

A Prospective Randomized Comparison of Active vs Expectant Management and Outcome Assessment of Maternal and Neonatal Outcome in Premature Rupture of Membranes at Term Pregnancy

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Received: 21-10-2022 / Revised: 18-11-2022 / Accepted: 16-12-2022

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Conflict of interest: Nil

Abstract

Aim: The study aimed to compare the maternal and neonatal outcome in patients with term PROM receiving active induction versus expectant management.

Methods: The present study was a prospective randomized controlled trial, conducted on 100 term antenatal women in the Department of Obstetrics and Gynaecology, RDJM Medical College and Hospital, Turki, Muzaffarpur, Bihar, India for one year.

Results: Majority of women in both the groups belonged to 20-25 years. The mean gestational age in active and expectant group was 38.64 ± 0.94 weeks and 38.48 ± 0.97 weeks. 34% of active management group and 30% of expectant management group were admitted in 4 -6 hours. 42% of active management group and 30% of expectant management group had a latency period of 12-20 hours and results were found to be statistically significant (p value = 0.005). 40% of active management and 20% of expectant management were delivered within 6 12 hours and 46% of active management and 28% of expectant management group were delivered within 12-20 hours and results were highly significant (p value = 0.0001). Majority of the antenatal women (70% in active management group and 54% in expectant management group) delivered vaginally. The most common indication of caesarean section was foetal distress in both groups.

Conclusion: Immediate labour induction in patients with term PROM resulted in significant shortening of latent period and PROM to delivery interval without any increase in caesarean section rate as compared to expectant management group.

Keywords: maternal, neonatal, PROM

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Introduction

The normal development, structural integrity and function of the fetal membranes are essential for the normal

progress and outcome of pregnancy. One of the most important functions of the membranes is to remain intact until the

onset of labor in order to maintain the protective intrauterine fluid environment. In most pregnancies labor begins at term in the presence of intact fetal membranes. [1,2] Without any intervention their spontaneous rupture usually occurs near the end of the first stage of labor. In 8-10% of pregnancies they fail to maintain their structural integrity, resulting in pre-labor rupture. [1,3] This can be either at term pre-labor rupture of membranes (PROM) or preterm pre-labor rupture of membranes (PPROM). Both are to some extent separate entities as in the latter “prematurity” become the main issue. [1,2]

Term PROM is an obstetric conundrum which is poorly defined with a multitude of obscure etiologies associated with significant maternal and fetal morbidity and has diverse and controversial management strategies. [1,4-7] Expectant management entails the increased risk of chorioamnionitis and its consequences and active interference brings with it the risk of C-Section. [4-7] At term, PROM can be physiological variation rather than a pathological event. PROM occurs when intrauterine pressure overcomes membrane resistance. This happens due to weakening of membranes either congenital or acquired (smoking and vitamin C deficiency), or because of damaging factors either mechanical during amniocentesis or damage by infection (Trichomonas infection, group B streptococci, bacterial vaginosis). Failure of mechanical support such as cervical dilatation can lead to premature rupture of membrane. [8] Other etiological factors are over-distended uterus, big baby, polyhydramnios and multiple pregnancy. [9]

Premature rupture of membranes is associated with several complications of pregnancy (i.e. pregnancy induced hypertension, uterine blunt trauma and uterine malformations). Several external factors are thought to cause premature rupture of membranes (i.e. drop in

barometric pressure, and sexual intercourse). [10]

Some researchers suggest that the evidence of infection within 12 hours of premature rupture of membranes indicates an antecedent infection, whereas evidence of infection after 72 hours indicates infection resulting from premature rupture of membranes. The majority of women at term presenting with premature rupture of membranes will go into labour spontaneously by the 48 to 72 hours. Some obstetricians believe that waiting for labour to begin spontaneously is preferable for mothers if there is no evidence of foetal or maternal compromise, since the risk of caesarean section may be low. [11]

The present study is being planned to compare the efficacy of active management and expectant management in patient of PROM at term on their fetomaternal and perinatal outcome.

Materials and Methods

The present study was a prospective randomized controlled trial, conducted on 100 term antenatal women in the Department of Obstetrics and Gynaecology, RDJM Medical College and Hospital, Turki, Muzaffarpur, Bihar, India for one year

All antenatal women with confirm diagnosis of PROM at term attending Outpatient Department (OPD) were enrolled for the study. Diagnosis of PROM were based on

- Clinical history of passage of liquor
- Palpation through cervical canal
- Pooling of fluid in posterior fornices seen by speculum examination
- Reduced liquor volume on sonography (AFI) in selected women where clinical finding were inconclusive.

Inclusion criteria:

- Pregnancy ≥ 37 weeks of gestation confirmed by LMP or by early sonography with diagnosis of PROM

- Single foetus in vertex presentation
- Absence of active labour or features suggestive of foetal distress including meconium-stained liquor
- No contraindication for vaginal delivery
- No known hypersensitivity to prostaglandin
- No intervention outside the hospital.

Exclusion criteria:

- PROM before 37 completed weeks
- Foetal distress or meconium-stained amniotic fluid at admission
- Patient with features of chorioamnionitis like fever, tachycardia, uterine tenderness and/or foul-smelling liquor
- Previous caesarean section or major uterine surgery
- Medical condition like heart disease, asthma, glaucoma, PET, DM, Rh incompatibility, twins
- IUGR, foetal anomalies and polyhydramnions.

Each antenatal woman included in the study were subjected to complete history taking (personal, obstetric and gynaecological); general examination, abdominal examination and vaginal examination Routine investigations including urine culture sensitivity and high vaginal swab culture sensitivity were done. Admission test and ultrasonography was also done. All pregnant women received broad spectrum antibiotics. Informed consent for inclusion criteria in the study was taken after proper counselling.

These patients were randomly divided into 2 groups:

Group 1 (active management)

Half of the patients where labour was induced within 6 hours after rupture of membranes.

Induction was done with 50 microgram oral misoprostol 4 hourly. Subsequently depending on the partogram, labour was

augmented with intravenous oxytocin. The dose of misoprostol was repeated after 4 hours if uterine contraction was <2 in 10 minutes. If active labour was not established after 4 dose of oral misoprostol, and I/V infusion of injection oxytocin dose of 1ml (5IU) in 500ml Ringer Lactate or Dextrose 5% was started after at least 4 hours of last dose of misoprostol, at the rate of 15 -20 drops (10Mu) per minutes as starting dose, which was increased by 10 drops (5Mu) every 20 -30 minutes as needed till uterine contraction rate of 3 contractions every 10 minutes for 2 consecutive 10 minutes period was achieved.

Group 2 (expectant management)

50 patients who were allowed to go into spontaneous labour for 24 hours.

If patient failed to go into labour within 24 hours, reassessment of cervical finding was done, and labour was induced with 50 mcg. Oral misoprostol following same protocol as in Group 1.

Partographic monitoring of labour was done in all women. Onset of labour was determined by either regular uterine contraction or progressive cervical dilatation. Active labour was determined by 3 or more uterine contractions in 10 minutes or 4 cm of cervical dilatation. Any adverse effect (tachysystole, hyper stimulation syndrome, hyper tonus) was recorded.

The main maternal outcomes included latency period (duration from rupture of membrane to the onset of labour pain); interval period (duration from rupture of membrane to delivery); vaginal delivery rates; operative delivery rates, maternal morbidity and mortality (postpartum haemorrhage, vaginal and cervical tears and chorioamnionitis). The foetal outcomes included serious neonatal morbidity and perinatal deaths with special concern to neonatal infection, neonatal jaundice, 5 minutes APGAR score <7 and

NICU admission rates. Data was collected and subjected to statistical analysis.

Results

Table 1: Demographic profile of patients

| Demographic parameter | Active management | Expectant management | P value |
|--------------------------------|-------------------|----------------------|---------|
| Age (years) | | | |
| <20 -12 | 12 | 14 | 0.12 |
| 20-25 | 16 | 16 | |
| 25-30 | 12 | 12 | |
| 30-35 | 8 | 6 | |
| >35 | 2 | 2 | |
| Gestational age (weeks) | | | |
| 37-38 | 18 | 16 | 0.42 |
| 38-39 | 26 | 28 | |
| 39-40 | 4 | 5 | |
| >40 | 2 | 1 | |
| Gravida | | | |
| 1 | 34 | 28 | 0.60 |
| 2 | 10 | 12 | |
| 3+ | 6 | 10 | |
| Parity | | | |
| 0 | 38 | 30 | 0.10 |
| 1 | 2 | 12 | |
| 2 | 4 | 4 | |
| 3+ | 6 | 4 | |
| Area | | | |
| Rural | 36 | 38 | 0.62 |
| Urban | 14 | 12 | |

Table 1 shows the demographic profile of 100 antenatal women. Majority of women in both the groups belonged to 20-25 years. The mean gestational age in active and expectant group was 38.64 ± 0.94 weeks and 38.48 ± 0.97 weeks. Majority of the patients were primigravida, belonged to rural area.

Table 2: Distribution of patients

| Distribution of patients | Active management | Expectant management | P value |
|-------------------------------------------|-------------------|----------------------|---------|
| Prom to admission interval (hours) | | | |
| <2 | 4 | 8 | 0.12 |
| 2-4 | 10 | 13 | |
| 4-6 | 17 | 15 | |
| 6-8 | 12 | 4 | |
| 8-10 | 3 | 8 | |
| 10-12 | 4 | 2 | |
| Latency period (hours) | | | |
| <6 | 8 | 9 | 0.005 |
| 6-12 | 17 | 8 | |
| 12-20 | 21 | 15 | |
| 20-24 | 4 | 10 | |
| >24 | 0 | 8 | |

| Prom to delivery interval (hours) | | | |
|------------------------------------------|----|----|--------|
| <6 | 7 | 5 | 0.0001 |
| 6-12 | 20 | 12 | |
| 12-24 | 23 | 14 | |
| >24 | 0 | 17 | |
| Mode of delivery | | | |
| LSCS | 10 | 16 | 0.25 |
| Instrumental delivery | 5 | 7 | |
| Vaginal delivery | 35 | 27 | |
| Indications of caesarean section | | | |
| Foetal distress | 4 | 6 | 0.80 |
| Prolonged 2nd stage | 3 | 3 | |
| Cervical dystocia | 0 | 2 | |
| Non-progress of labour | 1 | 2 | |
| Failure of induction | 2 | 3 | |

34% of active management group and 30% of expectant management group were admitted in 4 -6 hours. 42% of active management group and 30% of expectant management group had a latency period of 12 -20 hours and results were found to be statistically significant (p value = 0.005). 40% of active management and 20% of expectant management were delivered within 6 -12 hours and 46% of active

management and 28% of expectant management group were delivered within 12-20 hours and results were highly significant (p value = 0.0001). Majority of the antenatal women (70% in active management group and 54% in expectant management group) delivered vaginally. The most common indication of caesarean section was foetal distress in both groups.

Table 3: Co-relation of mode of delivery with duration of prom in active management group and expectant management group

| Mode of delivery (n = 50) | <6 hours | 6-12 hours | 12-18 hours | 18-24 hours | 24 hours | P value |
|-----------------------------------|----------|------------|-------------|-------------|----------|---------|
| Active management group | | | | | | |
| Vaginal delivery | 10 | 18 | 6 | 1 | 0 | 0.20 |
| Instrumental delivery | 1 | 6 | 3 | 1 | 0 | |
| LSCS | 0 | 1 | 2 | 1 | 0 | |
| Expectant management group | | | | | | |
| Vaginal delivery | 0 | 2 | 6 | 16 | 2 | 0.23 |
| Instrumental delivery | 0 | 2 | 6 | 6 | 4 | |
| LSCS | 0 | 1 | 1 | 2 | 2 | |

In active management group, 20% patients with PROM duration of < 6 hours and 36% patients with PROM duration 6 -2 hours delivered by vaginally. In expectant management group, 24 patients with PROM duration of 18-24 hours and 6 patients with PROM duration of > 24 hours delivered vaginally.

Table 4: Distribution of cases according to neonatal outcome

| Neonatal outcome | Active management | Expectant management | P value |
|---------------------------------|-------------------|----------------------|---------|
| Apgar score at 1 minute | | | 0.72 |
| <7 | 5 | 6 | |
| >7 | 45 | 44 | |
| Apgar score at 5 minutes | | | 1.00 |
| <7 | 3 | 4 | |
| >7 | 47 | 46 | |
| Birth weight | | | |
| <2.5 kg | 10 | 11 | 0.74 |
| 2.6-3.5 kg | 35 | 36 | |
| >3.6 kg | 5 | 3 | |
| NICU admission | 4 | 5 | |
| Still birth | 0 | 0 | |
| Neonatal death | 0 | 0 | |
| Healthy babies | 46 | 45 | |
| Neonatal morbidity | | | |
| Neonatal sepsis | 0 | 2 | 0.65 |
| Neonatal jaundice | 1 | 1 | |
| RDS | 1 | 1 | |
| Birth asphyxia | 2 | 1 | |
| None | 46 | 45 | |

The table shows the neonatal outcome in both the groups. Apgar score was >7 in 88% at 1 minute and in 92% at 5 minutes in expectant management group. Majority of the neonates had birth weight between 2.6 -3.5 kg in both groups.

Discussion

Usually in normal labour, membranes rupture in the phase of maximum slope and in the phase of deceleration, in active labor. Intrapartum rupture of the membranes has been attributed to generalized weakness due to uterine contractions and repeated stretching. The amnion has greater tensile strength than the chorion. Together they withstand greater bursting pressures than they do separately. The amount of physical stress tolerated by the membranes decreases as pregnancy advances. [12] Membranes supported by a closed cervix require much greater pressures to rupture than do membranes covering an open area of 3-4 cm in diameter.2 As gestational age advances the relative concentration of

collagen decreases . All these factors help to maintain membrane integrity throughout pregnancy but facilitate rupture of membranes in labor at term. In premature rupture of membranes (PROM), membranes rupture occurs before the onset of labour. Recently the author is using the term “Pre Labour rupture of membranes”. [13]

Normal labor is defined as a process that begins with the onset of regular uterine contractions and ends with the delivery of newborn and expulsion of placenta. Uterine contractions bring about demonstrable effacement and dilatation of the cervix (or) painful uterine contractions accompanied by any one of the following; [14] Ruptured membranes 2)mBloody “SHOW”3) Complete cervical effacement.

The mean age in active management group was 24.00±2.77 years and in expectant management group was 24.96±3.44 years. This was comparable to the study done by Mahmoud F et al and Mukharya J et al. [11,15] 64% patients in active

management group and 54% patients of expectant management group were primigravida. This was comparable to the study done by Butt et al and Kunt et al. [16,17] In the present study, 78% patients of active management group and 62% patients of expectant management group were nulliparous which is similar to the study done by Mukharya J et al. [15] Majority of the patients of both groups belonged to rural area and were unbooked. Similar study was done by Vaishnav J et al. [18] In the present study, 34% patients of active management group and 30% patients of expectant management group were admitted in 4-6 hours whereas 38% patients of active management group and 28% patients of expectant management group were admitted within 6-12 hours. Similar results were reported by Mukharya J et al and Gracakrupa et al. [15,19] No significant difference were found in present and past studies between PROM to admission interval.

About 99.9% patients of active management group and 84% patients of expectant management group had latency period (time interval between PROM to active labour) within 24 hours. In the present study, significant difference ($P = 0.005$) was found as regards to latency period in both groups. The latent period was shorter in the immediate induction group than the expectant group. The mean duration in immediate induction group was 8.9 ± 5.5 hours while in the expectant group was 16.1 ± 9.9 hours. The results were comparable to the study done by Shetty et al and Crane et al. [20,21] About 90% neonates of active management group and 88% patients of expectant management group had >7 Apgar score at 1 minute. 94% neonates of active management group and 92% patients of expectant management group had >7 apgar score at 5 minutes in both groups. There was no still birth and neonatal death in both groups. This is comparable to the study done by

Chaudhari S et al, Vaishnav et al and Mukharya J et al. [15,18,22]

Duff [23] Stated that expectant management is a practice that should be abandoned because it may be associated with an increased frequency of maternal and neonatal infection and increased hospital expenses and it is less favorably regarded by patients. But trial conducted by Amiram Gafni [24] et al., in term PROM differs from that of Duff. It represents a tradeoff between an increased risk of clinical chorioamnionitis and a longer period of waiting for the delivery if an expectant management strategy is chosen versus an aversion towards labour being induced artificially or the wish to avoid an intravenous infusion. Also, the difference in cost, in this study is very less. Hence, the choice becomes one of preference from the perspective of an informed patient. As has been done in other clinical settings, it will be important to find out which management strategy is preferred by fully informed women at the point of decision making. [25]

Conclusion

Immediate labour induction in patients with term PROM resulted in significant shortening of latent period and PROM to delivery interval without any increase in caesarean section rate as compared to expectant management group. There were no statistically significant differences in the rate of maternal and neonatal morbidity among both the groups.

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