

## Out Come of Expectant Management and Induction of Labour with Premature Rupture of Membrane in Term Pregnancy

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### ABSTRACT

**Introduction:** Overall, at least 50% of mothers with PROM near term deliver within 48 hours. The latency period is in general inversely related to the gestational age at the time of PROM. At term, labor is desirable since infections become more likely with more prolong intervals between rupture and delivery. Neonatal complications and perinatal mortality and morbidity also associated with PROM.

**Material and methods:** This randomized clinical trial study was carried out in the Department of Obstetrics and Gynecology Sir Salimuilah Medical College and Mitford Hospital Dhaka, during the period of January 2008 to September 2008. A total of 100 patients with term pregnancy had single fetus and cephalic presentation with PROM were enrolled in this study. After taking informed consent she was randomized in one of the two either groups according to the results of lottery. Fifty in Group I- Termination of the pregnancy (intervention group) by induction of labour and another 50 were in Group II- Expectant management for spontaneous delivery (expectant group). Randomization was 1:1 for intervention and expectant management. Proper history including demographic, past obstetric and medical history was taken, maternal temperature and Fetal heart rate was recorded. Antibiotics were given to all PROM women. The women of intervention group were induced by following ways -Women with riped cervix with oxytocin infusion and with unripe cervix, first underwent ripening by misoprostol followed by oxytocin infusion. Data was collected by standard questionnaire; results were compiled and relevant statistical calculation was done using computer-based software (SPSS).

**Results:** The mean age was 20-24 years were predominant in both groups. Low income patients were more common in both groups. Primigravida were predominant in both groups. The mean gestation age was almost similar in both groups, no significant ( $p > 0.05$ ) difference was found between two groups. Majority (80%) patients had time interval 1 to 12 hours between rupture membrane and onset of labour pain in group I. On the other hand 80% patients in group II had 12 to 24 hours time interval for onset of labour pain after rupture membrane. Normal vaginal delivery was higher in group I, whereas caesarean section (LSCS) was higher group II. No statistically significant ( $p > 0.05$ ) difference was found between two groups. Duration of time interval between onset of labour pain to delivery was <12 hours in group I 88.0% patients and 96.0% in group II respectively. No statistically significant ( $p > 0.05$ ) difference was found between two groups. Hundred percent cases was live birth in both groups. Neonatal infection and death were significantly ( $p < 0.05$ ) higher in group II. Puerperal sepsis was significantly ( $p < 0.05$ ) higher in group II. The mean duration of hospital stay was  $4.1 \pm 2.2$  and  $5.1 \pm 3.7$  days in group I and group II respectively but this was not significant ( $p > 0.05$ ).

**Conclusion:** In the present study there was no statistical difference in the mode of delivery and time interval between onset of labour pain and delivery in two groups though maternal complications, neonatal infection and perinatal death was higher where expectant management was followed.

**Key Words:** Induction of labour, Term pregnancy.

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## Introduction

Spontaneous rupture of the membrane at any time beyond 28 weeks of pregnancy but before the onset of labour is called premature rupture of the membranes (PROM).<sup>1</sup> PROM is usually followed by labour. The time interval between rupture of membranes and labour is defined as latent period. By induction, this latent period will be curtailed. Infection is the main risk for both the mother and neonate in which management is expectant. This risk needs to be balanced against the increase incidence of instrumental or operative interference in case of induction of labour. Although some authors impose an arbitrary latency period for the definition of PROM, varying from 1-12 hours, most define PROM simply as rupture of the membranes prior to the onset of contractions.<sup>2,3,4</sup> Etiology and pathogenesis of premature rupture of membranes is multifactorial in nature. In any given patient, one or more pathophysiologic processes may be evident. Choriodecidual infection or inflammation appears to play an important role in etiology of preterm PROM, especially at early gestational ages.<sup>2</sup> Current findings suggest that the most common causes of PROM are: infection/inflammation, dysregulation of cellular and structure processes involving extracellular matrix and detail membrane integrity and function, and possibly mistimed membrane amnion-chorion cell apoptosis or programmed cell death.

The diagnosis of PROM requires a thorough history, physical examination and selected laboratory studies. Patient report with history of sudden gush of fluid with continued leakage. The approach to the diagnosis of membrane rupture is clinical, with over 90% of cases being confirmed based on the presence of a suspicious history or ultrasonographic finding followed by documentation of fluid passing from the cervix or the presence of a Nitrazine/Ferning positive vaginal pool of fluid. Other causes of vaginal discharge (e.g. urinary incontinence, vaginitis, cervicitis, mucous show with cervical effacement and dilatation, semen, vaginal douches) should be excluded if the diagnosis is unclear.<sup>2</sup>

When PROM is suspected, it is important to avoid

performing a digital cervical examination; such examinations have been shown to increase morbidity and mortality. Evidence of fluid pooling in the vagina, or leaking from the cervical os when the patient coughs or when fundal pressure is applied, will help determine PROM.<sup>5</sup> Maternal consequences of PROM include increased risks of postpartum endometritis and post-cesarean section infection, presumably due to increased inoculum of vaginal microorganisms within the uterus. At term, labor is desirable since infectious complications become more likely with more prolonged intervals between rupture and delivery. A maternal inflammatory response may then occur within the fetal membranes, and amniotic fluid and systemic sepsis may occasionally result.<sup>4</sup> The overall incidence of chorioamnionitis ranges from 4.2% to 10.5%. The occurrence of chorioamniotic infection after PROM seems to be greater in hospitals caring for low socioeconomic segments of the population than in institutions taking care of the affluent.<sup>6</sup> This risk is inversely related to the gestational age at the time of rupture.<sup>7</sup> The incidence of neonatal sepsis varies similarly. At term, the overall incidence of neonatal sepsis is about 1 in 500 deliveries; with prolonged rupture at term this increases several folds. The diagnosis of chorioamnionitis is clinical. It requires the presence of fever (37.80 C) and at least two of the following conditions: maternal tachycardia, fetal tachycardia, uterine tenderness, foul odor of the amniotic fluid, or maternal leukocytosis. Histologic chorioamnionitis, characterized by varied degrees of polymorphonuclear leukocyte infiltration of the chorioamnion, is found more frequently than the clinical disease.<sup>10</sup> In the earlier stages chorioamnionitis may be silent or may be manifest by uterine contractions. As the infection progresses chorioamnionitis may result in maternal sepsis and serious sequelae may result, including renal failure, disseminated intravascular coagulation, septic shock, and adult respiratory distress syndrome. Generally, when the patient delivers and the infected products are expelled, the infection resolves quickly. When maternal fever and uterine tenderness persist beyond 24 hours following delivery, the infection is called endometritis. The fetus becomes exposed to pathogenic bacteria and

may develop a number of infectious complications including sepsis, pneumonia, omphalitis, urinary tract infection, and conjunctivitis and may result in the birth of a depressed infant ultimately fetal death.

The management of patient with PROM has changed markedly in past several years. Combination of better understanding of new born physiology improved neonatal care, refinements in antibiotic therapy and wide spread use of maternal and fetal monitoring improved the outcome of mother and infant.<sup>8</sup> Many obstetrician institute conservative management in Preterm Premature Rupture of Membranes before 34 weeks and would induced labour relatively early in women whose membrane rupture occurs subsequent to 37 weeks.<sup>9</sup> The term pregnancy (EGA > 37 weeks) with PROM in the absence of amnionitis can be managed expectantly or actively. Expectant management entails non-intervention while waiting for the patient to go into labour spontaneously, whereas active management entails induction of labour with an agent such as Pitocin.<sup>10</sup> PROM occurs in approximately in 10% in all pregnancy.<sup>11</sup> The incidence of PROM in Bangladesh is not known. In two different study in Bangladesh incidence of PROM is 8.2% in Dhaka Medical College at 1995 12 and 9.04% in Rangpur Medical College at 2004.<sup>13</sup> Expectant management results in antenatal hospitalization where induction of labour leads to a possible rise in the number of instrumental delivery or operative interference. Most of the patients in our country are illiterate, ignorant and poor so in view of this my aim was to determine the effectiveness, hospital stay and cost of induction of labour after PROM from 37 weeks onward compare to expectant management.

### **Aim and Objectives**

To determine impact of induction of labour after PROM in term gestation compared to expectant management.

### **Materials and Methods**

This randomized clinical trial study was conducted from January 2008 to September 2008 in pregnant

women of term pregnancy with single fetus with cephalic presentation with PROM who were admitted in department of obstetrics and gynecology, Sir Salimullah Medical College and Mitford Hospital, Dhaka. Women who are in established labour, had complications such as chorioamnionitis, meconium stained amniotic fluid, major fetal anomaly, severe PET, diabetes mellitus, chronic liver disease, heart failure and renal failure were excluded from this study. Hundred pregnant PROM women at 37 weeks were identified by their selection criteria. After the subject has given informed consent for participation in the study, she was randomized in one of the two either groups according to the results of lottery. GROUP I- Termination of the pregnancy (intervention group) by induction of labour and Group II- Expectant management for spontaneous delivery (expectant group). A data questionnaire was formed for recording all relevant parameter under instruction of the guide. Randomization was 1:1 for intervention and expectant management. Proper history including demographic, past obstetric and medical history was taken, maternal temperature was recorded. Fetal heart rate was recorded. Antibiotics were given to all PROM women. All women underwent an ultrasonography examination at entry. The women of intervention group were induced by following ways -Women with riped cervix with oxytocin infusion and with unripened cervix, first underwent ripening by misoprostol followed by oxytocin infusion. The data for this study were collected, coded and processed with adequate precautions to ensure patient confidentiality. Data was collected by standard questionnaire, results were compiled and relevant statistical calculation was done using computer based software (SPSS).

### **Results**

In this study 20-24 years age groups was predominant in both groups, however the mean age was almost similar in both groups ( $23.6 \pm 3.9$  vs  $24.9 \pm 4.1$  years). No significant ( $p > 0.05$ ) difference was found between two groups. Low income groups patients were more common in both

groups. No significant difference regarding socio-economic condition between two groups was observed. Regular antenatal care received were 42(84.0%) and 35(70.0%) in group I and group II respectively. No significant ( $p > 0.05$ ) difference was found between two groups. Primigravida was predominant in both groups (Group I - 28 and 22 Group II - 29 and 21, primigravida and multigravida respectively). History of abortion was found 22(44.0%) in group I and 15(30.0%) in group II. History of still born less in group I (2 and 8). H/O previous PROM was 12(24.0%) in group I and 15(30.0%) in group II. No significant ( $p > 0.05$ ) difference was found between two groups except history of still birth. Gestational age between 37-38 weeks were more common in both groups (32 vs 35), 39-40 weeks were 16(32%) vs 15(30%), however only 2(4%) patients were in Group I in  $> 40$  weeks and there were no patients in groups II. The mean gestational age was almost similar in both groups ( $38.2 \pm 1.2$  vs  $38.0 \pm 1.1$  weeks), no significant ( $t = 0.52$ ,  $df = 98$ ,  $p > 0.05$ ) difference was found between two groups. Anemia and edema were significantly higher in group I that was 46 (92%) vs 36(72%). Systolic and diastolic blood pressure was higher in group II ( $109.8 \pm 10.5$  vs  $119 \pm 8.0$ ) however weight was higher in group I ( $53.3 \pm 6.1$  vs  $49.3 \pm 6.2$ ). Height was similar in both groups ( $5.1 \pm 0.1$  vs  $5.1 \pm 0.2$ ), temperature was within normal range.

**Table I:** Method of induction (n=50)

Cervical condition	Oxytocin alone	Misoprostol followed by oxytocin infusion	Chi value	df	p value
	N	%	n	%	
Ripped cervix	36	100	0	0	0.001
Unripped cervix	0	0.0	14	100	

Ripped cervix was 36(100%) by oxytocin alone and unripped cervix was 14(100%) with misoprostol followed by oxytocin infusion. Difference was statistically significant ( $p < 0.05$ ) between two groups in chi square test.

**Table II:** Distribution of the time interval between rupture membrane and onset of labour pain (n=100)

Duration (hours)	Group I (n=50)	Group II (n=50)	chi value	df	p value
	N	%	n	%	
1 - 12	40	80.0	7	14.0	
13 - 24	7	14.0	40	80.0	43.72 1 0.001
25-48	2	4.0	3	6.0	
>48	1	2.0	0	0.0	

The time interval between rupture membrane and onset of labour pain was 40(80.0%) belongs to 1-12 hours in group I, however 40(80.0%) belongs to 13-24 hours in group II and the difference was statistically significant ( $p < 0.005$ ) between two groups.

**Table III:** Distribution of the time interval between onset of labour pain to delivery of the study patient (n=100)

Duration (hours)	Group I (n=50)	Group II (n=50)	t value	df	p value
	N	%	n	%	
< 12	44	88.0	48	96.0	1.22 1 0.134
12 - 24	6	2.0	2	4.0	

Duration of time interval between onset of labour pain to delivery was 44(88.0%) belongs to  $< 12$  hours in group I (labour induced either by oxytocin infused in ripe cervix or prior ripening with misoprostol followed by oxytocin infusion) and 48 (96.0%) in group II (expectant group). No statistically significant ( $p < 0.05$ ) difference was found between two groups.

**Table IV:** Mode of delivery of the study patients (n=100)

Mode of delivery	Group I (n=50)	Group II (n=50)	Chi value	df	p value
	N	%	n	%	
Normal vaginal delivery	26	52.0	23	46.0	0.36 1 0.548
Caesarian	24	48.0	27	54.0	

Normal vaginal delivery was higher in group I, whereas caesarean section (LSCS) was higher group II. No statistically significant ( $p > 0.05$ ) difference was found between two groups.

Hundred percent cases was live birth in both groups. Birth weight was almost similar between two groups. The mean Apgar score at 1 minute was 8.8 1.5 in group I and 7.6 1.4 in group II. The difference of Apgar score at 1 minute was statistically significant ( $p < 0.05$ ) between two groups. Neonatal infection (4 vs 15) and death (0 vs 5) were higher in group II which was statistically significant ( $p < 0.05$ ). Maternal complications was found only 4(8.0% in group I, whereas 15 (30.0%) found in group II. Puerperal sepsis was not found in group I and 7(14.0%) in group II. Maternal complications and puerperal sepsis were significantly ( $p < 0.05$ ) higher in group II. The mean duration of hospital stay was  $4.1 \pm 2.2$  days range from 2 to 7 days in group I and  $5.1 \pm 3.7$  days range from 2 to 10 days in group II. Duration of hospital stay was higher in group II but not significant ( $p < 0.05$ ).

## Discussion

This randomized clinical trial was carried out with an objective to determine impact of induction labour after PROM in term gestation compared to expectant management in terms of maternal and fetal outcome. A total of 100 women with term pregnancy with PROM age ranged from 18 to 32 years were included in the study, who were admitted in the Department of Obstetrics and Gynecology, Sir Salimullah Medical College and Mitford Hospital, Dhaka, during January 2008 to September 2008. Wagner et al. (1989) 14 have shown in their series, the mean age of patients with term pregnancy with PROM was  $27.7 \pm 5.6$  years and  $26.0 \pm 5.9$  years. Similarly, Hannah et al (1996) 15 in their study have shown the mean age was  $28.3 \pm 5.2$  years in group I and  $28.5 \pm 5.4$  years in group II. In the present study the mean age was  $23.6 \pm 3.9$  years in group I and  $24.9 \pm 4.1$  years in group II. The above study results are higher than the present study; this may be due to early marriage prevailing in our country.

In this current study it was found that PROM was more common in low income family in both groups. Regular antenatal checkup received by 84.0% in group I and 70.0% in group II, no significant ( $p > 0.05$ ) difference was found between two groups. Wagner et al. (1989)<sup>14</sup> have observed in their study that primigravid was 64.0% in group I and 77.0% group II, which is consistent with the present study, where primigravid was predominant in both groups. No significant ( $p > 0.05$ ) difference was found between two groups. In the current series the mean gestation age was almost similar in both groups, which was  $38.2 \pm 1.2$  weeks in group I and  $38.0 \pm 1.1$  weeks in group II. No significant ( $p > 0.05$ ) difference was found between two groups. Wagner et al. (1989)<sup>14</sup> observed similar findings in their study.

The time interval between rupture membrane and onset of labour pain was 1 -12 hours (80%) in group I, and >12 -24 hours (80%) in group II and the difference was statistically significant ( $p > 0.05$ ) between two groups. Grant et al. (1992)<sup>16</sup> obtained similar findings in their study. Regarding the mode of delivery Wagner et al. (1989)<sup>14</sup> observed no significant difference between two groups in terms of mode of delivery. Gafni et al. (1997)<sup>17</sup> and Hannah et al. (1996)<sup>15</sup> found in their study no statistically significant differences in cesarean section rates in their two study groups. Grant et al. (1992)<sup>16</sup> also reported 11.1% and 17.4% delivery conducted by cesarean section respectively in two groups which was not statistically significant ( $p > 0.05$ ). The above studies findings strengthen the present study result, where no statistically significant ( $p > 0.05$ ) difference was found between two groups regarding caesarean section (LSCS).

In this study it was observed that time interval between onset of labour pain to delivery was <12 hours in 88% patients in group I and 96.0% patients in group II but no statistically significant ( $p > 0.05$ ) difference was found between two groups. Similar findings were obtained by Grant et al. (1992).

In the present study the mean birth weight of the fetus was  $2.93 \pm 0.25$  kg in group I and  $2.81 \pm 0.38$  kg in group II. In Grant et al. (1992) 16 study the mean birth weight of fetus was much higher in both

groups than in my study. This might be the large size of fetus in the developed countries. Neonatal infection was seen in only one case with no perinatal death in Grant *et al* study. But in our study neonatal infection and perinatal death was significantly ( $p < 0.05$ ) higher in group II compared to group I. Gafni *et al.* (1997)<sup>17</sup> showed in their study a significant lower rate of maternal complication in their two groups, which support the present study findings where the puerperal sepsis was not found in group I and 7(14.0%) found in group II. Puerperal sepsis was significantly ( $p < 0.05$ ) higher in group II in the present study.

In this study the mean duration of hospital stay was  $4.1 \pm 2.2$  days in group I and  $5.1 \pm 3.7$  days in group II. Duration of hospital stay was higher in group II but no significant ( $p > 0.05$ ) difference was found between two groups.

### Conclusion

In the present study there was no statistical difference in the mode delivery and time interval between onset of labour pain and delivery in two groups. Hospital stay for delivery in two groups are almost same though maternal complications, neonatal infection and perinatal death was higher in group II where expectant management was followed after PROM. Thus, we can draw the inference from the study that each case of PROM needs to be managed individually depending upon the prevailing circumstances especially Bishop's score. However, comparison on larger population might be helpful to draw conclusion regarding intervention for delivery.

### Study limitation

1. Gestational age was ascertained mainly from the history and clinical examination. Majority of the patients did not have any antenatal record or investigation report.
2. The scopes of investigations were limited as it was conducted in a government medical college with limited facilities available for investigations.

**Conflict of interest:** no.

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