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Original Research Article

Comparison of immediate versus late induction in premature rupture of membranes with oral prostaglandins in term patients

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ABSTRACT

Background: Immediate induction involves initiating labor as soon as prelabor rupture of membranes (PROM) is confirmed to minimize infection risk and complications associated with prolonged membrane rupture, including chorioamnionitis. This study aimed to compare maternal and neonatal outcomes in terms of PROM-delivery interval, mode of delivery, maternal and neonatal morbidity following immediate and delayed induction in PROM.
Methods: This prospective cohort study included 200 patients. Group A (100 patients) underwent immediate induction following PROM with oral PGE1, while group B (100 patients) underwent induction 6 hours after PROM with oral PGE1. A maximum of three doses of PGE1 (50 mcg) were administered over 24 hours. Intermittent fetal heart monitoring using CTG was performed, maternal and fetal complications were recorded and managed accordingly. Results were compared between groups.
Results: The efficacy of oral PGE1 as an induction agent at 2 hours and 6 hours post-PROM was assessed based on PROM - delivery interval, duration of first stage of labor, and vaginal delivery within 24 hours. In the early induction group, 80% delivered within 24 hours compared to 56% in the delayed group. Only 3.5% in the early group required three doses versus 9% in the delayed group. Normal vaginal delivery occurred in 96% of early induction cases and 91% of delayed cases. Maternal pyrexia and sepsis were carefully monitored.
Conclusions: Early induction at 2 hours after PROM reduces PROM-delivery interval and improved the outcome of delivery, maternal satisfaction rates including lesser maternal and neonatal morbidity.

Keywords: Induction, Misoprostol, Membrane rupture

INTRODUCTION

Women's health has emerged as a central focus in contemporary healthcare, reflecting a growing recognition of its influence on family well-being, societal development, and long-term public health outcomes. Among the various aspects of maternal health, labor and delivery represent critical physiological and emotional events that significantly affect both maternal and neonatal outcomes. Appropriate management of labor not only reduces obstetric complications but also improves maternal satisfaction, neonatal safety, and overall quality of care. Consequently, evidence-based strategies for labor management remain a major priority in modern obstetrics.[1-3]

PROM refers to the spontaneous rupture of the fetal membranes before the onset of labor, while preterm PROM (PPROM) occurs before 37 completed weeks of gestation. PROM is one of the most common obstetric complications and is associated with increased risks of maternal and neonatal morbidity, particularly when the interval between membrane rupture and delivery is prolonged.[4,5] The etiology of PROM is multifactorial and

involves mechanical stretching of the membranes, inflammatory processes, ascending genital tract infections, oxidative stress, and biochemical degradation of collagen within the amniotic membranes. Several maternal and obstetric risk factors have been identified, including previous history of PROM, cervical insufficiency, uterine overdistension, genital tract infections, low body mass index, nutritional deficiencies, smoking, and poor socioeconomic conditions.[5,6]

At term, PROM complicates approximately 8-10% of pregnancies worldwide and remains a significant contributor to maternal and neonatal healthcare burden, especially in low- and middle-income countries.[4,7] Delayed onset of labor following membrane rupture increases the risk of chorioamnionitis, postpartum infection, neonatal sepsis, and operative delivery.[8] Therefore, timely and effective induction of labor is essential to minimize infectious morbidity while ensuring safe vaginal delivery.[7,8]

Labor induction is defined as the artificial initiation of uterine contractions before the spontaneous onset of labor to achieve vaginal birth when continuation of pregnancy may pose greater risks than delivery.[1,3] Various methods are available for induction, including mechanical techniques such as balloon catheters and pharmacological agents such as oxytocin and prostaglandins.[6] Among these, prostaglandins play a pivotal role because of their dual action in promoting cervical ripening and stimulating uterine contractions.[6,9]

Prostaglandins, particularly prostaglandin E1 and prostaglandin E2, facilitate cervical remodeling by increasing collagen degradation, enhancing water content within cervical tissue, and promoting cervical softening and effacement. Simultaneously, they stimulate myometrial contractility through receptor-mediated pathways, thereby promoting effective labor progression.[4,9] Oral prostaglandins have gained increasing attention due to their ease of administration, cost-effectiveness, patient acceptability, and reduced need for invasive interventions. Recent evidence suggests that oral prostaglandin regimens may provide effective induction with favorable maternal and neonatal outcomes, particularly in women with PROM at term.[9,10]

Despite advances in obstetric care, there remains ongoing debate regarding the optimal timing of labor induction following PROM. Immediate induction may reduce the duration of membrane rupture and associated infectious complications, whereas delayed or expectant management may allow spontaneous labor onset and potentially reduce intervention rates. Determining the balance between maternal safety, neonatal outcomes, and successful vaginal delivery continues to be an important area of clinical research.[7,8,11]

Given the substantial maternal and neonatal implications associated with PROM, there is a need for locally relevant evidence to guide clinical decision-making and optimize management protocols.

Therefore, the present study aims to evaluate and compare maternal and neonatal outcomes associated with immediate versus delayed induction of labor using oral prostaglandins in women with term PROM. The findings of this study may contribute to the development of safer, more effective, and evidence-based strategies for the management of PROM in contemporary obstetric practice.

METHODS

Study design

It was a prospective Cohort study at Institute of Maternal and Child Health, Kozhikode.

Sample population

Antenatal patients admitted with PROM were selected for the study.

Period of study

This study was carried out from February 2023 to January 2024.

Study setting

Study conducted at department of OBG, Government Medical College, Kozhikode.

Sample size

From a study by Krupa et al 40% of patients in the expectant group and 52% of patients in the early induction group delivered within 12 hrs of PROM. Expecting similar results with 20% marginal error, the minimum sample size required by the formula

$n=2(Z42+Z\beta)2\ pq/d^2$

Where p=p1+p2/2 and d=20, is 97.

Hence 100 patients were taken in each group.

Inclusion criteria included singleton pregnancy with cephalic presentation, gestational age between 37 and 41 completed weeks, spontaneous PROM confirmed by history and examination, admission to labor room within 6 h of PROM and unfavourable Bishop score and no evidence of immediate uterine contractions.

Exclusion criteria included PROM before 37 completed weeks, Features of chorioamnionitis, Meiconium stained liquor, medical or obstetric complications indicating prompt delivery, multiple pregnancies, contraindications

to prostaglandin use (bronchial asthma and cardiac disease).

After getting written informed consent from patients who meet the above criteria, a proper history taking and a thorough examination was done to exclude exclusion criteria. A detailed obstetric examination was done to note presentation, uterine contraction status, and fetal heart rate pattern. Speculum examination was done to confirm leaking. Vaginal examination was done to assess the modified Bishop's score.

100 patients who are induced immediately following PROM with oral PGE1 formed group A and 100 patients who are induced 6 hours following PROM with oral PGE1 formed group B. In both the groups PGE1 tablet was repeated if required after 4 hours of the induction for a maximum of 3 doses of PGE1 50 mcg over 24 hours. Intermittent fetal heart monitoring with CTG was done and colour of liquor noted. All the patients irrespective of duration of PROM was given cefuroxime by parenteral route till delivery. PROM to delivery interval was noted in both groups, whether delivered vaginally or by caesarean section. Any maternal and fetal complications faced was recorded and managed accordingly.

The outcomes assessed for the mother were PROM delivery interval, Induction delivery interval, maternal infectious morbidity, caesarean section and serious maternal morbidity or mortality. For the foetus/neonate, the outcomes assessed included early-onset neonatal sepsis, perinatal mortality.

Data was collected using a proforma. The study was conducted after getting approval from institutional ethics committee and institutional research committee. Written informed consent was taken from all patients. All data was kept strictly confidential.

RESULTS

P value from the chi-square test is 0.211 (greater than the taken significance level 0.05), so we can conclude that there is no significant association between study groups and parity. (In other words, samples from case and control group are comparable based on parity) (Figure 1).

Antepartum complications

Antepartum complications that were included in the study were gestational diabetes, gestational hypertension and its complications, hypothyroidism, anemia complicating pregnancy, heart diseases complicating pregnancy where vaginal delivery was not contraindicated.

P value from the chi-square test is 0.768 (Greater than the taken significance level 0.05), so we can conclude that there is no significant association between study groups and antepartum complications (Figure 2).

PROM/ delivery interval

P value from the chi-square test is 0.001 (Less than the taken significance level 0.05), so we can conclude that there is a significant association between study groups and PROM delivery intervals.

The results suggested that induction with Misoprostol could significantly accelerate the progression from PROM to vaginal delivery.

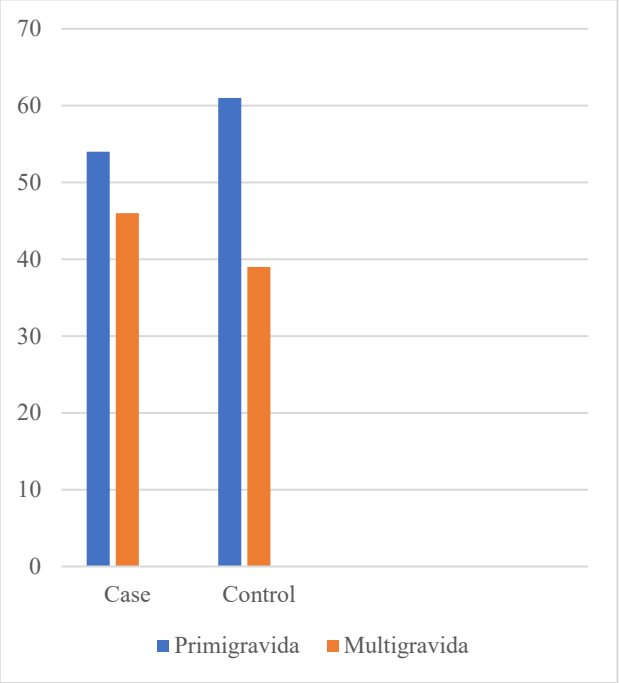

Figure 1: Comparison of parity among study groups.

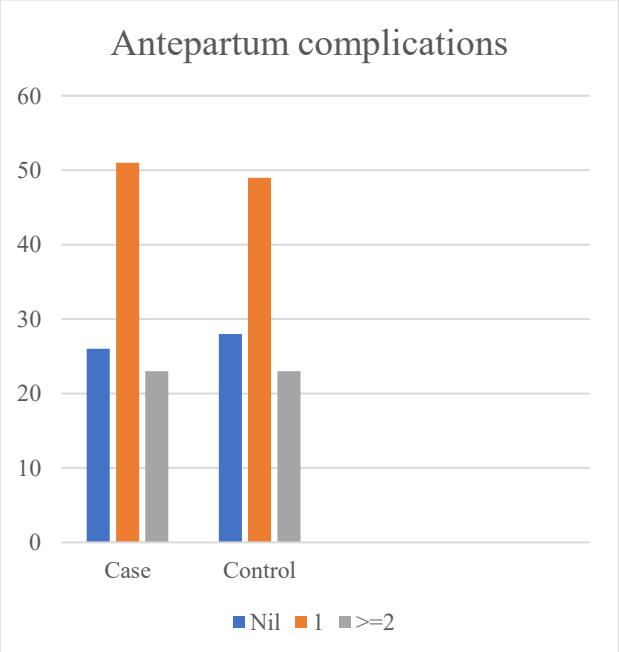

Figure 2: Comparison of antepartum complications.

Table 1: Cross tabulation of PROM-delivery interval among study groups.

Groups		PROM/ delivery interval			Total
		6-12 hours	12-24 hours	>24 hours	
Group A	Count	3	77	20	100
	% within group	3.0%	77.0%	20.0%	100.0%
Group B	Count	3	53	44	100
	% within group	3.0%	53.0%	44.0%	100.0%
Total	Count	6	130	64	200
	% within group	3.0%	65.0%	32.0%	100.0%

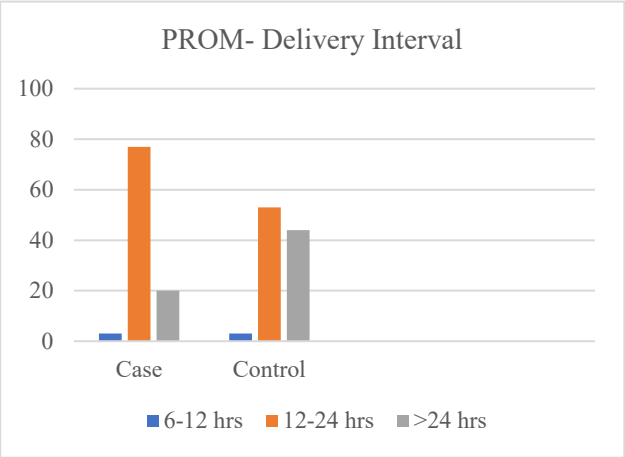

Figure 3: Comparison of the PROM delivery interval in case and control groups.

Number of doses of Oral PGE1 administered

P value from the chi-square test is 0.044 (Less than the taken significance level 0.05), so we can conclude that there is a significant association between study groups and number of doses of oral PGE1 administered. The observation gives us the inference that number of doses of oral PGE1 required for the initiation of labour was less in those patients induced at 2 hrs of PROM, as compared to those induced at 6 hrs.

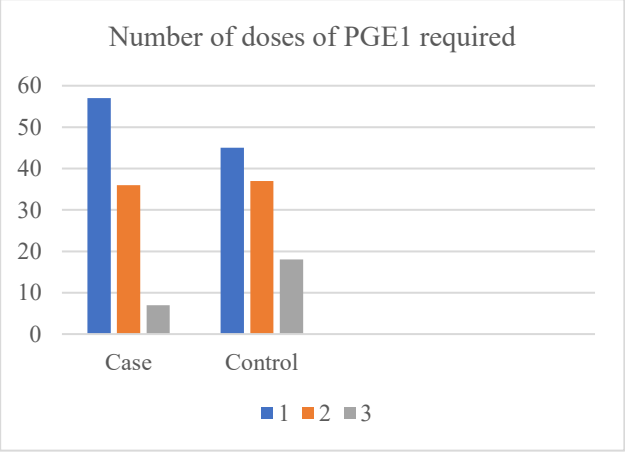

Figure 4: Comparison of number of doses of oral PGE1 required.

Induction delivery interval

The observation suggests that 56% of patients induced at 2 hrs of PROM delivered within 6-12 hrs of induction, when compared to 45% of patients who were induced at 6 hrs of PROM.

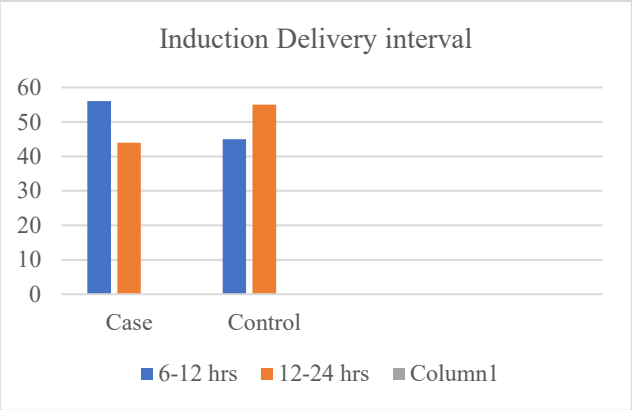

Figure 5: Comparison of induction delivery interval.

Mode of delivery

P value from chi-square test is 0.152 (Greater than taken significance level 0.05), which suggests that there is no significant association between study groups and mode of delivery.

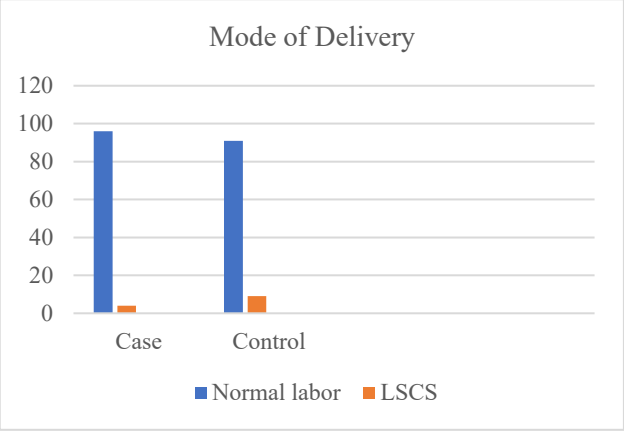

Figure 6: Comparison of mode of delivery among study groups.

Table 2: Number of patients who developed complications in study groups.

Group	Mode of delivery	Complications
A	NL	0
	CS	0
B	NL	1 case of mild atonic PPH
	CS	4 cases of maternal pyrexia

Table 3: Number of neonates requiring NICU admissions in study groups.

Groups	Mode of delivery	No. of NICU admissions	Indication
A	NL	0	-
	CS	0	-
B	NL	0	-
	CS	2	Sepsis screen positive

Sepsis screen done in 2 neonates of mothers with maternal pyrexia were positive. They were started on IV antibiotics vancomycin and ciprofloxacin, improved and discharged on neonatal day 5.

DISCUSSION

PROM is defined as rupture of membranes prior to the onset of labour. Labour may follow soon after the rupture of membranes. However, in case of delay in the onset of labour, the fetus is exposed to serious risks of infection and the ensuing complications. Induction of labour (IOL) is the process of initiating contractions in pregnant women who are currently not in labour, to help them achieve vaginal delivery within 24 to 48 hours. Misoprostol is a synthetic analogue of prostaglandin E1, the oral form of which has uterotonic properties, by contracting smooth muscle fibers in the myometrium and relaxation of the cervix, facilitating cervical opening. Prostaglandin E1 offers the benefit of being non-invasive, easy, and convenient. Furthermore, it is inexpensive and can be stored at room temperature. The risk of hyperstimulation with misoprostol seems to be related both to the dosage and route of administration. The efficacy of oral PGE1 as an induction agent at 2 hrs and 6 hrs of PROM is assessed by the time interval from onset of PROM to delivery, duration of first stage of labour, and occurrence of vaginal delivery within 24 hrs of PROM. Other outcome measures like operative delivery rates, neonatal and maternal outcomes were also looked into.

The present study was a prospective cohort study. 100 patients who are induced 2 hours following PROM were compared against 100 patients who are induced 6 hours following PROM with oral PGE1. 80 women (80%) in the early induction group (group A) delivered within 24 h of PROM as compared to 56 women (56%) in the control group (group B). While the rupture of membranes to delivery time was significantly reduced with early induction compared to controls, the time interval from induction to delivery was not statistically significant between both the groups. When 56% patients delivered within 12 hrs of PROM in the early induction group, 45% patients in the control group delivered in the same timeframe. Regarding the outcome of induction, when 91% patients in the control group underwent normal vaginal delivery following induction after 6 hrs of PROM, 96% patients induced at 2 hrs of PROM underwent normal vaginal delivery. Similar findings were reported by Hannah et al in the landmark TERMPROM trial, where active induction following PROM significantly reduced the interval from membrane rupture to delivery and lowered maternal infectious morbidity compared with expectant management.[8] The shorter PROM-to-delivery interval observed in the present study is clinically important because prolonged membrane rupture is known to increase the risk of ascending infection, maternal exhaustion, and neonatal sepsis. When 57 patients (28.5%) in the early induction group delivered when induced with a single dose of oral PGE1, only 45 patients (22.5%) in group B delivered so. Only 7 patients (3.5%) in the early induction group required 3 doses of oral PGE1 for initiation of labour, whereas 18 patients (9%) in the group B required the same, suggesting that women induced earlier required fewer doses of oral PGE1. This suggests that cervical responsiveness and uterine sensitivity may be more favorable when induction is initiated earlier after membrane rupture. Comparable observations were reported by Hofmeyr et al who concluded that prostaglandins are effective in achieving cervical ripening and successful induction with reduced induction-delivery intervals.[9-11] The vaginal delivery rate in the present study was higher in the early induction group (96%) compared with the delayed induction group (91%).

Five patients in the control group underwent LSCS in view of failure to progress, even after 24 hrs of PROM, whereas four patients developed maternal pyrexia following PROM and induction, with no signs of sepsis to the mother or CTG abnormalities to the fetus, necessitating a caesarean section. Two patients in the early induction group underwent LSCS in view of cephalopelvic disproportion followed by arrest of descent, and the other two patients failed to have significant labour progress even after 24 hrs of PROM. Twenty patients (10%) in the early induction group delivered after 24 hrs of PROM, as compared to 44 patients (22%) in the control group, significantly indicating the importance of early induction and its necessity in reducing the maternal exhaustion and anxiety faced during the above timeframe. Although both groups had favorable vaginal delivery rates, early induction appeared to reduce the likelihood of operative intervention. Similar findings have been documented by Middleton et al in a Cochrane review, which concluded that induction of labor in term PROM reduces maternal infection without increasing caesarean section rates.[12]

Uterine hyperstimulation was defined as tachysystole (six or more contractions in 10 minutes) or strong contractions lasting over 2 minutes with associated fetal heart rate changes necessitating delivery or administration of tocolytics. None of the patients in both the groups had features of uterine hyperstimulation and there were no statistically significant differences in the neonatal outcomes. The reduction in the number of cases with PROM of more than 24 hrs has reduced the number of baby swabs taken and the number of babies requiring neonatal intensive care unit admission for observation due to evidence of pyrexia in the mother. The occurrence of maternal pyrexia or other signs of sepsis was always looked for with caution. Any other foci of infection was looked for, in these patients and they were also ruled out of other underlying comorbidities such as diabetes mellitus which could complicate sepsis. Adverse effect of the drug misoprostol causing pyrexia was also taken into consideration after examining and ruling out other causes. An important observation in the present study was the lower incidence of maternal pyrexia and absence of signs of maternal sepsis in the early induction group. In contrast, several women in the delayed induction group developed maternal pyrexia requiring caesarean section. These findings are consistent with previous studies demonstrating that prolonged PROM duration is strongly associated with chorioamnionitis and maternal febrile morbidity. Mercer et al emphasized that increasing latency after membrane rupture contributes substantially to maternal infectious complications.[13] Early induction therefore appears beneficial in minimizing the duration of membrane exposure and reducing ascending infection. The study also found that fewer women in the early induction group remained undelivered after 24 hours of PROM compared with the delayed induction group. Prolonged PROM often contributes to psychological stress, maternal anxiety, and physical exhaustion. Therefore, reducing the duration between membrane rupture and delivery not only improves clinical outcomes but may also enhance maternal comfort and satisfaction. Similar conclusions were reported in studies evaluating active management of PROM, where early induction reduced prolonged labor and hospital stay.[14]

Despite the improved outcomes associated with early induction, the induction-to-delivery interval itself did not differ significantly between groups in the present study. This suggests that the major benefit of early induction lies primarily in reducing the waiting period after PROM rather than accelerating active labor once induction has begun. This observation aligns with findings from previous studies indicating that timely initiation of induction is more critical than the speed of labor progression itself.[15] The findings of the present study support current recommendations favouring active management of term PROM. WHO guidelines advocate timely induction in appropriate clinical settings to minimize complications associated with prolonged rupture of membranes.[16] Overall, the present study demonstrates that early induction resulted in shorter PROM-to-delivery intervals, higher rates of vaginal delivery within 24 hours, lower prostaglandin requirement, reduced maternal morbidity, and lower incidence of prolonged PROM without increasing operative delivery or adverse neonatal outcomes. These findings reinforce the role of early active management in women with term PROM and support the use of oral PGE1 as an effective, safe, and practical induction agent in contemporary obstetric practice. Thus, while misoprostol offers a practical and effective option for labor induction and cervical ripening, careful dosing and monitoring are crucial to balance its benefits with the risks associated with higher doses.[17]

Limitations

The limitations and shortcomings are an inevitable result of not having unlimited resources, funding, access to information, or a flawless system to follow. Only a small number of cases could be included because this was a one-center study. Moreover, patients who presented after 6 hours of PROM could not be included in the study. Although no differences in perinatal outcome were shown, the studies were not sufficiently large to exclude the possibility of uncommon serious adverse effects. In particular the increase in uterine hyperstimulation with fetal heart rate changes following misoprostol is a matter for concern. Thus, though misoprostol shows promise as a highly effective, inexpensive and convenient agent for labour induction, lower dose misoprostol regimens should be investigated further. Not all patients with maternal pyrexia were evaluated for the cause for the same. Hence, the etiology could not be attributed to maternal infections or adverse effect of the drug solely. However, the outcome of all patients turned out to be satisfactory. Other factors including education, employment, geography, socioeconomic class and psychological stress could not be taken into account.

CONCLUSION

Originally created for the treatment and prevention of gastroduodenal ulcers caused by nonsteroidal anti-inflammatory drugs, and for the treatment of duodenal ulcers caused by peptic ulcer disease, misoprostol has proven with time to be an effective induction agent when administered orally. The analysis concludes that the PROM delivery interval and the number of doses of PGE1 required for induction showed statistically significant association in both the groups, with early induction at 2 hours of PROM showing a reduction in the PROM delivery interval and requirement of fewer doses of PGE1 for labor induction. This has undoubtedly improved the outcome of delivery, and in turn, the maternal satisfaction rates including lesser maternal and neonatal morbidity.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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