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Propess versus Prostin E2 for cervical ripening and induction of labour

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Objectives: To compare the efficacy and safety of Propess and Prostin E2 for induction of labour (IOL) in women with an unfavourable cervix.
Methods: Medical records of women who had a singleton pregnancy at ≥37 weeks' gestation with cephalic presentation and had undergone IOL using Prostin E2 (between January and December 2017) or Propess (between April 2018 and March 2019) were retrospectively reviewed. The primary outcome was the duration from IOL to delivery. Secondary outcomes included delivery within 24 hours of IOL, mode of delivery, additional use of Prostin E2 or Propess, oxytocin use, failed IOL, maternal complications, and neonatal outcomes.
Results: In total, 471 women who received Prostin E2 (n=245) or Propess (n=226) were included in the analysis. Compared with the Prostin E2 group, the Propess group had a shorter IOL-to-delivery interval (1686 vs 2073 minutes, p=0.02), particularly among multiparous women (1078 vs 1568 minutes, p=0.009). Additionally, the Propess group had a higher rate of delivery within 24 hours of IOL overall (51.3% vs 37.6%, p=0.003), as well as among nulliparous (42.0% vs 29.7%, p=0.017) and multiparous (77.2% vs 56.2%, p<0.001) women. However, the Propess group had a higher rate of failed IOL overall (11.1% vs 5.7%, p=0.035), particularly among nulliparous women (14.2% vs 7.0%, p=0.003). Notably, the rate of failed IOL among multiparous women was lower in the Propess group (1.8% vs 2.7%, p<0.001). The Propess group had a higher rate of uterine hyperstimulation overall (23.5% vs 7.8%, p<0.001) and in both nulliparous (23.7% vs 5.8%, p<0.001) and multiparous (22.8% vs 12.3%, p<0.001) women. However, there was no significant increase in the incidence of non-reassuring fetal heart rate requiring Caesarean delivery. The Propess group even had lower rates of Caesarean section among multiparous women (7.0% vs 13.7%, p<0.001) and neonatal intensive care unit admission (0.9% vs 4.9%, p=0.01).
Conclusion: Propess appears to be a safe and effective alternative to Prostin E2 for IOL in women with an unfavourable cervix and intact membranes. Its use was associated with a shorter IOL-to-delivery interval and a higher rate of vaginal delivery within 24 hours of IOL. Although Propess was associated with a higher incidence of uterine hyperstimulation, there was no significant increase in the incidence of non-reassuring fetal heart rate requiring Caesarean delivery or neonatal morbidity.

Keywords: Delivery, obstetric; Dinoprostone; Labor, induced

Introduction

Induction of labour (IOL) is performed to stimulate uterine contractions to achieve vaginal delivery. According to a territory-wide audit conducted in 2014 by the Hong Kong College of Obstetricians and Gynaecologists, 23.4% of parturient women required IOL[1]. Common indications include prelabour rupture of membranes (36.8%), social reasons (21.6%), post-term pregnancy (14.4%), gestational diabetes (9.3%), and hypertensive disorders (4.6%). Decisions should be based on both maternal and fetal well-being; careful monitoring is required to detect potential risks such as uterine hyperstimulation.

Dinoprostone, also known as prostaglandin E2, stimulates the myometrium to produce uterine contractions and softens the cervix, facilitating cervical dilatation and effacement. Preparations of dinoprostone include vaginal suppository (Prostin E2), vaginal insert (Propess), and cervical gel (Prepidil). Prostin E2 is designed to dissolve and release 3 mg of dinoprostone over several hours and can be repeated to achieve delivery. Propess provides controlled release of dinoprostone over 24 hours at a rate of 0.3 mg/h; it requires only a single application, thus reducing the number of vaginal examinations, invasiveness, and patient discomfort. The vaginal insert can be removed to terminate its effect if uterine hyperstimulation or tachysystole occurs. Patient acceptability is higher for the vaginal insert than for the vaginal suppository[2].

Uterine hyperstimulation includes uterine tachysystole (≥5 contractions in 10 minutes for at least 20 minutes) and uterine hypertonia (≥1 contraction lasting

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>2 minutes). It may be associated with fetal heart rate abnormalities that can lead to fetal hypoxia, including deceleration, tachycardia, and decreased fetal heart rate variability, requiring emergency Caesarean section. Other complications include failed IOL and uterine scar rupture.

The National Institute for Health and Care Excellence recommends further research into the effects of different dinoprostone preparations on outcomes and cost-effectiveness[3,4]. Findings remain inconsistent. The vaginal insert is reportedly associated with longer intervals to vaginal delivery and lower rates of active labour[5], as well as higher rates of vaginal delivery and reduced oxytocin use[6], compared with other preparations. However, another study showed no clinically significant differences between the vaginal insert and alternatives[7]. These contrasting findings may reflect heterogeneity in indications, parity, pre-induction cervical status, primary outcomes, and administration regimens. Therefore, we aimed to compare the efficacy and safety of Propess and Prostin E2 for IOL in women with an unfavourable cervix.

Methods

In March 2018, our hospital replaced Prostin E2 with Propess for cervical ripening and IOL. Medical records of women who had a singleton pregnancy at ≥37 weeks' gestation with cephalic presentation and had undergone IOL using Prostin E2 (between January and December 2017) or Propess (between April 2018 and March 2019) were retrospectively reviewed. Women were excluded if they were at <37 weeks of gestation, had multiple pregnancies, a uterine scar, rupture of membranes, contraindications to vaginal delivery, evidence of spontaneous labour, or Bishop score ≥6.

Prostin E2, containing 3 mg of dinoprostone, was administered to the posterior vaginal fornix. If cervical ripening (Bishop score ≥6) or rupture of membranes occurred, no further Prostin E2 was administered, regardless of cervical status. If the cervix remained unfavourable (Bishop score ≤5), a second dose was inserted after 24 hours. If labour was not induced on the first or second day, the procedure was repeated on the third day. In the presence of painful uterine contractions, Prostin E2 administration was delayed until contractions subsided. If uterine hyperstimulation or non-reassuring fetal heart rate occurred, Prostin E2 was removed.

Propess, a 10 mg dinoprostone controlled-release pessary, was administered to the posterior vaginal fornix. If cervical ripening or rupture of membranes occurred, no further Propess was administered. However, if the cervix remained unfavourable after 24 hours, a second dose of Propess was inserted. Propess was removed in the presence of uterine tachysystole, uterine hypertonus, uterine hyperstimulation, successful cervical ripening, or rupture of membranes; it was also removed 24 hours after insertion. Although there is no consensus regarding a second dose[8], our departmental protocol considers it justified, given the aim of increasing vaginal delivery rates and decreasing Caesarean section rates, with subsequent reductions in neonatal and maternal morbidity.

Fetal heart rate was monitored using cardiotocography before administration, 2 hours after administration, and at the onset of contractions. If successful cervical ripening occurred, oxytocin infusion could be initiated approximately 30 minutes after removal of Prostin E2 or Propess.

The primary outcome was the duration from IOL to delivery. Secondary outcomes included delivery within 24 hours of IOL, mode of delivery (normal vaginal delivery, operative delivery, and Caesarean section), additional use of Prostin E2 or Propess, oxytocin use, failed IOL (failure to reach the active phase of labour, defined as cervical dilatation ≥3 cm in the presence of regular uterine contractions after ≥12 hours of oxytocin use with artificial rupture of membranes), maternal complications (uterine hyperstimulation, primary postpartum haemorrhage, and uterine rupture), and neonatal well-being (admission to the neonatal intensive care unit and Apgar score at 5 minutes).

The mean number of deliveries in our unit was approximately 3000 per year between 2016 and 2018. Assuming a 5% confidence limit, 80% power, and a 20% IOL rate, 176 women were required in each arm[9]. Statistical analysis was performed using SPSS (version 26.0; IBM, Chicago [IL], United States). The two groups were compared using Student's *t* test for normally distributed continuous variables, the Mann-Whitney *U* test for skewed data, and the Chi-squared test or Fisher's exact test for dichotomous variables. A p value of <0.05 was considered statistically significant.

Results

In total, 471 women who received Prostin E2 (n=245) or Propess (n=226) were included in the analysis (Table 1). Of the 245 women who received Prostin E2, 190 (77.6%) received a single dose, 38 (15.5%) received two doses, and 17 (6.9%) received three doses. Of the 226 women who received Propess, 195 (86.3%) received a

Table 1. Maternal and neonatal characteristics and outcomes among women receiving Prostin E2 or Propess for induction of labour (IOL).

Variable	Prostin E2 (n=245)*	Propess (n=226)*	p Value
Age, y	31.3±5.1	31.5±5.3	0.738
Parity			0.747
Nulliparous	172 (70.2)	169 (74.8)	
Multiparous	73 (29.8)	57 (25.2)	
Gestational age, weeks + days	39+4	39+5	0.278
Bishop score at IOL	3.3±1.2	3.1±1.4	0.095
Indication for IOL			0.297
Post-term	124 (50.6)	100 (44.3)	
Diabetic disorder	61 (24.9)	69 (30.5)	
Hypertensive disorder/proteinuria	15 (6.1)	24 (10.6)	
Fetal growth restriction/oligohydramnios	35 (14.3)	25 (11.1)	
Others	10 (4.1)	8 (3.5)	
No. of doses			-
1	190 (77.6)	195 (86.3)	
2	38 (15.5)	31 (13.7)	
3	17 (6.9)	0	
IOL-to-delivery interval, min	2073±1360	1686±1177	0.020
Delivered within 24 h	92 (37.6)	116 (51.3)	0.003
Mode of delivery			0.872
Normal vaginal delivery	153 (62.4)	128 (56.6)	
Instrumental delivery	34 (13.9)	31 (13.7)	
Caesarean section	58 (23.7)	67 (29.7)	
Failed IOL	14 (5.7)	25 (11.1)	0.035
Oxytocin use	116 (47.3)	108 (47.8)	0.924
Uterine hyperstimulation, tachysystole, or hypertonus	19 (7.8)	53 (23.5)	<0.001
Terbutaline use	0	0	-
Estimated blood loss, mL	268±195	276±232	0.686
Estimated blood loss ≥1000 mL	2 (0.8)	5 (2.2)	0.211
Neonatal weight, g	3219.6±552.0	3206.8±460.8	0.075
Apgar score at 5 min			-
7-10	245 (100)	226 (100)	
<7	0	0	
Admission to neonatal intensive care unit	12 (4.9)	2 (0.9)	0.010

* Data are presented as mean ± standard deviation or No. (%) of patients

single dose and 31 (13.7%) received two doses. The two groups were comparable in terms of maternal age, parity, gestational age, and Bishop score.

Compared with the Prostin E2 group, the Propess group had a shorter IOL-to-delivery interval (1686 vs 2073 minutes, p=0.02), particularly among multiparous women (1078 vs 1568 minutes, p=0.009); the difference among nulliparous women was not significant (1897 vs 2324 minutes, p=0.093) [Table 2]. Additionally, the Propess group had a higher rate of delivery within 24 hours of IOL overall (51.3% vs 37.6%, p=0.003) and in both nulliparous (42.0% vs 29.7%, p=0.017) and multiparous (77.2% vs 56.2%, p<0.001) women. However, the Propess group had a higher rate of failed IOL overall (11.1% vs 5.7%, p=0.035), particularly among nulliparous women (14.2%

Table 2. Subgroup analysis of maternal outcomes among nulliparous and multiparous women.

Outcome	Nulliparous (n=341)			Multiparous (n=130)		
	Prostin E2 (n=172)*	Propess (n=169)*	p Value	Prostin E2 (n=73)*	Propess (n=57)*	p Value
Induction-to-delivery duration, min	2324±1361	1897±1230	0.093	1568±1209	1078±724	0.009
Delivered within 24 h	51 (29.7)	71 (42.0)	0.017	41 (56.2)	44 (77.2)	<0.001
Caesarean section	48 (27.9)	63 (37.3)	0.065	10 (13.7)	4 (7.0)	<0.001
Failed induction of labour	12 (7.0)	24 (14.2)	0.003	2 (2.7)	1 (1.8)	<0.001
Uterine hyperstimulation, tachysystole, or hypertonus	10 (5.8)	40 (23.7)	<0.001	9 (12.3)	13 (22.8)	<0.001

* Data are presented as mean ± standard deviation or No. (%) of patients

vs 7.0%, p=0.003). Notably, the rate of failed IOL among multiparous women was lower in the Propess group (1.8% vs 2.7%, p<0.001).

The Propess group had a higher rate of uterine hyperstimulation overall (23.5% vs 7.8%, p<0.001) and in both nulliparous (23.7% vs 5.8%, p<0.001) and multiparous (22.8% vs 12.3%, p<0.001) women. No women required terbutaline for management of uterine hyperstimulation. In the Propess group, among the 53 women with uterine hyperstimulation, eight required emergency Caesarean section for fetal distress (n=1), abruptio placentae (n=1), and other indications (n=6) including failed IOL, cephalopelvic disproportion, lack of labour progress, and prolonged latent phase. In the Prostin E2 group, among the 19 women with uterine hyperstimulation, none required Caesarean section or tocolysis; all achieved vaginal delivery, except for one who required low forceps delivery for fetal distress. Among multiparous women, the Propess group had a lower rate of Caesarean section (7.0% vs 13.7%, p<0.001).

All neonates had an Apgar score ≥7 at 5 minutes. The Propess group had a lower rate of neonatal intensive care unit admission (0.9% vs 4.9%, p=0.01).

Discussion

Most women required only one dose of Prostin E2 or Propess to achieve successful IOL. Propess use was associated with a shorter IOL-to-delivery interval and a higher rate of delivery within 24 hours of IOL among both nulliparous and multiparous women, consistent with the findings of a previous study[10]. Nonetheless, Propess was associated with a higher rate of failed IOL among nulliparous women. In contrast, one study revealed longer intervals to vaginal delivery after Propess use[5], although another showed no significant differences between the vaginal insert and other vaginal or cervical prostaglandin preparations regarding delivery within 24 hours[7]. These contrasting findings may reflect heterogeneity in parity, pre-induction cervical status, primary outcomes, and administration regimens. The National Institute for Health and Care Excellence recommends administering one cycle of Prostin E2, with a second dose given 6 hours after the first if labour is not started. In contrast, our departmental protocol previously recommended administering a single dose of Prostin E2 over a 24-hour period. Differences in regimens may explain the discrepancy.

Propess use was associated with a higher rate of uterine hyperstimulation, consistent with findings in a systematic review and meta-analysis[6]. Uterine hyperstimulation occurred in 23.5% of women who received Propess, which is higher than the previously reported 5% to 15%. The difference may be related to the careful monitoring of fetal cardiotocography and maternal uterine hyperstimulation in the present study. No women required terbutaline. There was no significant increase in the rate of Caesarean section due to non-reassuring fetal heart rate secondary to uterine hyperstimulation. Moreover, there was no significant difference in Apgar score at 5 minutes between groups, and neonates in the Propess group had a lower rate of neonatal intensive care unit admission. This finding may be attributed to the shorter IOL-to-delivery interval associated with Propess. Prolonged active labour is known to increase neonatal intensive care unit admission due to higher risks of fetal distress, low Apgar score, and infection[11,12].

Approximately 11.1% to 14.3% of women underwent IOL for fetal growth restriction. Although

Propess was associated with more uterine hyperstimulation, there was no significant difference in Apgar score at 5 minutes or neonatal intensive care unit admission. This finding indicates that Propess is safe for fetuses with growth restriction.

The present study had several limitations. Its retrospective design permits assessment of correlation rather than causation. There may have been variability in the interpretation, documentation, and management of events and outcomes, given the involvement of multiple healthcare professionals in antepartum and intrapartum care. Further studies are needed to confirm our findings and to determine the optimal dosages and administration regimens of Prostin E2 and Propess, as well as the efficacy and safety of other dinoprostone preparations.

Conclusion

Propess appears to be a safe and effective alternative to Prostin E2 for IOL in women with an unfavourable cervix and intact membranes. Its use was associated with a shorter IOL-to-delivery interval and a higher rate of vaginal delivery within 24 hours of IOL. Although Propess was associated with a higher incidence of uterine hyperstimulation, there was no significant increase in the incidence of non-reassuring fetal heart rate requiring Caesarean delivery. The use of Propess was also associated with a higher rate of failed IOL; however, the overall Caesarean section rate was not significantly increased.

Contributors

Both authors designed the study, acquired the data, analysed the data, drafted the manuscript, and critically revised the manuscript for important intellectual content. Both authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

Both authors have disclosed no conflicts of interest.

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Data availability

All data generated or analysed during the present study are available from the corresponding author on reasonable request.

Ethics approval

This study was approved by the Kowloon Central / Kowloon East Cluster Research Ethics Committee (reference: KC/KE-21-0052/ER-3). The patients were treated in accordance with the tenets of the Declaration of Helsinki. The requirement for patient consent was waived by the Committee due to the retrospective nature of the research.

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