

Comparative analysis of management for premature rupture of membranes at term: active versus expectant

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Abstract

Background: Use with pregnancy beyond 36 weeks of gestational age was allocated randomly, each in induction and expectant groups.

Results: The duration of interval from induction to delivery was significantly shorter in the induction group (as compared with expectant group). There was no significant difference in maternal morbidity with induction and expectant line of management. Neonatal morbidity showed higher incidence in expectant group. no maternal or perinatal mortality in any group was noted.

Conclusion: There was shorter induction delivery interval but increased rate of operative intervention in cases with immediate induction of labour with patients of PROM at term using oral misoprostol. There was no significant difference in maternal morbidity with induction and expectant line of management. However, neonatal morbidity was higher in expectant group.

Keywords: PROM, misoprostol, cesarean v/s norma

Introduction

If the membranes rupture spontaneously before the onset of the regular painful uterine contractions after 37 weeks of the gestations, it is labelled as premature rupture of membranes at term.¹ Around 10% of women beyond 36 weeks of gestation experience. approximately 5-10% of all pregnancies suffer PROM out of which about 80% occur at term.²

PROM has multifactorial etiology. It can be a physiological process or a pathological occurrence at term. It occurs due to an increase in intrauterine pressure such that it exceeds membrane resistance. This may transpire due to weak membranes either due to congenital causes or acquired causes such as (deficiency of Vit C or smoking), or iatrogenic causes like mechanical damage during amniocentesis or infection.³ Other factors include hydramnios, multiple pregnancy, large for gestational age fetus, etc.⁴

Many complications arise from delay in labour, especially if the latent period exceeds 24hrs. If the labour is induced early, adversities such as incidence of chorioamnionitis,

neonatal antibiotic therapy requirement and admission rates in neonatal ICU, etc can be reduced, thereby reducing fetal and maternal morbidity overall.^{5,6}

Labour is induced when delivery has a favorable and beneficial for both mother and fetus⁶. There has been numerous and still contradictory reports in literature without much agreement, whether to induce labor immediately or to follow wait and watch policy for some time before induction. Some studies conclude expectant management is safe up to 48-98 hrs without any increased incidence of infection. However, Others back early intervention with comparable results without increased complications as mentioned before. Lately, attention has risen for the use of oral misoprostol for cervical ripening and labor induction and is considered as an substitute agent for induction in cases of PROM. This could be an efficient method of labour induction with term PROM, especially, in women with poor cervical score. Keeping this in mind, a randomized controlled study was planned and carried out.

Material And Methods

A prospective randomized study of patients presenting with spontaneous rupture of the membranes at term was done from May 2019 to April 2020 at Dhiraj Hospital, Waghodia. Seventy patients admitted with prelabour rupture of membranes at term i.e. beyond 36 weeks of gestation were enrolled in the study. Thirty five cases were allotted to two groups in the following manner:

- Group A: Active Management (Early induction of labour in patients with PROM)
- Group B: Expectant management (Delayed Induction of Labour ,i.e, after 24 hours in PROM patients)

Approval for the study protocol was sought from the local ethical committee.

Data Source: In patient case files of seventy patients presenting with spontaneous rupture of the membranes at term at Dhiraj Hospital, Waghodia from May 2019 to April 2020 were included in this study.

Sample size: 70 presenting with spontaneous rupture of the membranes at term.

Selection Criteria

Inclusion criteria

1. Premature rupture of membrane as defined above.
2. Features suggesting Absence of active labour.
3. Signs of fetal distress including meconium staining of liquor.
4. Single fetus with vertex presentation and no documented hypersensitivity to prostaglandins.
5. No vaginal delivery contraindication.
6. No intervention outside hospitals.
7. No other associated high-risk factor.

Exclusion criteria

1. Prostaglandins Hypersensitivity.
2. Previous major uterine surgery
3. Previous history of caesarean section.
4. Fetal distress in pregnancy.
5. Patients with high risk like PET, Diabetics, Rh incompatibility,twins
6. CPD
7. Medical conditions like heart disease, asthma and glaucoma.

Methodology Of data collection:

1. Comprehensive history was taken as per study proforma which was followed with General, abdominal and obstetric examination. Diagnosis of PROM was confirmed by sterile speculum per vaginum examination. Routine and specific investigations were done including obstetric sonography, if indicated.

2. Patients fulfilling the eligibility criteria were requested to willingly partake in the study. Those who accepted, were informed of the aims and procedures of the study and then informed consent was taken.
3. Patients were randomly allocated to Group A (Active Management) and Group B (expectant management) at random using computer generated tables for the motive of study, acknowledging the inclusion and exclusion criteria.

Management Protocol – Active Management (Group A): On admission, a sample of Vaginal swab was sent for culture and sensitivity examination, and again in postnatal period. Oral misoprostol 50µg oral tablets 4 hourly was administered after preliminary evaluation to induce labor. Afterwards, considering the progress of labor, it may have to be augmented with pitocin drip, as required. Continuous patient monitoring was done 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.’ Partographs were used for Maternal and fetal monitoring. Any surgical intervention and cause for it was evaluated. Instantaneous fetal outcome was observed by the help of APGAR score.

Expectant Management (Group B): Patients were kept under continuous supervision. Vitals such as patient’s pulse, B.P and temperature were recorded every 4 hours. As per requirement, patients were administered broad spectrum antibiotics. P/V examination whenever required was done upholding stringent aseptic measures. Patients were particularly observed for symptoms and signs of

chrioamnionitis. If patient fails to go into labor within 24 hours, re-assessment of cervical findings were done and labor was induced with oral 50 µgm misoprostol and then managed as patients in group A.

Results

Out of the selected 70 cases of PROM, 35 patients were induced with oral misoprostol and 35 cases were on expectant 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 38.50 weeks and Expectant group 38.49 weeks. In the study, majority of the cases (68%). were primigravida. The mean PV leaking time was lengthier in Expectant group for primigravida as well as for multigravida than in Induction group. Vaginal delivery occurred in 80% patients in induction group and 84% in Expectant Group(Table.1&2). In the APGAR score between the two groups, there was no significant variation. Maternal complications such as Nausea, Vomiting, Diarrhea were more in group A (i.e. 2) as compared to Group B (i.e. 0), while, failure to progress was more seen in Group B. Puerperal infection/Sepsis was seen in two cases of group B in contrast to 1 in induction group. There was no difference in the culture of vaginal swabs of both the groups. There were no complications of PPH & RPOC in any of the groups.(Table 3) Fetal distress was seen more in induction group A (4) as compared to Expectant group (i.e. 3). Neonatal Sepsis was seen more in Expectant group (i.e 5) as compared to induction group (i.e. 3). Incidence of hyperbilirubinemia was almost same in both the groups.(Table 4)

Table 1: comparison of the mode of delivery in the expectant versus active management group in relation to the parity

Parity	Spontaneous Delivery(n=56)		Instrumental delivery(n=2)		Caesarean section(n=12)	
	Group A	Group B	Group A	Group B	Group A	Group B
Primigravida(n=48)	20	18	1	1	4	4
Multigravida(n=22)	6	12	0	0	3	1
Total	26	30	1	1	7	5

Sig value = 0.189 (insignificant)

Table 2: Duration of premature rupture of membranes in relation to the maternal morbidity

PROM(hours)	Group A		Group B	
	No of cases	Morbidity	No of cases	Morbidity
<6	1	0	0	0
6-12	10	0	10	1
13-24	22	4	18	3
>24	2	1	7	4
Total	35	5	35	7

p value = >0.05 not significant. Therefore no statistically significant difference was found in the induction versus active management group in relation to the maternal morbidity.

Table 3: Comparison of induction and expectant group in relation to the maternal morbidity

Maternal morbidity	Induction Group (n=35)	Expectant Group (n=35)
Nausea, Vomiting, Diarrhoea	2	0
Puerperal Fever	2	2
Puerperal infection/sepsis	1	2
Prolonged labour	0	2
Chorioamnionitis	0	1
Total	5	7

Table 4: Comparison in the Induction group and Expectant group in relation to the neonatal morbidity

Neonatal morbidity	Induction Group (n=35)	Expectant Group (n=35)
Neonatal sepsis	2	5
Hyperbilirubinemia	1	3
RDS	1	0
Birth asphyxia	1	1
Total	5	9

Only 1 case of chorioamnionitis was detected in expectant group & Frequency of puerperal pyrexia was same in both the groups. No case of prolonged labour in induction group was seen, however, two cases were observed in expectant group.

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 4% of cases of induction group as compared to 10% of cases of expectant group, whereas hyperbilirubinemia was seen in 3% of cases of induction group as compared to 8.5% of cases of expectant group.

Discussion

PROM management in term pregnancy has been a much debated issue over past few decades with many studies stating divisive opinions regarding it. Clinicians often face the dilemma if to induce labour immediately, to reduce possible risk of infection should be the preference or to wait expectantly for the onset of spontaneous labour. Due to the improvement in the amenities and investigations for identification and management of maternal and neonatal infection, the recommended management approach for patients with the PROM at term has transformed significantly during the preceding decade. In considerable number of the reports, where instant induction with misoprostol administration was carried out, the latency period were significantly shorter, thereby, decreasing the extent of labor and as a result, period of hospitalization were also cut down. Nevertheless, expectant management was an additional method used where in ,the operative intervention rate was lesser for patients, without increase in the perinatal and maternal morbidity. In majority of cases, PROM at term is associated with spontaneous onset of labour within 24 hours. In studies published in 2005 and 2008 by Fabiana da Graca⁷ and Misbah Kausar Javid⁸

respectively, came to the conclusion that the wait and watch for the spontaneous onset of labour was associated with extended stay in hospital .in a study by Rovinsky and Shapiro⁹, recommendation was made in cases of expectant management for PROM for twenty four hours, since labour started spontaneously in around eighty five percent of their patients within that timeframe. Similarly, Gordon Gunn and Daniel Mishell¹⁰ reported that upto 90% of patients went into spontaneous labour within twenty four hours after expectant management. Perinatal mortality increased four folds in cases, when latent period extended for more than 24 hours. Study by David Conway and Gordon Stirrat¹¹ reported that 74% of females went into labour naturally before induction was required. In a similar fashion studies by Cammu H et al ¹², Grant et al¹³ came to similar conclusions. Aqeela Ayaz¹⁴ also reported results in adherence to beforementioned studies. In the present study, 95% of women went into labor spontaneously in expectant group , before induction was necessary.

Maternal Morbidity

In the contemporary study, the incidence of maternal morbidity was 14% in induction group and 20% in expectant group, which was due to puerperal pyrexia, sepsis and chorioamnionitis. Tan B P and Hannah ME¹⁸ in his study concluded that the incidence of chorioamnionitis was 0.8% in induction group and 1.4% in expectant group. Misbah Kausar Javid⁸ 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.

Extent of PROM in Group A (Induction) and Group B (Expectant Group): The contemporary study exhibited

that mean time interval for PROM to delivery was shorter in induction group (16.5 hrs) than expectant group (18.5hrs). The results of the present study are in adherence with the study conducted by Datta Mamta et al¹⁶, which showed that the mean time interval for PROM to delivery was 18.10 hours in induction group and 29.55 hours in expectant group. The outcomes of the present study are also in accordance with the study done by Fabiana da Graca⁷, wherein it was noted that the mean time interval for PROM to delivery was 18.9 hours in induction group in contrast to 27.5 hours in expectant group. This study showed results comparable to the study done by Bangal et al¹⁵ & that of Aqueela Ayaz, in which it was noted that the mean time interval for PROM to delivery was 11 hours in induction group as likened to around 17 hours in expectant group

Mode of delivery in relation in Induction (Group A) and Expectant (Group B) patients: Our study came to the conclusion that there was higher frequency of caesarean sections in patients of induction group (10%) in contrast to expectant group (7%), although the difference was not of significance between the two. Fabiana da Graca⁷ in her study accounted that 31% of the women in expectant group and around 20% in misoprostol group underwent caesarean sections, but similar to the present study this difference statistically insignificant with a p value of 0.22. However, study by Misbah Kausar⁸ displayed more incidence of caesarean rate in active group [34% as compared to 24%]. This study, therefore is in disagreement with the results of our study. J. Morales and Lazar AJ¹⁷ also showed that expectant/conservative management of cases with PROM at term decreases the frequency of caesarean section significantly without maternal and fetal compromise and thereby reducing risk of contracting infection. In present study, in induction group (Group A) 80% of primigravida and 60% of

multigravida had spontaneous vaginal delivery. While, 78% of primigravida in expectant group and 92% of multigravida underwent vaginal delivery spontaneously. Studies conducted by Hannah ME¹⁸ and Snehamay¹⁹ report incidences in compliance with the present study. In the present study spontaneous onset of labor in induction and expectant group were 74% and 85% respectively. Our study reported no significant difference between the two groups in respect to instrumental vaginal delivery with incidence of being 2% in both induction & expectant groups. Snehamay C¹⁹ exhibited the incidences of operative or instrumental vaginal delivery as 3.5% in induction and 14.2% in expectant group.

Neonatal Outcome

4% and 7% of the neonates showed low APGAR score in first minute in induction and expectant groups respectively. Studies by Fabiana da Graca⁷, Datta Mamta¹⁶ and Aqueela Ayaz¹⁴ showed similar incidences. 5% and 14% incidence of neonatal sepsis was seen in induction and expectant groups respectively in our study. However, 0% incidence of neonatal sepsis in induction group and 5 percent incidence was seen in expectant group in the study done by Aqueela Ayaz¹⁴. Similar incidences were reported by Bangal VB¹⁵ as in our study. Incidence of hyperbilirubinemia was higher in the expectant group as compared to that in induction group. In our study, respiratory distress was seen in 2% of neonates in induction group, and no case was seen in expectant group. Hence, both the above results in our study coincides with that of study by Sanchez Ramoz²⁰.

Conclusion

Oral misoprostol administration for Immediate induction of labour in cases of PROM at term lead to shorter interval between membrane rupture and delivery. There was no significant difference in maternal morbidity with induction and expectant line of management. Nevertheless,

expectant group showed higher incidence of neonatal morbidity. Oral misoprostol as a dosage of 50 µg was effective and safe for induction.

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