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Original Research

Maternal and Neonatal Outcomes Following Labor Induction With a Dinoprostone Vaginal Insert in Pregnancies With Prelabor Rupture of Membranes: A Retrospective Observational Study

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Abstract

Background: The safety and efficacy of the dinoprostone vaginal insert for labor induction in women with prelabor rupture of membranes (PROM) remains uncertain. This study compared clinical outcomes between women with PROM and those with intact membranes. **Methods:** In this single-centre retrospective study, singleton pregnancies at ≥37 weeks of gestation induced with a dinoprostone vaginal insert between January 2020 and June 2025 were categorized as PROM (n = 42) or controls (n = 84). Demographic characteristics, cervical status, labor characteristics, delivery mode, maternal complications, as well as neonatal outcomes were analyzed using the *t*-test or Mann-Whitney U test for continuous variables and the chi-square or Fisher's exact test for categorical variables, with a significance level of $\alpha = 0.05$. The study was approved by the institutional ethics committee (Approval No.: 2026/6295; Application ID: 29133). **Results:** Gestational age at delivery was significantly lower in the PROM group than in the control group (37.70 ± 1.17 vs. 39.54 ± 1.39 weeks; $p < 0.001$). Although pre-induction cervical dilatation was greater in the PROM group, post-induction cervical dilatation and cervical effacement were significantly lower than those in the control group (both $p < 0.001$). The overall cesarean delivery rate was higher in the PROM group, primarily driven by an increased incidence of cesarean delivery due to fetal distress (35.7% vs. 16.7%; $p = 0.008$). Tachysystole was rare in both groups (0% vs. 1.2%; $p = 0.478$). No cases of postpartum hemorrhage or third-degree perineal lacerations occurred, and hemoglobin concentration and blood transfusion rates were comparable between groups. Neonates in the PROM group had significantly lower birth weights (2770.60 ± 447.30 g vs. 3321.20 ± 344.50 g; $p < 0.001$) and lower 5-minute Apgar scores (8.33 ± 1.00 vs. 9.25 ± 0.65; $p < 0.001$). **Conclusions:** Pregnancies complicated by PROM were associated with a reduced cervical response to dinoprostone, higher cesarean delivery rates, primarily due to fetal distress, and less favorable neonatal outcomes, whereas maternal safety outcomes appeared acceptable. Careful patient selection and close intrapartum monitoring are recommended when using dinoprostone for labor induction in women with PROM.

Keywords: prelabor rupture of membranes; dinoprostone; labor; induction; cervical ripening; neonatal outcomes

1. Introduction

Prelabor rupture of membranes (PROM) is defined as the spontaneous rupture of the fetal membranes before the onset of labor and represents a common clinical condition in obstetric practice. It occurs in approximately 8% to 10% of term pregnancies. PROM can occur in both term and preterm pregnancies and requires careful monitoring, close surveillance, and timely obstetric intervention due to its association with an increased risk of maternal and neonatal morbidity [1].

Infectious complications associated with PROM, along with increased rates of cesarean delivery and adverse neonatal outcomes, constitute the primary clinical challenges associated with this condition [2]. In pregnancies complicated by PROM, timely delivery is recommended to reduce the risk of maternal and neonatal complications. In term and near-term pregnancies, expectant management is generally discouraged because the risk of intrauterine infection increases as the duration between membrane rupture and delivery lengthens.

In this context, although labor induction is commonly preferred in cases of PROM, there is still no clear consensus in the literature regarding the optimal induction agent or method of administration [1,3]. Although numerous studies have evaluated the effects of different induction methods on maternal and neonatal outcomes, the generalizability of these findings remains limited due to the heterogeneity in patient populations, indications for induction, and clinical protocols [4]. Previous studies have also demonstrated that dinoprostone-based labor induction may yield variable success rates and obstetric outcomes depending on maternal characteristics, cervical status, and the underlying indication for induction [5,6].

Prostaglandin E_2 (dinoprostone) is a well-established pharmacological agent that has long been used for labor induction due to its cervical ripening properties. The controlled-release vaginal dinoprostone insert (Propess®) provides gradual and physiologically consistent cervical ripening while reducing the risk of uterine hyperstimulation and allowing for rapid removal when necessary. These characteristics make it a clinically appropriate option, particularly in cases of PROM, where close maternal–fetal monitoring is essential [7,8].

Nevertheless, the efficacy and safety of prostaglandin use in cases of PROM, where membrane integrity is compromised, remain subjects of ongoing debate. Available evidence suggests that membrane rupture leads to inflammatory and biochemical changes in cervical tissue that may alter the response to prostaglandins. Although some studies have reported that prostaglandin-induced labor is associated with lower vaginal delivery rates and higher cesarean delivery rates, other studies have demonstrated acceptable maternal safety outcomes [3,4].

Conversely, the timing of delivery and the management strategies in cases of PROM have important implications for neonatal outcomes. Delivery at an earlier gestational age, fetal distress, low Apgar scores, and respiratory complications related to prematurity are among the neonatal risks frequently reported in these pregnancies. The need for neonatal intensive care during the early postnatal period emerges as a major determinant of neonatal morbidity associated with PROM [9].

Therefore, in cases of PROM, induction methods should be evaluated not only for their effects on the mode of delivery but also for their impact on maternal and neonatal outcomes. The aim of this study was to compare maternal and neonatal outcomes following labor induction with Propess® in pregnancies complicated by PROM and those with intact membranes. The findings of this study are expected to inform clinical decision-making regarding the use of Propess® in women with PROM and to provide insights for the development of individualized obstetric management strategies.

2. Materials and Methods

The study population comprised pregnant women admitted to the Department of Obstetrics and Gynecology at Konya City Hospital between January 2020 and June 2025 who underwent labor induction with a dinoprostone vaginal insert (Propess®, Ferring Pharmaceuticals, Copenhagen, Denmark).

PROM was defined as spontaneous rupture of membranes before the onset of labor in term pregnancies (≥37 weeks of gestation), diagnosed based on clinical findings, including visualization of amniotic fluid leakage and, when necessary, supported by diagnostic tests in accordance with standard obstetric practice.

The study population was divided into two groups according to membrane status at the time of induction: women with PROM (PROM group) and women with intact amniotic membranes (control group).

During the study period, a total of 1048 patients underwent labor induction. Of these, 126 patients (12.02%) met the eligibility criteria and were included in the final analysis. The majority of patients were excluded due to the strict inclusion criteria, which required singleton term pregnancies with cephalic presentation and labor induction using a dinoprostone vaginal insert, as well as the exclusion of patients with a history of uterine surgery, multiple gestations, fetal anomalies, and clinical infection.

A total of 126 patients were included in the study, comprising 42 patients in the PROM group and 84 in the control group. Medical records were reviewed to collect data on demographic characteristics, obstetric history, labor characteristics, delivery outcomes, and maternal and neonatal parameters. The unequal group sizes reflect the retrospective study design. All eligible PROM cases were included, and a larger control group was selected to improve statistical power. No *a priori* sample size calculation was performed due to the retrospective design of the study.

Group allocation was determined based on membrane status prior to the initiation of labor induction. Only patients with confirmed PROM before placement of the Propess® insert were assigned to the PROM group. Patients who experienced membrane rupture after the initiation of labor induction were not reclassified and were analyzed according to their original group assignment.

Women with singleton pregnancies, cephalic presentation, a gestational age of ≥37 weeks, and labor induction with a dinoprostone vaginal insert were included in the study. Exclusion criteria comprised multiple gestations, non-cephalic presentation, a history of prior uterine surgery, placental abnormalities, clinical chorioamnionitis at the time of hospital admission, and fetal congenital anomalies.

The control group included intact amniotic membranes at the time of labor induction, a gestational age of ≥37 weeks, singleton pregnancy with cephalic presentation, the absence of spontaneous onset of labor, use of a dinoprostone vaginal insert (Propess®) for labor induction and no clinical evidence of prelabor rupture of membranes or intrauterine infection. In cases where rupture of membranes occurred after placement of the dinoprostone vaginal insert, the insert was removed, and these patients were not reclassified as PROM, as group allocation was determined based on membrane status at the time of induction.

Cervical ripening was performed in all patients using a controlled-release dinoprostone vaginal insert (Propess®, 10 mg). The insert was placed in the posterior vaginal fornix according to the manufacturer's instructions. During labor induction, fetal heart rate and uterine activity were monitored at regular intervals. The vaginal insert was re-

moved upon the onset of active labor, the development of uterine tachysystole, the detection of non-reassuring fetal heart rate patterns, or upon completion of the maximum recommended application time (24 hours). In addition, it was removed in cases of severe uterine pain, intolerable maternal adverse effects, unexplained vaginal bleeding, suspected placental abruption, or clinical signs of chorioamnionitis. Propess® was also discontinued when a decision was made to perform cesarean delivery. Cervical status was assessed before and after Propess® application by measuring cervical dilatation and effacement. Maternal and fetal monitoring was continued thereafter. The duration of Propess® application was recorded in minutes [7].

Patients were closely monitored during labor induction with the dinoprostone vaginal insert (Propess®) in accordance with the manufacturer's recommendations and institutional protocols. The insert was promptly removed upon the onset of active labor, the development of uterine tachysystole, the detection of non-reassuring fetal heart rate patterns, or signs of fetal distress. In addition, the vaginal insert was removed in cases of severe uterine pain, intolerable maternal adverse effects, unexplained vaginal bleeding, suspected placental abruption, or clinical signs of chorioamnionitis. Propess® was also discontinued when a decision for cesarean delivery was made or when the maximum recommended application duration of 24 hours had been reached. Maternal and fetal monitoring was continued thereafter. For all patients, the following variables were recorded: changes in cervical dilatation and effacement following Propess® application, mode of delivery, duration of vaginal delivery, indications for cesarean delivery when applicable, occurrence of uterine tachysystole, postpartum hemorrhage, severe perineal lacerations, pre- and post-delivery hemoglobin levels, need for packed red blood cell (PRBC) transfusion, birth weight, and 1- and 5-minute Apgar scores.

Statistical Analysis

Continuous variables with non-normal distributions are presented as the median (interquartile range [IQR]), with minimum and maximum values additionally reported to facilitate the interpretation of highly skewed distributions. These variables were analyzed using the Mann-Whitney U test. Categorical variables are expressed as frequencies (n) and percentages (%) and were compared using the chi-square test or Fisher's exact test, as appropriate. Because baseline differences were observed between the PROM and control groups, multivariable linear regression models were additionally constructed for selected continuous obstetric and neonatal outcomes. Gestational age at delivery, gravidity, parity, and pre-Propess® cervical dilatation were included in the models as covariates. A two-sided p-value < 0.05 was considered statistically significant.

3. Results

During the study period, a total of 1048 patients underwent labor induction. Of these, 126 (12.02%) met the inclusion criteria and were included in the final analysis. The study population comprised 42 patients in the PROM group and 84 patients in the control group. The demographic and obstetric characteristics of the study population are presented in Table 1.

No statistically significant difference was observed between the groups in terms of maternal age ($p = 0.663$). Gravida and parity were significantly lower in the PROM group than in the control group ($p = 0.006$ and $p = 0.014$, respectively). Although the median parity was identical between the groups, the distributions differed, with a significantly lower parity in the PROM group ($p = 0.014$), the Mann-Whitney U test identified a significant difference in the overall distribution of parity values, with a wider range observed in the control group (0–3 vs. 0–1). No significant between-group difference was observed in the history of abortion ($p = 0.229$). Gestational age at delivery was significantly lower in the PROM group than in the control group ($p < 0.001$).

Cervical assessment findings before and after Propess® application and delivery-related outcomes are summarised in Table 2. Before Propess® administration, cervical dilatation was significantly greater in the PROM group than in the control group ($p = 0.001$). Although the median pre-Propess® cervical dilatation was 0 cm in both groups, the distribution differed significantly, with the PROM group exhibiting a wider IQR (0 [0–1] vs. 0 [0–0]), indicating greater variability in cervical dilatation at baseline. No significant difference in cervical effacement before Propess® administration was observed between the groups ($p = 0.480$). Following Propess® administration, both cervical dilatation and effacement rates were significantly lower in the PROM group compared with the control group ($p < 0.001$ for both parameters). No statistically significant difference was observed between the groups in terms of the duration of Propess® application ($p = 0.144$). Uterine tachysystole rates were low in both groups, with no significant difference between them ($p = 0.478$).

A statistically significant difference in the mode of delivery was observed between the groups (Table 2). The rate of vaginal delivery was significantly lower, whereas the cesarean delivery rate was significantly higher, in the PROM group compared with the control group ($p = 0.006$). Analysis of cesarean delivery indications demonstrated that fetal distress occurred significantly more frequently in the PROM group than in the control group ($p = 0.008$). No significant differences were found between the groups in terms of cesarean delivery performed due to cephalopelvic disproportion (CPD) or non-progressive labor. Among women who achieved vaginal delivery, the duration of vaginal delivery did not differ significantly between the PROM and control groups ($p = 0.948$). No cases of third-degree per-

Table 1. Demographic and obstetric characteristics of the study population.

Parameter	PROM group (n = 42)	Control group (n = 84)	*p*-value
Maternal age (years)	25.61 ± 3.41	25.94 ± 4.10	0.663*
Gravida	1 (1–3) [1–13]	1 (1–4) [1–24]	**0.006****
Parity	0 (0–1) [0–3]	0 (0–3) [0–11]	**0.014****
Abortion	0 (0–1) [0–6]	0 (0–2) [0–10]	0.229**
Gestational age at delivery (weeks)	37.70 ± 1.17	39.54 ± 1.39	<**0.001***

*Mean ± standard deviation (SD), using independent-samples *t*-test. **Median (min–max), using Mann-Whitney U test. Bold values indicate statistical significance ($p < 0.05$). Gravida, total number of pregnancies; parity, number of births ≥20 weeks of gestation; abortion, number of previous pregnancy losses. Values of 0 indicate no previous births for parity and no previous pregnancy loss for abortion. PROM, prelabor rupture of membranes.

Table 2. Prepartum, intrapartum, and postpartum clinical characteristics of the study population.

Parameters	PROM (n = 42)	Control (n = 84)	*p*-value
Pre-Propess® cervical dilatation (cm)	0 [0–1], (0–2)	0 [0–0], (0–2)	**0.001****
Pre-Propess® cervical effacement (%)	0 [0–0], (0–0)	0 [0–0], (0–20)	0.480**
Post-Propess® cervical dilatation (cm)	2 [1.25–5], (0–7)	5 [3.75–6], (0–8)	<**0.001****
Post-Propess® cervical effacement (%)	40 [10–60], (0–80)	55 [40–60], (0–90)	<**0.001****
Propess® duration (min)	453.88 ± 306.84	548.75 ± 357.80	0.144*
Tachysystole	0 (0%)	1 (1.2%)	0.478***
Delivery route			
Vaginal delivery	20 (47.6%)	61 (72.6%)	**0.006*****
Cesarean delivery	22 (52.4%)	23 (27.4%)	
Vaginal delivery duration (min)†	600 [534–763], (390–2500)	600 [480–1080], (180–1920)	0.948**
Cause of cesarean delivery†			
Fetal distress	15 (68.2%)	14 (60.9%)	
Cephalopelvic disproportion (CPD)	2 (9.1%)	7 (30.4%)	**0.008*****
Non-progressive labor	5 (22.7%)	2 (8.7%)	
Grade 3 laceration	None	None	N/A
Postpartum hemorrhage	None	None	N/A
Pre-delivery hemoglobin (g/dL)	12.03 ± 1.18	11.95 ± 1.17	0.747*
Post-delivery hemoglobin (g/dL)	10.96 ± 1.03	10.74 ± 1.28	0.303*
PRBC	2 (4.8%)	1 (1.2%)	0.257***

*Mean ± standard deviation (SD), using independent-samples *t*-test. **Median [IQR], (min-max), using Mann-Whitney U test. ***n (%), using the chi-square test or Fisher's exact test. Bold values indicate statistical significance ($p < 0.05$). N/A, not applicable.

† Analysed only in the relevant subgroup. For cervical assessment variables, a value of 0 indicates a closed cervix with no measurable cervical dilatation or effacement at the time of examination and does not represent missing data. PRBC, packed red blood cell.

Causes of cesarean delivery were analyzed only among patients who underwent cesarean delivery in each group; percentages were calculated using the number of cesarean deliveries in the respective group as the denominator (PROM: n = 22; control: n = 23).

ineal laceration or postpartum hemorrhage were observed in either group.

No significant differences were observed between the PROM and control groups in maternal hemoglobin levels before and after delivery. Pre-delivery hemoglobin levels were comparable between the groups ($p = 0.747$), and post-delivery hemoglobin levels also did not differ significantly ($p = 0.303$). Although PRBC transfusion was more frequently required in the PROM group, this difference was not statistically significant ($p = 0.257$).

Neonatal outcomes are presented in Table 3. The mean birth weight of neonates born in the PROM group was significantly lower than that of the control group ($p < 0.001$). Although 1-minute Apgar scores were similar between the groups ($p = 0.068$), 5-minute Apgar scores were significantly lower in the PROM group than in the control group ($p < 0.001$).

To determine whether the observed differences were independently associated with PROM status, multivariable linear regression analyses were performed after adjustment

Table 3. Neonatal outcomes of the study population.

Parameters	PROM (n = 42)	Control (n = 84)	*p*-value
Birth weight (g)	2770.60 ± 447.30	3321.20 ± 344.50	<**0.001***
1-min Apgar	7.69 ± 1.40	8.13 ± 0.87	0.068*
5-min Apgar	8.33 ± 1.00	9.25 ± 0.65	<**0.001***

*Mean ± standard deviation (SD), independent-samples *t*-test. Bold values indicate statistical significance ($p < 0.05$).

for gestational age at delivery, gravidity, parity, and pre-Propess® cervical dilatation. After adjustment, the control group remained independently associated with greater post-Propess® cervical dilatation (β = 1.400, $p = 0.009$) and higher post-Propess® cervical effacement (β = 13.369, $p = 0.028$). In addition, neonates in the control group had significantly higher birth weights (β = 245.6 g, $p = 0.003$) and higher 5-minute Apgar scores (β = 0.881, $p < 0.001$). Among women who achieved vaginal delivery, the duration of labor remained significantly longer in the control group (β = 259.4 min, $p = 0.046$) (Table 4).

4. Discussion

In this study, maternal and neonatal outcomes following labor induction using Propess® in pregnancies complicated by PROM were evaluated. Compared with pregnancies with intact membranes, PROM was associated with lower rates of vaginal delivery and higher rates of cesarean delivery. Furthermore, fetal distress was the leading indication for cesarean delivery in the PROM group, which also exhibited relatively less favorable neonatal outcomes. Nevertheless, the use of Propess® was associated with an acceptable maternal safety profile. However, the observed differences in outcomes between the groups should be interpreted with caution, as baseline imbalances, particularly in gestational age, cervical status, and obstetric characteristics, may have independently influenced cervical response and delivery outcomes. Notably, these associations remained significant after adjustment for gestational age at delivery, gravidity, parity, and pre-induction cervical dilatation, suggesting that membrane status itself may contribute to the observed differences.

Recent studies have continued to evaluate the safety and efficacy of dinoprostone for labor induction in pregnancies complicated by PROM, with generally comparable maternal and neonatal outcomes reported across different induction strategies. However, the optimal timing of induction and appropriate patient selection remain subjects of ongoing debate [10].

The significantly lower gestational age at delivery observed in the PROM group represents an expected finding and is consistent with current international guidelines. These clinical guidelines recommend avoiding delays in delivery following PROM due to the progressively increasing risk of intrauterine infection and support labor induction when clinically appropriate [1,9]. However, previous studies have reported that labor induction performed at an earlier gestational age, particularly in the presence of an insufficient cervical ripening, may adversely affect labor progression and increase cesarean delivery rates [8].

The higher pre-Propess® cervical dilatation observed in the PROM group may be attributable to the biochemical and inflammatory changes occurring in cervical tissue following membrane rupture. Previous studies have demonstrated that membrane rupture is associated with increased expression of inflammatory cytokines and matrix metalloproteinases in the cervix, leading to structural remodeling of cervical tissue [11].

However, in our study, the lower rates of cervical dilatation and effacement following Propess® administration in the PROM group suggest that disruption of membrane integrity may impair the cervical response to dinoprostone. This finding is consistent with previous studies demonstrating that PROM is associated with substantial inflammatory and biochemical alterations in the cervix and fetal membrane tissues, mediated by increased expression of proinflammatory cytokines and matrix metalloproteinases, which may alter tissue responsiveness to prostaglandin administration [12,13].

The significantly higher cesarean delivery rate observed in the PROM group, with fetal distress emerging as the primary indication, is consistent with previous reports in the literature. In the landmark study by Hannah et al. [14], women with PROM who underwent labor induction exhibited higher rates of cesarean delivery attributable to fetal distress. The more frequent occurrence of fetal heart rate abnormalities during labor induction in pregnancies complicated by PROM has been attributed to umbilical cord compression due to reduced amniotic fluid volume and increased uterine sensitivity to prostaglandins [15]. In the present study, the low incidence of tachysystole suggests that the higher cesarean delivery rate was more likely related to reduced fetal tolerance of labor than to uterine hyperstimulation.

From a maternal safety perspective, no cases of postpartum hemorrhage or severe perineal laceration were observed in either group. In addition, the absence of significant differences in pre- and post-delivery hemoglobin levels, along with comparable rates of PRBC transfusion, suggests that the use of Propess® has an acceptable maternal safety profile in pregnancies complicated by PROM. These findings are consistent with previous studies reporting that controlled-release dinoprostone vaginal inserts are safe with respect to maternal complications [12,16].

When neonatal outcomes were evaluated, neonates in the PROM group had significantly lower mean birth weights and lower 5-minute Apgar scores than those in the control group. These findings may be explained by the earlier gestational age at delivery and increased fetal stress associated with PROM. Previous systematic reviews and meta-analyses have demonstrated that PROM is asso-

Table 4. Multivariable linear regression analysis of obstetric and neonatal outcomes.

Outcome	β (95% CI)	SE	*p*-value
Post-Propess® cervical dilatation (cm)	1.400 (0.36–2.44)	0.524	**0.009***
Post-Propess® cervical effacement (%)	13.369 (1.47–25.27)	6.010	**0.028***
Vaginal delivery duration (min)	259.4 (5.20–513.60)	128.400	**0.046***
Birth weight (g)	245.6 (85.80–405.40)	80.700	**0.003***
5-min Apgar	0.881 (0.49–1.27)	0.196	**<0.001***

*Models were adjusted for gestational age at delivery, gravidity, parity, and pre-Propess® cervical dilatation. Regression coefficients (β) represent the difference between the control group and the PROM group (reference category). Bold values indicate statistical significance ($p < 0.05$). PROM was used as the reference category. CI, confidence interval.

ciated with an increased risk of neonatal morbidity, with prematurity-related complications playing a key role in determining neonatal outcomes [17,18]. It should be noted that Apgar scores may be influenced not only by neonatal condition but also by factors such as the type of anesthesia used during cesarean delivery. However, in the present study, all cesarean deliveries were performed under spinal anesthesia, thereby minimizing the potential impact of anesthesia-related variability on neonatal outcomes [10]. Although patients with clinical chorioamnionitis were excluded, subclinical intrauterine infection cannot be entirely ruled out and may have contributed to the observed fetal distress and adverse neonatal outcomes. However, although the difference in the 5-minute Apgar score was statistically significant, the mean score in the PROM group remained within the clinically normal range (8.33 ± 1.00). Therefore, the clinical significance of this finding should be interpreted with caution. Nevertheless, the association remained statistically significant after adjustment for gestational age at delivery, gravidity, parity, and pre-Propess® cervical dilatation.

This study has several limitations that should be considered when interpreting the results. First, its retrospective design precludes the establishment of a definite causal relationship between PROM and the observed outcomes. In addition, the study was conducted in a single center and included a relatively small sample size, which may limit the generalizability of the findings. Baseline differences were also observed between the PROM and control groups, particularly regarding gestational age at delivery and cervical status, which may have independently influenced maternal and neonatal outcomes. Although multivariable linear regression analyses were performed to adjust for these differences, residual confounding cannot be excluded due to the retrospective study design and relatively small sample size.

Although the same induction protocol was used in both groups, temporal variations in clinical practice and clinician decision-making may have affected the observed outcomes. In addition, cervical examinations and labor progression assessments were based on routine clinical records and were therefore subject to interobserver variability. Another limitation is the absence of fully standardized diagnostic criteria for fetal distress across all patients.

Some clinically relevant parameters were not consistently available, including umbilical cord pH, neonatal intensive care unit (NICU) admission, hypoxic-ischemic encephalopathy, the induction-to-delivery interval, and spontaneous expulsion of the dinoprostone vaginal insert. Vaginal insert spontaneous expulsion, especially in cases with PROM, may reduce the effectiveness of the Propess® system, as previously reported [12]. Furthermore, long-term neonatal outcomes were also unavailable.

Despite these limitations, the use of the same induction agent in both groups and the comparative study design provide a relatively consistent framework for evaluating maternal and neonatal outcomes associated with Propess® use. Nevertheless, prospective multicenter studies with larger patient populations are needed to further clarify the independent effect of membrane status on labor induction outcomes. Our findings suggest that labor induction with Propess® in pregnancies complicated by PROM is associated with an acceptable maternal safety profile. However, caution is warranted when interpreting vaginal delivery success and neonatal outcomes. Gestational age, cervical status, and fetal condition should all be considered when selecting the most appropriate induction method for patients with PROM.

Implications for Research

The findings of the present study highlight several important priorities for future research. First, there is a need for prospective, preferably multicenter, randomized studies with larger sample sizes to confirm the maternal and neonatal outcomes associated with the use of controlled-release dinoprostone vaginal inserts in pregnancies complicated by PROM. Future studies should be designed to carefully control for gestational age at delivery and baseline cervical status, as the lower gestational age and differences in pre-induction cervical dilatation observed in the PROM group in the present study appear to be closely associated with both the reduced cervical response to Propess® and the higher cesarean delivery rate, particularly for fetal distress.

In addition, further studies investigating the inflammatory and biochemical changes that occur in the cervix and fetal membranes following membrane rupture are warranted, as these mechanisms may help explain the reduced cervical ripening response to dinoprostone observed in the PROM group after Propess® application. Future studies should also incorporate standardized definitions of fetal distress and uniform intrapartum monitoring and management protocols to reduce intercenter variability and allow more reliable comparisons of cesarean section indications. Finally, considering that neonates in the PROM group had lower birth weights and lower 5-minute Apgar scores, future research should incorporate long-term neonatal follow-up to better determine the clinical significance of these short-term differences and evaluate their potential impact on subsequent neonatal and infant outcomes.

5. Conclusions

After adjustment for gestational age at delivery, gravidity, parity, and pre-induction cervical dilatation, pregnancies complicated by PROM remained independently associated with a reduced cervical response to dinoprostone, lower birth weight, and lower 5-minute Apgar scores compared with pregnancies with intact membranes. Nevertheless, although the difference in 5-minute Apgar scores was statistically significant, the mean values remained within the clinically normal range and should therefore be interpreted with caution.

Availability of Data and Materials

Data are available from the corresponding author on reasonable request.

Author Contributions

MGB, ŞD: Study conception and design, overall coordination of the study, supervision of data collection, data interpretation, statistical analysis, and drafting of the manuscript. OK, KK: Data collection, data curation, data analysis, and contribution to manuscript drafting. MSH, FKY: Data interpretation, contribution to data interpretation, and critical revision of the manuscript. AA: Methodological support, data interpretation, and critical revision of the manuscript. All authors read and approved the final version of the manuscript. All authors contributed substantially to the work and agreed to be accountable for all aspects of the study in accordance with the ICMJE authorship criteria.

Ethics Approval and Consent to Participate

The study was carried out in accordance with the guidelines of the Declaration of Helsinki. The study protocol was reviewed and approved by the Ethics Committee of Necmettin Erbakan University, Meram Faculty of Medicine (Approval No.: 2026/6295; Application ID: 29133). As this study was conducted retrospectively using fully de-identified patient data, the ethics committee waived the requirement for obtaining informed consent.

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Conflicts of Interest

The authors declare no conflicts of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/CEOG50940.

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