

Comparative study of Active versus Expectant management and Maternal and Neonatal outcome in Premature rupture of the membranes (PROM) in Tertiary Care Hospital, Tirupathi

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Abstract: Aim: Comparison of maternal fetal outcome with active versus expectant management in PROM

Material and Methods: From March 2007 to July 2008 a total of 103 pregnant women with PROM allocated randomly to expectant group A (53) and active group B (50) and fetal and maternal morbidity were compared at Government Maternity Hospital, Tirupati.

Results: PROM to delivery interval in expectant group was 30.49 ± 16.07 hours, in active group it was 17.46 ± 6.0 hours. Caesarean delivery rate in expectant group is 5.7% and 12% in active group. In group (A) 32 % of the patients had spontaneous labour but in group (B) it is 67%. Incidence of caesarean delivery and operative delivery was 12% and 18% in active group compared to 5.7% and 5.7% in expectant group. 81.1% and 96 % of babies in both groups at birth had APGAR ≥ 7 respectively. Neonatal mortality is 1.9% in expectant group and 2% in active group. Maternal morbidity in expectant cases was 3.81% and in active cases 4%. Neonatal morbidity in expectant group was 20.6% and in active cases was 18%.

Conclusion: Active management may be preferred in PROM cases to reduce hospital expenses, stay and hospital acquired infections.

Keywords: Term PROM, Induction of labour, Expectant management, Maternal and Neonatal outcome.

I. Introduction

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:¹

1. Ruptured membranes
2. Bloody "SHOW"
3. Complete cervical effacement.

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.² 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.² 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"³

The incidence of PROM varies from 2-18 % with an average of 10%, occurring in approximately 10% of all pregnancies⁴. In 70% of the cases it occurs in pregnancies at term³. Preterm PROM occurs in 3% of all pregnancies. It is responsible for approximately 30% of all preterm deliveries⁴.

Most Indian studies from Mumbai report an incidence of PROM between 7% and 12%. Daftary and Desai (2006) reported that PROM occurs in 5-20 % of all pregnancies⁴.

Maternal mortality in PROM is mainly due to chorioamnionitis, Puerperal sepsis and septic shock. Abruptio Placenta, retained placenta, primary and secondary PPH and endomyometritis are also significant

causes of maternal morbidity. Prolonged hospitalization without active intervention with uncertain fetal and neonatal prognosis lead to adverse psychosocial sequelae. Increased operative interference associated with induction of labour account for significant proportion of puerperal maternal morbidity.

Although the incidence of chorioamnionitis is 30% ,the reported incidence of neonatal sepsis is only 2-4%. Neonatal morbidity will also be increased because of the mechanical difficulties encountered with delivery, either by vaginal or abdominal route due to reduced volume of amniotic fluid. In the event of non-induction of labor in PROM, there may be good uterine contractions but reduced amount of liquor causes failed progression and consequently dry labor followed by rupture uterus..

According to Friedman (1951)³, where membranes rupture in latent phase, latent phase is longer but the remaining portion of curve is uninfluenced. If induction is attempted with intravenous oxytocin drip, the frequency of failed induction is attempted with intravenous oxytocin, the frequency of failed induction and subsequent cesarean delivery approaches 30-40% and protracted labor increases the risk of maternal and neonatal infection. Conversely if women are observed expectantly to allow the cervix to ripen and labor to begin spontaneously, infection, umbilical cord prolapse or compression of the cord may occur, these in turn lead to an increased frequency of caesarean delivery, and if women are hospitalized, increased expenses is incurred. The specific dilemma involves how best to treat patients with PROM. Hence this study is undertaken to determine the practice of actively inducing labor, in women with PROM at term is preferable than expectant management for 24 Hours and to study the maternal and neonatal outcome.

II. Materials And Methods

Study Groups:

Inclusion Criteria:

- a. Women at term gestation (37 - 40) weeks having PROM irrespective of gravidity
 - Gestational age assessment was done by
- i. LMP – Naegle’s formula
- ii. Ultrasound
- b. Singleton Pregnancy
- c. Pregnancy with Vertex Presentation

Exclusion Criteria:

- a. Women less than 37 Weeks of gestation and more than 41 Weeks of gestation.
- b. Women with medical disorders
- c. Women with obstetric high risk factors like Diabetes, Pregnancy induced hypertension, heart disease complicating pregnancy, Antepartum haemmarage etc.

Demographic details of patients were noted. Duration of leak, volume and characteristics of liquor at the time of admission were recorded. Systemic examination and obstetric examination were done. Sterile speculum examination without using any antiseptic was undertaken to reveal presence or absence of amniotic fluid leak through cervix .Total duration of leak was defined as the time between onset of leaking and delivery .Prophylactic antibiotic Inj. Ampicilli 1gm I.V stat was given to those having PROM.

Management:-

Women having PROM were randomly allotted to either active management or expectant management by random sampling using Fishers table. Informed consent was taken for either management.

Active management

After assessment of pelvis and Bishop’s Score, if cervix unfavorable i.e 0-5 ,induction with PGE₁ followed by augmentation with oxytocin drip was practised. If favorable i.e. 6 -13 of bishops score, Oxytocin drip 5 units in 500ml PL was given. Infusion started at 2 m IU/min and doubled every 20 minutes till there is optimal response i.e. 3 contractions in 10 min each lasting for 45 seconds. If labour had not supervened drip is again repeated after 2 – 4 hours.

During active management

- a. Monitoring once in every ½ hr for maternal pulse rate, uterine action with descent of head, Fetal heart sounds rate was noted. Per vaginal examination done and temperature was recorded once in 4 hours in active labour.

Expectant management for 24 Hours

After admitting a woman with PROM, vitals recorded every 4th hourly .Abdominal examination done for uterine action and descent of head. Repeated per vaginal examinations were avoided. Pad given for

observation and for any meconium stained leak or foul smelling infected discharge .Prophylactic antibiotic given. Maternal pulse rate and fetal heart sounds uterine action monitored every half an hourly.

Expectant management is abandoned in the following conditions.

Signs and symptoms of chorioamnionitis : fever of more than 100⁰ F, maternal tachycardia more than 100, fetal tachycardia more than 160 beats per minute, uterine tenderness, foul odor of amniotic fluid and maternal leucocytosis .Fetal distress was fetal heart rate less than 110 and more than 160 beats per minute.

Mode of delivery was noted as

- a. Spontaneous onset of labor, delivered vaginally
- b. Outlet or vacuum
- c. Caesarean section

The mother was followed up in the puerperium for one week for any signs and symptoms of morbidity high fever, foul smelling lochia, subinvolution etc.

By maintaining 4th hourly – temperature, pulse rate chart. In the presence of fever other causes like breast engorgement, Respiratory tract infection and prior urinary tract infection were excluded.The smell and colour of lochia were noted. Rate of involution of uterus and duration of hospital stay was also noted.

Neonatal outcome

The newborn babies were examined for APGAR score at 1 min of birth. Their birth weight, Presence of caput & excessive moulding, temperature (Fever) , Any resuscitation required with oxygen (or) ambu bag, feeding problems were noted. The progress of the babies in the neonatal period was observed for one week for any fever and feeding problems

Data regarding each case was made out based on the following proforma.

Table I comparison of mode of delivery

Maternal outcome	expectant Management		Active Management		Chi Square	P Value
	No	%	No	%		
Vaginal delivery	49	88.6	35	70.1	6.20	0.04

Expectant group-spontaneous vaginal delivery

Without augmentation	32.2%
With augmentation	67.8%

Maternal outcome	Expectant management		Active management		Chi square	P value
	No.	%	No.	%		
Operative	6	11.4%	15	30	6.20	0.04
a. O+V	3	5.7	9	18		
b. C/S	3	5.7	6	12		

O = Outlet, V= Vacuum extraction, C/s = Caesarean section

In expectant management only 32% of patients delivered spontaneously without any augmentation and 67% were managed actively in expectant group after 24 hours.

Table I : Indicates that operative rate is more in the active management group (30%) when compared to (11.4%) in the expectant management group which is statistically significant.

Table II comparison of duration of labour in PROM cases

S.No	Time Interval	Cases		T – Value	P – Value
		Expectant Management Mean ± S.D	Active Management Mean ± S.D		
1.	Time Interval form PROM to Active Phase (Hrs)	23.57 ± 14.75	7.22 ± 4.46	7.63	<0.001
2.	From Active Phase to delivery (Hrs)	6.98 ± 1.99	4.21 ± 1.99	6.54	< 0.001
3.	From PROM to Delivery (Hrs)	30.49 ± 16.07	11.46 ± 6.01	7.86	< 0.001

Table II shows that time interval from PROM to active phase and from active phase to delivery and the total time taken for delivery from ROM is more in the expectant management with PROM group compared to active management with PROM which is statistically significant.

Table III Comparison of neonatal morbidity

Neonatal Morbidity	expectant Management		Active Management		Chi Square	P Value
	No	%	No	%		
NIL	41	77.4	40	80.0	2.47	0.29
A	4	7.5	5	8		
B	5	9.4	3	6		
C	1	1.8	1	2		
D	1	1.8	1	2		
Total	11	20.6	9	18		

a = Meconium b = Resuscitation c = Fever d= Feeding problems

Table III Indicates that the neonatal morbidity in all these groups is almost same and very less.

Table IV Comparison of neonatal outcome

S.No		expectant Management		Active Management	
		No	%	No	%
a.	APGAR				
	< 7	10	18.9	7	14.0
	≥7	43	81.1	43	86.0
b.	Fetal outcome				
	Alive	52	98.1	49	98.0
	Death	1	1.9	1	2

Table IV shows that for 81.1 to 96 % of babies in all the groups, the APGAR at birth at 1 min is ≥ 7. Neonatal mortality in the PROM cases is very less i.e. 1.9-2%

Table V comparison of maternal Morbidity

Maternal Morbidity	expectant Management		Active Management	
	No	%	No	%
Fever + PPH + Unhealthy Lochia	2	3.81	2	4
NIL	51	96.2	48	96

Table V indicates that 96% of the patients in all the groups are without morbidity.

Table VI Comparison of maternal hospital stay in PROM cases

	Expectant Management Mean ± S.D	Active Management Mean ± S.D	T – Value	P – Value
Hospital stay of Mother (days)	3.66 ± 1.27	2.76 ± 1.73	3.30	0.001

Table VI indicates that the hospital stay of the mother is more in Expectant group (3.66 ± 1.27 days) than in active group (2.76 ± 1.73 days) which is statistically significant.

III. Discussion

The present study was randomized controlled trial:

The women in the study were from a homogenous population, and both the groups were comparable with respect to mean maternal age, gestational age, parity, educational status, socio economic status and residence. Therefore differences in outcome should be primary due to the different management plans and not due to other medical or obstetric complications.

In the present study the mean maternal age associated with spontaneous PROM is 22.84 ± 3.71 years. The author has taken same age women to avoid bias with teenage or elderly women. This finding correlates with those of Varner and Galask⁵ who reported the mean age as 25 years in the PROM. Most of the women (78%) were primigravida, similar to study done by kodkany and Telang⁶ Semezuek sikora⁷ et al, and Chaudari Snehamay⁸ et al., But the age and parity appeared to have no significance associated in patients with PROM which is also supported by study conducted by Jamil A.Fayez⁹, et al, on management of PROM.

The studies have shown that low-socioeconomic status, malnutrition, poor hygiene, over exertion, occupational fatigue and long working hours are risk factors for PROM^{10,11}.

Only seventeen women (32%) in the expectant group went into spontaneous labour without any augmentation within 24 Hrs, whereas 67% of women in expectant group required augmentation after 24 hours. This is in controversy to Grant et al., (1992)¹² where the optimum latent period should be more than 12 hours, as certain biological changes occur during this phase which favor efficient labor and spontaneous vaginal delivery.

The cesarean section rate is less 5.7% (3) in expectant group as compared to 12% (6) in active group. The operative delivery is more i.e. 18% (9) in active group versus expectant group i.e. 5.7% (3). So the overall operative delivery rate is low in the present trial in the expectant group i.e., 11.4% in contrast to 30% in the active group in PROM cases which is statistically significant.

Kappy et al.,¹³ have suggested that immediate intervention is not the best management for all term patients with PROM. An increased incidence of cesarean delivery was noted for the lack of progress in term patients with PROM who were managed with induction of labor compared with patients managed by observation. It is concluded that conservative approach in a term pregnancy with PROM and an unfavourable cervix seems to decrease the incidence of cesarean section.

Forty nine women (88.6%) in the expectant group had a spontaneous vaginal delivery as compared with 35 (70%) in the active group.

Interval from Rom to active phase and time interval from active phase to delivery is significantly more in the expectant group than in active group. The time from the rupture of membranes to delivery was significantly shorter in the active group i.e. 11.46 ± 6.01 Hrs and in expectant group was 30.49 ± 16.07 . This observation is similar to the trial conducted by David, et al.,¹⁴ and Hannah et al.,⁶ where the mean time interval between the onset of labor and delivery was longer in the expectant group than in the induced group.

54% of the patients in active group of PROM had mixed polymicrobial infection on culture sensitivity of vaginal swab compared to 58.4% in expectant group. Most of the organisms isolated in this study were E.coli, group B streptococcus, Klebsiella, staph aureus and β hemolytic streptococci which are similar to that in the study conducted by H. Flores-Herrera, et al in Mexico¹⁵. In their study, the microorganisms associated with PROM were yeast, ureaplasma urealyticum, Group B streptococcus and bacterial vaginosis group of organisms and C. Karat, et al.,¹⁶

The maternal morbidity, neonatal morbidity and mortality, and hospital stay of the neonate are least and there is no significant difference in both the management groups in PROM – because of (1) effective antibiotics (2) Limited Per vaginal examinations (3) aseptic precautions followed (4) correction of dehydration (5) Good intensive neonatal care.

This is similar to Duffp et al., (1984),¹⁷ Umed Thankor¹⁸ et al., A shetty, K. Stewart et al, (2002)¹⁹ Chaudhuri Snehamay, et al.,²⁰ where patients with PROM may be safely managed in a expectant manner without increased risk of maternal and neonatal infection.

Women in the expectant Group had significantly longer hospitalization i.e., 3.66 ± 1.27 days versus 2.76 ± 1.73 days in the active group. The results are in consistent with the study of Wanger et al.,²¹ where delayed induction was associated with longer hospitalization with consequent increased cost. In the randomized study of wagner et al., cesarean section rate did not differ between the groups, but women in the expectant group had significantly longer hospital stay.

Duff¹⁷ 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 Gafni²² 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.

IV. Conclusion

In this study, in the expectant management of PROM cases even after waiting for 24 Hrs, 67.8% of the patients did not deliver spontaneously and required augmentation. And the patients in the expectant group were in labor for many hours thus increasing the anxiety of both mother and clinician.

Though the cesarean section rate and operative vaginal delivery is more in the active group, there is no significant difference in both the groups in terms of maternal morbidity, neonatal morbidity and mortality. Prolonged hospitalization of mother in the expectant group and continued observation with the uncertain fetal or neonatal prognosis has a psychological impact on the mother and may impair maternal infant bonding. This study did not examine relative costs of the alternative plans of management but any immediate induction can minimize the length of hospitalization and curtail costs of medication. Finally active management may be preferred in PROM cases to reduce the hospital expenses, stay and hospital acquired infection

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