

INDUCTION OF LABOUR VERSUS EXPECTANT MANAGEMENT FOR PREMATURE RUPTURE OF MEMBRANES AT TERM

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ABSTRACT

Background: Premature rupture of the membranes at term is spontaneous rupture of the membranes after 37 wks of the gestations and before the onset of the regular painful uterine contractions. It occurs in ten percent of cases. These cases are either managed conservatively or by immediate induction of labour.

Objective: To find out the efficacy and safety of induction of labour versus expectant management in women with premature rupture of membranes beyond 36 weeks gestation, in terms of induction delivery interval, operative interventions, and fetal outcome

Material and Methods: A prospective, randomized controlled study was carried out for a period of two years from November 2008 to October 2010 at Rural Medical College, Loni. One hundred pregnant women with term PROM were assigned randomly, each in induction and expectant group.

Results: The mean interval from induction to delivery was significantly shorter in the induction group as compared with expectant group. Incidence of maternal morbidity was comparable in both the groups. Neonatal morbidity was higher in expectant group. Incidences of hyper stimulation were more with induction group as compared to expectant group. There was no maternal or perinatal mortality in any group. Intrapartum complications and mode of delivery were similar in both groups.

Conclusion: Immediate induction of labour in cases of PROM at term using oral misoprostol resulted in shorter induction delivery interval but increased rate of operative intervention. Maternal morbidity was comparable with induction and expectant line of management. However, neonatal morbidity was higher in expectant group.

Keywords: Premature rupture of membranes, Induction of labour, maternal morbidity, Neonatal morbidity, Misoprostol

1. INTRODUCTION

Pre-labour rupture of the membranes at term is defined as spontaneous rupture of the membranes after 37 wks of the gestations and before the onset of the regular painful uterine contractions. It occurs in about 10% of women beyond 36 weeks of gestation.¹ About 80% of the women at term with PROM go in to spontaneous labour within 24-48 hrs. Minority of patients (10-25%) have a latent period of more than 24hrs from PROM to the onset of labour. The chances of infection increase, if the latent period exceeds 24hrs. Keeping these considerations, there was a tendency to induce labor at the earliest. Early induction of labour helps in decreasing risk of chorioamnionitis, need for neonatal antibiotic therapy, neonatal intensive care (NICU) admission, and increased maternal satisfaction.¹⁻³ Induction of labour is indicated, when it is agreed that the fetus or mother will benefit from delivery.⁴ There has been conflicting reports in

literature eluding consensus, whether to induce labor immediately or to wait for some time before induction. Some studies have found expectant management safe up to 48-98 hrs without any increased incidence of infection. Others advocate early intervention with equally good results without increased complications as mentioned above.⁴⁻⁸ Recently, a great interest has been raised in the use of oral misoprostol for cervical ripening and labor induction and is considered as an alternative agent for induction in cases of PROM. It appears to be an effective method of labour induction with term PROM. Particularly women with poor cervical score can benefit from such approach.⁴ In view of this, a randomized controlled study was done with the following objectives. 1. To study the efficacy and safety of induction of labour versus expectant management in women with premature rupture of membranes beyond 36 weeks gestation, in terms of operative

interventions, and fetal outcome. 2.To compare the maternal and neonatal outcome between inductions versus expectant management. 3.To evaluate the efficacy and safety of oral misoprostol for induction of labour in PROM.

2. MATERIAL AND METHODS

This study is a prospective randomized study of patients presenting with spontaneous rupture of the membranes beyond 36 weeks' gestation at Pravara Rural Hospital, the teaching hospital of Rural Medical College, Loni from November 2008 to November 2010. One hundred women admitted with prelabour rupture of membranes at term i.e. beyond 36 weeks of gestation were enrolled for the study. Fifty cases were allotted to each group as follows -

Group I – Induction of labor at early stage in PROM (Active management).

Group II – Delayed Induction of Labour in PROM after 24 hours (Expectant management).

The local ethical committee approved the study protocol.

2.1 Source of Data: Indoor case file of hundred patients presenting with spontaneous rupture of the membranes beyond 36 weeks' gestation at Pravara Rural Hospital, the teaching hospital of Rural Medical College, Loni from November 2008 to November 2010 were included in the study.

2.2 Sample size: The predicted sample size of the study was 100.

2.3 Selection Criteria

2.3.1 Inclusion criteria:

1. Premature rupture of membrane as defined.
2. Absence of active labour or features suggestive of fetal distress including meconium staining of liquor.
3. Singleton pregnancy with vertex presentation and no known hypersensitivity to prostaglandins.
4. No contraindication to vaginal delivery.
5. No intervention outside hospital.
6. No other associated high risk factor.

2.3.2 Exclusion criteria:

1. Hypersensitivity to prostaglandins.
2. Previous caesarean section.
3. Previous major uterine surgery.
4. CPD.
5. Patient with fetal distress.
6. Medical conditions like heart disease, asthma and glaucoma.
7. Patients with high risk like PET, Diabetics, Rh incompatibility, twins.

2.4 Method of collection of data: Detailed history was noted as per study proforma; General, abdominal and obstetric examination was carried out. Premature rupture of membrane (PROM) was confirmed by sterile speculum examination of vagina. Routine and specific investigations were done including USG obstetrics, if required. 2. After being interviewed, the women who met the eligibility criteria were invited to voluntarily participate in the study. Those who accepted, were carefully informed of the aims and procedures of the study and then asked to sign the informed consent form. 3. Patients were randomly assigned to Group I (Induction of labour) and Group II (expectant management) at random using computer generated tables for the purpose of study, keeping in mind the inclusion and exclusion criteria.

2.5 Management Protocol – Active Management (Group I):

Vaginal swab for culture and sensitivity was sent on admission, and again in postnatal period. After initial assessment, labor inductions were done by oral misoprostol 50µg oral tablets 4th hourly. Subsequently, depending on progress labor may have to be augmented with pitocin drip. Patient was monitored for any hyper stimulation or tachysystole or hyper tonus associated with fetal distress. Labor induction was considered successful, if women delivered within 24 hours of initiating induction method or if there was a definite change in cervical score after 6 hours of induction. Maternal and fetal monitoring were done by using partographs. Any surgical intervention and cause for it was evaluated. Any complication arising during induction, labor or after delivery was noted. Broad spectrum antibiotics were given. Immediate fetal outcome was monitored by the help of APGAR score. Maternal and fetal infection was watched for, in postnatal period till discharge from the hospital.

2.6 Management Protocol – Expectant Management (Group II):

Patients were kept under constant supervision. Maternal pulse, B.P and temperature were recorded 4th hourly. Patients were given broad spectrum antibiotics. Patients were given clean sterile swabs and no unnecessary P/V examinations were carried out. P/V whenever required was done maintaining strict aseptic measures. Patients were particularly observed for symptoms and signs of chorioamnionitis. TLC, DLC and vaginal swab

culture were sent on admission. If patient fails to go into labor within 24 hours, re-assessment of cervical findings were done and labor was induced with 50 µgm misoprostol orally. Patients were meticulously monitored during induction and labor as for group I case. They were also kept under observation till discharge as mentioned for group I.

3. RESULTS

Out of the 100 cases of PROM studied, 50 cases were induced with oral misoprostol and 50 cases were kept on expectant line of management. Most of the cases were in the age group of 15-20 and 21-25 years. Average gestational ages in weeks were same for both the groups i.e. Induction Group 38.56 weeks and Expectant group 38.52 weeks. In the study, majority of the cases (73%) were primigravida. The mean PV leaking time was longer in Expectant group for primigravida as well as for multigravida than in Induction group. Vaginal delivery occurred in 78%

patients in induction group and 84% in Expectant Group (Table 1, 2). There was no difference in the APGAR score between the two groups. Maternal complications like Nausea, Vomiting, Diarrhea were more in Induction group (i.e. 3) as compared to Expectant (i.e. 0), whereas, failure to progress was more common in Expectant group. Puerperal Sepsis was seen in three cases of expectant group as compared to one in induction group. There was no difference in the culture of vaginal swabs of both the groups. There was no case of postpartum haemorrhage and retained placenta in any of the groups (Table 3). Fetal distress was seen more in induction group (i.e. 4) as compared to Expectant group (i.e. 3). Neonatal Sepsis was more in Expectant group (i.e. 7) as compared to induction group (i.e. 4). Incidence of hyperbilirubinemia was almost same in both the groups (Table 4).

Table No. 1: Mode of delivery in relation to parity in Induction group and Expectant group

Parity	Spontaneous delivery (n=81)		Instrumental delivery (n=2)		Caesarean section (n=17)	
	Group I	Group II	Group I	Group II	Group I	Group II
Primi (n=73)	33 (82.5%)	26 (78.8%)	1 (2.5%)	1 (3%)	6 (15%)	6 (18.2%)
Multi (n=27)	6 (60%)	16 (94.2%)	0	0	4 (40%)	1 (5.9%)
Total	39 (78%)	42 (84%)	1 (2%)	1 (2%)	10 (20%)	7 (14%)

Significant value = 0.189 (insignificant)

Table No. 2: Maternal morbidity in relation to total duration of PROM:

PROM (Hours)	Induction Group		Expectant Group	
	No. of cases	Morbidity	No. of cases	Morbidity
< 6	01	0	0	0
6-12	14	0	15	1(7%)
13-24	32	5(16%)	27	3(11%)
>24	3	2(67%)	8	5(62%)
Total	50	7 (14%)	50	9(18%)

Value of $\chi^2 = 0.544$, $p > 0.05$, Not Significant. By conventional criteria, this difference in maternal morbidity among induction group and expectant group is not statistically significant.

Table No. 3: Maternal morbidity in Induction Group and Expectant group:

Maternal morbidity	Induction Group (n=50)	Expectant Group (n=50)
Nausea, Vomiting, Diarrhoea	3	0
Puerperal Pyrexia	3	3
Puerperal sepsis	1	3
Prolonged labour	0	2
Chorioamnionitis	0	1
Total	7	9

One case of chorioamnionitis was observed in expectant group. Incidence of puerperal pyrexia was same in both the groups. There was no case of prolonged labour in induction group, where as two cases were seen in expectant group.

Table No.4: Neonatal morbidity in Induction group and Expectant group

Neonatal morbidity	Induction Group (n=50)	Expectant Group (n=50)
Neonatal sepsis	4(08%)	7(14%)
Hyperbilirubinemia	1(02%)	3(06%)
RDS	1(02%)	0
Birth asphyxia	1(02%)	1(02%)
Total	7(14%)	11(22%)

Value of Z =1.59, p<0.05, significant

After applying Z test for difference between two proportions there is significant difference between proportion of neonatal morbidity in Induction and Expectant group. Neonatal sepsis was seen in 8% of cases of induction group as compared to 14% of cases of expectant group, whereas hyperbilirubinemia was seen in 2% of cases of induction group as compared to 6% of cases of expectant group.

4. DISCUSSION

The management of PROM in term pregnancy has been a controversial issue over past few decades. Whether to induce labour immediately, for the possible risk of infection or to wait expectantly for the onset of spontaneous labour, are the issues, which make the decision difficult. The recommended management strategy for the women with the PROM at term has changed considerably during the last decade, partly because of improvement in the facilities for identification and treatment of maternal and neonatal infection. In majority of the reports, where

immediate induction with misoprostol was done, the latency period were significantly shorter, hence the duration of labor and hospitalization period were reduced. However, expectant management was another approach used where in, the operative intervention rate was lesser, without rise in the perinatal and maternal morbidity. PROM at term is associated with spontaneous onset of labour within 24 hours, in most of the cases. Misbah Kausar Javid⁹, Fabiana da Graca¹⁰ concluded that the waiting for spontaneous onset of labour was associated with prolonged stay in hospital. Rovinsky and Shapiro¹¹ recommended expectant management for PROM for twenty four hours, since labour started spontaneously in 85% of their patients within that time. Gordon Gunn and Daniel Mishell¹² reported that 80-90% of women went into spontaneous labour within twenty four hours. Perinatal mortality was four times more, when latent period extended for more than twenty four hours. David Conway and Gordon Stirrat¹³ in their study of PROM,

reported that 74% of women went into labour spontaneously before induction was necessary. Cammu H et al¹⁴, Grant et al¹⁵ reported similar results. Aqeela Ayaz's¹⁶ results were also consistent with the above studies. In the present study, 98% of women went into labor spontaneously in expectant group, before induction was necessary.

4.1. Duration of PROM in Induction and Expectant Group: The present study showed that mean time interval for PROM to delivery was shorter in induction group (15.5 hrs) than expectant group (18.5hrs). The results of the present study are consistent with the study done by Fabiana da Graca¹⁰, wherein it was noted that the mean time interval for PROM to delivery was 18.9 hours in induction group as compared to 27.5 hours in expectant group. The results of the present study are also comparable with the study done by Datta Mamta¹⁷, wherein it was noted that the mean time interval for PROM to delivery was 18.10 hours in induction group as compared to 29.55 hours in expectant group. The results of the present study are also similar to the study conducted by Aqeela Ayaz¹⁰, wherein it was noted that the mean time interval for PROM to delivery was 11.6 hours in induction group as compared to 17 hours in expectant group.

4.2 Maternal Morbidity: In the present study, the incidence of maternal morbidity was 14% in induction group and 18% in expectant group, which was due to puerperal pyrexia, sepsis and chorioamnionitis. Tan B P and Hannah ME⁸ in his study concluded that the incidence of chorioamnionitis was 0.8% in induction group and 1.4% in expectant group. Misbah Kausar Javid⁹ in his study reported, 3% incidence of chorioamnionitis in induction group and 7.8% in expectant group. The rate of postpartum pyrexia in induction group was less than 1% and in expectant group it was less than 1.8%. In present study, there was no case of chorioamnionitis in induction group whereas, 2% of the cases of expectant group had chorioamnionitis. Puerperal pyrexia was 6% in both the groups. Fabiana da Graca¹⁰ in her study regarding to maternal post partum follow up, the results were favorable in both the groups with minimal rates of puerperal infection, requirement of antibiotic therapy and other complications. There was no significant difference between the two groups. The results of the present study are in agreement with the results of Fabiana da

Graca¹⁰. The present study had one case of chorioamnionitis in expectant group. Aqeela Ayaz¹⁶ concluded that chorioamnionitis is a serious complication resulting from expectant treatment because of increase interval between premature rupture of membranes and delivery. In the present study, the common organisms isolated in vaginal swabs were E.coli, Candida, staphylococcus, pseudomonas and coagulase negative staphylococcus. Bacterial vaginosis is often cause of PROM, as well it helps in onset of labor due to its cytokines action. In the present study, prophylactic antibiotic were given to all the mothers. In another study conducted by Gibbs et al¹⁸ found the higher rate of (12 %) chorioamnionitis in a conservatively managed group, while no patient case of induction with oral misoprostol developed chorioamnionitis. Therapeutic safety of prostaglandins is narrow and hence dose required to induce optimal uterine activity may provoke gastro intestinal side effects like nausea, vomiting and diarrhoea. In the present study, gastrointestinal side effects (nausea, vomiting and diarrhea) were noted in 8% case of induction group.

4.3. Mode of delivery in relation in Induction Group and Expectant Group: The present study showed that there was higher incidence of caesarean sections in induction group (20%) then in expectant group (14%). Though the difference was insignificant. The main indications of Caesarean section in Induction group were failure of Induction (12%) and fetal distress (8%). Whereas, Caesarean section in expectant group was mainly performed for fetal distress (6%) and failure to progress (6%). Fabiana da Graca¹⁰ reported that caesarean section were done in 31% of women in expectant group, versus 20% in misoprostol group, but this difference was not statistically significant. (p=0.22) The results of the present study are not consistent with the results of Misbah Kausar⁹ who reported lesser incidence of caesarean rate in expectant group. [24% versus 34%]. J. Morales and Lazar AJ¹⁹ have noted that conservative management of patients with premature rupture of membranes at term will significantly decrease the incidence of caesarean section without placing the mother and baby at high risk of high infection. The present study is in agreement with study of J. Morales and Lazar AJ¹⁹. In present study, 83% of primigravida and 60% of multigravida had

spontaneous vaginal delivery in induction group. Whereas, in expectant group 59% of primigravida and 94% of multigravida had spontaneous vaginal delivery. These incidences are in agreement with the above studies of Hannah ME⁸ and Snehamay C²⁰. In the present study spontaneous onset of labor in induction and expectant group were 78% and 84 % respectively. In the present study incidence of instrumental vaginal delivery was 2% in induction group and 2% in expectant group. There is no significant difference between the two groups. Snehamay C²⁰ observed in his study that operative or instrumental vaginal delivery were 3.5 % in induction and 14.2% in expectant group.

4.4. Neonatal Outcome: In the present study, the major causes of neonatal morbidity were neonatal sepsis, hyperbilirubinemia, respiratory distress syndrome and birth asphyxia.

4.4.1 Apgar Score: Low APGAR score in first minute was noted in 6% of neonates in induction group and in 8% of neonates in the expectant group. These incidences are in agreement with the studies of Fabia da Graca¹⁰, Datta Mamta¹⁷ and Aqueela Ayaz¹⁶.

4.4.2 Neonatal Sepsis: In the present study the incidence of neonatal sepsis was 8% in induction group and 14% in expectant group. There was no incidence of neonatal sepsis in induction group and five percent incidence was seen in expectant group in the study carried out by Aqueela Ayaz¹⁶ in 2008. The rates of neonatal infections were not significantly different in the study carried by Hannah ME⁸. Neonatal infection were 3% for induction in prostaglandin group and 2.8% for expectant group. The most common micro organisms associated with PROM causing neonatal sepsis include group B streptococcus, E. coli, Coagulase negative staphylococcus, Haemophilus influenzae and Listeria monocytogenes.²¹ Commonly present organisms in present study is staphylococcus, streptococcus, gram negative staphylococcus. Prophylactic antibiotics were given to neonates born after twenty four hours of PROM and prolonged labor. Therapeutic antibiotic were given to all neonates positive blood cultures. Common combinations of antibiotics used are injection Cefotaxime 100mg/kg/day BD and amikacin 10mg/kg/day. Another combination used is

injection Ampicillin 150mg/kg/day and Gentamycin 4mg/kg OD was given.

4.4.3 Hyperbilirubinemia: Incidence of hyperbilirubinemia was higher in the expectant group (6%) as compared to that (2%) in induction group. Sanchez Ramoz²² found 18% and 15.05% cases had hyperbilirubinemia with oxytocin and misoprostol group respectively.

4.4.4 Respiratory Distress Syndrome: Sanchez Ramoz²² reported higher incidence of respiratory distress in induction group as compared to expectant group. In the present study, 2% of neonates suffered from respiratory distress in induction group, whereas, no case was seen in expectant group. Hence, the result of present study coincides with that of study by Sanchez Ramoz²².

CONCLUSION

Immediate induction of labour in cases of PROM at term using oral misoprostol resulted in shorter interval between membrane rupture and delivery. Immediate induction of labour at term also resulted in increased operative intervention. Maternal morbidity was comparable with induction and expectant line of management. However, neonatal morbidity was higher in expectant group. Oral misoprostol in a dose of 50 µg was effective and safe for induction, as there were no major maternal and neonatal drug related complications.

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