

INDUCTION OF LABOUR VERSUS EXPECTANT MANAGEMENT IN WOMEN WITH PREMATURE RUPTURE OF MEMBRANES BETWEEN 34 TO 37 WEEKS OF GESTATION

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Summary

Objective: To compare the effect of induction of labour on mother and neonates with that of expectant management in case of premature rupture of membranes (PROM) between 34 to 37 weeks of gestation.

Methods: A total of 122 eligible women with PROM were randomly selected for either induction of labour (case, n=60) or expectant management (control, n=62). It was conducted in Chittagong Medical College and Hospital from October 2007 to September 2008 in the department in obs and gynae. In this randomized control trial induction was done by i/v oxytocin infusion. Expectant management was done by bed rest, wearing of sanitary pad to detect colour change or malodour of liquor. These patients were allowed to go into spontaneous labour. Outcomes were evaluated by maternal chorioamnionitis, puerperal sepsis, neonatal sepsis and hospital stay of mother.

Result: Expectant management was associated with increased chorioamnionitis (R.R.4.194, 95%CI 1.258 to 13.981), puerperal sepsis (R.R.6.774, 95%CI 0.0859 to 53.417), neonatal sepsis (R.R.4.839, 95%CI 1.106 to 21.174) and hospital stay (7.85 vs 4.15 days) which was statistically significant $p < 0.0001$.

Conclusion: In case of induction of labour in women with PROM between 34 to 37 weeks of gestation gives better pregnancy outcome in respect to chorioamnionitis, puerperal sepsis, neonatal sepsis and also result in shorter hospital stay in comparison to expectant management.

Key words

PROM; preterm labour; chorioamnionitis

Introduction

PROM can be defined as rupture of chorioamniotic membranes prior to labour regardless of the gestational age¹.

In most of the cases, this occurs near term but when membrane rupture occurs before 34 to 37 weeks of gestation, it is known as preterm PROM². PROM is usually followed by labour. The latent period, which is the time from membranes rupture until delivery, generally is inversely proportional to the gestational age at which PROM occurs². In women with preterm PROM 50% will go into labour within 24 to 48 hours and 70% to 90% within 7 days³. Management of PROM between 34 to 37 weeks of gestation varies from place to place. Most popular trend is in favor of expectant management. A very few patients are managed by induction of labour, of them mostly already develop chorioamnionitis. This dilemma can be explained by a lack of good clinical evidence in favour of induction of labour. For this reason we designed a study to compare the effect of induction of labour on mother and neonates with that of expectant management in case of PROM between 34 to 37 weeks of gestation.

Material and methods

A hospital based randomized control trial was done in the department of Obstetrics and Gynaecology, Chittagong Medical College and Hospital from October 2007 to September 2008. Pregnant women at their 34 weeks to 37 weeks of gestation with PROM were included. Pregnant women at their 34 weeks to 37 weeks of gestation with PROM with labour pain on admission, with medical diseases like diabetes melitus, hypertension, jaundice, with obstetrical complication like chorioamnionitis, fetal distress, malpresentation, APH, fetal anomalies, IUGR estimated on ultrasound, H/O previous C/S and multiple pregnancies were excluded. After identifying eligible women and taking informed consent for participation in the study, she was randomized to either induction of labour with oxytocin (case) or expectant management for spontaneous delivery (control). Randomization was done by the process of lottery. Initially 128 samples were taken, 64 in each group but 4 samples were dropped out among them case and 2 samples were dropped out among the control. So, finally 60 were case and 62 were control. After study entry baseline demographics, past obstetric and medical history were recorded in a data collection sheet.

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Subsequently a careful physical examination was done for every patient especially to search for signs of infection. Maternal temperature was measured and baseline blood sample was sent for complete blood count and a high vaginal swab was collected for aerobic culture & sensitivity during speculum examination. By speculum examination degree of cervical dilatation and effacement were determined and cord prolapse were excluded. Vaginal examination was avoided except those who showed signs of labour. Ultrasonography was done for every patient for gestational age, presentation, expected fetal weight and amount of liquor volume. During speculum examination following findings were associated with PROM. Pooling – The collection of amniotic fluid in the posterior fornix. Ferning – Fluid from the posterior fornix was placed on a slide and allowed to air-dry. Then examine under microscope and amniotic fluid form a fernlike pattern of crystallization. P^H indicator paper – Alkaline P^H of amniotic fluid (7-7.5) was demonstrated by seeing colour change (blue) in P^H indicator paper. If no fluid was found, a dry pad was placed under the patient's perineum and observed for leakage. Other confirmatory test for PROM include observed loss of fluid from cervical os when the patient coughs or performs a valsalva maneuver during speculum examination, oligohydromnios on ultrasound examination.

Case: Pregnant women with PROM between 34 to 37 weeks of gestation were managed actively by oxytocin I/V infusion for induction of labour and I/V ceftriaxon (1gm). Patients were allowed to deliver vaginally and caesarean section was done for obstetric complications.

Control: Pregnant women with PROM between 34 to 37 weeks of gestation were managed by expectant management by hospital admission, bed rest, wearing of sanitary pad to detect color change or malodor of liquor, I/V ceftriaxon (1gm)/day for first and 2nd day followed by capsule cefixime 200mg twice daily for five days. These patients were allowed to go into spontaneous labour. In Expectant management group (control): Maternal monitoring was done by recording of vital signs, body temperature, pulse, uterine tenderness, smell and colour of liquor 4 hourly. Fetal surveillance was done by auscultation of fetal heart rate 4 hourly and kick count. Indication for delivery in expectant management were included: Labour, the diagnosis of chorioamnionitis and fetal distress or if a patient reaches more than 37 weeks of gestation. All neonates following delivery were examined by neonatologist and if necessary related investigation were done.

Outcome measures: We compared demographic characteristics, gestational age at rupture of the membranes and latency period, mode of delivery, birth weight, development of clinical chorioamnionitis, puerperal sepsis and neonatal sepsis between case and control, hospital stay of mother both for herself and her baby.

Operational definitions:

1. Neonatal sepsis was diagnosed by clinical findings (Aponea, temperature instability, intolerance for feedings, lathergic, respiratory distress and 2 or more of the following criteria.

- I. Total WBC count less than 5000/mm³
- II. polymorph count less than 1800/mm³
- III. IT ratio (immature and total neutrophil ration) > .2
- IV. Biochemical infection parameter CRP more than 6mg/L.

2. Chorioamnionitis: Clinical diagnosis of chorioamnionitis was done according to the following criteria including maternal temperature \geq 37.8° C (100.4° F) and two or more of the following criteria:

- I. Uterine tenderness,
- II. Malodorous vaginal discharge,
- III. Maternal tachycardia (> 100 beats/min) and
- IV. Fetal tachyardia (\geq 160 beats/min)

3. Puerperal sepsis: Diagnosis of temperature > 100.4° F on two occasion at least 1 hour apart excluding 1st 24 hrs postpartum with uterine tenderness or malodorous lochia without another obvious source of fever in the postpartum period.

4. Hospital Stay: From admission to discharge of the mother.

The study protocol was approved by the ethical review committee of Chittagong Medical College & Hospital.

Data were statistically analyzed by computer with SPSS (version 12). Mean values were compared with the unpaired t test and proportions were compared by the Chi-square test. The level of significance was taken when P < 0.05.

Results

A total of 122 women with PROM between 34 to 37 weeks of gestation were enrolled in the patient trial from October of 2007 to September 2008. Among them, 60 patients were case, in whom labour was induced by I/V oxytocin and 62 patients were control, whose were allowed to go into labour spontaneously.

Table I : Age distribution of the patients

Age Groups (Years)	Number Of Patients	
	Case	Control
20	15(25.0)	11(17.7)
21 to 25	26(43.3)	28(45.2)
26 to 30	16(26.7)	19(30.6)
31 to 35	03(5.0)	04(6.5)

Data expressed in number (percentage) P=0.192 (NS) Comparison were made by the unpaired t test

Table I shows age distribution of the patients, majority of the patients were 21-25 years age group for both the case and the control. Mean age among the case was 23.98 years \pm 4.12 SD and among the control was 24.94 years \pm 3.90 SD. Mean age among the total was 24.47 \pm 4.02 SD (range 18-35).

Table II : Distribution of gestational age at the time of admission

Groups At Admission (In weeks)	Number Of Patients	
	Case	Control
34 to \leq 36	26(43.3)	36(58.1)
>36 to 37	34(56.7)	26(41.9)

Data expressed in number (percentage) P=0.123 (NS) Comparison were made by the unpaired t test

Table II shows distribution of gestational age at the time of admission. Mean gestational age among the case was 35.50 weeks \pm 1.00 SD and the control was 35.23 weeks \pm 0.95 SD. Mean gestational age among the total was 35.36 weeks \pm 0.98 SD.

Table III : Distribution of mode of delivery

Mode Of Delivery	Number Ofpatients	
	Case	Control
Vaginal delivery	40(66.7)	43(69.4)
Caesarean section	20(33.3)	19(30.6)

Data expressed in number (percentage) P=0.845 (NS) Comparison were made by the χ^2 test

Table III shows among the case 40 patients were delivered vaginally, 20 patients were delivered by caesarean section. Among the control group 43 patients were delivered vaginally, 19 patients were delivered by caesarean section.

Table IV : Distribution of aerobic microbiological study of high vaginal swab

High Vaginal Swab	Number Of Patients	
	Case	Control
No Growth	31(51.7)	32(51.6)
E. Coli	18(30.0)	19(30.6)
Candida Albicans	07(11.6)	07(11.4)
Klebsiella	02(3.3)	01(1.6)
Staphylococcus	01(1.7)	03(4.8)
Streptococcus Viridens	01(1.7)	00

Data expressed in number (percentage) P=0.855 (NS) Comparison were made by the χ^2 test

Table IV shows in both groups; E Coli was predominant culture positive organism in high vaginal swab.

Table V : Distribution of latency period by gestational age groups

Latency Period Grades	Gestational Age Groups At Admission (Inweeks)			
	34 To \leq 36 Weeks		>36 To 37 Weeks	
	Case	Control	Case	Control
< 24 Hours	07(26.9)	1(2.8)	04(11.8)	1(3.8)
= 24 to 48 Hours	17(65.4)	05(13.9)	26(76.5)	11(42.3)
> 48 to 72 Hours	02(7.7)	11(30.6)	04(11.8)	11(42.3)
> 72 Hours to 1 Week	00	13(36.1)	00	03(11.5)
1 to 2 Weeks	00	06(16.7)	00	00

Data expressed in number (percentage) P=0.001 (HS) Comparison were made by the χ^2 test

Table V shows among the case from 34 to \leq 36 weeks of gestation 65.4% had a latency period of 24 to 48 hours, where as on the other hand among the control at the same gestational age 36.1% had a latency period of 72 hours to 1 week. In case group from >36 to 37 weeks of gestation all patients were delivered within 72 hours but in control group at the same gestational age 11.5% patients were delivered from 72 hours to 1 week.

Table VI : Distribution of maternal morbidity in relation to out come variable

Morbidity	Number Of Patients	
	Case	Control
Chorio-amnionitis	03(5.0)	13(21.0)
Puerperal Sepsis	01(1.7)	07(11.3)

Data expressed in number (percentage). R.R. of chorioamnionitis among the control was 4.194 (95%CI 1.258 to 13.981). R.R. of puerperal sepsis among the control were 6.774 (95%CI 0.859 to 53.417).

Table VI shows among the case 5 % had chorioamnionitis and 1.7 % had puerperal sepsis. Among the control 21% had chorioamnionitis and 11.3% had puerperal sepsis.

Table VII : Distribution of neonatal sepsis

Neonatal Sepsis	Number Of Patients	
	Case	Control
Present	02(3.3)	10(16.1)
Absent	58(96.7)	52(83.9)

Data expressed in number (percentage). R.R. of neonatal sepsis among the control was 4.839 (95% CI 1.106 to 21.174).

Table VII shows among the case 3.3% newborn developed sepsis but it was 16% among the control.

Table VIII : Distribution of hospital stay

Hospital Stay (Days)	Number Of Patients	
	Case	Control
1 to 3 Days	35(58.3)	10(16.1)
4 to 6 Days	10(16.7)	21(33.9)
7 to 9 Days	12(20.0)	10(16.1)
10 to 12 Days	03(5.0)	10(16.1)
13 to 15 Days	00	02(3.2)
> 15 Days	00	09(14.5)

Data expressed in number (percentage) P=0.000 (HS)

Comparison were made by the unpaired t test

Table VIII shows among the case 58.3% stayed in hospital for 1-3 days but among the control 33.9% stayed in hospital for 4 -6 days. Mean hospital stay among the case was 4.15 ± 2.87 SD and among the control was 7.85 days ± 4.59 SD.

Discussion

In this study the mean (\pm SD) maternal age of the case group and control group were 23.98 ± 4.12 and 24.94 ± 3.90 years respectively and there was no statistical significance between the two groups ($P > 0.05$). In this research the mean (\pm SD) gestational age at admission was 35.50 ± 1 week in the case and 35.23 ± 0.95 week in the control group, which was not significant statistically. Other studies from different countries have reported similar result^{4,5}. In our study among the case 66.7% mother delivered vaginally and 33.3% delivered by caesarean section. In control group 69.4% delivered by vaginally and 30.6% delivered by caesarean section. So, induction of labour does not increase the risk of caesarean section ($p > 0.5$). Other studies also support this result^{4,6,7}. Up to 80% of early preterm birth are associated with an intrauterine infection that precedes the rupture of membranes⁸. Organism may reach the uterus through the placenta from the circulation but most bacteria found in the uterus in association with preterm labour are of vaginal origin. Vaginal organisms appear to ascend first into the choriodecidual space. There they liberate a number of endotoxins and exotoxins, different types of cytokines and ultimately cause chorioamnion weakening and rupture⁹. In this study due to limited facility only aerobic culture of high vaginal swab was done. Beside that group B streptococcus could not be detected due to limitation of resources. In intervention group 48.3% had positive culture, of them E. coli and Candida albicans were the most prevalent organism. In expectant management group 48.4% mother showed positive culture and also E. coli and candida albicans were prevalent organism. Bergeron MG et al showed that there was increased association between genital tract infection and early onset of neonatal sepsis by group B streptococcus¹⁰. Stoll BJ et al showed that there were changes in pathogens causing early onset of neonatal sepsis. There was marked decrease in group-B streptococcus sepsis from 5.9 to 1.7 per 1000 live births of infants and an increase in E. coli sepsis from 3.2 to 6.8 per 1000 live birth¹¹. In the interventional group after taking demographic data and doing relevant investigation labour was induced. Of them most of the mother delivered within 48 hours (90% of PROM). In expectant management group patients were allowed to go spontaneous labour. Among them 90.3% mother delivered within 1 week. So, the latency period was highly significance ($P < 0.001$). Marcer BM et al and Nelson LH et al showed that expectant management was associated with prolonged latency period ($P < 0.001$)^{5,12}.

It has been proposed that amniotic fluid posse's certain bacteriostatic properties that protect against potential infection process and that a decrease in amniotic fluid volume may impair the gravid women ability to combat such infection¹³. Chorioamnionitis and puerperal sepsis are the most common maternal morbidity. In this study, in interventional group 6.7% mother had morbidity. Among them 5% had chorioamnionitis, 1.7% had puerperal sepsis. There were 32.3% mother had morbidity in expectant management group, of them 21% had chorioamnionitis & 11.3% had puerperal sepsis. R.R. of chorioamnionitis among the control was 4.194 (95%CI 1.258 to 13.981) and R.R. of puerperal sepsis among the control was 6.774 (95%CI 0.859 to 53.417). Which was highly significant. Naef III RW et al showed that the chorioamnionitis was more in expectant management group than intervention group (16% versus 2% P=0.007)⁴. Hartling L et al and Dare MR et al showed in their study that there was significant difference in the incidence of clinical chorioamnionitis favoring intentional delivery^{6,7}. In this research, there was statistical significant neonatal morbidity among the control group. In interventional group 3.3% had neonatal sepsis but it was 16.1% in control group. RR of neonatal sepsis in control group was 4.839(95%CI 1.106-21.174). This result coincides with other studies^{4,5,6}. In our study mean hospital stay among the cases were 4.15 ± 2.87 days and among controls were 5.85 ± 4.59 days. Which was highly significant (p<0.001). Naef III RW et al showed that maternal hospital stay (5.2 ± 6.8 days versus 2.6 ± 1.6 days, P = 0.006) was significantly longer in the control group. Our findings are consistent with those of other studies^{4,6}.

Conclusion

Among the women with rupture of membranes between 34 to 37 weeks of gestation, induction of labour reduces infectious morbidity in both mothers and neonates and also shorter hospital stay.

Disclosure

All the authors declared no competing interestes.

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