OBSTETRIC AND PERINATAL OUTCOME IN INDUCTION OF LABOR COMPARED WITH EXPECTANT MANAGEMENT FOR PRELABOR RUPTURE OF THE MEMBRANES AT TERM

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ABSTRACT

Objective: To compare the management outcome of induction of labor with expectant management in patients with term pre labor rupture of membranes (PROM).

Study Design: Randomized controlled trial.

Place and Duration of Study: This study was conducted in the department of Obstetrics & Gynaecology; Combined Military Hospital Rawalpindi from 25th July 2010 to 25th January 2011.

Methods: A total of 384 patients were selected for this study, which were divided into two groups by lottery method. Patients in group A were induced with tablet prostaglandin E2 and group B patients were managed expectantly for 24 hours. The outcome of mothers and neonates was recorded on a pre-designed proforma.

Results: The mean duration between PROM to onset of active labor in group A was significantly less (8.4 ± 2.3 hours) as compared to group B in which it was (9.6±2.1 hours) (p = 0.000). The mean duration between PROM to delivery in group A was significantly less in group A (17.4 ± 2.0) versus group B (22.2 ± 2.0 hours) (p = 0.000). The spontaneous vaginal delivery (SVD) rate was considerably higher (p=0.056) in group A in which 161 (83.8%) patients delivered by SVD and 31 (16.1%) patients by LSCS. In group B, 146 (76.0%) patients delivered by SVD and 46 (23.9%) patients by LSCS. In group A, 8 (4.1%) patients developed chorioamnionitis and 13 (6.7%) patients in group B (p = 0.262). In group A there were 178 (92.7%) neonates with APGAR score of > 5 at 1 minute in contrast to 173 (90.1%) in group B with (p = 0.363). Similarly in group A at 5 minutes, there were 178 (92.7%) neonates with APGAR score of > 7 and 173 (90.1%) in group B (p = 0.460). There were 9 (4.6%) cases of neonatal sepsis in group A, in comparison with 12 (6.2%) patients in group B (p = 0.501).

Conclusion: The mean duration of labor in induced patients was less as compared to patients with expectant management.

Keywords: Expectant management, Induction of labor, Prelabor rupture of membranes, Prostaglandin.

INTRODUCTION

Pre labor rupture of membranes (PROM) at term is defined as rupture of membranes with a latent period before the onset of uterine activity at or beyond 37 weeks of gestation. Its frequency at term is approximately 8%[1,2].

The etiology of PROM is uncertain having difficulties in diagnosis and perinatal risks to mother and her baby[3].

Maternal risks of PROM include subclinical chorioamnionitis, increased chances of operative delivery, placental abruption, primary and secondary postpartum haemorrhage, risk of postpartum endomyometritis and maternal pyelonephritis.

Fetal risks include fetal distress due to cord prolapse, cord compression, placental abruption, mechanical difficulty in delivering baby due to reduced liquor volume and 2-4% risk of neonatal sepsis[4].

Despite the extensive work in this field, there is still no universally accepted management protocol for PROM at term[5]. Choice of decision is between immediate induction and awaiting a certain period of time up to 24 hours-72 hours[6,7]. After 36 weeks, expectant management may be justified initially because it can be anticipated that 75-85% patients will deliver within 24 hours and risk of cesarean section may be lowered[8] if managed expectantly by continuous observations of maternal and fetal condition, antibiotics and amnioinfusion when needed. However with

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expectant management there is an increased risk of maternal and neonatal infection, cord compression and placental abruption. It may also prolong the hospital stay and increase the anxiety of patient. Induction of labor using various methods may therefore be alternatively adopted. Prostaglandins use is commonest method employed for induction of labor in such cases[9,10].

Evidence supports idea that induction of labor as opposed to expectant management decreases the risk of chorioamnionitis without increasing the caesarean delivery rate[7,11]. However benefits has to be compared with the risks of induction of labor which may include minor side effects like nausea and abdominal discomfort or risk of uterine hyperstimulation and fetal distress.

The application of PGE2 vaginal suppositories for maturing and stimulation of labor is a modern, efficient and easy to use method in obstetrics which is very acceptable[12,13].

Aim of our study is therefore to compare the effects of induction of labor with PGE2 versus expectant management, on maternal and fetal well-being, in women with term prelabor rupture of membranes. This comparative study was conducted in an attempt to reduce the maternal and neonatal morbidity due to complication of PROM and to improve maternal and fetal outcome and if it proves that management outcome of induction of labor in term PROM is better than expectant management, it will be helpful in 1) avoiding unnecessary delay awaiting spontaneous onset of labor, 2) better maternal outcome in terms of lesser cesarean deliveries and lesser cases developing chorioamnionitis and 3) better neonatal outcome in terms of better APGAR scores and lesser cases of neonatal sepsis.

MATERIAL AND METHODS

These randomized, controlled trials were conducted in the department of Gynaecology and Obstetrics Combined Military Hospital Rawalpindi from 25th July 2010 to 25th January 2011. Inclusion criteria were confirmed PROM, patients of age between 20 to 35 years having estimated gestational age 37or more weeks based on an ultrasound examination before 20 weeks of gestation, singleton pregnancy with the fetus in cephalic presentation, no signs of fetal compromise as evaluated by electronic fetal heart rate record at the time of admission, previous normal delivery (one or more) and Bishop'score of ≤ 5. Exclusion criteria were previous history of cesarean section or any other uterine surgery, being in labor at admission, strongly suspected or confirmed chorioamnionitis or if any reasons for immediate induction, e.g. patients with severe pre-eclampsia. Diagnostic criteria forchorioamnionitis included fever > 100.4°F, uterine fundal tenderness, maternal tachycardia (>100/min), fetal tachycardia (>160/min) and purulent or foul amniotic fluid. All patients presenting with PROM at labor ward and fulfilling the inclusion criteria and giving informed consent were included in the study. Diagnosis of PROM was confirmed by visual pooling of clear fluid in the posterior fornix of the vagina or leakage of fluid from the cervical os on sterile speculum examination. Inclusion and exclusion criteria were strictly followed to avoid any confounding factor like pre existing fever, meconium and frequent vaginal examinations. Study was commenced after the approval from hospital ethical committee. Three hundred and eighty four patients were included in the study by consecutive sampling method and they were randomly divided into two equal groups of 192 patients in each group. The randomization was done by lottery method.

Demographic information like age, diagnosis and other relevant data was recorded on pre designed proforma. A detailed history was taken and obstetrical examination was performed at the time of admission. After confirming diagnosis, vaginal examination was carried to assess the Bishop's score. Fetal well being was assessed by observing the color of liquor, electronic fetal heart sound record and the biophysical profile. Routine investigations included a blood complete picture, cross match

and urine examination. Prophylactic antibiotic cover was provided with injection Ampicillin 1 gm I/v 6 hourly after test dose.

Women in group A were induced with tablet Prostaglandin E2 (3 mg), placed in the posterior fornix 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 were given (6 mg). Fetal heart rate was monitored hourly and maternal vital signs were monitored 6 hourly.

Expectantly managed women were watched for spontaneous onset of labor. They were induced after 24 hours of admission with Prostaglandin E2 if not in labor. The latent period was noted, and apartogram was maintained during labor.

Where labor needed to be augmented or where Bishop's score was favourable that is, six or more, syntocinon infusion was used. 5 IU of syntocinon were added to 1000 ml of Ringer's lactate and started at a rate of four milli units per minute with the help of infusion pump, the rate doubled every half hour till regular uterine contractions were established or to a maximum of 32 milli units per minute.

Where inductions failed or signs of maternal or fetal compromise developed, cesarean section was performed. Newborns were assessed by a pediatrician at the time of delivery and their APGAR scores noted at one and five minutes. New borns of patients with PROM of more than 24 hours were admitted to NICU, antibiotics were started and were observed for further signs of sepsis. In both groups mode of delivery, development of chorioamnionitis, APGARscore and neonatal sepsis within first 24 hours after birth were recorded. Temperature above normal level (36 ^{0}C), presence of tachycardia (above 160 bpm),presence of tachypnea (above 60 breaths per minute),WBC count < 6,000 and CRP> 1.0 mg/dl were taken as diagnostic criteria for neonatal sepsis.

The data was compiled using SPSS version 12.0. Descriptive statistics such as mean and standard deviation were calculated for age of patient, gestational age, duration between PROM to onset of active labor, duration between PROM and delivery and APGAR score at 1 and 5 minutes. Frequencies and percentages were calculated for mode of delivery, chorioamnionitis and neonatal sepsis. Independent samples "t" test was applied on quantitative variables to compare both groups. Chi Square test was applied on mode of delivery, chorioamnionitis and neonatal sepsis between two groups. A *p*-value of < 0.05 was taken as statistically significant.

Table-1: Comparison of Mode of Delivery and Chorioamnionitis in both groups.

	Groups		*p*-value
	Group A	Group B	
Mode of Delivery			
SVD	161	146	0.056
	83.85%	76.04%	
LSCS	31	46	
	16.14%	23.95%	
Chorioamnionitis			
Yes	8	13	0.262
	4.17%	6.77%	
No	184	179	
	95.83%	93.23%	

Group A = Induction of Labor with Prostaglandin E2, Group B = Expectant Management Group, SVD: Spontaneous vaginal delivery, LSCS: Lower segment cesarean section

RESULTS

Average age in group A was 26.53 ± 3.576 and in group B was 26.39 ± 3.606 years (p = 0.701). The mean gestational age in group A was 38.69 ± 1.054 weeks and in group B the mean gestational age was 38.60 ± 0.909 weeks (p = 0.417) with a range of 37-40 weeks.

The mean duration between PROM to onset of active labor in group A was significantly less (8.4 ± 2.3 hours) as compared to group B in which it was (9.6 ± 2.1 hours), (p < 0.000). The mean duration between PROM to delivery in group A was significantly less (17.4 ± 2.0 vs. 22.2 ± 2.0 hours, p < 0.000) as compared to group B).

There was insignificant difference in mode of delivery and frequency of chorioamnionitis between both the groups (Table-1). Similarly insignificant difference was observed between both the groups in APGAR score at 1 and 5 minutes and meonatal sepsis. (Table-2)

In group A, 9 (4.68%) patients developed neonatal sepsis whereas in group B, there were 12 (6.25%) patients having neonatal sepsis. There was no significant difference in both groups with regards to neonatal sepsis (*p*-value > 0.05) as given in table-2.

Table-2: Comparison of APGAR Score at 1 and 5 minutes and Neonatal Sepsis in both groups.

	Group		*p*-value
	Group A	Group B	
APGAR score at 1 minute			
≤ 5	14	19	0.363
	7.29%	9.90%	
> 5	178	173	
	92.70%	90.10%	
APGAR score at 5 minutes			
≤ 7	14	19	0.363
	7.29%	9.90%	
> 7	178	173	
	92.71%	90.10%	
Neonatal Sepsis			
Yes	9	12	0.501
	4.69%	6.25%	
No	183	180	
	95.31%	93.75%	

Group A = Induction of Labor with Prostaglandin E2, Group B = Expectant Management Group

DISCUSSION

Rupture of membranes prior to the onset of labor is a common event but its management has been controversial since long. Various obstetricians favored early induction of pre labor rupture of membranes because of risk of infections[14] and others were in favor of expectant management with fetomaternal monitoring[15].

In our study, the length of interval from pre labor rupture of membranes to active labor was shorter in patients with induction group. As compared to the expectant group, as observed in the study of Chaudhri and Naheed[16]. In another study conducted by Snehamay et al[17] the duration of active labor interval was 3.79 ± 2.0 vs 3.89 ± 2.6 hours of prelabor rupture of membranies.

Our results also showed shorter interval from rupture of membrane to delivery in patients with induction group. As Chaudhri and Naheed[16] and to Snehamay et al[17]. So our results are comparable with the results of above mentioned studies.

In our study, the cesarean section rate was 16.1% in the induction group and 23.9% in the expectant group. Our results are similar with and comparable to Chaudhry and Naheed[16] in which caesarean section rate was 11.1% vs 15.8%. In another study conducted by Snehamay et al[17] the caesarean section rate was 17.8% vs 28.5%. While significantly high caesarean section rate was observed in local study of Malik and Naz[15] in induction group than expectant management group 14.6% vs 8.3% and study of Zamzami[18] in which caesarean section rate was twice in induction group than expectant group. This difference can be due to differences in protocol of various institutions regarding labor management or method of induction and sample size.

In our study, SVDs were 83.8% in induction group while 76.0% in expectant group. As compared with the study of Chaudhry and Naheed[19] in which SVDs were 77.6% vs 76%, which are comparable with our results. In another study conducted by Snehamay et al[17] SVD was 78.5% vs 57.1% which are also comparable with our study.

Although high rate of chorioamnionitis was found among conservatively managed women but could not reach the statistical significance. So none of the method is associated with significantly increased maternal infectious morbidity[20].

The chorioamnionitis in our study was 4.1% in induction group as compared to expectant group in which it was 6.7%. While in another

study Clinical chorioamnionitis was seen in (2.3%) women in the Induction of Labor group versus 15 (5.6%) women in the expectant management group[21]. In another study conducted by Hannah et al[21] the chorioamnionitis was 4% vs 8.6%. In the study of Snehamayet al[17] the chorioamnionitis was not observed in any patient in both groups. Therefore our results are comparable with the results of the above mentioned studies.

In our study the APGAR score of newborn < 5 was comparable with the study of Snehamay et al[17]who found the APGAR score of baby < 5 at 1 minute of 6% in induction group as compared to 8% in expectant group. Chaudhri and Naheed[16] found 10.67% and 13.3%, which is also comparable with our study.

In our study, the proportion of APGAR score of newborn of ≤ 7 at 5 minutes was also 7.2% vs 9.8% in induction group and expectant group respectively. While in the study of Snehamayet al[17] the APGAR score <7 at 5 minutes was not found in any baby in both groups. In the study of Ben-Haroushet al[22] the APGAR score of < 7 at 5 minute was almost similar with no significant difference in two groups. Our results are same as in the study of Ben-Haroush et al[22].

In our study the neonatal sepsis was 4.6% in induction group and 6.2% in expectant group. Comparable with Chaudhry and Naheed[16]. In another study the neonatal sepsis was 2% vs 2.8%. In the study of Snehamay et al[17]the neonatal infection was 3% in induction group and 4% in expectant group.

CONCLUSION

Induction management is more advantageous in labor in terms lesser interval to onset of active labor, lesser interval to delivery, less cesarean sections and lesser chorioamnionitis.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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