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Immediate Versus Delayed Induction with PGE2 Gel in Term Premature Rupture of Membranes: Comparative Study of Maternal Outcome

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Abstract: ***Introduction: As 10% of pregnancies result in premature membrane rupture at term, it can cause complications, both maternal and neonatal, so early diagnosis and proper management is important. The purpose of our study to analyse and compare maternal outcome in Immediate Versus Delayed Induction with PGE 2 gel in Premature Rupture of Membranes at term. Material And Methods: A randomized, controlled comparative study was conducted from April 2021 to February 2022 in the Department of Obstetrics and Gynecology, SMS Medical College, Jaipur.160 cases of premature rupture of membranes (80 cases in each group) were randomly allocated to either immediate induction (Group A) or delayed induction (Group B), with gestational age between 37to 40 weeks. All women with premature rupture of membranes at term were admitted in labour room and history was elicited regarding time of rupture of membranes, duration and amount of leaking with general, systemic and obstetric examination and follow-up for progress of labour and maternal outcome was studied. Results: In our study, 68.7% women in group A had single gel and 31.25% women had repeat gel.21 women (26.25%) in delayed induction group entered in active labor during the waiting period. They did not require induction. Induction with PGE2 gel, immediately after PROM resulted in significantly shorter PROM-delivery interval (14.56hrs vs 23.05 hrs) in comparison to expectant management. However, no significant difference was observed in mode of delivery (vaginal delivery rate 87.5% in immediate induction group and 83.75% in delayed induction group). Conclusion: We conclude that in comparative study of immediate versus delayed induction with PGE2 gel in premature rupture of membranes, the interval from PROM to delivery was higher in delayed induction group than immediate induction group, which was statistically significant. The rate of caesarean section was statistically insignificant among both groups. Among maternal complications, there was no statistically significant difference between both the groups. Hence both methods of management can be used in PROM at term. However, the women in delayed induction group were in labour for many hours.***

Keywords: Premature rupture of membranes (PROM), Immediate induction, delayed induction, PGE2 gel

1. Introduction

The chorio-amniotic membranes encircle and shield the foetus during pregnancy. When the foetal membranes are still intact, labour starts at term. Near the conclusion of the first stage of labour, the spontaneous rupture typically happens if there are no interventions. If the membranes rupture after 37 weeks of gestation it is called term Premature Rupture of Membranes, which is a major occurrence since it can lead to problems for the mother like increased operative procedures, maternal morbidity and very rarely mortality.[1] Premature Rupture of Membranes occurs in 5-10% of all pregnancies of which approximately 80% occur at term[2]. The aetiology of PROM is multifactorial, at term PROM can be physiological variation rather than a pathological event.3 PROM occurs when intrauterine pressure overcomes membrane resistance.[3] Some authors, such as Cammu H et al, hold that aggressive management of premature rupture of membranes with immediate induction of labour results in a higher caesarean section rate. However, they also contend that expectant management of premature rupture of membranes at term does not increase perinatal and maternal morbidity[4].

A good number of women will be able to go into labour with an expectant management followed by a delayed oxytocin induction without an increase in the caesarean section rate or infectious morbidity for the mother.[5]

This study was undertaken so to arrive at an optimum management of term PROM, so as to have better maternal outcome by comparing Immediate Versus Delayed Induction with PGE2 gel in Premature Rupture of Membranes.

2. Material and Methods

This was a randomized, controlled comparative study conducted in the Department of Obstetrics and Gynecology, SMS Medical College, Jaipur from April 2021 to February 2022. The study included sample size of 160 cases of premature rupture of membranes, at term (80 cases in each group) was randomly allocated to either immediate

induction (Group A) or delayed induction (Group B). All women with premature rupture of membranes at term were admitted in labour room and history was elicited regarding time of rupture of membranes, duration and amount of leaking with general, systemic and obstetric examination and follow-up for progress of labour and maternal outcome was studied. These women 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 women who were not in labour were randomly divided by coin tossing into 2 groups:-

In ***Group-A:*** Women were immediately induced by intracervical instillation of 0.5 mg PGE2 gel. If Bishop's Score did not improve after 6 hours, then application of PGE2 gel was repeated (Max.2 doses). In ***Group-B:*** Women were observed for 12 hours for spontaneous onset of labour following which, induction with PGE2 gel was done. Both groups were closely monitored by: Temperature recording 4 hourly, Fetal heart rate ascultation every 30 min, no digital vaginal examination till woman was clinically in active labour, signs of chorioamnionitis, antibiotic every 8 hours. The criteria for diagnosis of chorioamnionitis is temperature >38 ^{o}C and any two of following:-

Maternal tachycardia, fetal tachycardia, foul smelling discharge and maternal leukocytosis.

Labour was managed as per hospital protocol. LSCS was performed for fetal distress, non-progress of labour or failure of induction.

Both groups were reassessed after 12 hours, to see if they are going into labour or need PGE_2 gel.

In Group-B those going in spontaneous labour were noted. Both groups were further followed in terms of vaginal delivery or LSCS. The two groups were compared with respect to PROM-delivery interval, mode of delivery and maternal complications.

Selection Criteria

- **Inclusion Criteria:** Singleton live term pregnancy (37-40 weeks), Cephalic presentation, Spontaneous PROM with clear liquor, PROM <8 hours, Modified Bishop's Score <6
- **Exclusion Criteria:** Chorioamnionitis, Gravida 4 and above, Medical or obstetric indications for prompt delivery, Not giving written consent, Participating in any other study.

3. Results

Out of 160 women, 80 were assigned to the immediate induction group (with PGE2 gel) and 80 to the delayed induction group (expectant management followed by induction with PGE2 gel). Baseline characteristics were similar in both the groups.

Table 1: Distribution of cases according to Age

S No.	Age Distribution (in years)	Group A		Group B	
		No. of Women	Percentage	No. of Women	Percentage
1.	18-24	26	32.5	24	30
2.	25-30	51	63.75	54	67.5
3.	≥31	3	3.75	2	2.5
	Total	80	100	80	100
	Mean±SD	25.66±3.02		25.75±2.52	
	P-Value	0.8			

In above table we found than mean age for group A was 25.6 years and for group B it was 25.75 years, which was comparable.

Table 2: Distribution of cases according to PROM-Delivery interval (PDI)

S No.	PDI (in hours)	Group A		Group B	
		No. of Women	Percentage	No. of Women	Percentage
1.	5-10	8	10	1	1.25
2.	11-15	38	47.5	6	7.5
3.	16-20	34	42.5	10	12.5
4.	≥21	0	0	63	78.75
	Total	80	100	80	100
	Mean±SD	14.56±2.57		23.05±4.34	
	P-Value	<0.0001			

In above table we found that mean PDI for group A was 14.56 hours and for group B it was 23.05 hours. In our study, earliest PROM-delivery interval was 9 hours in immediate induction rate and longest PROM-delivery interval was 29 hours in delayed induction group. There was significant difference found between these group as p value was <0.05.

Table 3: Distribution of cases according to Method of induction

S NO.	Mode of induction	Group A		Group B		Total	P-Value
		No. of Women	Percentage	No. of Women	Percentage		
1	Single gel	55	68.75	-	-	55	<0.0001
2	Repeat gel	25	31.25	-	-	25	<0.0001
3	Spontaneous onset	-	-	21	26.25	21	<0.0001
4	Delayed induction (single gel)	-	-	40	50.00	40	<0.0001
5	Delayed induction (Repeat gel)	-	-	19	23.75	19	<0.0001
	Total	80	100	80	100.00		

In above table we found that 68.7% women in group A had single gel and 31.25% women had repeat gel.21 women (26.25%) in delayed induction group entered in active labor during the waiting period. They did not require induction. In group B, 50% women had single gel followed by 23.75% women had repeat gel. There was significant difference found between these group as p value was <0.05.

Table 4: Distribution of patients according to Mode of delivery

S NO.	Mode of delivery	Group A		Group B		Total	P-Value
		No. of Women	Percentage	No. of Women	Percentage		
1.	Vaginal Delivery	70	87.5	67	83.75	137	0.49
2.	LSCS	10	12.5	13	16.25	23	0.5
	Total	80	100	80	100.00		

In above table we found that majority 87.5% women in group A and 83.75% women in group B who had vaginal delivery followed by 12.5% women in group A and 16.25% women in group B who had LSCS.

Table 5: Distribution of cases according to maternal Complications

S No.	Maternal complications	Group A		Group B		Total	P-Value
		No. of Women	Percentage	No. of Women	Percentage		
1	PPH	3	3.75	3	3.75	6	1
2	Chorioamnionitis	1	1.25	2	2.5	3	0.56
2	No maternal complications	76	95	75	93.75	151	0.73
	Total	80	100	80	100		

We found that 1.25% women in group A and 2.5% women in group B had chorioamnionitis. Chorioamnionitis was found more in group B, because of greater PROM to delivery interval.

4. Discussion

The major concern regarding management of the patients with PROM is whether to allow them to enter labor spontaneously or to induce labor early. There are evidences which support that induction of labor decreases the risk of chorio-amnionitis without increasing the caesarean delivery rate. Few literatures favour early induction in PROM because of risk of infections and others favor expectant management with feto-maternal monitoring.

Our total study population was 160 pregnant women. In the present study we found than mean age for group A was 25.6 years and for group B it was 25.75 years. The mean age of our study was comparable to Gupta S et al[6] who found that mean maternal age for Group A was 24.6 years and for group B it was 23.8 years. In our study majority 68.7% women in group A had single gel and 31.25% women had repeat gel. In group B, 26.25% women delivered without induction, because there was more time to for the cervix to ripen, which is significant, rest 50% women had single gel, 23.75% women had repeat gel. Significantly lesser number of women in delayed induction group required induction as compared to immediate induction group. There was significant difference found between these group as p value was <0.05. **Agnes J M B et al**[7] found that 38% of cases entered active labour in the delayed induction group. The results were similar to that of **Krupaet al**[8] which showed that significantly higher doses of PGE2 were required in immediate induction group. This is comparable to the following studies: **Dare et al**: 50% (in 12 hours), **Krupa et al**: 80% (in 24 hours) and **Poornima et al**: 60% (in 12 hours).

The mean PDI for group A was 14.56 hours and for group B it was 23.05 hours, showing early delivery in immediate induction group. There was significant difference found between these group as p value was <0.05.

Agnes J M B et al[7] found that the most of the patients (48%) delivered within 14 to 20 hours of PROM. The earliest PROM-delivery interval was 8 hours (one woman in early induction group). In our study, earliest PROM-delivery interval was 9 hours in immediate induction group. One of the women in delayed induction group had the longest PROM-delivery interval of 30 hours, while in our study it was 29 hours. More number of patients (78%) in the early induction group delivered within 14 hours of PROM as compared to the delayed induction group. The PROM-delivery interval was significantly more in the delayed induction group as compared to the early induction group (statistically significant: Pearson chi P value: 0.00). The mean PROM delivery interval in group A was 14.58 hours whereas in group B 18.79 hours showing early delivery in early induction group. We found that majority 87.5% women in group A and 83.75% women in group B had vaginal delivery while 12.5% women in group A and 16.25% women in group B had LSCS. Discussion 52 In this aspect, our inference was different from that of Agnes J M B et al48who found that there were more number of caesarean sections in the early induction group when compared to the delayed induction group which was statistically significant (P value: 0.049). Our inference was similar to Gupta S etal[6], Poornima et al[9], Choudhuri and Naheed et al[10]who showed the incidence of caesarean section was marginally higher in delayed induction group as compared to immediate induction group. We found that 1.25% women in group A and 2.5% women in group B had chorioamnionitis. Chorioamnionitis was found more in group B, because of greater PROM to delivery interval. Our finding was comparable to Agnes J M B et al48 who found that there was no significant difference in chorioamnionitis in both the groups.

5. Conclusion

We conclude that in comparative study of immediate versus delayed induction with PGE2 gel in premature rupture of membranes, the duration of labour from PROM to delivery was higher in delayed induction group than immediate induction group, which was statistically significant. The rate of caesarean section was statistically insignificant among both groups. Among maternal complications, there was no statistically significant difference between immediate

induction and delayed induction groups. However, in delayed induction group 21 women (26.25%) had spontaneous labor, which was statistically significant. Significantly lesser number of women in delayed induction group required induction as compared to immediate induction group. Hence delayed induction can be used in PROM at term. According to our study findings, we can wait for spontaneous onset of labor unless any fetal compromise. However, the women in delayed induction group were in labor for many hours.

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6. Declarations

Conflict of interest: The authors declare that they have no conflict of interest and there is no violation of human rights.

Ethical Approval: The study received approval from the institutional ethics committee.

Informed consent: Written informed consent was obtained from the study participants.

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