



Original Research Article

Randomized clinical trial of active induction versus expectant management in premature rupture of the membranes at term

Shobha Bembalgi¹, Tejashree M^{2,*}, Preetha F Naykar³

¹Dept. of Obstetrics and Gynecology, Karnataka Institute of Medical Sciences, Hubli, Karnataka, India

²Dept. of Obstetrics and Gynecology, Bowring and Lady Curzon Medical College and RI, Bangalore, Karnataka, India

³Dept. of Obstetrics and Gynecology, Shivmoga Institute of Medical Science, Shivmoga, Karnataka, India



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ABSTRACT

Immediate induction of labour in cases of pregnancy with PROM used to be a standard practice to avoid potential complications but induced labour is likely to be associated with increased risks of fetal and maternal complications due to oligohydramnios like cord compression and high rate of operative delivery. Purpose of this study is to determine in case the practice of actively inducing labour in women with PROM at term is preferable than expectant management for 12 hours and also to study the maternal and neonatal outcome.

A total of 150 pregnant women were randomized into two groups who are between 18-35 years, at term gestation (37-40 weeks) having PROM irrespective of gravida. Women were immediately induced by Tab. Misoprostol(25microgrmas) in immediate induction group. Women who presented with PROM were observed for 12hrs from time of PROM without any intervention to accelerate the labour in conservative management group. An observation between the two groups of patients would be made with respect to maternal and fetal outcome. We observed that there was statistically insignificant increase in duration of labour and increased rate of caesarean section in expectant group. Maternal complications in both groups were found to be insignificant. However, women who were managed expectantly developed more puerperal pyrexia, wound infection and prolonged hospitalization than women who were managed with induction method. There was no statistically significant difference in the perinatal complications.

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1. Introduction

Premature rupture of membranes (PROM) is defined as rupture of membrane before the onset of labour. When it occurs at or after 37 completed weeks of gestation it is called Term PROM. Pregnancy with PROM at term can be managed by either expectant or active induction. The concern with expectant management is the risk of infection to mother and fetus, whereas immediate induction can increase caesarean (CS) rate¹ Seaward and colleagues on term PROM concluded that since risk of infection is small in the initial first 24hours of PROM at term, expectant management and waiting for spontaneous labour

may be advised in selected patients for the first 12-24 hrs if a patient wish for expectant management.² Immediate induction of labour (IOL) is used to be a standard practice in cases of PROM in pregnancy to circumvent the potential complications of intrauterine infection and oligohydramnios.

However induced labour is likely to be prolonged with increased risks of fetal and maternal complications due to oligohydramnios like cord compression and high rate of operative delivery.³ The specific dilemma involves which is the best method to treat patient with PROM. Hence this study is undertaken to determine whether the practice of actively inducing labour is preferable than expectant management for 12 hrs, in women with PROM at term.

* Corresponding author.

E-mail address: tejakrish239@gmail.com (Tejashree M).

2. Materials and Methods

This was a Randomized controlled trial performed at Karnataka medical college in Hubballi from January 1st 2016 to December 31st 2016.

2.1. Inclusion criteria

1. Singleton pregnancy.
2. Pregnancy with vertex presentation.
3. Patient not in active labour.
4. Normal CTG.

2.2. Exclusion criteria

1. Ruptured membrane more than 12 hours.
2. Patients with features of chorioamnionitis..
3. Fetal distress and meconium stained amniotic fluid at admission.
4. Malpresentations and multiple gestations.
5. Previous caesarean section.
6. Pregnancy induced hypertension, gestational diabetes, bad obstetric history, h/o antepartum haemorrhage, cephalopelvic disproportion.
7. Medical disorders in pregnancy.
8. Oligohydramnios, IUGR and fetal anomalies.
9. Patient who refused to give consent to participate in study.

Pregnant women with history of pre labour rupture of membranes before onset of labour pains were admitted to labour room.

2.3. Detailed history were noted and physical examination done

In obstetric examination - height of the uterus, presentation and lie of fetus and amount of liquor were noted. All parameters of maternal and fetal wellbeing were recorded. A sterile speculum examination was done to demonstrate presence of liquor amni. When no amniotic fluid was seen on speculum examination in the vagina patient was asked to cough, to see drainage of amniotic fluid. In case of doubt about fluid from vagina, fluid was collected smeared on slide and was examined under microscope for ferning.

In case of chorioamnionitis, clinical criteria (i.e. maternal pulse and temperature, fetal tachycardia, uterine irritability and tenderness) were used for diagnosis. Both the groups were given prophylactic antibiotic. Single pelvic examination was done to note the presence or absence of membrane, presenting part and its station.

A total of 150 patients were enrolled in study. Based upon a computer - generated 1:1 allocation process 150 patients were randomized into 2 groups, i.e. expectant or induced. Sealed opaque envelopes with Sequential numbers were used to conceal group assignment. These envelopes

were opened just prior to the patient being taken to labor room.

For women in immediate induction group, labor was immediately induced by Tab.Misoprostol (25micrograms). For women with expectant management, patient observed for 12hrs from time of PROM (≤ 6 hrs), if labor did not supervene then induction started. A comparison was done between the two modes of management with respect to maternal and fetal outcome.

The variables included were obstetric, maternal, fetal outcomes and studied in each group separately and compared.

3. Data Analysis and Results

Appropriate statistical analysis of data was done using student t test for parametric data and chi-square test for non-parametric data. The data obtained was subjected to statistical computation using statistical package for social science (SPSS) version 20.0 and value of $P < 0.05$ was considered significant and $P < 0.0001$ as highly significant.

4. Results

Table 1: Comparison of demographic profile in study groups

| | Expectant | Induced | p value |
|-------------------------|------------------|----------------|----------------|
| Mean Age | 23.8 | 22.8 | 0.09 |
| Obstetric index | | | |
| Primi | 37 | 45 | |
| Multi | 38 | 30 | |
| Mode of delivery | | | |
| FTVD | 60 | 54 | 0.5 |
| LSCS | 13 (17.3%) | 18 (24%) | |
| APGAR | | | |
| APGAR 1 | 7.8 | 7.5 | 0.48 |
| APGAR 5 | 8.4 | 8.4 | |

There were no statistically significant differences between two groups in sample or demographic characteristics.

Table 2: Duration of labour since induction and admission among study participants

| Duration | Mean (SD) |
|--------------------------|------------------|
| Primi | |
| Admission since delivery | 13.9 (3.4) |
| Induction since delivery | 8.8 (2.1) |
| Multi | |
| Admission since delivery | 11.1 (3.4) |
| Induction since delivery | 6.7 (1.8) |

The mean (SD) duration of time since induction to delivery was 8.8 ± 2.1 hours and admission to delivery was 13.9 ± 3.4 hours in primiparous women. Among the

Table 3: Association between neonatal complication and study groups

| Group | Neonatal complication | | Odds Ratio (95% CI) | p value |
|------------------|-----------------------|------------|---------------------|---------|
| | Yes (n=17) | No (n=133) | | |
| Expectant | 2 (5.7) | 33 (94.3) | | — |
| Expectant failed | 6 (15) | 34 (85) | 2.9 (0.6-15.4) | 0.21 |
| Induced | 5 (8.8) | 52 (91.2) | 1.6 (0.3-8.6) | 0.59 |
| Induction failed | 4 (22.2) | 14 (77.8) | 4.7 (0.7-28) | 0.09 |

Table 4: Association between maternal complication and study groups

| Group | Maternal complication | | Odds Ratio (95% CI) | p value |
|------------------|-----------------------|------------|---------------------|---------|
| | Yes (n=17) | No (n=133) | | |
| Expectant | 4 (11.4) | 31 (88.6) | | — |
| Expectant failed | 7 (17.5) | 33 (82.5) | 1.6 (0.4-6.1) | 0.46 |
| Induced | 4 (7) | 53 (93) | 0.6 (0.1-2.5) | 0.47 |
| Induction failed | 2 (11.1) | 16 (88.9) | 0.9 (0.1-5.8) | 0.97 |

multiparous women the mean (SD) duration of time since induction to delivery was 6.7 ± 1.8 hours and admission to delivery was 11.1 ± 3.4 hours.

Table 3 shows association between perinatal complications in the study participants and labour management at the subgroups. The neonatal complications was found in 5.7%, 15%, 8.8% and 22.2% of those underwent expectant management which was successful, failed expectant management with secondary induction, early induction which was successful and early induction failed respectively. Induction failed group had higher chance of having neonatal complications, but it was not statistically significant.

Table 4 shows association between maternal complications and the study participants and labour management at the subgroups. The maternal complications was found in 11.4%, 17.5%, 7% and 11.1% of those underwent expectant management which was successful, failed expectant management with secondary induction, early induction which was successful and early induction failed respectively. Expectant failed group had higher chance of having maternal complications, but it was not statistically significant.

5. Discussion

Pre-labor rupture of membranes (PROM) at term is rupture of membranes prior to the onset of labor at or beyond 37 weeks gestation. Majority of pregnant women goes into spontaneous labor within 24 hours following PROM. The major concern regarding management of the patients with PROM is whether to allow them to enter labor spontaneously or to induce labor early. There are evidences which supports that induction of labor decreases the risk of chorio-amnionitis without increasing the caesarean delivery rate. Few literatures favour early induction of PROM because of risk of infections and others favor expectant management with feto-maternal monitoring.

There was no significant difference in age of patient between two groups. Maximum number of patients who presented with PROM between 37-41 weeks gestation were primigravidas (37% and 45%) in Expectant and Induced group respectively, The results obtained are comparable with the analysis conducted by Janhavi M et al,⁴

The parameters evaluated for maternal and fetal wellbeing, including uterine hyperstimulation, passage of meconium observed and interventions for fetal concerns were again similar in the two groups.

Snehamay et al,⁵ in their review concluded that caesarean section rate was about 17.8% following immediate induction of labour with prostaglandin E2 and it was also note worth that delayed oxytocin augmentation was carried out in 28.5% cases. These results are comparable to the current study in which caesarean section rate was 24% in group of patients induced with prostaglandin E1 tablet and 17.3% in expectant group.

Mean APGAR score were found to be 7.8 and 7.5 at 1 minute among expectantly and actively managed cases respectively with p value of 0.06 and APGAR score at 5 minute among expectantly and managed patients were 8.4 in both groups with p value of 0.48. No statistically significant difference between the groups. Which was compared with study Fatima S⁶ where there was no significant difference between two groups as far as Apgar Score at 5 minutes is concerned.

In our study, duration of pre labour rupture of membranes to active labor interval was shorter in patients with induction group which is 11.5 ± 3.5 hours as compared to the expectant group which is 13.8 ± 3.7 hours.

Duration from PROM to active labour was prolonged among expectant group when compared to active group among both primigravida and multigravida and was statistically significant. It is comparable to the study of Seema Tariq, Shamaila Tanveer, Javaria Nousheen,⁷ the duration of PROM to active labour interval was shorter in patients with induction group which is 8.6 ± 1.7 hours as

compared to the expectant group, which is 9.3 ± 1.2 hours.

A study conducted by Shalev⁸ also concluded that regimens of 12 and 72 h expectant management of PROM are similar regarding infectious complications and pregnancy outcomes. In the present study Expectant failed group had higher chance of having maternal complications, but it was not statistically significant. Fetal distress was increased in failed induction group in the present study but similar in both groups in Shalev study.

6. Limitations of the Study

1. Absorption of misoprostol can be varied.
2. We relied upon APGAR score for assessing the neurobehavioural outcome of the baby.
3. Only the immediate effects were studied, cases are not followed up for long term effects.

7. Further Scope for Study

In our study we found with PROM of 12 hrs there was no increase in caesarean section rate and there was no adverse outcome among expectant and induced group in terms of maternal and neonatal outcome.

Studies can be done with different duration for expectant management and different methods for labour induction can be tried in induction group.

8. Conclusion

We conclude that in comparative study of active versus expectant management of premature rupture of membranes, the duration of labour from admission to delivery interval was higher in expectant group than induced group was statistically significant among both primi and multigravida. The rate of caesarean section and instrumental delivery were statistically insignificant among both the groups. Among maternal and perinatal complications, there was no statistically significant difference between the expectant and induction groups.

Hence both methods of management can be used in premature rupture of membranes at term. However, the patients in expectant management group were in labor for many hours thus increasing the anxiety of mother and clinician. Active management is responsible for shortening the latency period, the total time between pre-labour rupture of membranes and delivery and total maternal hospital stay.

9. Source of Funding

None.

10. Conflict of Interest

The authors have no conflict of interest to disclose.

11. Details of Ethics Approval

The Institutional Review Board of Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India approved the study on November 23, 2015.

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Author biography

Shobha Bemalgi, Professor and Head

Tejashree M, Assistant Professor  <https://orcid.org/0000-0002-8913-1079>

Preetha F Naykar, Post Graduate

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