

## Comparison of Maternal and Neonatal Outcome of Induction of Labour with Expectant Management in Patients with term Prelabour Rupture of Membranes

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### ABSTRACT

**Objective:** To compare the maternal and neonatal outcomes of induction of labour with expectant management in patients with term prelabour rupture of membranes.

**Study Design:** Quasi-experimental study.

**Place and Duration of Study:** Labour ward of department of Gynecology and Obstetrics, Pak Emirates Military Hospital, Rawalpindi Pakistan, from May to Nov 2017.

**Methodology:** A total of 1800 women with term (gestational weeks  $\geq 37$  weeks assessed on Last menstrual period) premature rupture of membrane between 20-35 years were included. Patients with twin pregnancy, suspected or confirmed chorioamnionitis and scarred uterus were excluded. Patients were randomly allocated either to active (Group-A) or expectant management group (Group-B) by table of random numbers. Mode of delivery, APGAR score, neonatal sepsis and development of chorioamnionitis was recorded for both the groups within first 24 hours after birth.

**Results:** In our study, mode of delivery in Induced Group was spontaneous vaginal delivery in 819(91.0%) and caesarean section in 81(9.0%) whereas mode of delivery in Expectant Group was spontaneous vaginal delivery and caesarean section in 776(86.22%) and 124(13.78%) respectively. Neonatal sepsis was 144(16.0%) in Expectant Group and 104(11.56%) in Induced Group. Chorioamnionitis was 161(17.89%) in expectant group and 92(10.22%) in Induced Group. APGAR  $< 7$  at 1 minute was 204(22.67%) in Expectant and 174(19.33%) in Induced Group. APGAR  $< 7$  at 5 minutes was 91(10.11%) in expectant and 71(7.89%) in induced group.

**Conclusion:** This study concluded that management outcome of induction of labor in term prelabour rupture of membranes is better than expectant management.

**Keywords:** Expectant management, Induction, Prelabour rupture of membrane.

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### INTRODUCTION

Rupture of the membranes without reaching the term has not been an uncommon phenomenon for the obstetric teams around the globe.<sup>1</sup> Its frequency at term is 10%.<sup>1-3</sup> There could be multiple adverse effects related to premature rupture of membranes and infection to mother and fetus may be one of them.<sup>1,3</sup> This points out the importance of appropriate management strategies for prelabour rupture of membranes at term. Due to these adverse effects the main dilemma for the treating team has always been to induce the labor or wait for the normal labor process.

Some authors favour expectant management for at least 24 hours because 80% of pregnant women will start spontaneous labor within 28 hours.<sup>4</sup> However, other studies support active management because of inconvenience of expectant management and expense

of prolonged hospitalization.<sup>5</sup> Evidence supports the idea that induction may be beneficial in protecting the mother and baby against the infections and chorioamnionitis and may also reduce the incidence of caesarean section which has its own complications.<sup>1,2,5</sup> Labor should therefore be induced shortly after term prelabour rupture of membranes as it results in shorter interval till delivery and is usually preferred by patient because of shorter hospital stay and equivalent safety profile.

There has been no hard and fast rule regarding the management of PROM. However it has now been an established fact that delayed management after the PROM and waiting for expectant management may prove both mother and fetus towards various serious adversities.<sup>6</sup> Therefore some consensus has been made that if within 6 hours of rupture of membranes there is no spontaneous labor then patient may get more benefit if labor is induced.<sup>7,8</sup> Still there has been an opinion that if fetal and maternal parameters are within range and both are not distressed then expectant management may be better for both the mother and fetus.<sup>7-9</sup>

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In study conducted by Shafqat Fatima, Sarwat Rizvi mode of delivery in induced group was SVD in 87% and instrumental in 3% whereas mode of delivery in expectant group was SVD and instrumental in 73% and 10% respectively.<sup>2</sup> In another study neonatal sepsis was 14% in expectant group and 8% in induced group.<sup>3</sup> In study conducted by Dr Shanthi K, Dr Parmeela D APGAR was <7, 18.9% in expectant and 14% in induced group.<sup>4</sup> Another study showed chorioamnionitis 13% and 8% in expectant and induced group respectively.<sup>10</sup>

We belong to a country with high maternal and child mortality ratio. Most cases which come to hospital for delivery are un-booked. Cost of maternal or fetal infection after the delivery may be enormous for both the patient and the health system. We need a solid plan for our patients which have presented with or had PROM in the hospital after weighing all the risks and benefits. We therefore planned this study with the objective to compare frequency of outcome of induction of labour with expectant management in patients with term prelabour rupture of membranes managed at our tertiary care teaching hospital.

### METHODOLOGY

The quasi experimental study was conducted at Labor ward of Department of Gynaecology and Obstetrics, Pak Emirates Military Hospital, Rawalpindi Pakistan, from May 2017 to November 2017. Sample size was calculated with the help of calculator by world health organization. For this purpose, level of significance=5%, anticipated population proportion=18.9%,<sup>4</sup> and anticipated population proportion=14%.<sup>4</sup> Sample size=approximately 900 patients in both the groups (total 1800 cases). Non-probability, consecutive sampling was used to recruit the patients for this study.

**Inclusion Criteria:** Pregnant women (aged between 20-35 years) with premature rupture of membranes for 4 hours and estimated Gestational age of  $\geq 37$  weeks based on an ultrasound examination before 20 weeks of gestation with ingletion with the fetus in cephalic presentation were included in the study.

**Exclusion Criteria:** Parganat women with live fetus showing no signs of fetal compromise as evaluated by CTG and previous normal delivery with Bishop' score of <5. Presence of multiple fetuses or evidence of chorioamnionitis or presence of any other definitive reason for immediate induction of labor e.g. patients with severe pre-eclampsia, bleeding, intrauterine growth retardation were also excluded from the

study. Scarred uterus and patient being in labor at admission as characterized by regular painful uterine contractions (two contractions in 10 minutes and gradually shortening) were part of exclusion criteria

The study was conducted after complete evaluation of risk/benefit ratio to the patients and was conducted once ethical approval was granted via letter dated 25/4/16. Name, age and diagnosis of the patients and relevant information was entered in a structured proforma. Routine history/systemic/obstetric and vaginal examinations protocol were followed after written informed consent. Bishop's score was calculated for each patient after the vaginal examination. The gestational age was confirmed from history, the date of last menstrual period and ultrasound examinations. Color of liquor, CTG, heart rate of the fetus and the biophysical profile were the parameters used to assess the well being of fetus. Protocols of hospital and department were followed regarding the baseline investigations and prophylactic antibiotic. Patients were randomly allocated either to active (Group-A) or expectant management group (Group-B) by table of random numbers. Women in group A were induced with tablet prostin E2 (3mg) placed in the posterior fomix of vagina. After 6 hours Bishop scoring was done and if patient did not go into active labor, the dose was repeated. Maximum of two doses can be given (6mg). All the monitoring was done for both mother and fetus as per protocol. Onset of labor was observed in the expectant management group without any active intervention. They were induced after 24 hour with Prostin E2 if not in labor. The latent period was noted, and a partogram maintained during labour. Where labour needed to be augmented or where Bishop's score is favourable that is, six or more, syntocinon infusion was used. Use of oxytocin and caesarean section in case of failed cases was decided the by the on duty consultant gynaecologist. Apgar scores for the neonates was noted at one and five minutes and detailed assessment was done by the neonatology team for any specific management in NICU.

The data record was entered in a computer using SPSS version 21.0 Mean and standard deviation were calculated for age of patient, gestational age, duration between PROM to onset of active labor and duration between PROM and delivery. Effect modifiers were controlled by stratification. Post stratification chi-square test was applied. Frequencies and percentages were calculated for mode of delivery, chorioamnionitis and APGAR score <5 at 1&5 minutes and neonatal

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sepsis. Chi Square test was applied for mode of delivery, chorioamnionitis, neonatal sepsis and APGAR score between two groups. The *p*-value of  $\leq 0.05$  was taken as statistically significant.

### RESULTS

Majority of the patients 1536(85.33%) were between 20-30 years of age. Age range in this study was from 20-35 years with mean age of  $28.72 \pm 2.24$  years. The mean duration between PROM to onset of active labor in Group-A was  $11.03 \pm 4.75$  hours and in Group-B was  $10.82 \pm 4.66$  hours. The mean duration between PROM and delivery in Group-A was  $13.69 \pm 3.83$  hours and in Group-B was  $13.53 \pm 3.74$  hours.

In ur study, mode of delivery in induced group was spontaneous vaginal delivery in 819(91.0%) and caesarean section in 81(9.0%) whereas mode of delivery in expectant group was spontaneous vaginal delivery and caesarean section in 776(86.22%) and 124 (13.78%) respectively. Neonatal sepsis was 144(16.0%) in expectant group and 104(11.56%) in induced group. Chorioamnionitis was 161(17.89%) in expectant group and 92(10.22%) in induced group. APGAR <7 at 1 minute was 204(22.67%) in expectant and 174(19.33%) in induced group. APGAR <7 at 5 minutes was 91 (10.11%) in expectant and 71(7.89%) in induced group. (Table-I). Outcome with respect to gestational age is shown in Table-II. Table-III & IV have shown outcome with respect to duration between PROM to onset of active labor and PROM and delivery respectively.

**Table-I: Comparison of Outcome of Induction of Labour with Expectant Management in Patients with Term Prelabor Rupture Of Membranes (n=1800)**

Outcome	Group-A (n=900)	Group-B (n=900)	p-value
<b>Mode of delivery</b>			
Spontaneous vaginal delivery	819(91.0%)	776(86.22%)	0.001
Caesarean section	81(9.0%)	124(13.78%)	
<b>Chorioamnionitis</b>			
Yes	92(10.22%)	161(17.89%)	0.0001
No	808(89.78%)	739(82.11%)	
<b>Neonatal sepsis</b>			
Yes	104(11.56%)	144(16.0%)	0.006
No	796(88.44%)	756(84.0%)	
<b>APGAR score &lt;7 at 1 min</b>			
Yes	174(19.33%)	204(22.67%)	0.083
No	726(80.67%)	696(77.33%)	
<b>APGAR score &lt;7 at 5 min</b>			
Yes	91(10.11%)	71(7.89%)	0.100
No	809(89.89%)	829(92.11%)	

**Table-II: Outcome with respect to Gestational Age (n=1800)**

Outcomesq	Group A (n=900)		Group B (n=900)		p-value
	Gestational Age		Gestational Age		
	37-39	40-42	37-39	40-42	
<b>Mode of delivery</b>					
Spontaneous vaginal delivery	522(58%)	297(33%)	488(54.2%)	288(32%)	0.725
Caesarean section	44(4.8%)	37(4.1%)	76(8.4%)	48(5.3%)	0.322
<b>Chorioamnionitis</b>					
Yes	13(1.4%)	79(8.7%)	54(6%)	107(11.8%)	0.001
No	528(61.4%)	255(28.3%)	510(56.6%)	229(25.4%)	0.809
<b>Neonatal sepsis</b>					
Yes	38(4.2%)	66(7.3%)	64(7.1%)	81(9%)	0.229
No	528(58.7%)	268(29.8%)	500(55.6%)	255(28.3%)	0.965
<b>APGAR score &lt;7 at 1 min</b>					
Yes	125(13.9%)	49(5.4%)	147(16.3%)	57(6.3%)	0.962
No	441(49%)	285(31.7%)	417(46.3%)	279(31%)	0.749
<b>APGAR score &lt;7 at 5 min</b>					
Yes	79(8.7%)	12(1.3%)	67(7.4%)	04(0.4%)	0.110
No	487(54.1%)	322(35.8%)	497(55.2%)	332(36.8%)	0.919

**Table-III: Outcome with respect to Duration between Premature Rupture of Membranes to onset of Active Labor (n=1800)**

Outcome	Group-A (n=900)		Group-B (n=900)		p-value
	Duration		Duration		
	$\leq 10$	$> 10$	$\leq 10$	$> 10$	
<b>Mode of delivery</b>					
Spontaneous vaginal delivery	347(38.5%)	472(52.4%)	289(32.1)	487(54.1)	0.037
Caesarean section	00	81(9%)	25(2.7%)	99(11%)	0.0001
<b>Chorioamnionitis</b>					
Yes	70(77.7%)	22(2.4%)	101(11.2%)	60(6.7%)	0.029
No	277(30.7%)	531(59%)	213(23.7%)	526(58.4%)	0.021
<b>Neonatal sepsis</b>					
Yes	00	104(11.5%)	14(1.5%)	131(14.5%)	0.001
No	347(38.5%)	449(49.9%)	300(33.3%)	455(50.5%)	0.124
<b>APGAR score &lt;7 at 1 min</b>					
Yes	47(5.2%)	127(14.1%)	62(6.8%)	142(15.7%)	0.470
No	300(33.3%)	426(47.3%)	252(28%)	444(49.3%)	0.048
<b>APGAR score &lt;7 at 5 min</b>					
Yes	46(5.1%)	45(5%)	35(3.8%)	36(4%)	0.874
No	301(33.4%)	508(56.4%)	279(31%)	550(61.1%)	0.133

### DISCUSSION

There has been no fixed management for patients with premature rupture of membranes. If active management has been delayed there might be risk to mother and baby. This may be the reason due to which some experts recommend early intervention to induce the labor in such cases. Few think contrary to this and state that early intervention or active management may lead to caesarean section and may be harmful for mother and baby in other ways.<sup>11</sup> We therefore conducted this study to look for the better plan in our setup and

compare the two options in our patients and observe which option has been more suitable for our patients.

**Table-IV: Outcome with respect to Duration between Premature Rupture of Membranes to Delivery (n=1800)**

Outcome	Group A (n=900)		Group B (n=900)		p-value
	Duration		Duration		
	≤12	>12	≤12	>12	
<b>Mode of delivery</b>					
Spontaneous vaginal delivery	304 (33.7%)	515 (57.2%)	289 (32.1%)	487 (54.1%)	0.959
Caesarean section	00	81 (9%)	23 (2.5%)	101 (11.2%)	0.0001
<b>Chorioamnionitis</b>					
Yes	31(3.4%)	61(6.7%)	59(6.5%)	102(11.3%)	0.637
No	273(30.3%)	535(59.4%)	253(28.1%)	486(54%)	0.852
<b>Neonatal sepsis</b>					
Yes	00	104(11.5%)	14(1.5%)	131(14.5%)	0.001
No	304(33.7%)	492(98.4%)	298(33.1%)	457(50.7%)	0.605
<b>APGAR score &lt;7 at 1 min</b>					
Yes	46(5.1%)	128(14.2%)	62(6.8%)	142(15.7%)	0.396
No	258(28.6%)	468(52%)	250(27.7%)	446(49.5%)	0.880
<b>APGAR score &lt;7 at 5 min</b>					
Yes	46(5.1%)	45(5%)	35(3.8%)	36(4%)	0.874
No	258(8.7%)	551(61.2%)	277(30.7%)	552(61.1%)	0.511

In our study, mode of delivery in induced group was SVD in 91.0% and cesarean section in 9.0% whereas mode of delivery in expectant group was SVD and CS in 86.22% and 13.78% respectively. Neonatal sepsis was 16.0% in expectant group and 11.56% in induced group. Chorioamnionitis was 17.89% in expectant group and 10.22% in induced group. APGAR was <7 at 1 minute was 22.67% in expectant and 19.33% in induced group. APGAR was <7 at 5 minute was 10.11% in expectant and 7.89% in induced group. In study conducted by Shafqat Fatima, Sarwat Rizvi mode of delivery in induced group was SVD in 87% and instrumental in 3% whereas mode of delivery in expectant group was SVD and instrumental in 73% & 10% respectively.<sup>2</sup> In another study neonatal sepsis was 14% in expectant group and 8% in induced group.<sup>3</sup> In study conducted by Dr Shanthi K, Dr Parmeela D APGAR was <7, 18.9% in expectant and 14% in induced group.<sup>4</sup> Another study showed chorioamnionitis 13% and 8% in expectant and induced group respectively.<sup>10</sup>

A prospective randomized study,<sup>12</sup> compared similar parameters as in our study and came up with the conclusion that the patients which were in the group which waited 24 hours for the spontaneous labour had more chances of fetal distress and leading to caesarean section and compared to the group which was actively managed with induction of labor after the PROM.<sup>12</sup> Our results supported their findings as

induction of labor group was clearly superior in terms of better outcome in our study as well.

Another similar study concluded that there was no statistically significant difference in patients undergoing caesarean section in both the groups with induction of labor and expectant management.<sup>13</sup> Chaudhuri *et al.* and Gracakrupa *et al.* had different results in this regard and chances of spontaneous vaginal delivery were clearly more in the actively managed group as compared to the expectant management group.<sup>14,15</sup> Shanthi *et al.* in a study done in India revealed that expectant management group has more chances of vaginal delivery as compared to the expectant management group.<sup>16</sup> Our results demonstrated that expectant management group had more chances for caesarean section as compared to actively managed group.

Umairah *et al.* concluded in their study that neonatal sepsis was more common among the babies born to expectant management groups mothers as compared to active management group mothers.<sup>17</sup> Our study showed similar results and neonatal sepsis was statistically significantly more in babies born to expectant management group mothers. We had no difference in APGAR scores at 1 and 5 minutes of babies born to mothers in both groups. These findings have been slightly different from findings of Javaid *et al.*<sup>18</sup>

Hannah *et al.* in their study way back in 1996 concluded that chorioamnionitis was more in patients with expectant management group as compared to active management group.<sup>19</sup> We did not find any such difference in our study. Reason might be small sample size or short study duration. Future studies with large sample size and patient from multiple centres may generate different results.

**CONCLUSION**

Premature rupture of membranes if dealt with active management and induction of labor may give better results in terms of maternal and fetal outcome as compared to the expectant management.

**Conflict of Interest:** None.

**Author's Contribution**

Following authors have made substantial contributions to the manuscript as under:

ZM & ST: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

SZ & AM: Critical review, concept, data acquisition, data analysis, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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