Tohoku J. Exp. Med., 2025, **265**, 135-141

Clinical Characteristics of the Controlled-Release Dinoprostone Vaginal Delivery System (PROPESS)

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Adequate cervical ripening is essential before labor induction. However, effective methods for cervical ripening are limited in Japan. Although the controlled-release dinoprostone vaginal delivery system (PROPESS) was approved in Japan in 2020, it has not gained widespread acceptance over traditional methods. This observational study aimed to analyze the characteristics and precautions of the PROPESS based on cases of administration for cervical ripening conducted at five hospitals in the Mie Prefecture, Japan, between April 2020 and September 2021. We retrospectively evaluated cases wherein PROPESS was used for cervical ripening to determine its clinical characteristics. A total of 123 pregnant women were included in this study. The most common reason for PROPESS device removal was painful regular uterine contractions within 3 min after administration. Among these women, 48.5% had PROPESS removed within 4 h after administration. PROPESS removal due to non-reassuring fetal status occurred in 12 of the 123 (9.8%) women, with removal occurring within 4 h after administration in 8 of these cases. Among these eight cases, four (50.0%) had accompanying uterine hyperstimulation. The peak time from PROPESS administration to vaginal delivery was 28-32 h for primiparas and 4-8 h for multiparas. This study provides a comprehensive overview of PROPESS usage, highlighting the need for strict monitoring within 4 h after PROPESS administration to ensure its safety. This study provides valuable insights for facilities in Japan planning to implement the PROPESS in the future.

Keywords: cervical ripening; controlled-release dinoprostone vaginal delivery system; labor induction; vaginal delivery
Tohoku J. Exp. Med., 2025 March, **265** (3), 135-141.
doi: 10.1620/tjem.2024.J096

Introduction

A critical factor that contributes to the success of vaginal delivery is cervical ripening, a process that involves softening, thinning, and dilation of the cervix, ultimately reducing the likelihood of failed induced labor. Inducing labor when the cervix is still immature is associated with a two-fold increase in the rate of cesarean sections (CSs) (Luthy et al. 2004; Vrouenraets et al. 2005). Therefore, adequate cervical ripening must occur before labor can be induced. Perinatal data from Japan in 2019 revealed that labor acceleration or induction is performed in 29.1% of all deliveries (Japan Society of Obstetrics and Gynecology 2021). In the United States, the rate of induced labor has been steadily increasing, with 31.4% of all deliveries involving induction (Osterman et al. 2021). These factors highlight the need for effective cervical ripening methods.

Various techniques for cervical ripening are available, including membrane sweeping, mechanical methods, and prostaglandins (Tsakiridis et al. 2020). In other countries, pharmacological methods for cervical ripening such as prostaglandins administration have already been widely

Received February 1, 2024; revised and accepted September 1, 2024; J-STAGE Advance online publication September 12, 2024
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used for more than 30 years. The pharmacological method using vaginal prostaglandin E2 (PGE2) is probably as effective as the mechanical method using a balloon catheter. Vaginal PGE2 probably has a higher risk of hyperstimulation with fetal heart rate (FHR) changes over a balloon catheter (Chen et al. 2016; de Vaan et al. 2023). However, the use of vaginal PGE2 reduces the risk of intrauterine infection and umbilical cord prolapse associated with balloon catheter insertion (Heinemann et al. 2008; Hasegawa et al. 2015). In Japan, cervical ripening primarily relies on membrane sweeping and mechanical methods, as the introduction of prostaglandin vaginal drugs has been slow. A controlled-release dinoprostone vaginal delivery system (PROPESS, Ferring Pharmaceuticals, Saint-Prex, Switzerland) was approved by the Japanese Ministry of Health, Labor, and Welfare in January 2020. Despite this, PROPESS has not gained widespread acceptance in Japan, where membrane sweeping and mechanical methods remain the norm. Therefore, this study aimed to evaluate the clinical characteristics of PROPESS based on available data of cases wherein it was administered. By shedding light on the practical aspects of PROPESS use, this research could offer valuable insights to healthcare facilities in Japan planning to adopt the PROPESS in the future.

Materials and Methods

This observational study was conducted across five hospitals in Mie Prefecture, Japan, between April 2020 and September 2021. This study was conducted in accordance with the principles of the Declaration of Helsinki; its research protocol was approved by the Institutional Review Board of the Mie University Hospital (approval number: H2022-060). The need for informed consent was waived since this was a retrospective analysis. Eligible patients had the opportunity to opt out of participating in the study.

Pregnant women treated with the PROPESS for cervical ripening were included in this study. The inclusion criteria were singleton pregnancies, cephalic presentation, gestational age ≥ 37 weeks, and initial Bishop score ≤ 6. The exclusion criteria were previous uterine surgery, FHR abnormalities before PROPESS insertion, placenta previa, placental abruption, malpresentation, chromosomal abnormalities, or contraindications to PROPESS. Attending obstetricians who had obtained licenses as specialists from the Japan Society of Obstetrics and Gynecology determined the Bishop score and used the PROPESS.

Upon admission, all pregnant women provided informed consent for treatment with the PROPESS. The PROPESS was positioned in the posterior vaginal fornix, with continuous monitoring of the FHR and uterine activity during insertion. PROPESS removal was performed after 12 h or in the event of: (i) painful regular uterine contractions within 3 min; (ii) membrane rupture or amniotomy; (iii) uterine hyperstimulation with associated signs; (iv) non-reassuring fetal status (NRFS); or (v) side effects, such as nausea, vomiting, or hypotension. Patients requiring further cervical ripening despite PROPESS use underwent additional cervical ripening using a balloon catheter, with a maximum insertion period of up to 2 days if cervical ripening remained insufficient. In cases necessitating labor induction or augmentation, predelivery oxytocin was initiated, with an administration period of up to 3 days. The induction was considered unsuccessful if these methods did not result in a vaginal delivery.

The collected data included maternal age, gravidity and parity, height and weight, body mass index (BMI), gestational age at admission, indication for labor induction, initial Bishop score, Bishop score at PROPESS removal, reasons for PROPESS removal, administration duration of PROPESS, adverse events associated with PROPESS, the use of predelivery oxytocin, delivery mode, time from PROPESS administration to vaginal delivery, labor duration, umbilical arterial pH, birth weight, and 1- and 5-min Apgar scores. We did not have access to information that could identify individual participants after data collection.

Statistical analyses were performed using GraphPad Prism 8 software (GraphPad Software Inc.). The normality of distribution was determined using the Shapiro-Wilk test. The Cox proportional hazards model was employed to analyze factors associated with successful vaginal delivery. Statistical significance was set at $P < 0.05$. Data are presented as median (interquartile range) or number (%).

Results

A total of 123 pregnant women were included in this study. The patients' clinical characteristics are presented in Table 1.

Delivery mode and neonatal outcomes

Vaginal delivery was achieved in 73.2% (90 of 123) of the patients, with 66.7% (56 of 84) in primiparas and 87.2% (34 of 39) in multiparas. CS was performed for NRFS in 33.3% of cases, labor arrest in 30.3%, induction failure in 24.2%, severe hypertension in 9.1%, and fore-lying umbilical cord after cervical ripening in 3.0%. The median umbilical arterial pH, birth weight, and 1- and 5-min Apgar scores were 7.291 (7.256-7.330), 3008 g (2771-3289), and 8 (8-8) and 9 (9-9), respectively.

Bishop score

The change in the Bishop's score from the PROPESS insertion to its removal was 2 (1-3) in primiparas and 1 (1-3) in multiparas. The proportion of pregnant women with a Bishop score ≥ 7 at PROPESS removal was 11.9% (10 of 84) in primiparas and 12.8% (5 of 39) in multiparas. In addition, 40.5% (34 of 89) of primiparas and 23.1% (9 of 39) of multiparas underwent additional cervical ripening using a balloon catheter.

Reason for PROPESS removal and PROPESS administration time

The reasons for PROPESS removal are listed in Table

Table 1. Clinical characteristics.

	Total n = 123	Primipara n = 84	Multipara n = 39
Maternal age, median (IQR)	34 [30-38]	34 [30-37.3]	34 [31-38]
BMI (kg/m2), median (IQR)	26.1 [23.5-29.0]	26.2 [23.5-28.9]	25.6 [23.3-28.6]
Gestational age at admission (days), median (IQR)	276 [269-284.5]	277.5 [272-285]	271 [264-281.5]
Initial Bishop score, median (IQR)	2 [1-3]	2 [1-3]	3 [2-4]
Indication of labor induction			
Prolonged pregnancy, n (%)	38 (30.2)	28 (32.9)	10 (24.4)
GDM/DM, n (%)	28 (22.2)	18 (21.2)	10 (24.4)
HDP, n (%)	25 (19.8)	19 (22.4)	6 (14.6)
FGR, n (%)	13 (10.3)	6 (7.1)	7 (17.1)
Oligohydramnios, n (%)	6 (4.8)	3 (3.5)	3 (7.3)
Others, n (%)	16 (12.7)	11 (12.9)	5 (12.2)

BMI, body mass index; DM, diabetes mellitus; FGR, fetal growth restriction; GDM, gestational diabetes mellitus; HDP, hypertensive disorder of pregnancy; IQR, interquartile range.

Table 2. Reasons for PROPESS removal.

	Total n = 123	Primiparas n = 84	Multiparas n = 39
Painful regular uterine contraction within 3 minutes, n (%)	68 (55.3)	42 (50.0)	26 (66.7)
12 hours after insertion of PROPESS, n (%)	32 (26.0)	26 (31.0)	6 (15.4)
Non-reassuring fetal status, n (%)	12 (9.8)	7 (8.3)	5 (12.8)
Membrane rupture, n (%)	4 (3.3)	3 (3.6)	1 (2.6)
Nausea (side effect), n (%)	1 (0.8)	1 (1.2)	0 (0)
Others, n (%)	6 (4.8)	5 (6.0)	1 (2.6)

2. The most common reason was painful regular uterine contractions within 3 min. Among these participants with PROPESS removal, 45.2% (19 of 42) of primiparas and 53.8% (14 of 26) of multiparas had the PROPESS removed within 4 h. Of the 12 patients (9.8%) with PROPESS removal for NRFS, eight underwent removal within 4 h, and four (50.0%) of the eight cases had accompanying uterine hyperstimulation. Other reasons for removal included sliding of the PROPESS from the vagina (2.4%), the decision to perform emergency CS owing to severe hypertension during PROPESS insertion (1.6%), and genital bleeding (0.8%).

The PROPESS administration time is shown in Fig. 1. The median administration time for PROPESS was 400 min

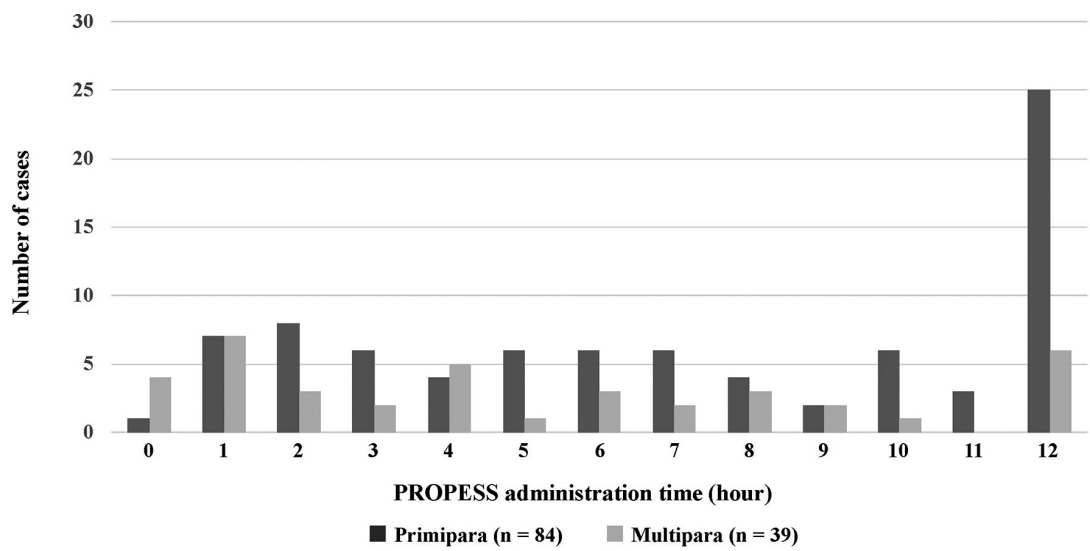

Fig. 1. PROPESS administration time.

(180-715 min).

Use of oxytocin

The proportion of pregnant women who received pre-delivery oxytocin for induction or augmentation of labor after PROPESS removal was 68.3% (84 of 123), with 78.6% (66 of 84) in primiparas and 46.2% (18 of 39) in multiparas. The median oxytocin dose was 3.11 IU (1.46-7.50). Twenty eight of 84 (33.3%) primiparas and 22 of 39 (56.4%) multiparas went into labor during or after PROPESS administration.

Time from PROPESS administration to delivery

The time from PROPESS administration to delivery in primiparas and multiparas is shown in Fig. 2 and 3, respectively. Data on the time from PROPESS administration to delivery were missing for three of the women in this study. The proportion of pregnant women who delivered vaginally within 12 and 24 h after PROPESS insertion was 20.8% (25 of 120) and 31.6% (38 of 120), respectively. Among multiparas who delivered vaginally (n = 34), 55.9% and 61.8% delivered within 12 and 24 h after PROPESS insertion, respectively. Twelve of 34 (35.3%) multiparas delivered vaginally within 4 h after PROPESS insertion. The peak time from PROPESS administration to vaginal delivery was 28-32 h in primiparas and 4-8 h in multiparas.

Factors associated with successful vaginal delivery

The factors associated with successful vaginal delivery included multiparity and Bishop's scores ≥ 7 at PROPESS removal (Table 3). Gestational age at admission ≥ 40 weeks and BMI ≥ 30 kg/m^2 were associated with a signifi-

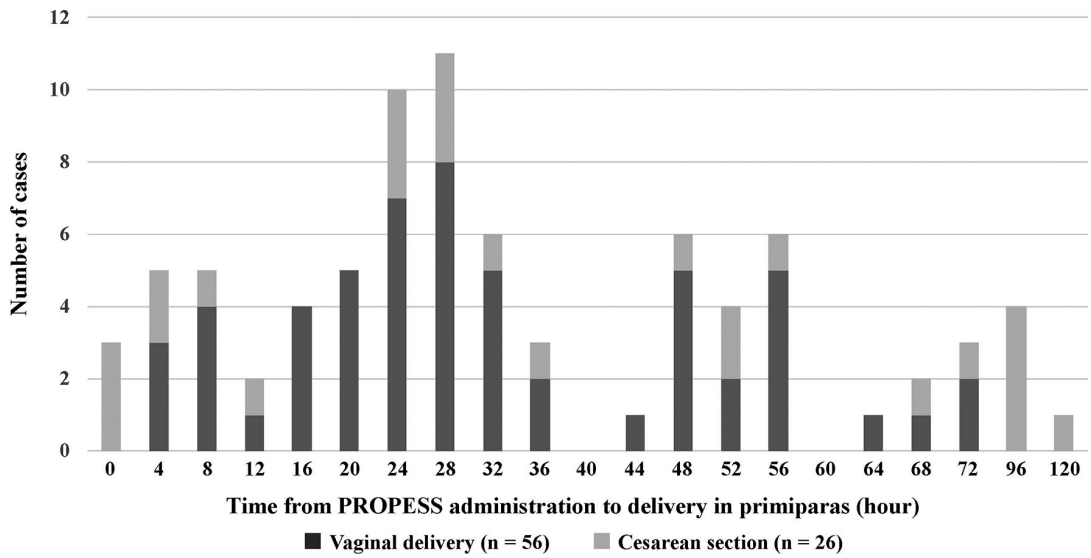

Fig. 2. Time from PROPESS administration to delivery in primiparas.

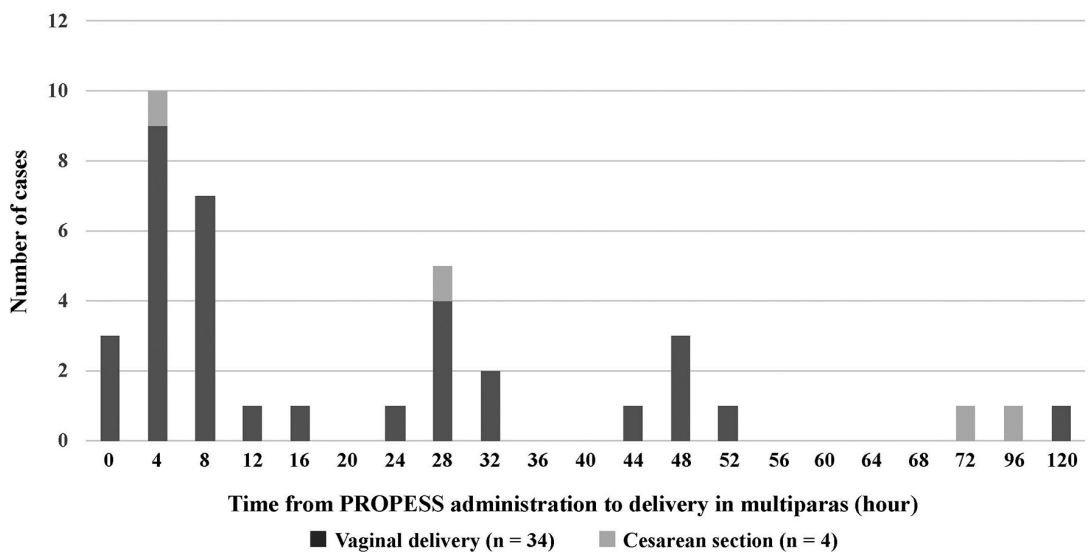

Fig. 3. Time from PROPESS administration to delivery in multiparas.

Table 3. Factors associated with successful vaginal deliveries.

	Hazard ratio (95% CI)	P-value
Multiparity	2.94 (1.83-4.65)	< 0.01
Bishop score ≥ 7 at removal of PROPESS	3.49 (1.77-6.52)	< 0.01
Gestational age at admission ≥ 40 weeks	0.48 (0.30-0.78)	< 0.01
BMI ≥ 30 kg/m^2	0.42 (0.21-0.76)	< 0.01
Maternal age ≥ 35 years	0.86 (0.55-1.33)	0.48
Birth weight ≥ 3,500 g	0.74 (0.36-1.38)	0.36

CI, confidence interval; BMI, body mass index.

cantly increased risk of failed vaginal delivery.

Discussion

Numerous studies have assessed the PROPESS in terms of its effectiveness, cost-benefit, and safety (Larrañaga-Azcárate et al. 2008; Diguisto et al. 2017; Itoh et al. 2021; Walker et al. 2022). However, detailed reports on the utilization of the PROPESS are scarce. Herein, we aimed to characterize the various features of PROPESS use for cervical ripening. This study had four main findings. First, the primary reason for PROPESS removal was painful regular uterine contractions within 3 min, and in approximately half of the cases, PROPESS was removed within 4 h. Second, the majority of NRFS events during PROPESS administration occurred within 4 h after administration. Third, approximately 50% of all deliveries in multiparas involved PROPESS use alone, without the need for oxytocin. Fourth, the peak time from PROPESS administration to vaginal delivery was 28-32 h in primiparas and 4-8 h in multiparas.

Dinoprostone is a synthetic prostaglandin that is chemically identical to PGE2. It induces cervical ripening by enhancing collagenase activity, promoting inflammatory responses, catabolizing progesterone, and increasing glycosaminoglycans (Osmers et al. 1991; Aronsson et al. 2005; Christiaens et al. 2008; Myers et al. 2009). PGE2 also acts directly on PGE2 receptors in the myometrium, reducing cyclic adenosine monophosphate levels in uterine smooth muscles, ultimately leading to uterine contractions (Wikland et al. 1982; Senior et al. 1993; Arulkumaran et al. 2012). The PROPESS tends to induce uterine contractions more readily than do mechanical uterine ripening methods, thus necessitating careful monitoring to prevent excessive uterine contractions. Herein, painful regular uterine contractions within 3 min were the primary reason for PROPESS removal, with approximately half of the cases involving removal within 4 h. Onset of active labor was the most common reason for retrieval of dinoprostone vaginal insert during labor induction (Rugarn et al. 2017). The reason why its removal was likely to occur within 4 h after PROPESS administration in this study may be attributed to the pharmacokinetics of PGE2, of which the peak plasma concentration occurred approximately 4 h after PROPESS administration in non-pregnant Japanese women who were administered the PROPESS for 12 h (Itoh et al. 2021). Moreover, this study suggests that NRFS is most likely to occur within 4 h after PROPESS administration, with half of the cases experiencing uterine hyperstimulation. These findings underline the importance of using the PROPESS while maintaining strong monitoring, particularly within the first 4 h of administration. This information is important for planning the timing of PROPESS use.

PGE2 induces cervical ripening and uterine contractions, which, when using the PROPESS alone, may contribute to vaginal delivery. Mechanical cervical dilation produces physical changes in cervical tissue and activates molecular mechanisms that promote cervical maturation through positive feedback. However, these actions alone are often insufficient for inducing delivery; predelivery oxytocin for induction or augmentation of labor is indicated. We previously reported that PROPESS administration for cervical ripening resulted in a higher rate of vaginal delivery among pregnant women, with a reduced need for predelivery oxytocin compared with mechanical cervical dilation (Yamaguchi et al. 2021). A previous metaanalysis also suggested that there was an increased need for oxytocin induction and/or augmentation of labor after balloon ripening, compared with locally applied prostaglandins (Vaknin et al. 2010). In this study, approximately 50% of all deliveries in multiparas involved PROPESS use alone, without the need for oxytocin. The PROPESS alone was found to be associated with vaginal delivery, eliminating the need for oxytocin, particularly in multiparas. This approach benefits both clinicians and patients.

Highlighting that labor and delivery require medical assistance is important. The peak time from PROPESS administration to vaginal delivery was 28-32 h in primiparas and 4-8 h in multiparas. In other words, these timeframes necessitate a higher level of medical intervention. This information is valuable for planning the timing of PROPESS administration. Particularly, we recommend that the PROPESS be administered such that these timeframes occur during daytime hours.

Additionally, in this study, we conducted an analysis of factors associated with vaginal delivery using the PROPESS. The results are consistent with those of various studies that have identified factors associated with successful vaginal delivery (Ramos et al. 2017; Meier et al. 2019;

Ismail et al. 2021).

There are two limitations in this study. First, this study was retrospective, single-arm design. Second, the sample size was small. Nevertheless, it should be noted that the study exhibits a notable strength in offering a detailed profile of PROPESS usage. In summary, this study revealed the detailed profile of the PROPESS. Understanding the clinical characteristics elucidated by this study is crucial when considering its application. We anticipate that the results of this study will offer insights to healthcare facilities in Japan that are preparing for the introduction of the PROPESS.

Acknowledgments

The authors would like to thank Editage (http://www.editage.com/) for English language editing.

Author Contributions

All authors contributed to this study's conception and design. Material preparation and data collection were performed by Mizuki Yamaguchi, Sho Takakura, Yuya Tamaishi, Shoichi Magawa, Shintaro Maki, Masafumi Nii, Kayo Tanaka, Kuniaki Toriyabe, Kyohei Yamaguchi, Marie Makino, Naoki Watashige and Goki Maegawa. Data analysis was performed by Mizuki Yamaguchi, Sho Takakura and Hiroaki Tanaka. The first draft of the manuscript was written by Sho Takakura and all authors commented on previous versions of manuscript. All authors read and approved the final manuscript.

Conflict of Interest

The authors declare no conflict of interest.

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