10 mg of dinoprostone over 24 hours. The effect of PGE2 has been investigated and there are many studies in the literature comparing the efficacy of the different formulations available in the market [6]. In Saudi Arabia , there was a study conducted on 2018 including a 217 women, 109 were assigned to dinoprostone vaginal tablets and 108 were assigned to dinoprostone vaginal pessary and it showed no significant differences between both preparation of dinoprostone [7]. The effect of parity on dinoprostone slow release for ripening the cervix was studied in 2015 in turkey, dinoprostone is more effective agent for induction of labor in patients with low parity (≤ 2) [8]. In literature, there are many studies for the different forms and preparations of dinoprostone and their effect to achieve cervical ripping and labor have been published [6]. We need more studies focusing on our population's in Saudi Arabia and to find if the parity and body mass index are playing a role in dinoprostone efficacy on cervical ripping or not. In our study, we evaluated PGE2 slow release on ripping cervix on different patient parities and evaluated the maternal outcome secondary to induction of labor by dinoprostone slow release.

Material and methods

Study period and population

A retrospective cohort study conducted at King Faisal Specialist Hospital and Research Centre (KFSHRC) city of Riyadh, Kingdom of Saudi Arabia. Ethical board review approval was obtained. Our population included all patients whom admitted for induction of labor at term and postdate over a period of 1 year from 1st of January till 31 December 2018. Induction of labor by prostaglandin E2 (Propess®) inserted in the posterior fornix of the vagina with normal saline.

Data collection

The Data collected from labor and delivery registry for all deliveries who had induction of labor from electronic chart of the patients. Data was collected by primary investigator and entered on excel sheets in encrypted format.

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Inclusion Criteria

- Gestational age 37 weeks or more.
- Singleton pregnancy.
- Cephalic presentation.
- Intact amniotic membrane.
- No amniotic membrane sweeping.
- Reassuring non-stress test.
- Unfavorable cervix (Bishop score ≤ 4).

Excluding criteria

- Preterm
- Multiple gestation
- Rupture membrane
- Previous failed induction in current pregnancy.
- Favorable cervix.

Patients characteristics:

In each patient we identified the maternal age, booking BMI, parity, gestational age (term or postdate), fetal growth (normal, Intrauterine growth restriction or macrocosmic), amniotic fluid level (normal, oligohydramnios or polyhydramnios), if the (Propess®) felt down before 24 hours, hyperstimulation, ripping the cervix within 24 hours or not, need augmentation by oxytocin, need second course of (Propess®), need for prostin gel , mode of delivery (vaginal delivery , cesarean section (CS) for fetal distress or failure to progress and if Postpartum haemorrhage developed after delivery.

Ethical consideration

Our patients identified by medical records database ICIS system®. The data collected are the results of routine medical practice for patient workup.

Results

A total of 191 patients identified, we excluded 4 patients due to incomplete informations. The initial data analysis start on different parity and outcome, for fall out (Propess®) was 8.5 % in para (P)0, 5.6% on P≤2 and more on group P≥3 around 11.67%. The (Propess®) was effective on ripping cervix within 24 hours 51.67% on P0, 77.94% on P≤2 and 59.32% on P≥3.The hyper stimulation of uterine contraction was 10% on P0 07.35%on P≤2 and 8.47% on P≥3.The need for oxytocin for augmentation the labor after ripping by (Propess®) was 33.3% on P0, 32.35% on P≤2 and 33.90% on P≥3. Some of the patient who had failure to reach cervical ripping by (Propess®) had another medical product for cervical ripping (prostin) was 10% on P0, 07.35% on P≤2 and 8.47% on P≥3. Some of the patients had second course of (Propess®) for cervical ripping were 13.3% on P0, 05. 88% on P≤2 and 23.73% on P≥3. In regards of mode of delivery, vaginal delivery rate was 66.7% on P0, 89.6% on P≤2 and 86.4% on P≥3 (Table 1). The secondary data analysis were comparing the (Propess®) out come on different patient's body mass index. The (Propess®) were falling out in 3.23% on normal body mass index, 10% of overweight patients and 9.4% of obese patients. The (Propess®) was effective on cervical ripening in 70.97% of normal body mass index, 56% of overweight patients and 65% of obese patients. The rate of hyper stimulation were 19.35% of normal body mass index, 10% of overweight patients and 4.72% of obese patients. The need for augmentation of labor by intravenous oxytocin were 29.03% of normal body mass index, 26% of overweight patients and 37.74% of obese patients. The need for second course of induction by another medication (prostin) were 6.45% of normal body mass index, 8% of overweight patient and 8.57% of obese patients. The need for second (Propess®) for induction were 9.68% of normal body mass index, 20% of overweight patients and 13.21% of obese patients (Table 2). The vaginal deliveries were rate 80.7% of normal body mass index, 80.65% of overweight patients and 76% of obese patients (Table 2).

We assessed vaginal delivery rate in different fetal estimated weight, the rate was 82.05% of intrauterine growth restriction, 75% of macrocosmic fetuses and 81.43% of normal weight fetuses (Table 3). Also, we assessed the mode of delivery on different amniotic fluid

Table 1. Effectiveness of (Propess®) and its outcome on different patient's parities

		P0 Number Percent	**P≤2** Number Percent	**P≥3** Number Percent
Fall out	No	54 (91.53%)	64 (94.12%)	53 (88.33%)
	Yes	05 (8.47%)	04 (5.88%)	07 (11.67%)
Ripening within 24 hours	No	29 (48.33%)	15 (22.06%)	24 (40.68%)
	Yes	31 (51.67%)	53 (77.94%)	35 (59.32%)
Hyperstimulation	No	54 (90.00%)	63 (92.65%)	54 (91.53%)
	Yes	10 (10.00%	05 (07.35%)	05 (8.47%)
Need for Oxytocin	No	40 (66.67%)	46 (67.65%)	39 (66.10%)
	Yes	20 (33.33%)	22 (32.35%)	20 (33.90%)
Need for Prostin	No	54 (90.00%)	63 (92.65%)	54 (91.53%)
	Yes	06 (10.00%)	05 (07.35%)	05 (8.47%)
Need for 2nd Propess	No	52 (86.67%)	64 (94.12%)	45 (76.27%)
	Yes	08 (13.33%)	04 (05.88%)	14 (23.73%)
Mode of Delivery	CS for failure to progress	03 (5.00%)	03 (4.41%)	00 (0.00%)
	CS for fetal distress	17 (28.33%)	04 (5.88%)	08 (13.56%)
	vaginal deliveries	40 (66.67%)	61 (89.70%)	51 (86.44%)
Total		60 (32.09%	68 (36.36%)	59 (33.15%)
		187 (100%)		

index, the vaginal delivery around 81.21% of the normal amniotic fluid index, 88.24% of oligohydramnios patient and 60% of polyhydramnios patients (Table 4). Post-partum hemorrhage developed in 05.26% of the total patient who's induced by (Propess®) (Table 5).

Discussion

In the period of this study, the (Propess®) was the major method for induction of labor as the other medical method (prostaglandin gel E2) was almost out of stock. The fall out of (Propess) was higher in patients with high parity (P≥ 3) and high body mass index. There was no difference in augmentation rate by oxytocin in different parities but the increase in obese patient may be explained that the higher body mass index need more oxytocin to achiev adequate contractions. The *P≤2* patients group had higher response to (Propess®) in cervical ripping, less need to second course of induction of labor and more achieved vaginal delivery may be due previous cervical dilatation on previous delivery as previous studies. The hyper stimulation rate seen more in normal body mass index may be due to high dose related to body mass index. This study shows no increase of cesarean section rate due to fetal distress in patients with oligohydramnios compare to normal amniotic fluid index. In regards to patients with intrauterine growth restriction and normal estimated fetal weight, there were no difference in the rate

Table 2. Effectiveness of (Propess®) and its outcome on patients with different body mass index

		Normal Number Percent	**Obese** Number Percent	**over weight** Number Percent
Fall Out	No	30 (96.77%)	96 (90.56%)	45 (90%)
	Yes	01 (3.23%)	10 (9.44%)	05 (10%)
Ripening within 24 hours	No	09 (29.03%)	37 (34.90%)	22 44. 00%
	Yes	22 (70.97%)	69 (65.10%)	28 (56%)
Hyperstimulation	No	25 (80.65%)	101 (95.28%)	45 (90.00%)
	Yes	06 (19.35%)	05 (4.72%)	05(10.00%)
Need for Oxytocin	No	22 (70.97%)	66 (62.26%)	37 (74.00%)
	Yes	09 (29.03%)	40 (37.74%)	13 (26.00%)
Need for Prostin	No	29 (93.55%)	97 (91.51%)	46 (92.00%)
	Yes	02 (6.45%)	09 (8.57%)	04 (8.00%)
Need for 2nd Propess	No	28 (90.32%)	92 (86.79%)	40 (80.00%)
	Yes	03 (09.68%)	14 (13.21%)	10 (20.00%)
Mode of Delivery	CS for failure to progress	01 (03.23%)	03 (2.83%)	02 (4.00%)
	CS for fetal distress	05 (16.13%)	13 (12.26%)	10 (20.00%)
	vaginal delivery	25 (80.65%)	90 (84.90%)	38 (76.00%)
Total		31 (16.58%)	106 (56.68%)	50 (28.09%)
		187 (100%)		

Table 3. (Propess®) effect on mode of delivery on patient with different estimated fetal weight.

Growth	**IUGR** **Number** **Percent**	**Large size** **Number** **Percent**	**Normal** **Number** **Percent**
CS for failure to progress	01 (02.56%)	01 (12.50)	04 (2.86%)
CS for fetal distress	06 (15.38%)	01 (12.50%)	22 (15.71%)
Vaginal delivery	32 (82.05%)	06 (75.00%)	114 (81.43%)
Total	39 (20.86%)	08.00 (04.28%)	140 (74.87%)
	187 (100%)		

Table 4. (Propess®) on mode of delivery on different fetal amniotic fluid level

Amniotic Fluid level	**Normal** Number Percent	**Oligohydramnios** Number Percent	**Polyhydramnios** Number Percent
CS for faliure to progress	05 (03.03%)	00 (00.00%)	01 (20.00%)
CS for fetal distress	26 (15.76%)	02.00 (11.76%)	01 (20.00%)
vaginal deliver	134 (81.21%)	15 (88.24%)	03 (60.00%)
Total	165 (88.23%)	17 (09.55%)	5 (2.81%)
	187 (100%)		

Table 5. (Propess®) effect on maternal complication (PPH)

	Post-Partum Hemorrhage	**No Post-Partum Hemorrhage**
CS deliveries Number (Percent)	00.00 (00.00%)	35.00(18.71%)
vaginal delivery Number (Percent)	08 (4.28%)	144 (77%)
Total	08 (4.28%)	179 (95.72%)
	187 (100%)	

of fetal distress and cesarean section rate. Therefore, it is considered a safe method for induction of labor on those high risk patients.

Conclusion

(Propess®) is an effective method for cervical ripening especially in P≤2, but less effective on high parity and high body mass index patients. The nulliparous need second course of induction of labor more than the P≤*2*. There is no difference for the requirement of intravenous syntocinon for augmentation of labor in different parities but more require in obese patients. No increase of fetal distress and cesarean section rate on the patients with oligohydramnios or intrauterine growth restriction in compare to normal fetus.

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