BMC Pregnancy and Childbirth

RESEARCH

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Use of vaginal dinoprostone for women with term prelabor rupture of membranes and an unfavorable cervix within 6 h versus within 6–24 h

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Abstract

Background Most guidelines propose inducing labor within 24 h following term (37 or more weeks of gestation) prelabor rupture of membranes (PROM). However, the exact timing for initiating induction within the 24 h period remains unknown. This study aims to comparatively assess the efficacy and safety of the use of vaginal dinoprostone within 6 h versus within 6–24 h for singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6).

Methods This was a retrospective cohort study including singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6) in which labor was induced using vaginal dinoprostone. Women were divided into two groups according to the timing of the use of induction (within 6 h versus within 6–24 h after PROM). Baseline maternal data, maternal and neonatal outcomes were recorded for statistical analysis.

Results 450 women were included, 146 (32.4%) of whom were induced within 6 h of PROM and 304 (67.6%) were induced within 6–24 h. Cesarean delivery rate (15.8% versus 29.3%, $p = 0.002$) and nonreassuring fetal heart rate tracing (4.8% versus 10.5%, $p = 0.043$) in group with vaginal dinoprostone within 6 h were significantly lower than those in group with vaginal dinoprostone within 6–24 h. There was no significant differences in terms of duration from IOL to vaginal delivery.

Conclusion Induction of labor within 6 h with vaginal dinoprostone after PROM for singleton pregnancies with an unfavorable cervix (Bishop score < 6) significantly associated with less cesarean section, less nonreassuring fetal heart rate tracing, compared to induction of labor within 6–24 h after PROM.

Keywords Vaginal Dinoprostone, Term prelabor rupture of membranes, Cesarean section

Introduction

Prelabor rupture of membranes (PROM) is defined as the rupture of the fetal membranes before the onset of regular uterine contractions [1], which occurs in term fetuses with an incidence of approximately 8% [2, 3]. Given that the risk of intraamniotic infection increases with the duration of Prelabor Rupture of Membranes (PROM), most guidelines [1, 2, 4] propose inducing labor within 24 h following PROM. However, the exact timing for initiating induction within the 24 h period remains

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a subject of controversy. Recently, a systematic review and meta-analysis have suggested that for women presenting with PROM symptoms at or beyond 36 weeks, induction of labor should ideally occur within 12 h, and potentially even within 6 h. This approach significantly reduces the incidence of chorioamnionitis, endometritis, neonatal sepsis, and neonatal intensive care unit (NICU) admissions [5]. Moreover, a retrospective cohort study has demonstrated that induction of labor (IOL) initiated less than 6 h after PROM, with the use of intravenous oxytocin, is significantly associated with less antibiotic use, shorter latency to delivery, lower incidence of non-reassuring cardiotocogram results, and shorter hospital stays, compared to IOL initiated more than 6 h after PROM [6]. However, the IOL method utilized in both studies was oxytocin. If the cervix is unfavorable (Bishop score < 6) [7–9], IOL would necessitate cervical ripening. This process mirrors labor induction without PROM and is typically initiated with vaginal dinoprostone (PGE_2) [10]. Some studies have confirmed the efficacy and safety of the use of PGE_2 for labor induction in women with PROM and an unfavorable cervix (Bishop score < 6) [11–13], and others have further demonstrated that the use of PGE_2 in pregnant women undergoing IOL with PROM can shorten the total delivery time, and does not increased the risk of cesarean section compared with pregnant women undergoing IOL without PROM [14–16]. However, there is limited evidence concerning the timing of IOL with PGE_2 for singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6) within 24 h. The objective of this study is to comparatively assess the efficacy and safety of the use of PGE_2 within 6 h or within 6–24 h for PROM and an unfavorable cervix (Bishop score < 6), providing more data for clinical practice guidelines.

Materials and methods

Patients and methods

A retrospective cohort study was conducted among 450 singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6) who underwent IOL with PGE_2 from January 1, 2020, to December 31, 2022, at our birth centre. The patients enrolled in this study were divided into two groups according to the timing of induction (within 6 h versus within 6–24 h after PROM). This study was conducted in accordance with the principles of the Declaration of Helsinki with regard to studies involving human subjects and in line with Law 14/2007 for biomedical research. The study protocol was approved by the Ethics Committee of Maternal and Child Health Hospital of Hubei Province, Tongji Medical College, Huazhong University of Science and Technology ([2023] IEC (092)). All patients who participated in the study signed written informed consent for therapeutic procedures and for the publication of those reports.

Inclusion and exclusion criteria

The inclusion criteria encompassed singleton cephalic gestation with PROM, ≥ 37 weeks of gestation, a baseline cervix Bishop score of less than 6 points for the cervix, and a necessity of PGE_2 for labor induction within 24 h after PROM. The exclusion criteria were as follows: women underwent IOL with PGE_2 > 24 h, women with intact membranes, gestation period of less than 37 weeks, history of cesarean section, women who were allergic to PGE_2, women with glaucoma or asthma, women with contraindications for labor such as pelvic stenosis or placenta previa.

Induction of labor protocol at the study center

The diagnosis of PROM was made by vaginal examination after observing the leakage of amniotic fluid through the cervical orifice. Patients were induced with a slow-release vaginal insert containing 10 mg of dinoprostone (prostaglandins PGE_2 Propess®, Ferring SAS, Gentilly, France). The slow-release vaginal insert was stored in a freezer at a temperature between -20 °C and -10 °C. Once the vaginal device was placed, the pregnant woman underwent closely fetal heart rate (FHR) within 2 h. The device was promptly removed if there was a change in the FHR pattern [14], or in case of uterine hyperstimulation, defined as over five contractions in 10 min for more than 20 min or contractions lasting longer than 2 min [17]. If none of the above occurred, FHR monitoring was performed nearly every 6 h, and the device was removed when the woman had regular uterine contractions, reached favorable cervical ripening (Bishop score > 6), or being placed in the vagina for over 24 h. After the removal or self-expulsion of the PGE_2, the patient was transferred to the delivery ward for spontaneous labor or augmentation by oxytocin infusion with a 60-min interval if uterine contractions were not adequate. Epidural analgesia was provided under maternal request once the uterine orifice dilation reaches 1 cm. Continuous monitoring of uterine activity and FHR was performed during labor. Antibiotics were started for the following indications: PROM latency > 18 h or fever > 38 °C [18]. Antibiotics for PROM and these two indications included penicillin G, 5 million units IV initial dose, then 2.5–3.0 million units every 4 h until delivery [18].

Observation indicators

Information including maternal age, gestational age, pre-pregnancy body mass index (BMI), term BMI, vaginal delivery history, hypertensive disorder, gestational diabete, initial Bishop score, labor and perinatal

period were collected and recorded in a form specially designed for this trial. To compare the efficacy and safety of the use of PGE_2 within 6 h versus within 6–24 h for singleton pregnancies with PROM, cesarean section, nonreassuring fetal heart rate tracing (NRFHT), interval between IOL and vaginal delivery, chorioamnionitis and neonatal intensive care unit (NICU) admission, apgar ≤ 7 at 5 min were regarded as the primary outcome variables. Secondary outcome variables included the length of first stage of labor, length of second stage of labor, length of third stage of labor, indications for cesarean section, intrapartum fever, postpartum hemorrhage, episiotomy, perineal laceration, cervical laceration, paravaginal hematomas, uterine rupture, oxytocin addition, in-hospital days and neonatal weight, fetal fecal contamination and neonatal sepsis. Cesarean section on maternal request is defined as the cesarean section based solely on maternal request without any maternal or fetal medical indications. Failed induction is defined as a cervical Bishop score of less than 6 after 24 h of PGE_2 insertion. Chorioamnionitis is defined as an intrapartum maternal temperature of ≥ 38.0℃, accompanied by at leastone of the following symptoms: maternal or fetal tachycardia, uterine tenderness upon abdominal exam or purulent, foul-smelling vaginal discharge [19].

Statistical analysis

All analyses were conducted using the Statistical Package of Social Sciences software (SPSS Version 19.0 Inc., Chicago, IL, USA). Continuous variables were presented as means ± standard deviation, and categorical variables were presented as frequency and percentage (%). Student's t-test was performed to compare the variables in a Gaussian distribution. The chi-square test or Fisher's exact test were used to evaluate the categorical variables. The Mann–Whitney test was used to evaluate the difference in a non-Gaussian distribution between the two groups. The difference was considered statistically significant when $p < 0.05$.

Results

A total of 3695 deliveries underwent IOL with PGE_2 at our birth centre during the study period. After applying the exclusion criteria, 450 pregnant women were recruited into the study. Of the recruited pregnant women, 146 (32.4%) underwent IOL within 6 h and 304 (67.6%) underwent IOL within 6–24 h after PROM. The flowchart of the patients included in the study is showed in Fig. 1. As shown in Table 1, baseline characteristics of pregnant women with labor induction in group with IOL within 6 h and group with IOL within 6–24 h were comparatively analyzed. There were no significant differences in maternal age, gestational age, pre-pregnancy BMI,

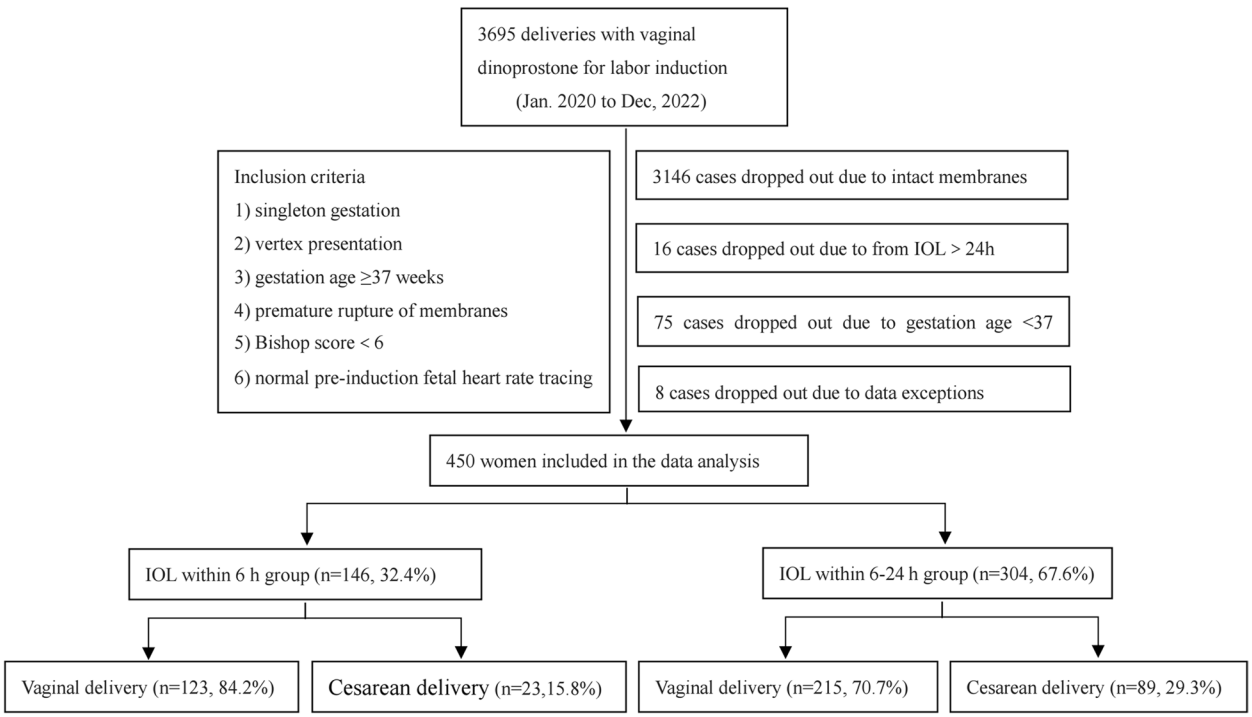

Fig. 1 Flow diagram

Table 1 Demographic characteristics

Characteristic	IOL within 6 h (*n*=146)	IOL within 6-24 h (*n*=304)	*p* value
Maternal age (y)	29.7 ± 2.8	29.5 ± 2.8	0.458
Gestational age (weeks)	38.8 ± 0.9	38.8 ± 0.9	0.573
Pre-pregnancy BMI (kg/m^2)	20.8 ± 2.6	20.9 ± 2.5	0.926
Term BMI (kg/m^2)	26.5 ± 2.8	26.6 ± 2.7	0.645
Primiparity (n, %)	138 (94.5)	290 (95.4)	0.687
Multiparity (n, %)	8 (5.5)	14 (4.6)	0.687
Hypertensive disorder (n, %)	7 (4.8)	19 (6.3)	0.536
Gestational diabete (n, %)	17 (11.6)	44 (14.5)	0.412
Initial Bishop score ($\overline{X} \pm s$)	3.9 ± 0.6	4.0 ± 0.6	0.119

BMI body mass index

Student's t-test were used

$p < 0.05$ was considered significant

term BMI, primiparity rate, multiparity rate, hypertensive disorder rate, gestational diabete rate, initial Bishop score between the two groups ($p > 0.05$).

Overall, normal vaginal delivery rate, cesarean section rate and forceps delivery rate were 82.9% (121/146), 15.8% (23/146) and 1.3% (2/146) in the group with IOL within 6 h, while normal vaginal delivery rate, cesarean section rate and forceps delivery rate were 69.7% (212/304), 29.3% (89/304) and 1.0% (3/304) in the group with IOL within 6–24 h, respectively. None of the patients underwent severe maternal and neonatal adverse outcomes such as uterine rupture, neonatal sepsis, maternal or neonatal death. Further, the indications for cesarean section in the group with IOL within 6 h included NRFHT ($n=6$, 26.1%), failure to IOL ($n=6$, 26.1%), maternal request ($n=2$, 8.7%), dystocia ($n=4$, 17.4%), fetal fecal contamination ($n=1$, 4.3%), other (cord prolapse, placental abruption…) ($n=4$, 17.4%), and those in the group with IOL within 6–24 h included NRFHT ($n=30$, 33.7%), failure to IOL ($n=21$, 23.6%), maternal request ($n=18$, 20.2%), dystocia ($n=7$, 7.9%), fetal fecal contamination ($n=3$, 3.4%), other (cord prolapse, placental abruption…) ($n=10$, 11.2%). As shown in Table 2, cesarean delivery rate (15.8% versus 29.3%, $p=0.002$), NRFHT rate (4.8% versus 10.5%, $p=0.043$) and maternal request for cesarean delivery rate (1.4% versus 5.6%, $p=0.037$) in the group with IOL within 6 h was significantly lower than those in the group with IOL within 6–24 h. There were no significant differences in the time interval from IOL to vaginal delivery, the length of first stage of labor, the length of second stage of labor, the length of third stage of labor, intrapartum fever, chorioamnionitis, postpartum hemorrhage, perineal laceration, cervical laceration, paravaginal hematomas, episiotomy, uterine rupture, oxytocin addition and in-hospital days between the two groups.

The main neonatal outcome variables of two groups were comparatively analyzed (Table 3). In the group with IOL within 6 h, fetal fecal contamination rate was 8.9% ($n=13$), and there was no newborn with an Apgar ≤ 7 at 5 min in the group with IOL within 6 h. In terms of treatment, 1.4% ($n=2$) of the newborns required admission to NICU. In the group with IOL within 6–24 h, fetal fecal contamination rate was 9.5% ($n=29$) and there were one newborn with an Apgar ≤ 7 at 5 min. Regarding treatment, 1.6% ($n=5$) of the newborns required admission to NICU. There were no newborns with neonatal sepsis in either group. There were no statistical differences in any of the neonatal variables collected between the two groups.

Discussion

This study aims to assess the efficacy and safety of the use of PGE_2 within 6 h versus within 6–24 h for singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6). According to our data, initiating IOL with PGE_2 within 6 h after PROM can significantly reduce the rate of cesarean sections, compared to initiating IOL within 6–24 h. Furthermore, in our study, inducing labor with PGE_2 within 6 h after PROM significantly reduces the risk of NRFHT, and shows a downward trend in chorioamnionitis incidence in the group induced with PGE_2 within 6 h after PROM. Our results suggest that, for singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6), they should have IOL with PGE_2 within 6 h.

In the largest trial to date on this topic (TERMPROM trial), Hannah et al. [20] reported immediate IOL with oxytocin or prostaglandin E2 and expectant management for women with term PROM yield had similar rates of neonatal infection and cesarean section. However, clinical chorioamnionitis was less likely to develop in the women in the induction-with-oxytocin group than in those in the expectant-management (oxytocin) group (4.0% versus 8.6%, $p<0.001$), as was postpartum fever (1.9% versus 3.6%, $p=0.008$). The latest Cochrane Review on term PROM included twenty-three trials involving 8615 women and their babies suggested that IOL with oxytocin or prostaglandins within 24 h can reduce the risk of maternal infectious morbidity (chorioamnionitis and/or endometritis) (average risk ratio (RR) 0.49; 95% confidence interval (CI) 0.33 to 0.72) and definite or probable early-onset neonatal sepsis (RR 0.73; 95% CI 0.58 to 0.92) without an apparent increased risk of caesarean section (average RR 0.84; 95% CI 0.69 to 1.04), compared to expectant management > 24 h [2]. Based on the Hannah's largest randomized controlled trial [20] and

Table 2 Obstetric characteristics and maternal outcomes

Characteristics/Outcome	IOL within 6 h ($n=146$)	IOL within 6–24 h ($n=304$)	*p* value
Minutes from IOL to vaginal delivery (m,$\overline{X} \pm s$)	1006.6 ± 509.7	965.7 ± 508.1	0.477
Length of first stage of labor (m,$\overline{X} \pm s$)	470.0 ± 247.8	426.8 ± 193.0	0.075
Length of second stage of labor (m,$\overline{X} \pm s$)	35.0 ± 30.4	29.4 ± 23.1	0.077
Length of third stage of labor (m,$\overline{X} \pm s$)	9.6 ± 8.2	8.6 ± 6.4	0.210
Epidural Analgesia (n, %)	117 (80.1)	221 (72.7)	0.087
Mode of delivery (n, %)			
Vaginal delivery	123 (84.2)	215 (70.7)	0.002
Normal	121 (98.4)	212 (98.6)	
Forceps	2 (1.6)	3 (1.4)	
Cesarean delivery	23 (15.8)	89 (29.3)	0.002
NRFHT (n, %)	7 (4.8)	32 (10.5)	0.043
Failure to IOL (n, %)	6 (4.1)	21 (6.9)	0.242
Maternal request for CS (n, %)	2 (1.4)	17 (5.6)	0.037
Intrapartum fever (n, %)	16 (11.0)	38 (12.5)	0.638
Chorioamnionitis (n, %)	2 (1.4)	10 (3.3)	0.352
Postpartum hemorrhage (≥ 500 ml) (n, %)	12 (8.2)	18 (5.9)	0.360
Episiotomy (n, %)	26 (17.8)	44 (14.5)	0.361
I-degree perineal laceration	113(77.4)	225(74.0)	0.437
II-degree perineal laceration	32(21.9)	78(25.7)	0.387
III- and IV-degree perineal laceration	0 (0)	0 (0)	-
Cervical laceration (n, %)	16 (11.0)	25 (8.2)	0.345
Paravaginal hematomas (n, %)	2 (1.4)	3 (1.0)	0.661
Uterine rupture	0 (0)	0 (0)	-
In-hospital days (d,$\overline{X} \pm s$)	4.6 ± 1.4	4.6 ± 1.3	0.852
Oxytocin addition (n, %)	67 (45.9)	145 (47.7)	0.719

PROM prelabor rupture of membranes, *IOL* induction of labor, *NRFHT* nonreassuring fetal heart rate tracing, *CS* cesarean section

Student's t-test, chi-square test or Fisher's exact test and Mann–Whitney test were used

$p < 0.05$ was considered significant

Table 3 Neonatal outcomes

Outcomes	IOL within 6 h ($n=146$)	IOL within 6–24 h ($n=304$)	*p* value
Neonatal weight (g,$\overline{X} \pm s$))	3167.3 ± 320.3	3137.3 ± 453.9	0.474
NICU admission (n, %)	2 (1.4)	5 (1.6)	1.000
Apgar ≤ 7 at 5 min (n, %)	0 (0.0)	1 (0.3)	1.000
Fetal fecal contamination (n, %)	13 (8.9)	29 (9.5)	0.828
Neonatal sepsis (n, %)	0 (0)	0 (0)	-

NICU neonatal intensive care unit

Student's t-test, chi-square test or Fisher's exact test were used

$p < 0.05$ was considered significant

the Cochrane Review [2], ACOG recommends IOL within 24 h for term PROM. IOL with prostaglandins has been demonstrated to be as effective as oxytocin for labor induction, though it's associated with higher rates of chorioamnionitis [21]. As we all know, IOL for women with an unfavorable cervix (Bishop score < 6) necessitates initial cervical ripening. However, in Hannah's trial, IOL with either oxytocin or PGE_2 was randomly assigned, without considering the Bishop score of the cervix. Moreover, among the 23 trials included in the latest Cochrane meta-analysis, only six assessed PGE_2, with a small sample size and low quality of trials and evidence. In recent years, studies have reported the timing of IOL with oxytocin within 24 h in patients with term PROM

[5, 6], but few articles have focused on the timing of IOL with PGE_2 within 24 h. To provide more evidence regarding the timing of IOL with PGE_2, we comparatively analyzed the perinatal results in singleton pregnancies with an unfavorable cervix (Bishop score < 6) after undergoing IOL with PGE_2 within 6 h versus within 6–24 h from PROM.

In our study, normal vaginal delivery rate was 82.9% (121/146) in the group with IOL within 6 h, and 69.7% (212/304) in the group with IOL within 6–24 h, respectively. None of the patients underwent severe maternal or neonatal adverse outcomes such as uterine rupture, neonatal sepsis, maternal or neonatal death. The result demonstrated that the use of PGE_2 in pregnant women undergoing IOL with term PROM is safe for the mother and the fetus. Many previous studies have reported that IOL with prostaglandin E2 within 24 h and expectant management for women with PROM result in similar rates of cesarean section [20, 22–24]. By contrast, Larrañaga et al. [25] conducted a retrospective study of 744 single pregnancies with term PROM and an cervix Bishop < 4, and the results suggested that IOL with PGE_2 within 12 h can significantly reduce the rate of cesarean section compared with the expectant management group (9.3% versus 17.6%, $p = 0.04$). In our study, the rate of cesarean section in the group induced with PGE_2 within 6–24 h after PROM was significantly higher than that in the group induced with PGE_2 within 6 h after PROM (29.3% versus 15.8%, $p = 0.002$). The top three reasons for cesarean sections in the group induced with PGE_2 within 6–24 h after PROM were NRFHT, failure of induction, and maternal request. Among them, the incidence of NRFHT in group induced with PGE_2 within 6–24 h was significantly higher than that in group induced with PGE_2 within 6 h (10.5% versus 4.8%, $p = 0.043$), and the reason for this requires further study. It is worth noting that the incidence of maternal request in group induced with PGE_2 within 6–24 h was significantly higher (5.6% versus 1.4%, $p = 0.037$), which was probably because with the extension of PROM, the patients were more concerned about the safety of the fetus, and they were more willing to the end delivery by cesarean section as soon as possible. Previous studies have shown that women view induction of labor more positively than expectant management, and none of the pregnant women with PROM wanted to wait for their own contractions and spontaneous labour [11, 20]. Kulhan and Kulhan [26] preformed a retrospective cohort study and reported the rate of intrapartum maternal fever among nulliparous women with term PROM undergoing labor induction with PGE_2 was 37.5%. Gulersen et al. [19] reported that the rate of chorioamnionitis in nulliparous, term, singleton, vertex pregnancies with PROM and an unfavorable cervix (Bishop score < 6) who underwent PGE_2 ripening was 18.1%. In our study, the rate of intrapartum fever was12% (54/450), and there was no difference in the incidence of intrapartum fever between the two groups. There was no statistical significance in the incidence of chorioamnioitis in group induced with PGE_2 within 6 h and in group induced with PGE_2 within 6–24 h (1.4% versus 3.3%), which possibly due to the limited sample size and the low incidence. The reason why the rate of infection associated with PGE_2 use in our study and Devillard et al. study was lower compared to that reported by Gulersen et al. may be attributed to the timely use of antibiotics as recommended by revised guidelines from CDC [18] or French national guidelines [27].

The primary strength of our study lies in its novelty. To the best of our knowledge, after reviewing the literature, this is the first study to compare the efficacy and safety of using PGE_2 within 6 h or within 6–24 h for singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6). However, this study does have some limitations. Firstly, fetal acidosis (ph and/or lactates at umbilical cord) is an important criterion of fetal morbidity,which was not recorded at delivery in our hospital during the time we conducted this study. This indicator should be recorded in future studies. Secondly, being a single-center, retrospective study, its results may not be as objective as those derived from multicenter, prospective studies. Thirdly, even though our sample size is one of the largest in reports focusing on outcomes associated with PGE_2 ripening in this patient demographic, the rates of maternal complications such as chorioamnionitis, uterine rupture, and neonatal complications including Apgar scores ≤ 7 at 5 min and NICU admissions were extremely low. Therefore, it remains uncertain whether there is a significant difference in the rates of serious complications between the two groups. A multi-center, prospective randomized controlled trial with a big sample size is still essential to study the timing of IOL with PGE_2 for singleton pregnancies with PROM and an unfavorable cervix (Bishop score < 6) within 24 h.

Conclusions

Our results suggest that, for singleton pregnancies with an unfavorable cervix (Bishop score < 6), IOL with PGE_2 within 6 h of PROM is significantly associated with less cesarean section, less NRFHT, and with no evidence of any harm for both the mother and the baby, compared to IOL with PGE_2 within 6–24 h after PROM. Thus, we suggest that women with PROM and an unfavorable cervix (Bishop score < 6) should be evaluated promptly, and, if PROM is confirmed, they should have IOL with PGE_2 within 6 h.

Abbreviations

PROM	Prelabor rupture of membranes
IOL	Induction of labor
PGE_2	Vaginal dinoprostone
NRFHT	Nonreassuring fetal heart rate tracing
BMI	Body mass index
FHR	Fetal heart rate
NICU	Neonatal intensive care unit

Acknowledgements
We would like to thank all the participants of the trial and the obstetricians and nurses for the diagnosis and treatment of these pregnant women.

Authors' contributions
DC conceived the study, interpreted the results, and revised the manuscript. LY analyzed the data and drafted the manuscript. GS conceived the study. PG, JC, BL collected the data.

Funding
This research received no external funding.

Availability of data and materials
Access to the qualitative data will be given upon request to the corresponding author after taking any necessary precautions to safeguard participants' privacy and confidentiality.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the principlesof the Declaration of Helsinki with regard to studies involving human subjects and in line with Law 14/2007 for biomedical research. This study was approved by the Ethics Committee of Maternal and Child Health Hospital of Hubei Province, Tongji Medical College, Huazhong University of Science and Technology ([2023] IEC (092)).Informed consent was obtained from all subjects involved in the study.

Consent for publication
Written informed consent was obtained from the patients to publish this paper. All authors have read and agreed to the published version of the manuscript.

Competing interests
The authors declare no competing interests.

Received: 10 September 2023 Accepted: 16 August 2024
Published online: 20 August 2024

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