

# Comparison of induction of labor versus expectant management in PROM patients 2018-2019

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## Abstract

**Background:** Premature rupture of membrane at term (term PROM) is a common obstetric condition that is associated with increased maternal and neonatal complications. Its management is still controversial.

**Objective:** This study aimed to compare maternal outcomes in induced versus expectant management of patients with term PROM to access to the clinical management that reduces the rate of maternal infections without increasing the need for cesarean section.

**Materials and Methods:** This randomized prospective study comprised 100 patients with term PROM. Half of them were managed by expectant protocol, up to 12 hours, and the other half by induction of labor directly was upon admission with oxytocin. The primary studied outcome was a maternal infection, and the secondary outcome was the cesarean section rate.

**Results:** The rates of cesarean section were significantly higher in the induction group (32% vs. 10%,  $P < 0.05$ ), whereas clinical chorioamnionitis was less likely to happen in this group. However, it was not statistically significant (2% vs. 4%,  $P > 0.05$ ).

**Conclusion:** Expectant management of 12 hours is better than early induction because it allows a large number of patients to deliver vaginally without an increase in the cesarean section rate and infectious morbidity for mother.

**Keywords:** Chorioamnionitis; Expectant management; Induction of labor; Premature rupture of membrane; Term PROM.

associated with term PROM for the mother (chorioamnionitis, endometritis) and the baby. [4] The incidence of chorioamnionitis is less than 10%, and it increases 12 to 40% after 24 hours of PROM. [5,6] The risk factors of chorioamnionitis with PROM at term involve: frequent vaginal exams following PROM (>8), GBS status, duration of active labor  $\geq 12$  hours, a latent period between 24 and 48 hours. [7,8]

When PROM occurs at term, spontaneous onset of labor usually happens within 12 to 24 hours. [9,10] Since the 1960s, the expectant management by waiting for labor to happen spontaneously has been the golden standard for the management of PROM, considering it a safe procedure, and mostly it leads to vaginal delivery, but it's associated with a high incidence of maternal infections where some reports mentioned that the duration of the latent phase-which is the period between rupture of the membranes and spontaneous onset of labor- plays the main role in increasing the infections. Recently, many schools have recommended induction of labor immediately and have considered it the most appropriate treatment because it decreases the PROM-delivery interval, so it reduces the maternal infection rate without increasing cesarean section. [11-13] Currently, there are no specific guidelines practicing for this clinical case, and the results differ according to the protocols of the medical center in which these studies are conducted.

Accordingly, the primary aim of this study was to compare maternal outcomes in induced versus expectant management of patients with term PROM to access the clinical management that reduces the rate of maternal infections without increasing the need for cesarean section.

## I. INTRODUCTION

Premature rupture of membranes (PROM) refers to the loss of integrity of the fetal membranes before the onset of regular uterine contractions at term gestation ( $\geq 37+0$  weeks' gestation). [1,2]

PROM occurs in almost 10% of all pregnancies (from 2.7% to 17%). It happens with 60% to 80% of cases at term. [3]

Infections remain the most serious complication

## II. Materials and Methods

### Study design and setting

We performed a randomized prospective study that included 100 patients admitted at the Department of Obstetrics and Gynecology, Tishreen University Hospital, Latakia, Syria, with term PROM from January 2018 to January 2019. Informed consent was taken from all patients after clarification of the aim of the study.



**Selection of participants**

The inclusion criteria were term PROM (gestational age 37-41 weeks and spontaneous PROM confirmed by history and examination), singleton pregnancy, and cephalic presentation. Women were excluded from the study if there was a contraindication for induction of labor (such as Previous cesarean section) or if there were medical or obstetric complications indicating to prompt delivery (like features of chorioamnionitis or systemic complications) or if they were inactive labor (effective uterine contractions), Bishop score above 6, or if the diagnosis of PROM is not documented. Thus, 100 patients were finally enrolled and analyzed in this study.

**Outcome measures**

The primary measured outcome was maternal infection before delivery "Clinical chorioamnionitis." It was defined as: fever (>38.0 °C) in addition to two other signs: maternal tachycardia >120 bpm, fetal tachycardia >160 bpm for 10 minutes or longer, Maternal leukocytosis (WBC >15,000 cells/mm<sup>3</sup>, CRP > 40 mg/L, uterine tenderness and foul/purulent fluid. [14] The secondary outcome was the cesarean section rate.

**Procedure of Study**

Patients who agreed to participate in the study were randomly divided into two groups: The immediate induction group included 50 patients, who were induced immediately upon admission. The expectant management group included 50 patients, who were observed upon admission for 12 hours until labor to occur spontaneously. All the patients were given IV antibiotics (1-gram ceftriaxone) until delivery.

For women in the immediate induction group, induction of labor with high dose protocol oxytocin was done with 10 U oxytocin in 1000 ml of RL with an infusion rate of 4 ml U/min. Infusion of oxytocin doubled every 20 minutes until three contractions in 10 minutes lasted for 45–60 seconds were obtained. A vaginal examination was done every 4 hours to assess the progress of labor. Uterine contractions and fetal heart rate (CTG) were monitored during induction until delivery. After 12 hours, if the active labor did not happen, it was named as failed induction. Emergency cesarean section was performed for fetal distress, non-progress of labor, failed induction, and chorioamnionitis.

The expectant management group was monitored for uterine contractions for 12 hours. Unnecessary vaginal examinations were avoided and done only if uterine contractions were effective in assessing the progress of labor. If labor did not start in 12 hours since admission, induction of labor with an oxytocin infusion was done with the previous way.

Signs of clinical chorioamnionitis were monitored in all patients till delivery (especially the oral temperature every 4 hours, pulse rate every 1 hour, noticing any change in color or smell of liquid, repeating CRP-CBC every 12 hours until the patient is discharged).

**III. Statistical analysis**

Continuous variables were presented as the means ± standard deviations. Categorical variables were presented as both numbers and percentages.

The student's t-test for continuous variables, the chi-square or the chi-square test with a Fisher exact test for 2×2 tables for categorical variables were used for comparisons between the two groups. P-value < 0.05 was considered statistically significant. All statistical procedures were analyzed using IBM SPSS Statistics ver. 20

**IV. Results**

A total of 100 patients with PROM at term were enrolled in this study. 50 patients were managed by induction of labor immediately upon admission and 50 patients were expectantly managed.

Table 1 shows the baseline characteristics of the patients. There were no significant differences in demographic characteristics between the two groups.

Table 1. Baseline characteristics of the patients(N=100)

Characteristics	Expectant group (N=50)	Induced group (N=50)	P-value
Age (years)	22.80 ± 3.96	22.98 ± 3.87	0.819
Gestational age(weeks)	38.33 ± 0.82	38.29 ± 0.76	0.84
Smoker	3 (6%)	2 (4%)	0.695
Parity			0.648
Nulliparous	14(28%)	12(24%)	
Multiparous	36(72%)	38(76%)	

As expected, the mean interval between PROM and delivery was greater in the expectant group than in the induced group, and the differences were statistically significant (18.68 ± 5.72 vs. 15.30 ± 4.33, P < 0.05) [Table 2].

Table 2: PROM-delivery interval

Variable	Expectant group	Induced group	P-value
Prom delivery interval(Mean) hours	18.68 ± 5.72	15.30 ± 4.33	<0.01

Table 3: Onset of labor

Onset of labor	Expectant group	Induced group	P-value
Spontaneous	26(52%)	0(0%)	<0.000
Stimulated	24(48%)	50(100%)	

As shown as in Table 3, 26(52%) patients had spontaneous onset of labor within 12 hours of rupture of the membrane in the expectant group "latent period" and 24(48%) patients required induction of labor after passage 12 hours, whereas all patients of the induction group 50(100%) were directly induced upon admission with a statistically significant difference (P < 0.05).

Table 4: shows the number of vaginal examinations

Vaginal examinations	Expectant group	Induced group	P-value
< 4	22(44%)	20(40%)	0.265
4 – 8	26(52%)	28(56%)	
>8	2(4%)	2(4%)	

Digital vaginal examinations were done only if uterine contractions were effective in assessing the progress of labor. As shown in Table 4, there was no statistical difference in the number of these examinations between the two groups (P>0.05).

Table 5: shows maternal outcomes

Variable	Expectant group	Induced group	p-value
Chorioamnionitis	2(4%)	1(2%)	0.558
Mode of delivery			<0.007
Vaginal	45(90%)	34(68%)	
Caesarean section	5(10%)	16(32%)	

The incidence of chorioamnionitis in the expectant group was 2(4%) versus 1(2%) in the induction group, but there were no statistically significant differences between the two groups (P > 0.05). Patients in the induced group had a significantly higher rate of cesarean delivery 16 (32%) compared with the expectant management group 5 (10%) (P < 0.05) [Table 5].

**V. Discussion**

This randomized prospective study showed no significant difference in the incidence of chorioamnionitis in expectant and immediate induction groups, which were 4% and 2%, respectively. Perhaps the clear decrease in the incidence of maternal infections in our research was due to the following: giving IV antibiotics until delivery, reducing the number of digital vaginal examinations, and the duration of the latent phase, which plays an important role in the development of infections, was 12 hours at approximately 50% of patients of expectant management, and the active management patients were directly induced upon admission without waiting for natural latency to finish. These results are not in agreement with the previous studies that demonstrated fewer chorioamnionitis with the induction of labor, such as a study conducted by Sadeh-Mestechkin et al. [15] that reported chorioamnionitis 9,1% in the expectant group versus 4,9 % in the induced group. That result might have been achieved because of the length of the latent period in the expectant group was 48 hours before labor induction. In addition, this group included more nulliparous women. A study conducted by Shah K and Doshi H. [16] also observed an apparent decrease in the incidence of chorioamnionitis in the induced group (4, 6 % versus 22,5%). That result may have been achieved because of using the intracervical PGE2 gel instead of oxytocin in the induced group, which led to a significantly shorter PROM delivery interval than in the expectant group (13 vs. 22 h)

In the present study, there were statistically significant differences in mode of delivery between the two group patients; 5 (10%) patients in the expectant group were attracted to cesarean section versus 16 (32%) patients in the active management. The main indication in both groups was the failure of induction. Direct oxytocin induction has appeared to be ineffective in cervical ripening, resulting in increased length of labor and failing induction. This study disagreed with a study conducted by Sadeh-Mestechkin et al. [15] that showed an increase in the cesarean section rate among expectant management patients (16.4% versus 7.1%). The main indication in both groups was the failure of labor progress. Shah K and Doshi H. [16] mentioned that there was not much difference in the incidences of cesarean delivery in expectant and immediate induction groups, which were 22 and 24 %, respectively.

**VI. Conclusion**

This study showed that induction of labor with oxytocin for patients of term PROM shortens the PROM-delivery interval. However, expectant

management of 12 hours is better than immediate induction because it allows a considerable number of patients to go into labor spontaneously and deliver vaginally without an increase in the cesarean section rate and infectious morbidity for mother.

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