

PREMATURE RUPTURE OF MEMBRANES AT TERM: IMMEDIATE INDUCTION OF LABOR VERSUS EXPECTANT MANAGEMENT

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ABSTRACT

Objective: To compare the maternal outcomes of immediate induction of labor with expectant management in women presenting with premature rupture of membranes (PROM) at term.

Methods: One hundred and fifty two women with PROM at term were randomized into either immediate induction of labor with oxytocin or expectant management for a period of 12 hours. The primary outcome measure was the incidence of clinical endometritis in each group. Secondary outcomes were the mode of delivery, the neonatal outcome and the proportion of women in the expectant management group that progressed to spontaneous labor.

Results: The immediate induction arm had a lower caesarean section rate, (7.9% vs 28.9%, P=0.001), higher spontaneous vaginal delivery rate (92.1% vs 71.1%; P=0.001) and lower incidence of clinical endometritis (0% vs 5.3%, P=0.006), when compared with the expectant management arm. The estimated duration of labor was shorter in the expectant management arm (8.9±2.17hours vs 10.6±2.35hours; P=<0.001). Neonatal morbidity rates were comparable in both groups.

Conclusion: Immediate induction of labor in women with PROM at term resulted in significantly lower rate of infectious morbidity without increasing the risk of operative delivery. It is therefore recommended as the management option of choice.

Keywords: Premature rupture of membranes, induction of labor, endometritis

INTRODUCTION

Premature rupture of membranes (PROM), is the rupture of fetal membranes prior to the onset of labour.^{1,2,3} This rupture of fetal membranes may occur anytime during the course of pregnancy. It however becomes a problem if the fetus is preterm or in the case of a term fetus, if the period between rupture of membranes and onset of labor lasts beyond 24 hours, after which the risk of infection is increased.^{2,4,5} PROM complicates about 5-10% of all pregnancies, and 60-80% of cases occur at term.^{4,6,7}

When PROM occurs remote from term, the general consensus is expectant management in the absence of evidence of infection, fetal or maternal compromise. However, when PROM occurs at term, the dilemma is whether to induce labour

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immediately or to carry out expectant management for a period of 12-24 hours.

The management of women with PROM at term involves a balance between the risks of infection and the risks associated with induction of labour. The risk of chorioamnionitis with PROM at term is estimated to be less than 10%, this value increases to 24% after 24 hours, hence the argument for active management involving immediate delivery, considering the knowledge that the risk of infection increases with the duration of PROM.⁸ About 50% of women with PROM will progress to spontaneous labour within 12 hours of rupture of membranes, this increases to 75-85% within 24 hours. This forms the basis for expectant management which involves non-intervention for 12-24 hours to await onset of spontaneous labour. However, about 15-25% still requires intervention before progressing to labour after a 24-hour waiting period. Studies comparing these two options of management have shown that perinatal and maternal outcomes are similar in both groups⁹⁻¹⁴.

We therefore conducted the present study to compare these two management modalities of PROM in Ile-Ife, Nigeria to provide an objective platform for decision on the management for women presenting with PROM at term in our setting.

MATERIALS AND METHODS

This study was conducted in the Antenatal, Postnatal and Labour Wards of the Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), Ile Ife, Osun state, Nigeria between January and November, 2011. All women diagnosed with PROM at gestational age of 37 completed weeks or more with a singleton fetus in longitudinal lie and cephalic presentation were educated about the study and signed informed consent was obtained from willing participants. Women with breech

presentation, multiple pregnancies, previous caesarean section, PROM longer than 12 hours before presentation, labor at presentation, evidence of chorioamnionitis, or any contraindication to vaginal delivery were excluded from the study.

The diagnosis of premature rupture of membranes was confirmed by direct observation of egress of amniotic fluid from the cervix on sterile speculum examination in the women recruited for this study. The women who met the inclusion criteria were randomized into two groups, A and B by blocked (restrictive) randomization using the random table of computer generated numbers. Each consecutive patient was randomized by opening the corresponding envelope at the diagnosis of prelabor rupture of membranes at term.

Each study participant had her baseline data including the admission vital signs recorded in the study proforma. An endocervical swab and blood sample for white blood cell count were obtained from all women to be recruited for this study on admission and a preliminary cardiotocograph was done to assess the fetus. Prophylactic antibiotics was withheld from women in both study arms, except in association with caesarean section or those on expectant management who develop clinical suspicion of chorioamnionitis after an endocervical swab had been collected.

Women in Group A had immediate induction of labor. After confirming the diagnosis of PROM, a vaginal examination was carried out to assess the Bishop score of the cervix to assess favourability for induction. If the score was ≥ 6 , the woman was commenced on oxytocin, 5 IU in 5% Dextrose water intravenous infusion titrated to commence at 5mIU/minute and rate of infusion increased by 10 drops (5 mIU/min) every 30minutes until at least three contractions in 10minutes, each lasting more than 40 seconds was achieved. It was then maintained at this rate. If the bishop's score was

however <6 , a single dose of 25 micrograms misoprostol was passed into the posterior vaginal fornix for the purpose of cervical ripening. The Bishop score was reassessed after 6 hours, and oxytocin infusion as described above was commenced. White blood cell count was assessed at admission. Labour was monitored using the partograph.

Women in Group B were admitted for expectant management, which entailed admission into the antenatal ward. They were required to keep a perineal pad to monitor any change in colour or odour of the amniotic fluid. The vital signs were recorded hourly, and a temperature reading of greater than 37.5°C or pulse rate above 100 beats per minute was reported and white blood cell count was done at admission. In the absence of complications or onset of spontaneous labour, labour was induced 12 hours after diagnosis of rupture of foetal membranes was made. A vaginal examination was done to assess the Bishop's score of the cervix. If ≥ 6 , labour was induced with oxytocin infusion in incremental doses, as described above. However, if the score was <6 , a single dose of 25 micrograms misoprostol was passed into the posterior fornix for the purpose of cervical ripening. The cervix was reassessed 6 hours after for possible induction of labor with oxytocin infusion.

After the delivery, the duration of labor was estimated, as the period between the onset of palpable uterine contractions and delivery of the fetus, and the APGAR scores determined. The neonate was subsequently followed up for the first week of life, vis a vis, the need for neonatal intensive care unit admission, and antibiotic treatment. The women were reviewed in the postnatal ward, every patient in the study groups had a post-delivery assessment for clinical features of endometritis and a white blood cell count. Women with clinically suspected endometritis (with features such as

abdominal tenderness, abnormal vaginal bleeding, foul smelling discharge or temperature greater than or equal to 38°C on two occasions after 24 hours of delivery) had a full blood count and blood culture in addition to the endocervical swab to strengthen the diagnosis of infection and such women were given appropriate antibiotics. The women were reviewed in the postnatal clinic one week postpartum and again six weeks postpartum. There a history of the puerperal period and the neonatal period of the baby were obtained.

Data obtained at the end of the study were analyzed using the computer software SPSS version 16. Frequency tables were generated and results tested for significance using the student t-test for continuous variables and Chi-squared for categorical variables with the level of significance set at $p < 0.05$. Ethical approval was obtained for this study from the Research and Ethics Committee of OAUTHC, Ile-Ife.

RESULTS

One hundred and fifty two women participated in this study. This constituted about 7.4% of the 2,064 deliveries within the study period. There were 76 women in each arm of the study. There was no statistically significant difference in age, parity, gestational ages, admission vital signs or white blood cell count for the two groups that were compared. There was however a statistically significant difference in the Bishop's scores of the two groups at time of intervention. The mean Bishop's score in the immediate induction group was 4.53 ± 1.81 compared to 6.24 ± 1.59 in the expectant management arm, with p-value of 0.001 (Table 1). The Bishop's score was determined for only 36 women in the expectant management group who did not go into spontaneous labor.

In the expectant management arm of the study, 40 women (52.6%) had spontaneous onset of labor

within 12 hours. In the immediate induction group, 52 women (68.4%) required cervical ripening, while only 20 (26.3%) of those in the expectant management arm required cervical ripening. In the immediate induction group, 12 (23.1%) of the women requiring cervical ripening started having uterine contractions after 25 micrograms of misoprostol was inserted vaginally while 14 (70%) of the women requiring cervical ripening in the expectant management arm had a similar response.

The mean duration of labor in the immediate induction group was 10.6 ± 2.35 hours compared with 8.9 ± 2.17 hours in the expectant management group. This difference was statistically significant ($p < 0.001$). The dose of oxytocin required for adequate uterine contraction ranged between 5mIU/minute to 20mIU/minute, with the women in the expectant management arm requiring a lower dose to achieve adequate uterine contraction (Table 2).

There was a statistically significant difference in the mode of delivery between the two groups ($p = 0.001$). In the immediate induction group, six women (7.9%) had caesarean section and there was no instrumental vaginal delivery, while 22 women (28.9%) in the expectant management group had caesarean section. 70 women (92.1%) and 54 women (71.1%) had vaginal delivery in the immediate induction group and the expectant management group respectively (Table 3). The most common indication for caesarean section was non reassuring fetal status which was found in 4 (66.7%) of the caesarean sections in the immediate induction group and 14 (63.6%) of those in the expectant management group (Table 3).

Four women (5.3%) in the expectant management group had clinical features of endometritis, while none of those in the immediate induction group had similar symptoms (Table 3). Twelve women (15.8%) in the immediate induction group had a positive

endocervical swab culture, while eighteen (26.3%) had a positive culture in the expectant management group. The prevalent organism isolated was *E. coli*.

There was no statistically significant difference in the mean birth weights, APGAR scores at one and five minutes or need for neonatal intensive care unit admission between the two groups. There were 2 perinatal deaths in the expectant management group (Table 4).

DISCUSSION

This prospective randomized study was carried out to evaluate the outcomes of the options of management of PROM at term. In the expectant management arm of the present study, 52.6% of the women developed spontaneous onset of labor within 12 hours, this was higher than the 33% reported by Omole-Ohonsi¹⁵ but less than 68% reported by Sterling et al¹³, and 78% by the TERMPROM study group.⁹ The higher figures in the latter studies were probably due to a longer waiting period of 24 hours and 4 days respectively, before induction of labor.

In the immediate induction arm of our study, 23.1% of the participants requiring cervical ripening progressed to labor after insertion of 25 micrograms misoprostol vaginally. About 70% of those who had cervical ripening in the expectant arm had a similar response. This is probably due to an increased response of the uterus to exogenous prostaglandins following spontaneous rupture of membranes at term, coupled with the high concentration of endogenous prostaglandins from the choriodecidual space following spontaneous rupture of fetal membranes. These may act synergistically to not only cause cervical ripening but to go ahead and stimulate uterine contractions. Fewer women in the expectant management arm of the study required cervical ripening before induction of labor. This was probably responsible for the difference in labor characteristics in the two arms of the study.

The mean duration of labor was shorter in the expectant management arm, 8.9 ± 2.17 hours, compared with 10.6 ± 2.35 hours in those that had immediate induction of labor. This was similar to the findings of Hannah et al⁹ and Sperlings et al.¹³ The study by Omole-Ohonsi¹⁵ however did not reveal any difference in duration of labor. This was probably due to the different induction agents in the two arms of the study. Misoprostol, was used for induction in those that had immediate induction of labor and oxytocin in the expectant management arm of that study. The shorter duration of labor in the expectant management arm of the study was probably a reflection of the state of the cervixes at the time of intervention.

With respect to the mode of delivery, there was a statistically significant difference in the caesarean section and operative vaginal delivery rate in our study. The caesarean section rate was significantly higher in the expectant management arm of the study (28.9% vs 7.9%, $p=0.001$). This was at variance with the previous belief^{11,12,14,16} that immediate induction of labor increased the risk of operative intervention, but was similar to the findings of Omole-Ohonsi¹⁵ who found a 29% caesarean section rate in the expectant management arm and 7 % in the immediate induction arm of their study. Akyol and colleagues¹⁷ had similar findings of a higher caesarean section rate in the delayed induction arm of their study. The commonest indication for caesarean section was non reassuring fetal heart rates tracing, which was the same in other studies.^{13-15,17} The higher caesarean section rate for those in the immediate induction arm in previous literature was probably due to state of the cervix at the time of induction. In our study, that was corrected for by carrying out cervical ripening in those with unfavorable cervixes.

There was no statistically significant difference in the APGAR scores at 1 and 5 minutes, which was

similar to the findings in the TERMPROM study group, but at variance with the findings of a better APGAR score profile in the expectant management arm of the study by Alcalay and colleagues.¹⁸ The need for admission into the neonatal intensive care unit was comparable in both arms of the study. Some, 2.6%, of the babies in the expectant management arm of our study had positive blood cultures and symptoms of neonatal sepsis, characterized by fever and tachypnea while none in the immediate induction arm had similar findings. This was comparable to 2.8% of the babies in the expectant management (oxytocin) arm of the TERMPROM study group.⁹

In the expectant management arm of our study, 5.3% of the participants had postpartum infectious morbidity with clinical features of endometritis; postpartum fever (oral temperature $>38^{\circ}\text{C}$ measured on at least 2 occasions, after the first 24 hours of delivery) and uterine tenderness and one patient developed overt puerperal sepsis with secondary postpartum haemorrhage requiring blood transfusion. None of the women in the immediate induction arm had similar symptoms. This is in support of the increased risk of intrauterine infection with the duration of rupture of membranes. This is comparable to the 3.6% of participants in the expectant management arm of the TERMPROM study group⁹ who had similar symptoms with a smaller percentage, 1.9%, in the immediate induction group of the same study. This is also similar to the findings of other workers.^{13,19,20} However, some investigators have reported a lower risk of infection among women who had expectant management.^{21,22} This was attributed to the longer duration of labour in the immediate induction of labor arm with the associated increased frequency of vaginal examination in that group.²³

Positive postpartum endocervical swab cultures were found in 15.8% of those in the immediate

induction arm and 26.3% of those in the expectant management arm of our study. The higher incidence of infection in the expectant management arm is similar to the findings of Hannah and colleagues⁹, but the difference is not as marked. This is probably due to the shorter waiting period of 12 hours employed in our study, compared to 4 days by the TERMPROM study group. The risk of intrauterine infection with prelabour rupture of membranes is less than 10% within the first 24 hours and increases to 24%²⁴, with values as high as 40% quoted after 24 hours⁸, hence the choice of 12 hours employed in our study.

The limitations observed in this study include the diagnosis of fetal distress based on persistent fetal heart rate abnormalities corroborated with the cardiotocographic findings. There were no facilities for fetal scalp blood pH or other tests to confirm fetal distress in our Centre. The duration of labor was also an estimate as the exact onset of labor could not be determined.

The maternal and neonatal outcomes were better in the group of women who had immediate induction of labor with oxytocin. Despite the divergent views, one way of reducing infectious morbidity associated with PROM is the institution of an active management protocol involving labor induction if fetal maturity is not in doubt.⁸ This study has shown that immediate induction with oxytocin reduces the risk of maternal infectious morbidity without increasing the rates of caesarean section or operative vaginal births. This option of management is safe and should be favorably considered in the management of PROM at term.

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