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A comparative study on premature rupture of membranes at term: Immediate induction with PGE2 gel vs delayed induction with oxytocin

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Abstract
Background: Premature rupture of membranes is a common occurance in term pregnancies. It is of significant value in maternal journey as it can cause complications, both maternal and neonatal, so early diagnosis and proper management is important. The purpose of our present study is to assess the effectiveness of early induction with PGE2 gel in comparison to delayed induction with oxytocin in pregnant woman with term premature rupture of membranes.
Method: A prospective study was conducted at GMERS Medical College and Hospital, Ahmedabad, India. 150 term pregnant patients with premature rupture of membranes fulfilling the inclusion criteria were selected and randomly assigned to receive either early induction with intracervical PGE2 gel or expectant management for 12 hours followed by induction with intravenous oxytocin drip. The two groups were analysed with respect to labour characteristics, mode of delivery and maternal and neonatal morbidity.
Result: In our study, 30% women had spontaneous onset of labor during the waiting period of 12 hours and required oxytocin only for augmentation in later first stage of labor. Induction with PGE2 gel immediately after PROM resulted in significantly shorter PROM delivery interval (14 hrs vs 22 hrs) in comparison to expectant management, especially in nulliparous women. However, no significant difference was observed in the mode of delivery (vaginal delivery rate of 85% in immediate induction group and 78.7% in delayed induction group) and infectious morbidity in mother and fetus in both the groups.
Conclusion: In multiparous women with PROM at term, both immediate induction with PGE2 gel and expectant management followed by oxytocin induction resulted in similar intrapartum outcomes. But in nulliparous women, immediate induction with PGE2 gel stands as a far better option in comparison to expectant group with respect to PROM delivery interval and cesarean section rate for non progress of labor and induction failure.

Keywords: Premature rupture of membranes (PROM), oxytocin, PGE2 gel, expectant management

Introduction
Premature rupture of membranes (PROM) is defined as the loss of integrity of membranes with leakage of amniotic fluid before onset of labor. PROM complicates 5-10% of pregnancies and occurs in approximately 60-80% at term [1]. 60-70% term PROM cases go into spontaneous labour within 24 hours and additional 20-30% will start within 72 hours [2].
The fetus with its intact membranes enjoys a great degree of protection and isolation from pathogens present in its surrounding environment, but the scenario is totally different in PROM where the fetus is exposed to micro-organisms, so the chances of infection and rate of consequent morbidity is significantly increased. To avoid such complications, labour is usually induced but the timing of induction is still controversial, immediate or delayed (after 12 hours).
Early interference may increase the incidence of operative deliveries and delayed induction is associated with increased risk of sepsis. As per cochrane review, there is no substantial difference in immediate induction or expectant management group in relation to feto-maternal outcome.
With concern to the above factors, the present study was undertaken to determine whether early induction with intracervical PGE2 gel is preferable to delayed induction with intravenous oxytocin drip after an expectant management of 12 hours.

Methods
A prospective study was carried out on 150 antenatal women with term PROM admitted in

department of obstetrics and gynecology, GMERS Medical College and Hospital, Ahmedabad, India from August 2018 to March 2019. The women were selected as per the following criteria and then randomly allocated into two groups.

Inclusion Criteria

- Singleton uncomplicated pregnancy with cephalic presentation
- Gestational age between 37-41 weeks
- Spontaneous PROM as confirmed by history and examination
- Modified bishop score <6
- No detectable uterine contractions on admission
- Clear liquor and duration of PROM <8 hours

Exclusion criteria

- Preterm PROM (before 37 completed weeks)
- Meconium stained liquor
- Patients with features of chorioamnionitis
- Medical or obstetric complications indicating prompt delivery or cesarean section
- Gravida 4 and above
- Modified bishop score >6

160 antenatal women with PROM at term were included after proper history taking and written informed consent. These patients were monitored for 1 hour to determine fetal well being and onset of labour. Prophylactic antibiotic was administered and non-stress test was performed. Those patients who were not in labour were randomly divided into 2 groups.

In group A, patients were immediately induced by intracervical instillation of 0.5mg PGE2 gel. If bishop score did not improve after 6 hours, then application of PGE2 gel was repeated (maximum 2 doses).

In group B, patients were observed for 12 hours for spontaneous onset of labour, following which induction with intravenous oxytocin drip was done, 5U in 500ml ringer lactate with infusion rate of 2mIU/min. The rate was increased every 20 minutes until 3 contractions lasting for 45 seconds were established, upto maximum infusion rate of 32mIU/min.

Both groups were closely monitored by:

- Temperature recording 4 hourly
- Fetal heart rate auscultation every 30 minutes
- No digital vaginal examination till patient was clinically in active labour
- Signs of chorioamnionitis
- Antibiotic every 8 hours

The criteria for diagnosing chorioamnionitis was temperature > 38o C and any two of the following: maternal tachycardia, fetal tachycardia, foul smelling discharge, maternal leukocytosis. Labour was managed as per the hospital protocol.

Failure of induction was considered if patient did not go into active labour after 24 hours of admission. LSCS was performed for fetal distress, non progress of labour and failure of induction. The two groups were compared with respect to admission delivery interval, mode of delivery and maternal and neonatal outcome.

Results

Of the total 160 women taken into consideration, 80 were assigned to immediate induction (group A) and the other 80 were observed for 12 hours followed by delayed induction (group B). The baseline obstetric parameters were similar in both the groups.

Table 1: Pre induction characteristics of study population

Pre induction characteristics	Group A (immediate induction) n = 80	Group B (delayed induction) n = 80
Maternal age (years)	24.6 ± 3.8	23.8 ± 4.2
Gestational age (weeks)	39.2 ± 1.2	38.9 ± 0.9
Parity	1.4 ± 0.6	1.6 ± 0.5
PROM to admission interval (hours)	4.8± 1.9	5.2 ± 1.6
Modified bishop score on admission	3.8± 1.4	3.7 ± 1.2

Table 2: Method of induction of labor

Method of induction	Group A (immediate induction) n=80	Group B (delayed induction) n=80
PGE2		
Single dose	54(67.5%)	-
Repeat dose	26(32.5%)	-
Delayed induction		
Spontaneous onset	-	24(30.0%)
Oxytocin induced	-	56(70.0%)
Oxytocin augmentation during labor	44(55.0%)	68(85.0%)

Of the total 80 patients in group A, 67.5% of women showed significant improvement in bishop score only after single dose of PGE2 gel. The rest 32.5% needed repeat instillation.

In delayed induction group, 30% of women went into spontaneous labor while still under observation, whereas 70% subsequently required induction with intravenous oxytocin drip.

In group A and group B, 55% and 85% of women respectively needed oxytocin augmentation during later first stage of labor.

Table 3: Admission Delivery Interval

Admission delivery interval (hours)	Group A (immediate induction) n=80	Group B (delayed induction) n=80
<12 hours	28 (35.0%)	11 (13.7%)
12-24 hours	45 (56.3%)	53 (66.3%)
>24 hours	7 (8.7%)	16 (20.0%)
Mean interval (hours)	14 hours	22 hours

Of the total study group, maximum number of women (61.3%) delivered in the time range of 12-24 hours.

In group A, 35% delivered within 12 hours whereas it was only 13.7% in group B. 13.7% of the women in group B who remain undelivered even after 24 hrs were nulliparous women in contrast to 5.0% in group A. Mean admission delivery interval was significantly more in delayed induction group in comparison to the immediate induction group (22 hours vs 14 hours).

This indicated early delivery in induction group therefore reducing the risk of infectious morbidity.

Table 4: Mode of delivery

Mode of delivery	Group A (immediate induction) n=80	Group B (delayed induction) n=80
Vaginal	68 (85.0%)	63 (78.7%)
Instrumental	1 (1.3%)	3 (3.8%)
LSCS	11(13.7%)	14 (17.5%)
Fetal Distress	6 (7.5%)	3 (3.8%)
Induction Failure	2 (2.5%)	4 (5.0%)
NPOL	3 (3.8%)	7 (8.7%)

The rate of vaginal and cesarean delivery were almost similar in both the groups. However, the indication for LSCS varied. The indication of fetal distress was more in group A (7.5%) in comparison to group B (3.8%).

On the contrary, there were significantly more cesarean section taken for non progress of labor and induction failure in group B (13.7%) when compared to group A (6.3%). 11.3% of them were nulliparous in expectant management group in whom LSCS was taken.

Table 5: Feto-maternal Outcome

Feto-maternal Outcome	Group A (immediate induction) n=80	Group B (delayed induction) n=80
Clinical Chorioamnionitis	1 (1.3%)	2 (2.5%)
APGAR score		
<7 at 1 min	8 (10%)	11(13.7%)
<7 at 5 min	1 (1.3%)	3 (3.8%)
Neonatal infection (NICU admission)	2 (2.5%)	3 (3.8%)

Due to the routine use of prophylactic antibiotic in both the groups, only 2 women in the expectant group showed clinical signs of chorioamnionitis. The maternal and neonatal morbidity rates were almost similar in both the groups. 2 and 3 neonates, in group A and group B respectively required NICU admission due to neonatal infection.

Discussion

In majority of the women, it is acknowledged, that spontaneous labor starts within 24 hours of PROM3. To reduce the risk of infection and shorten the delivery time in term PROM with low bishop score, induction can be initiated4. The management is still controversial and there is no standard protocol for it. In our study, both the groups were comparable with respect to obstetric characteristics.

In this study, in the immediate induction group, 67.5% women required single application of PGE2 gel. Ben-Haroush *et al*. [5] reported 80% success rate with single PGE2 gel induction whereas in study of Gonen *et al.* [6] it was 93%.

30% of women while still under observation went into spontaneous labor in our study. This is similar to the observation of George *et al.* [7] in which 35.6% and study of Snehmay [8] in which 32.1% went into spontaneous labor within 12 hours.

In the present study, both the duration of the latent and active phase of labor were significantly shorter in immediate induction group as comparison to conservative management group, 14 hours vs 22 hours, respectively. Similar findings have been demonstrated in many studies: Shah *et al.* [9] (13hrs vs 22 hrs), Bangal *et al*. [10] and Alcay *et al*. [11] The induction delivery interval was shortened by 10 hours in PGE2 induction group in comparison to expectant group in study by Krupa *et al*. [12]

In our current study, there was not much significant difference in the vaginal delivery rate in both the groups and the incidence of cesarean section was marginally higher in group B in comparison to group A. In this aspect, our inference was similar to that of Krupa *et al.* [12] and Alcalay *et al*. [11] who demonstrated similar rates of vaginal delivery and cesarean delivery in between the two groups. There was no difference in the rates of cesarean among immediate induction and conservative management group in a large prospective randomized trial of about 5000 women conducted by Hannah *et al*. [13]. On the contrary, the rate of cesarean was higher in delayed induction group in the study observed by Choudhuri and Naheed *et al.* [14] and Carbonne *et al.* [15]

However, the cesarean taken for induction failure and non pregress of labor was 13.7% in expectant management group in comparison to 6.3% in PGE2 gel induction group which was significantly high in our study. Similar group finding was observed by Akyol *et al*. [16] and Conway *et al*. [17] In our study, cesarean section taken for fetal distress was 7.5% in PGE2 induction group in comparison to 3.8% in delayed induction group. Shah *et al*. [9] reported no significant difference in meconium stained liquor in both the groups in his study.

In our study, the rate of maternal and neonatal infectious morbidity were low in both groups, probably due to routine and regular use of antibiotics, proper aseptic precautions and limited per vaginal examinations. Similar low rates of fetomaternal infection were observed in both groups in other studies also: Conway *et al*. [17] and Grant *et al*. [18] In contrast, Shah *et al*. [9] found higher maternal neonatal morbidity in expectant group.

Conclusion

To conclude, delayed induction with oxytocin after an observation period of 12 hours is a reasonable option with respect to PGE2 gel induction in term PROM in multiparous

women without compromising the maternal and neonatal outcome. However, in nulliparous women immediate induction with PGE2 gel results in decreased PROM delivery interval and lowers the cesarean delivery rate for non progress of labor and failed induction when compared with delayed induction. There was no difference in feto-maternal outcome as observed in immediate and delayed induction group.

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