Original Research

Caesarean sections and outcomes of labor induction after the introduction of a new intravaginal device: retrospective analysis

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Background: To evaluate the outcomes and process of labour induction following the introduction of a new vaginal device with slow releasing dinoprostone (Propess). *Methods*: Data were collected on the indications for labour induction, the process of induction and delivery, and the outcomes of delivery for 171 term pregnancies between 1 January 2020 and 31 August 2020. Excluded from this study were patients with preterm delivery, multiple pregnancies, or pre-labour rupture of membranes. Data for the standard dinoprostone medication (PG) and Propess groups was analysed and compared. *Results*: Of the 93 women (54.4% of total) induced in the PG group, 55 (59.1%) received Prostin tablets, 17 (18.3%) received 1 mg of Prostin gel, and 21 (22.6%) received 2 mg of Prostin gel. Seventy eight women (45.6%) received the new intravaginal device (Propess group). The five most frequent indications for labour induction were post-term pregnancy (53, 31.0%), GDM (42, 24.6%), oligohydramnios (30, 17.5%), IUGR (21, 12.3%), and hypertensive disease (20, 11.7%). The Bishop scores were unfavourable in the majority of cases (119, 69.6%). The length of induction was less than 24 hours in 134 women (78.4%). Oxytocin was used more frequently ($p = 0.001$) in the Propess group and these women underwent more frequent caesarean section (20.5% vs 12.9%, $p = 0.31$). The status of babies was good in both groups. *Conclusion*: Introduction of the Propess device to mainstream medical practice has led to rapid implementation and resulted in improved workflow and positive outcomes for both the baby and mother.

Keywords

Induction of labour; Intravaginal device; Outcome of labour induction

1. Introduction

Induction of labour (IOL) is common in obstetric practice and is necessitated by a perceived risk that continuation of pregnancy could compromise fetal or maternal well-being. Severe fetal growth restriction, chorioamnionitis and gestational diabetes mellitus (GDM) in post-term pregnancy are some instances where prompt delivery may be a preferred mode of action to the continuation of pregnancy [1].

IOL is an easy choice in cases with a dilated cervix. However, IOL is challenging in cases with a long, firm and unprepared cervix, especially in women who are preterm [2]. In an unprepared cervix, the elicitation of tissue remodeling is a neccessary prerequisite for cervical dilation and subsequent vaginal birth of the baby [2].

A controversial issue with IOL is what to do following an unsucceful IOL. Although the majority of IOLs lead to the active phase of labour, the final outcome depends on many factors such as gestational age, maternal weight, the consecutive number of pregnancy, and the lack of preparedness of the cervix [3]. In the case of IOL failure, some clinicians suggest there is an obligation to do a caesarean section. However, this can be too invasive and too drastic an approach compared to the initial IOL indication, especially when fetal well-being is ensured and repeat IOL can lead to a successful outcome [4]. On the other hand, repeat IOL cases that suffer adverse outcomes are subject to a wide spectrum of interpretations regarding the cause. This can be difficult to explain and defend in court [5]. Improving the success rate of initial IOL and reducing the need for repeat IOL is therefore an important aim in obstetrics.

Another important issue is the general public's perception of IOL as an unnecessary medical interference into the natural events of pregnancy and delivery [6]. There is also a widespread belief that labour after IOL is more painful and problematic compared to a natural start of labour, thus further reinforcing the stigmatisation of IOL [7]. Meanwhile, there is growing support for IOL to become routine immediately after the expected date of delivery (EDD) or even in the 39th week of pregnancy. This is because recent research on post-term pregnancies has shown a higher rate of foetal mortality [8]. These trends further strengthen the need for reliable, safe and easy to use medications for IOL.

The current standard drugs for IOL, prostaglandin gels and prostaglandin vaginal tablets, require multiple daily repetitions for successful induction. There is also a need for frequent cardiotocographic (CTG) monitoring of the baby's heart rate during induction as evidence of its well-being [9]. Failure of initial IOC then requires repetition of induction and further prolongs total duration of the process. To handle multiple daily planned inductions, an alternative approach is needed to allow implementation of new recommendations

for additional term inductions. One solution could be a vaginal device as a novel mode of induction. The aim of this study was to evaluate the outcomes following IOL using a new mode of medication and to compare these outcomes to the standard mode of labour induction.

2. Materials and methods

About 2200 pregnant women deliver annually in the Department of Perinatology, University Medical Centre, Maribor, Slovenia. High risk pregnancies from the north-east part of Slovenia are also managed in this tertiary healthcare centre. In mid-2020, a new prostaglandin vaginal device under the Propess brand name was introduced at this institute for labour induction in everyday clinical practice. The aim of this study was to evaluate the parameters of induction, delivery, outcomes of delivery, and neonatal outcomes for pregnant women that received Propess for IOL (Propess group). These were compared to outcomes from previous standard medications used for IOL (intravaginal Prostin tablets, Prostin gel 1 mg, Prostin gel 2 mg), referred to here as the PG group. Data was collected for pregnant women that underwent IOL at our institution between 1 January 2020 and 31 August 2020. The Slovenian National Perinatal Information System (NPIS) was used to identify relevant patients. This registers all deliveries in Slovenia past the 22nd week of gestation with fetuses heavier than 500 g, as required by law. Excluded from this series were pregnant women with preterm labour (gestational age <37 weeks), multiple pregnancies, or pre-labour rupture of membranes (PROM). Data was collected on the characteristics of the selected patient population and on the state of the cervix at the time of labour induction. In our department, the decision to induce was not dependent on the Bishop score of the cervix. If the state of the baby or the mother required it, labour was induced regardless of the readiness of the cervix. However, if the delivery was not urgent and the cervix was unfavorable for induction, membrane stripping was proposed to the patient in order to improve the Bishop score. This was done in an informal manner and irrespective of the later choice of induction drug. The decision on whether to perform membrane stripping was left to the examining obstetrician at the clinic and was not explicitly recorded.

For each patient in the study population, additional relevant information was extracted directly from medical documentation. Data for all 5 segments considered by the Bishop score [10] were collected from medical records, thus allowing calculation of this score for every patient. Since parity plays a vital role in the success of induction, a modified Bishop score previously described in the medical literature was calculated [11, 12]. One point is added to the original Bishop score for multiparas and one point is subtracted for women in their first delivery [11, 12].

Our department has developed elaborate labour induction protocols for each of the PGE2 medications used in the PG group. We recommend Prostin vaginal gel 2 mg (dinopros-tone) for primiparas with a non-inducible cervix, and Prostin vaginal gel 1 mg (dinoprostone) for multiparas. The final choice of medication is made by the obstetrician-in-charge. Prostin vaginal gel 2 mg is applied through the applicator into the vaginal posterior fornix with finger control. A second dose is inserted 6 hours later in case of no response. This is followed by a 24-hour pause. With no signs of cervical dilation even after the 24-hour pause, IOL is continued with the application of a maximum of two additional doses of Prostin vaginal gel 2 mg inserted 6 hours apart. In contrast, Prostin gel 1 mg (dinoprostone) is applied 6 hours apart up to four times. In the case of no contractions leading to cervix dilation, there is a 24-hour pause. If there is no response after this 24-hour pause, a maximum of 4 doses is applied again depending on the onset of uterine activity. In the PG group, a Foley catheter was never used in repeat attempts to induce. This was not because of adverse experiences with the Foley catheter, but rather because of the previously established protocols.

The Prostin tablet 3 mg (dinoprostone) was inserted high into the posterior fornix of the vagina with one finger. Two more doses were re-applied 8 hours apart if there was no uterine response. After a 24-hour pause, the protocol was repeated a final time.

The Propess intravaginal delivery system was used as a method of induction in the Propess group. This comprises a preparation of 10 mg dinoprostone dispersed throughout a hydrogel polymer matrix and designed for slow intravaginal release of 10 mg dinoprostone at a rate of 0.3 mg/h. The flat, semi-transparent polymeric vaginal delivery system is rectangular in shape (29 mm by 9.5 mm) and 0.8 mm thin with rounded corners contained within a knitted polyester retrieval system. It is removed from the freezer just prior to insertion. No thawing was required prior to use. It was inserted high into the posterior fornix of the vagina with one finger and left in place for a maximum of 24 hours [13]. After insertion, the withdrawal tape was left outside the vagina to allow removal. The patient stayed recumbent for 20 to 30 minutes after insertion. Propess is removed when there is onset of contractions with cervical dilation. The sequential use of oxytocin is possible 30 minutes after removal of the vaginal delivery system.

If induction in the Propess group did not occur after 24 hours, this was immediately followed by application of one of the following options: Prostin gel 1 mg, Prostin gel 2 mg, Prostin tablet 3 mg, or supracervical insertion of a Foley catheter inflated between the inner cervical ostium and amniotic membranes with 40 mL of saline solution and left in place for a maximum of 24 hours. In case of an earlier cervical dilation, the Foley catheter simply fell out of the vagina. The choice of option was made by the obstetrician-in-charge and with agreement from the patient. If the above protocols did not lead to the onset of vaginal delivery, a caesarean delivery usually followed. This decision was left to the obstetrician-in-charge.

Every drug application in the PG group (Prostin gel 1 mg, Prostin gel 2 mg, or Prostin tablet 3 mg) was followed by hourly cardiotocography (CTG) and repeated every 2 hours until the onset of regular contractions or PROM. After insertion of the Propess intravaginal system, an hourly CTG was performed and repeated every 6 hours. For specific cases, the CTG monitoring frequency was modified by the obstetrician-in-charge.

Data was extracted on the demographic characteristics of the mother and events during induction, labour and delivery such as fetal scalp blood sampling. For the latter, blood was collected from fetal scalp during suspicious intrapartum CTG tracing to distinguish fetuses experiencing hypoxia (pH less than 7.25) from those that were not, thus avoiding unnecessary caesarean sections. Data was also collected on complications before and after birth, and on the mode of delivery. Neonatal data including birth weight, birth length and APGAR score at 1, 5 and 10 minutes were also extracted. After the initial data screening, the summary results of outcomes and characteristics (count, average, standard deviation) were compared between the PG and Propess groups.

Statistical analysis was performed using the SPSS software version 27.0 for Mac OS (IBM Corp., Armonk, NY, USA). The Chi-Squared test was used to compare categorical variables, while the Mann-Whitney U-test was used for continuous variables. The population characteristics were expressed as continuous or categorical variables and calculated as frequencies or averages (standard deviations), respectively. Statistically significant differences were identified when p was less than 0.05. A sample size of 174 patients is required for an 80% chance of detecting at the 5% significance level an increase in the primary outcome measure (frequency of unsuccesful induction or of caesaren section) from 2% in the control group to 13% in the experimental group. The institutional ethics committee approved the study.

3. Results

During the study period, labour was induced in 171 pregnant women at our institute. Of these, 93 (54.4%) received traditional medications (PG group) and 78 (45.6%) received the new intravaginal Propess device (Propess group). In the PG group, Prostin tablets were used in 55 (59.1%) women, Prostin gel 1 mg in 17 (18.3%) women, and Prostin gel 2 mg in 21 (22.6%) women.

The large majority of cases (147, 86.0%) entered pregnancy in a healthy condition and without disease. However, almost half (83, 48.5%) the women had a BMI >30 at delivery, with 41 (44.1%) in the PG group and 42 (53.9%) in the Propess group. More than half the women (53.2%) were in their first pregnancy. Fifty two percent underwent labour induction in either the 40th week (62, 36.3%) or 41st week (27, 15.8%) of pregnancy. A large majority were non-smokers (158, 92.4%). More details regarding the characteristics of the pregnant women are shown in Table 1.

The five most frequent indications for labour induction were post-term pregnancy (53, 31.0%), GDM (42, 24.6%), oligohydramnios (30, 17.5%), IUGR (21, 12.3%) and hypertensive disease (20, 11.7%). Bishop scores were unfavourable (<5) in the majority of cases (119, 69.6%). Only 7 cases (4.1%) had a Bishop score greater than 9. The length of induction was less than 24 hours in 134 (78.4%) women, with a small minority having labour induction for more than 48 hours (12, 7.0%). The first round of induction ended with a 24-hour pause in only 15 (8.8%) cases. This subgroup was even smaller in the Propess group (2, 2.6%). Of these 15 women, 8 (53.3%) received one dose of prostaglandins (in any form) during the second round of induction. Overall, induction failed in just 3 cases, representing 1.8% of the overall study population. One of these women was from the PG group and the other two were from the Propess group. More details regarding the induction process are shown in Table 2.

During delivery, spontaneous rupture of membranes occurred in 52 (30.4%) patients, while amniotomy was performed in 86 (50.3%) patients only after substantial cervical dilation (well over 3 cm). Oxytocin was used more frequently in the Propess group than in the PG group (71.8% vs 49.9%) overall and for both phases of labour and with higher doses (Table 3). There was no difference in the meconium and amniotic fluid number between the PG and Propess groups, however there was a somewhat higher fetal scalp blood sampling number with a higher number of cases in the pre-acid or acid range (pH less than 7.25) in Propess group (p = 0.13). Delivery lasting longer than 6 hours was more frequent in the Propess group (16.7%) than in the PG group (10.8%). Additional details regarding vaginal delivery are shown in Table 3.

Episiotomies were performed in 40.4% of patients and were more frequent in the PG group (46.2%) than in the Propess group (33.3%). Smaller lacerations were present in 29.8% of cases and were equally distributed between the two groups. Two patients (2.2%) in the PG group suffered a 3rd degree rupture of the perineum. The frequency of manual placenta removal was similar in both groups. Epidural analgesia was used more frequently in the Propess group (19.2%) than in the PG group (8.6%). Similarly, caesarean section was more frequent in the Propess group (20.5%) than in the PG group (12.9%). Pathological CTG or labour arrest was the most frequent reason for operative delivery. Further details regarding vaginal delivery are shown in Table 4. The status of babies was good in both groups and there were no significant differences (Table 5).

The largest difference associated with parity was for the duration of induction in the PG group (Table 6). Caesarean section was also more frequent in nulliparas in the Propess group (Table 6).

4. Discussion

This retrospective analysis of labour induction at our institution has provided some significant insights. The first is that labour induction is a highly successful procedure (98.2%). Only 3 cases out of 171 failed to reach cervix dilation and

Table 1. Characteristics of the pregnant women going into the induction of labour with standard prostaglandin medications (PG group) and Propess (Propess group).

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	*p* value
Number of days at hospital							
Less than 6 days	62	66.7	48	61.5	110	64.3	0.48
6 or more days	31	33.3	30	38.5	61	35.7	
Patient age							
Average	31.2		31.1		31.1		0.90
SD	5.7		5.0		5.4		
Max	44		40		44		
Min	19		20		19		
Patients height							
Average (cm)	166.3		167.4		166.8		0.28
SD (cm)	6.2		6.7		6.4		
Min (cm)	145.0		155.0		145.0		
Max (cm)	190.0		183.0		190.0		
Patients weight at conception							
Average (kg)	71.5		73.1		72.3		0.61
SD (kg)	15.8		17.3		16.5		
Min (kg)	42.0		44.0		42.0		
Max (kg)	124.0		114.0		124.0		
Patients weight at delivery							
Average (kg)	83.1		85.5		84.2		0.37
SD (kg)	18.0		16.9		17.5		
Min (kg)	53.0		52.0		52.0		
Max (kg)	144.0		118.0		144.0		
Weight difference between conception and delivery							
Average (kg)	11.6		12.4		11.9		0.52
SD (kg)	8.5		7.6		8.1		
Max (kg)	44.0		31.0		44.0		
BMI at delivery							
Average	30.0		30.5		30.2		0.59
SD	6.3		5.7		6.0		
Min	19.5		20.1		19.5		
Max	52.9		42.1		52.9		
Smoking							
No	85	91.4	73	93.6	158	92.4	0.59
Yes	8	8.6	5	6.4	13	7.6	
Diseases before the pregnancy							
No	79	84.9	68	87.2	147	86.0	0.68
Hypertension	0	0.0	1	1.3	1	0.6	
Acquired heart failure	0	0.0	1	1.3	1	0.6	
Chronic pulmonary disease	1	1.1	0	0.0	1	0.6	
Chronic kidney disease	1	1.1	1	1.3	2	1.2	
Kidney stones	1	1.1	0	0.0	1	0.6	
Type 1 diabetes	1	1.1	1	1.3	2	1.2	
Thyroid disease	6	6.5	2	2.6	8	4.7	
Epilepsy	1	1.1	0	0.0	1	0.6	
Mental disorder	0	0.0	1	1.3	1	0.6	
Hepatitis B	1	1.1	0	0.0	1	0.6	
Gallstones	1	1.1	0	0.0	1	0.6	
Congenital thrombophilia	1	1.1	0	0.0	1	0.6	
Chronic inflammatory bowel disease	0	0.0	1	1.3	1	0.6	
Other autoimmune disease	1	1.1	2	2.6	3	1.8	

Table 1. Continued.

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	p value
Diseases in pregnancy							
No	27	29.0	14	18.0	41	24.0	0.09
Hypertension	1	1.1	5	6.4	6	3.5	
Asymptomatic bacteriuria	2	2.2	2	2.6	4	2.3	
Gestational diabetes	31	33.3	34	43.6	65	38.0	
Hyperemesis	0	0.0	2	2.6	2	1.2	
First trimester bleeding	6	6.5	8	10.3	14	8.2	
Second trimester bleeding	3	3.2	2	2.6	5	2.9	
Third trimester bleeding	0	0.0	1	1.3	1	0.6	
Placenta praevia	0	0.0	1	1.3	1	0.6	
Anemia	2	2.2	3	3.9	5	2.9	
Thrombocytopenia	0	0.0	1	1.3	1	0.6	
RhD isoimmunization	0	0.0	1	1.3	1	0.6	
Liver disease in pregnancy	1	1.1	1	1.3	2	1.2	
IUGR	12	12.9	12	15.4	24	14.0	
Fetal defect before birth	1	1.1	2	2.6	3	1.8	
Polyhydramnios	1	1.1	2	2.6	3	1.7	
Oligohydramnios	5	5.4	5	6.4	10	5.8	
Risk for preterm labour	0	0.0	2	2.6	2	1.2	
Colpitis	21	22.6	15	19.2	36	21.0	
Varicose veins	1	1.1	0	0.0	1	0.6	
External cephalic version	1	1.1	0	0.0	1	0.6	
Gestational week of induction							
37. week	12	12.9	13	16.7	25	14.6	0.88
38. week	11	11.8	12	15.4	23	13.5	
39. week	19	20.4	15	19.2	34	19.9	
40. week	36	38.7	26	33.3	62	36.3	
41. week	15	16.1	12	15.4	27	15.8	
Consecutive delivery							
First delivery	49	52.7	42	53.8	91	53.2	0.88
Second or higher delivery	44	47.3	36	46.2	80	46.8	

the onset of labour, thereby necessitating termination of the pregnancy with a caesarean section [14]. This is even more striking considering the study population was comprised of somewhat obese women (48.5% had a BMI >30 at delivery) and for about half the women it was their first pregnancy. Both are very unfavorable factors for labour induction according to the medical literature [15]. Data from the NPIS show that 70% of pregnant Slovenian women have a normal BMI at the time of pregnancy, 18% are overweight and 8% are obese [16]. Recent reviews have also reported high rates of progression to delivery following IOL [17], although not as high as observed in the present study. It is helpful to be able to provide the present data for local counseling about labour induction, especially for cases of prophylactic inductions post-term (52.0%).

One of the most important insights from this study is that the Bishop score is not a reliable prognostic indicator for the success of induction. Our data for Bishop scores were extracted directly from patient records and are thus considered reliable. Although some authors have claimed the Bishop score is an important prognosticator for the success of labour induction, others disagree [18, 19]. In our clinical practice, we do not consider it as a criterion when deciding on whether or not to induce labour. We believe the currently available devices for labour induction are sufficiently effective in the majority of cases, as confirmed by the present analysis. This is especially important for prophylactic labour induction in cases of post-term pregnancies for gestational diabetes with and without insulin. Even in these cases, the Bishop score is only barely considered in the clinical decision-making. In the opinion of the authors, even various modifications of the Bishop score have only minor significance in the labour induction process. Some authors agree and others disagree with this claim [20, 21]. Nevertheless, the Bishop score could be more relevant when labour induction is needed for preterm pregnancies, since the frequency of failed inductions increases dramatically in such cases [22].

The third insight from this study is that prolongation of labour induction in term pregnancies does not appear to be a dangerous option, either for the baby or the mother, but

Table 2. Characteristics of an induction of labour with standard prostaglandin medications (PG group) and Propess (Propess group).

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	*p* value
Indications for induction							
Post-term pregnancy	27	29.0	26	33.3	53	31.0	0.54
GDM	19	20.4	23	29.5	42	24.6	0.17
Oligohydramnion	22	23.7	8	10.3	30	17.5	0.02*
IUGR	11	11.8	10	12.8	21	12.3	0.84
Hypertensive disorders	8	8.6	12	15.4	20	11.7	0.17
Reduced fetal movement	8	8.6	5	6.4	13	7.6	0.17
BFD	7	7.5	5	6.4	12	7.0	0.78
Nonreassuing or pathological CTG	4	4.3	6	7.7	10	5.8	0.35
SGA	8	8.6	2	2.6	10	5.8	0.09
Polyhydramnion	4	4.3	5	6.4	9	5.3	0.54
Changing position of the baby	2	2.2	1	1.3	3	1.8	0.67
Hepatic disease	1	1.1	1	1.3	2	1.2	0.90
Status post MFIU	2	2.2	0	0.0	2	1.2	0.67
Single umbilical artery	2	2.2	0	0.0	2	1.2	0.67
Reumatoid artritis SLE	0	0.0	1	1.3	1	0.6	0.89
Toxoplasmosis in pregnancy	0	0.0	1	1.3	1	0.6	0.89
Status post left nephrectomy and right hydronephrosis	0	0.0	1	1.3	1	0.6	0.89
Bishop score							
Bishop score—Cervical position							
Backed and retroponated	51	54.8	46	59.0	97	56.7	0.44
Somewhat retroponated	36	38.7	24	30.8	60	35.1	
Centered	6	6.5	8	10.3	14	8.2	
Bishop score—Cervical Effacement							
Preserved	47	50.5	41	52.6	88	51.5	0.19
Shortend	44	47.3	31	39.7	75	43.9	
Disappeared	2	2.2	6	7.7	8	4.7	
Bishop score—Cervical consistency							
Hard	34	36.6	28	35.9	62	36.3	0.67
Mildely soft	55	59.1	47	60.3	102	59.6	
Soft	4	4.3	3	3.8	7	4.1	
Bishop score—Cervical dilatation							
Closed	14	15.1	11	14.1	25	14.6	0.67
Insertive for 1 finger	55	59.1	51	65.3	106	62.0	
Insertive for 2 or more fingers	24	25.8	16	20.5	40	23.4	
Bishop score—Station							
Fetal leading part unreachable	14	15.1	12	15.4	26	15.2	0.99
Fetal leading part reachable	79	84.9	65	83.3	144	84.2	
Fetal leading part fixed	0	0.0	1	1.3	1	0.6	
Bishop score—Summary (Grouping)							
Group 1–5 points and lower	64	68.8	55	70.5	119	69.6	0.97
Group 2–6–8 points	25	26.9	20	25.6	45	26.3	
Group 3–9 points and higher	4	4.3	3	3.8	7	4.1	
Duration of an induction							
24 h or less	66	71.0	68	87.2	134.0	78.4	0.04*
Between 24.5 h and 48 h	18	19.4	7	9.0	25.0	14.6	
48.5 h or more	9	9.7	3	3.8	12.0	7.0	
Number of dosages 1. round							
1	37	39.8	0	0.0	37.0	21.6	-
2	32	34.4	0	0.0	32.0	18.7	
3	19	20.4	0	0.0	19.0	11.1	
4	5	5.4	0	0.0	5.0	2.9	
None		0.0	78.0	100.0	78.0	45.6	

Table 2. Continued.

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	p value
Medication for induction 1. round							
Propess		0.0	78	100.0	78	45.6	-
Prostin gel 1 mg	17	18.3	0	0.0	17	9.9	
Prostin gel 2 mg	21	22.6	0	0.0	21	12.3	
Prostin tbl	55	59.1	0	0.0	55	32.2	
4.0 Duration of induction (Propess group)							
Group 1 (till 6 h)			8	10.3	8	4.7	-
Group 2 (till 12 h)			27	34.6	27	15.8	
Group 3 (till 18 h)			10	12.8	10	5.9	
Group 4 (more than18 h)			33	42.3	33	19.3	
				0.0	93	54.4	
24 h pause							
No	80	86.0	76	97.4	156	91.2	0.008*
Yes	13	14.0	2	2.6	15	8.8	
Number of doses (2. round)							
1	7	7.5	1	1.3	8	4.7	-
2	3	3.2	0	0.0	3	1.8	
3	1	1.1	0	0.0	1	0.6	
4	2	2.2	1	1.3	3	1.8	
None	80	86.0	76	97.4	156	91.2	
Medications for induction (2. round)							
Foley 7 h	0	0.0	1	1.3	1	0.6	-
Prostin gel 1 mg	3	3.2	1	1.3	4	2.3	
Prostin gel 1 mg + Foley 6 h	0	0.0	1	1.3	1	0.6	
Prostin gel 2 mg	3	3.2	0	0.0	3	1.8	
Prostin tbl	7	7.5	0	0.0	7	4.1	
None	80	86.0	75	96.2	155	90.6	
Sum of all doses							
1	37	39.8	76	97.4	113	66.1	-
2	29	31.2	1	1.3	30	17.5	
3	14	15.1	0	0.0	14	8.2	
4	7	7.5	0	0.0	7	4.1	
5	1	1.1	1	1.3	2	1.2	
6	3	3.2	0	0.0	3	1.8	
7	2	2.2	0	0.0	2	1.2	
Unsuccessful induction							
Unchanged cervix	1	1.1	2	2.6	3	1.8	0.46
No 24 h pause	0	0.0	1	1.3	1	0.6	
24 h pause	1	1.1	1	1.3	2	1.2	

Note: *Statistically significant.

offers the possibility of a successful outcome in cases of slow responders. Slow responders were rare and the majority of inductions led to the onset of delivery during the first round of prostaglandin repetitions. This insight is valuable as our protocol for Prostin tablets 3 mg differs somewhat from the official recommendation of only two repetitions rather than the three in our protocol [23]. However, our protocol was introduced decades ago by older colleagues with extensive clinical experience and hence we continue to practice it. Introduction of the 24-hour pause was useful for slow responders and delayed cervical dilation. In the opinion of the authors, continuation of the induction process is a much better option in terms of success and safety compared to immediate caesarean delivery [24]. This is especially true for the less attractive option of forcing the start of labour with early amniotomy when the cervix is still preserved and unstretchable [25]. Even with the extended induction scenario, the average length of labour induction was still acceptable, especially in recent years where this process now occurs in a comfortable hospital room and not in the stressful environment of the delivery ward as before. In the majority of cases (78.4%) in this study, the duration of induction was less than 24 hours, with

Table 3. Characteristics of deliveries after the induction of labour with standard prostaglandin medications (PG group) and Propess (Propess group).

	PG group (n = 93)		Propess group (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	p value
Presentation							
Occipito-anterior	92	98.9	76	97.4	168	98.3	0.46
Occipito-posterior		0.0	1	1.3	1	0.6	
Deflexed (millitary attitude)	1	1.1	1	1.3	2	1.2	
Membrane rupture							
Spontanous rupture of membranes (SRM)	36	38.7	19	24.4	55	32.1	0.11
Amniotomy (AT)	53	57.0	53	68.0	106	62.0	
Caesarean section (SC)	4	4.3	6	7.7	10	5.9	
Time from ruputre to delivery							
Immediate	3	3.2	4	5.1	7	4.1	0.23
6 hours or less	78	83.9	57	73.1	135	79.0	
More than 6 hours	12	12.9	17	21.8	29	17.0	
Cervical dilatation (cm) at the time of amniotomy							
0	3	3.2	4	5.1	7	4.1	-
2	10	10.8	16	20.5	26	15.2	
3	28	30.1	27	34.6	55	32.2	
4	12	12.9	9	11.5	21	12.3	
5	2	2.2	1	1.3	3	1.8	
6	2	2.2		0.0	2	1.2	
7	3	3.2		0.0	3	1.8	
8	1	1.1		0.0	1	0.6	
9	1	1.1		0.0	1	0.6	
Spontanous rupture of membranes (SRM)	31	33.3	21	26.9	52	30.4	
Cervical dilatation (cm) at the time of spontaneous rupture of membranes (SRM)							
1	1	1.1	1	1.3	2	1.2	-
2	7	7.5	8	10.3	15	8.8	
3	10	10.8	4	5.1	14	8.2	
4	6	6.5	4	5.1	10	5.8	
5	2	2.2	0	0.0	2	1.2	
6	1	1.1	0	0.0	1	0.6	
10	4	4.3	0	0.0	4	2.3	
Portion		0.0	4	5.1	4	2.3	
(blank)	62	66.7	57	73.1	119	69.6	
Oxytocin usage							
No	54	58.1	22	28.2	76	44.4	0.001*
First	33	35.5	46	59.0	79	46.2	
Second	2	2.2	2	2.6	4	2.3	
Both	4	4.3	8	10.3	12	7.0	
Dosage of oxytocine (max mUnit/min)							
No	54	58.1	22	28.2	76	44.4	0.0002*
10 or less	32	34.4	40	51.3	72	42.1	
More than 10	7	7.5	16	20.5	23	13.5	

no significant difference between the PG and Propess groups. Nevertheless, it is worth noting that 42.3% of inductions in the Propess group lasted more than 18 hours. Therefore, patience and trust in the effectiveness of the device play an important role, especially because strong uterine contraction is rarely registered in this group [26]. Clearly, the slow-release system prevents excessive doses of prostaglandins that could cause strong and acute uterine contractions without having an effect on cervix dilation. It is also important to note that the Propess system should not be removed from the vagina at the first uterine contractions, but only when sufficient cervix dilation is reached. In our experience this can otherwise lead to an extended length of induction. This contrasts somewhat with official recommendations for the Propess device, which place more emphasis on uterine contractions and less on cervical dilation as a reason for Propess removal from the vagina. This can lead to organisational confusion [27]. Of the three cases with unsuccessful induction in this study, two

Table 3. Continued.

	PG group (n = 93)		Propess group (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	*p* value
Maximal doses of oxytocin (max mL/h)							
0	54	58.1	22	28.2	76	44.4	-
12	10	10.8	7	9.0	17	9.9	
24	5	5.4	9	11.5	14	8.2	
36	8	8.6	9	11.5	17	9.9	
48	7	7.5	7	9.0	14	8.2	
60	3	3.2	7	9.0	10	5.8	
72	4	4.3	5	6.4	9	5.3	
84	0	0.0	3	3.8	3	1.8	
96	0	0.0	4	5.1	4	2.3	
108	1	1.1	2	2.6	3	1.8	
120	1	1.1	3	3.8	4	2.3	
Amniotic fluid							
Clear, milky or bloody	89	95.7	76	97.4	165	96.5	0.54
Meconium	4	4.3	2	2.6	6	3.5	
Fetal scalp blood sampling							
No	89	95.7	70	89.7	159	93.0	0.13
Yes	4	4.3	8	10.3	12	7.0	
Fetal scalp blood sampling results							
No	89	95.7	70	89.7	159	93.0	0.40
Less than 7.25	1	1.1	3	3.8	4	2.3	
7.20–7.25	1	1.1	3	3.8	4	2.3	
More than 25.0	2	2.2	2	2.6	4	2.3	
Delivery duration							
Immediate	2	2.2	4	5.1	6	3.5	0.28
Less or equal than 6 hours	81	87.1	61	78.2	142	83.0	
More than 6 hours	10	10.8	13	16.7	23	13.5	

Note: *Statistically significant.

occurred after a 24-hour pause, meaning the failure rate in the second-round subgroup was 2/15 (13.3%). This rate is still very low, especially considering that one failed case in the Propess group did not go into second-round induction because of the patient's decision. It also highlights the importance of proper counseling of patients in setting their expectations concerning the length of induction [28].

Deliveries in both groups were unremarkable and the baby's condition was excellent. This is even more important considering that labour induction was started because of the increased risk of morbidity for the mother or child. Once started, the duration of deliveries in the majority of cases was in the 6-hour range (83.0%). The Propess group had slightly more deliveries taking longer than 6 hours (16.7%) compared to the PG group (10.8%). Induced deliveries appear to be faster than deliveries with a spontaneous onset [29], meaning the positive effect of induction can be transferred to the delivery itself.

Oxytocin was used more frequently in the Propess group and at higher doses. The Propess device is known to allow very fast usage of oxytocin. According to the official recommendations, oxytocin can be introduced as soon as 30 minutes after removal of the Propess device from the vagina. In the PG group, oxytocin could only be used 8 hours after the

initiation of induction, thus preventing more extensive use [30]. It will be interesting to see whether this trend continues into the future as more experience is gained with the Propess device. The Propess group showed slightly more frequent fetal scalp blood sampling with more (pre)acidosis range results and a somewhat higher incidence of caesarean sections and VE than the PG group. Although difficult to explain, it is unlikely the new device is directly causal. One explanation may be there were more cases of epidural analgesia in the Propess group and these were associated with a longer duration of labour, more frequent use of oxytocin at higher doses, and a higher rate of operative deliveries. We believe these differences are likely to disappear as experience with the Propess intravaginal device increases. This may also be the case for delivery abnormalities such as stagnation of cervix dilation and fetal head descent. There were very few instances of postpartum hemorrhage (PPH) in this study, with only 4.3% in the PG group and 2.6% in the Propess group. This agrees with another study that showed that a previously reported higher incidence of PPH following IOL was due more to unfavorable obstetrical conditions than with the induction itself [31]. Conditions of the baby after birth were satisfactory in both the PG and Propess groups.

Table 4. Complications of a delivery after the induction of labour with standard prostaglandin medications (PG group) and Propess (Propess group).

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	p value
Episotomy							
No	50	53.8	52	66.7	102	59.6	0.09
Yes	43	46.2	26	33.3	69	40.4	
Trauma in delivery							
No	65	69.9	53	67.9	118	69.0	0.85
Smaller trauma (Rupture I, II degree, vulva, vagina, cervix)	26	28.0	25	32.1	51	29.8	
Rupture III and IV degree	2	2.2	0	0.0	2	1.2	
Other procedures							
No	86	92.5	75	96.2	161	94.2	0.82
Manual removal of placenta	2	2.2	2	2.6	4	2.3	
Manual exploration of uterus	2	2.2	1	1.3	3	1.8	
Abrasion	3	3.2	0	0.0	3	1.8	
Analgesia during delivery							
No	21	22.6	15	19.2	36	21.1	0.30
Petidin	49	52.7	43	55.1	92	53.8	
Other	15	16.1	11	12.8	26	15.2	
Epidural	8	8.6	15	19.2	23	13.5	
Complications of a third period of a delivery							
No	89	95.7	76	97.4	165	96.5	0.50
Postpartum bleeding	4	4.3	2	2.6	6	3.5	
Bleeding due to trauma	1	1.1	0	0.0	1	0.6	
Operative delivery							
No	78	83.9	58	74.4	136	79.5	0.31
Caesarean section (SC)	12	12.9	16	20.5	28	16.4	
Vacuum extraction (VE)	3	3.2	4	5.1	7	4.1	
Abnormalities during delivery							
None	85	91.4	64	82.1	149	87.1	0.07
Cervix did not open	1	1.1	3	3.8	4	2.3	
The head did not descend	0	0.0	2	2.6	2	1.2	
Both of above	0	0.0	3	3.8	3	1.8	
Fetal distress	6	6.5	5	6.4	11	6.4	
Labor arrest	1	1.1	0	0.0	1	0.6	
Both of above	0	0.0	1	1.3	1	0.6	
Indicatons for SC							
Dilatation of a cervix in time of nonreassuring CTG (cm)							
2	2	2.2	2	2.6	4	2.3	-
3	3	3.2	1	1.3	4	2.3	
4	1	1.1	1	1.3	2	1.2	
5	1	1.1	0	0.0	1	0.6	
7	1	1.1	0	0.0	1	0.6	
8	0	0.0	1	1.3	1	0.6	
9	0	0.0	1	1.3	1	0.6	
10	2	2.2	3	3.8	5	2.9	
No data	0	0.0	3	3.8	3	1.8	
Portion	1	1.1	0	0.0	1	0.6	
Preacidosis							
Preacidosis	1	1.1	4	5.1	5	2.9	-
Cervix dilatation at the time of a caesarean section (cm)							
7	1	1.1	0	0.0	1	0.6	-
8	0	0.0	1	1.3	1	0.6	
9	0	0.0	1	1.3	1	0.6	
10	0	0.0	2	2.6	2	1.2	

Table 4. Continued.

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	p value
Cervix dilatation at the time of labor arrest (cm)							
3	0	0.0	3	3.8	3	1.8	-
4	0	0.0	2	2.6	2	1.2	
7	0	0.0	2	2.6	2	1.2	
Unknown	2	2.2	2	2.6	4	2.3	
Version to transverse position during delivery							
	1	0.0	1	1.3	1	0.6	-

Table 5. Neonatal outcomes after the induction of labour with standard prostaglandin medications (PG group) and Propess (Propess group).

	PG (n = 93)		Propess (n = 78)		Total (n = 171)		
	N	%	N	%	N	%	p value
Birth weight							
2000 g–2500 g	3	3.2	5	6.4	8	4.7	0.09
2500 g–2999 g	23	24.7	10	12.8	33	19.3	
3000 g–3499 g	25	26.9	22	28.2	47	27.5	
3500 g–3999 g	23	24.7	30	38.5	53	31.0	
4000 g–4499 g	19	20.4	10	12.8	29	17.0	
4500 g–5000 g	0	0.0	1	1.3	1	0.6	
Birth weight							
Average (g)	3407.4		3464.6		3433.5		0.50
SD (g)	558.5		550.3		553.9		
Apgar score after 1 minute							
Average	8.4		8.3		8.4		0.64
SD	1.3		1.5		1.4		
Apgar score after 5 minutes							
Average	8.9		8.9		8.9		1.00
SD	0.7		0.6		0.6		
Apgar score after 10 minutes							
Average	9.0		9.0		9.0		1.00
SD	0.5		0.6		0.6		

Table 6. Comparison of the most important IOL outcomes between PG group and Propess group according to the parity.

	PG group (Nullipara = 49) (Multipara = 44)		Propess group (Nullipara = 42) (Multipara = 36)		Total (n = 171)		p value
Induction duration (h) (mean (SD))							
Nullipara	26.0 (19.6)		18.3 (14.3)		22.4 (17.7)		0.04*
Multipara	13.5 (9.3)		18.3 (14.3)		15.7 (10.9)		0.07
24 h pause (N (%))							
Nullipara	12	92.3	0	0.0	12	80.0	0.03*
Multipara	1	7.7	2	100.0	3	20.0	
Labour duration (h) (mean (SD))							
Nullipara	4.1 (2.4)		4.8 (2.8)		4.5 (2.6)		0.20
Multipara	2.8 (1.3)		3.2 (1.3)		3.0 (1.3)		0.17
Postpartum bleeding (N (%))							
Nullipara	4	100.0	1	50.0	5		0.33
Multipara	0	0.0	1	50.0	1		
Caesarean section (N (%))							
Nullipara	9	75.0	12	75.0	21	75.0	1.00
Multipara	3	25.0	4	25.0	7	25.0	

Note: *Statistically significant.

The exceptionally rapid implementation of the new device is surprising. Our group switched to the new device almost overnight in an environment where many doctors with different medical backgrounds (e.g., gynaecologists, obstetricians) work around the clock. The reason for this is likely to be in the advantages offered by the Propess device. It is very easy to use and only one insertion is needed for 24 hours and without the need for frequent repetitions. The slow and gradual release of prostaglandins leads to less painful cervical dilations, fewer hypertonisations (none were recorded in the PG and Propess groups), ease of removal in the case of complications (none were recorded), and the possibility of faster therapy with oxytocin after removal of the device. In the author's experience, easy removal can be disadvantageous if the device is removed before cervical dilation. In several cases, the Propess device fell out of the vagina unnoticed and this was found only some time later. In these cases, a delayed effect and later insertion of the device extended the length of induction. The reason for the device falling out could be that it does not expand in the vagina as stated in official documents and remains thin throughout the induction. The problem of the device falling out of the vagina unnoticed was solved by fixing the cord to the patient's leg with a tape.

Both Propess and Cervidil are dinoprostone intravaginal systems. In Slovenia, Propess is the only one registered and its distribution began only recently. We have no experience with Cervidil, but official documents state the Propess vaginal system is active for 24 hours whereas Cervidil is active for only 12 hours [32]. The longer effectiveness of Propess is likely to be an advantage in our view. To the best of our knowledge, there are no studies that have directly compared these two similar intravaginal systems.

In terms of other studies that compared different forms of PG including vaginal pessary, Alfirevic *et al.* [33, 34] recently published two systematic reviews that included 280 randomised clinical trials comprising a total of 48,068 women. Their analysis suggested that most interventions have similar utility and differ mainly in terms of their cost. Therefore, it is the responsibility of individual departments to find the best method for induction that suits their own needs.

Recent studies have advocated term induction from the 39th week of pregnancy onwards. If these suggestions become part of mainstream medical practice [35], the authors believe the Propess device offers a feasible option that can easily be incorporated into the workflow of delivery wards and perinatology departments. This device could even find a place for labour induction at home because of its ease of use and high safety profile, similar to the finding that balloon catheters are safe and feasible for nulliparous women [36].

5. Conclusions

The Propess device has shown remarkably fast implementation into mainstream medical practice and resulted in improved workflow, process of induction and delivery without affecting positive outcomes for the baby and mother.

Author contributions

Project development: FM, VA. Data collection: VA. Manuscript writing: VA, FM. Manuscript editing: VA, FM. Data analysis and interpretation: FM, VA.

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of UMC Maribor (Reg. No. UKC-MB-KME 50/20). All patients signed a written informed consent form to allow the use of their medical records retrospectively for research purposes.

Conflict of interest

The authors declare no conflict of interest.

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