

Comparison of Fetal and Maternal Outcome in Active vs Conservative Management of Prelabor Premature Rupture Of Membranes (PPROM) at 34 to 37 Weeks of Gestation

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ABSTRACT

Background: The precise management of obstetrical crisis like preterm premature rupture of membrane is necessary to be designed for an optimum outcome.

Objective: To compare the conservative management with active management of prelabor premature rupture of membranes at 34–37 weeks of gestation.

Study Design: Randomized control trial.

Subjects & Methods: The patient's data was collected from the department of Gynecology and Obstetrics, MCH Centre, F G Polyclinic Hospital and PIMS Islamabad from 1st July 2019 to 30th March 2020. Women were divided in two groups with 90 cases in each group. Fetal and maternal both morbidity and mortality was judged on the basis of number of cases of fetal distress, chorioamnionitis and mode of delivery.

Results: Out of 180 fetuses, a total no of 140 survived. In group A mortality rate was 18.89%, 10% developed neonatal sepsis, 2.22% delivered prematurely, 3.33% had RDS. In group B mortality rate was 25.55%, 5.55% had neonatal sepsis and died, 10% developed RDS, 6.66% deaths were due to prematurity with low birth weight. In conservative management group duration of admission was higher compared to active group with p value <0.05. Duration of NICU stay was 8.88% vs. 15.55% in Active & Conservative group respectively with p-value <0.05. The rate of respiratory distress was 5.55% vs. 20% in Active & Conservative group respectively with p-value <0.05. Mortality rate was 25.5% vs. 18.89% in active & conservative management group respectively but this difference was not statistically significant with p-value >0.05.

Conclusion: Conservative management of premature preterm rupture of membranes is more appropriate choice of management than active treatment if decided earlier

Keywords: Chorioamnionitis, Fetal distress, NICU, PPRM, Prematurity.

Authors' Contribution:

^{1,2}Conception; Literature research; manuscript design and drafting; ^{2,3} Critical analysis and manuscript review; ^{1,3} Data analysis; Manuscript Editing.

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Introduction

Almost 5% of pregnancies are being complicated by preterm rupture of membranes & accounts for

almost 30% of preterm deliveries with increase in perinatal morbidity and mortality in neonatal period with resulting premature births and neonatal sepsis¹. Premature babies less than 32

weeks of gestation are at more risk of neonatal mortality & morbidity & resulting complications which includes intraventricular hemorrhage, respiratory distress syndrome, and NEC². Women having PPROM should be managed on conservative grounds till term, keeping in mind risks of intrauterine sepsis as term approaches but there are benefits to fetus by delaying delivery³. Choice between active & conservative management from 34-36 weeks of gestation age always remained controversial.⁴ Retrospective cohort study conducted by Bendix included 234 women with PPROM between 22 to 33 weeks of gestation showed that obstetrical complications before 28 weeks were 64% and decreases to 11% after 28 weeks of gestation manifesting in first 3 days in 45% patients and more than 12 days of PPROM in 25%⁵. Studies in Canada showed that lack of consensus in management from 34 - 36 weeks of gestation age and they concluded that management decision in women with PPROM must be done with detailed evaluation keeping in mind all risks and benefits along with serial reassessments in outpatient.⁶ Jean et al compared both active and conservative management in PPROM cases less than 37 weeks & included 4 studies in a systematic review and found that no difference exists between active & conservative management in terms of duration of stay in the NICU, RDS, or sepsis in neonate.⁷ Chorioamnionitis was decreased in active than in conservative group. But these studies did not compare neonatal morbidity which has emotional and financial implications for the family. One other study focused on this period but it did not prescribed antibiotics for PPROM, although these drugs may help to reduce infectious complications in mother and child.^{8,9}

Aim of our study was to compare the fetomaternal outcome between active and conservative management of PPROM at 34 to 37 weeks of gestation so that we could apply it on general population, in order to improve maternal and fetal outcomes. Rationale of our study was that in a resource poor country like Pakistan where sepsis and use of antibiotics puts financial burden over family, waiting may improve neonatal outcome. Study compared neonatal mortality in both active & conservatively managed group. Its major strength

was that it compared two practices of critical care, which avoided biases related to indications for active induction of labor or conservative management, when treatment received and the outcomes were being affected by patient characteristics. Such studies can provide more useful information to more randomized trials. Pregnancies management with conservative treatment and delaying latency period for a few days to a week by drug therapies would help the fetus to reach pulmonary maturity and the incidence of the most commonly occurring complication of fetal mortality and morbidities due to RDS can be avoided.

Methodology

It was a Randomized control trial study with simple random sampling technique conducted at Mother & Child Health Unit, PIMS Islamabad and Federal Govt Polyclinic Hospital Islamabad from 1st July 2019 to 30th March 2020. All women with PPROM at 34-37 weeks of gestation were included in study. Women with PPROM having intrauterine fetal death, preeclampsia and eclampsia, gestational diabetes (OGTT > 186 mg/dl), gestational age > 37 weeks of gestation and who developed symptoms of sepsis, having advanced labor and who developed complications of PPROM were excluded from study. Approval was taken from Ethical committee. Total of 180 patients were enrolled. Demographic data collected. Diagnosis was established on the basis of history, examination and investigations (TLC, fever). Pre-labor premature rupture of membranes was defined as rupture, or breakage, of the amniotic sac before gestational age of 37 weeks and more than one hour before the onset of labor. Prematurity was defined as birth of a baby at less than 37 weeks gestational age. Merits and demerits of the study were explained and their written informed consent was also taken from study participants. The patients were allocated in groups randomly by offering them to pick up any one of the two folded slips bearing letter "A" and "B". Group A was managed conservatively and in group B active management was planned according to the following protocols. In conservatively managed group continued clinical monitoring of mothers and fetus was done every

four hour. Fetal heart rate was monitored with cardiotocogram for at least 10 minutes. Dexamethasone therapy was given to all patients. They were advised rest and given injectable antibiotics for 24 hours followed by oral antibiotic, erythromycin 500mg 6 hourly and metronidazole orally 400 mg 8 hourly. The total leukocyte count and CRP was performed biweekly. BPP and AFI were also done twice weekly. Patients who developed chorioamnionitis or fetal distress were sent for emergency cesarean sections. Patients in whom labor started spontaneously without any complications, vaginal delivery was preferred. Patients who attained fetal maturity of 37 completed weeks were subjected to active management i.e. induction of labor. In actively managed group, the patients were informed at initial consultation that induction of labor might be associated with failure where emergency cesarean section would have to be performed. The patients were induced for start of labor at the time of presentation with intravenous oxytocin infusion or prostaglandin E2 per vaginally until patient delivered or developed any maternal or fetal complications. The infusion was set up and dose was doubled every 30 minutes and titrated against the uterine activity till 3-4 moderately severe painful contractions were observed. Continued clinical monitoring of the mother and the fetus was performed. Maternal pulse, temperature and color of liquor monitored four hourly. Monitoring of uterine contraction and fetal heart rate auscultation with the help of CTG was done every half hour during labor. The mode of delivery and any maternal or fetal complication was noted for each group. Data was entered and analyzed using SPSS version 23. Descriptive statistics were calculated as mean and standard deviation for quantitative variables like age, weight, height, BMI etc. Frequency and percentages were presented for qualitative variables like fetal APGAR score, sepsis, hospital stay. Chi square test was applied to compare fetal outcome (APGAR score >7, birth weight >2.5kg, sepsis) and maternal outcome (chorioamnionitis, fever, raised TLC count, hospital stay). The results of p-value < 0.05 were considered significant.

Results

Total of 180 women with the onset of preterm PROM at 34-37 weeks of gestation were recruited and randomly selected into Group A and B. Women in group A were treated conservatively until they reached fetal maturity and the ones in group B were treated with active management after consultation.

Demographic details in terms of maternal age, height, weight, BMI are shown in Table I.

Maternal outcomes in each group in terms of mode of delivery, PROM, Maternal sepsis, duration of hospital stay are shown in Table II with significant p value of <0.05.

Fetal outcomes in each group in terms of Fetal age, weight, Neonatal ICU stay, fetal APGAR, sepsis, mortality are shown in Table III with significant p value of <0.05.

Table I: Distribution of Maternal Parameters (N = 90 each group)

VARIABLES	MEAN ± SD CONSERVATIVE MANAGEMENT GROUP	MEAN ± SD ACTIVE MANAGEMENT GROUP
Maternal age	28 ± 4	29 ± 5
Weight (Kg)	65.6 ± 6.4	65.3 ± 6.2
Height(cm)	162.9 ± 7.5	163.2 ± 7.2
BMI	24.8 ± 3.5	26.8 ± 2.1

Table II: Comparison of Maternal Outcome between the two groups (N = 90 each group)

		CONSERVATIVE MANAGEMENT N=90	ACTIVE MANAGEMENT N=90	P- VALUE
1	MODE OF DELIVERY			
	LSCS	17	21	0.46
	SVD	73	69	
2	PPROM duration (hours): MEAN ± SD	8.4 ± 25.4	10.8 ± 16.4	0.815

3	MATERNAL SEPSIS	8 (8.8%)	3 (3.3%)	0.106
4	MATERNAL DAYS OF ADMISSIO N>5days	9	0	0.000

Table III: Comparison of fetal outcome between the two groups

		CONSERVATIVE MANAGEMENT	ACTIVE MANAGEMENT	P-VALUE
1	FETAL AGE (WEEKS) :MEAN ± SD	35.20 ±0.73	35.38 ± 0.80	0.135
2	FETAL WEIGHT (Kg) :MEAN ± SD	2.36 ± 0.46	2.41 ± 0.57	0.534
3	NICU STAY	8	14	0.04
4	Fetal APGAR score > 7 5-7 <5	76 12 2	72 14 4	0.623
5	RESPIRATORY DISTRESS	5	18	0.03
6	NEONATAL SEPSIS	21(23.3%)	13(14.4%)	0.091
7	NEONATAL MORTALITY	17	23	0.185

Discussion

In our study prolonged NICU stay of babies was observed in group with active management & these results were related to interventions requiring both clinician experience & judgment. Prolonged period from PPROM to delivery put neonates at risk of infection. Neonatal critical care was same in 3 centers but NICU stay, which also depended on subjective medical perceptions, varied between three centers. PPROM occurring at 34-36 gestation

is associated with increased neonatal morbidity & mortality when compared with term gestation with OR: 3.1, 95% & CI: 1.56–6.31¹⁰ and these findings are consistent with our study findings which showed prematurity led to increase in mortality and morbidity.

In our study, the cesarean section rate was 15.3% & 18.9% in conservative & active group respectively. Study conducted by Gouda AP et al showed similar findings with increase in cesarean rate in active group compared to conservative group. Study conducted by Sumaira et al showed cesarean rate of 12% & 22% in conservative & active group respectively with more cesarean rate in active group and all these are in consistent with our study findings.^{11, 12} Regarding maternal outcome, we found in that 11(6.1%) cases of women with preterm premature rupture of membrane developed septicemia with 8.8 % & 3.3% in conservative vs active group respectively with more incidence in Conservative group . These findings are consistent with results of studies carried out by Dar S et al & Van Der et al & both found similar incidence of sepsis in women with PPROM with more incidence in conservative group.^{13, 14}

Regarding fetal outcomes, our study found that the neonatal birth weight of 2.36±0.46 kg & 2.41 ± 0.57 kg in conservative and actively management group respectively. Gouda et al in their study showed similar findings of neonatal birth weight.¹⁴Fetal distress, another fetal outcome in our study was found in 4.5% & 16% in conservative vs active group respectively and these findings are consistent with study conducted by Gouda et al which showed that increase rate of fetal distress with need of surfactant was higher in the actively managed group.¹¹Neonatal APGAR score, in our study, taken at 5 minutes revealed that in conservative management group 76 neonates had score >7 and 14 had ≤7 while in active management group 72 neonates had >7 score and 18 had ≤7 which are almost consistent with findings of study carried by Shafqat et al.^{14, 15}.Regarding admission in NICU, the results of our study revealed that a total of 49(55%) neonates from conservative management group and 46(51%) from active management group were admitted in NICU. This is contrary to results of other studies which showed a much less number of neonates who were admitted in NICU and it's

because more premature babies were included in our study.¹⁶

Our study results showed that length of NICU stay significantly decreased in conservative group when compared to actively managed group. Similar findings were observed by Gouda et al¹¹ and Meryem Kurek et al¹⁷ and they observed that the length of NICU stay was more for smaller birth weight babies, similarly the duration of NICU stay was more in actively managed group which had smaller babies. The PPROM trial documented that pre term babies stayed for longer duration in NICU in active group & conservative group respectively with $p < 0.0001$.¹⁸

In our study neonatal sepsis was found in 23.3% and 14.4% in conservative and active management group respectively. Study conducted by Laila E et showed that neonatal sepsis was 18% and 10% in conservative and actively managed group respectively with more incidence in conservative group and these findings are consistent with our study findings.¹ But Laila E found 6% mortality rate in both groups which was less than our study which showed mortality rate of 15% & 20% in active & conservative group respectively and it is because more premature babies were included in our study.¹ Dars s et al reported in their study that incidence of neonatal sepsis increases and prematurity accompanies prolonged rupture of membrane which are consistent with our findings.¹³ Our study observed fetal morbidity after PPROM is a consequence of maternal intrauterine infection, placental abruption, umbilical cord compression as well as prolonged fetal compression. There is a chance of development of infections and other complications if pregnancy is prolonged but if the mother shows no signs of positive cultures in the vaginal fluid, the advantage of managing the PROM remote from term outweighs the risks associated with it. These observations were also made by others that monitoring the fetus round the clock for the complications like infections, placental abruption, umbilical cord compression resulting in fetal compromise, or an early onset of labor is required. This is because of the observation that in many cases labor commences soon after the initial rupture of the amniotic membrane.^{18, 19}

In case of delivering the fetus too soon and managing the preterm PROM via active means, will

lead to fetal complications accompanying with the fetus being premature and underdeveloped. RDS or respiratory distress syndrome is one of the leading causes of postpartum neonatal complications and morbidities that can lead to neonatal mortalities if there is known pulmonary immaturity. Pulmonary immaturity can be easily tested via fluid collected in the vagina after amniotic membrane rupture. On the other hand, active management is helpful in maintaining the fetus and the mother when there is a known history of infection, amnionitis or chorioamnionitis in the mother. The test cultures from the vaginal walls and surrounding tissue are observed for group B streptococcus and if turned out positive, the mother is soon put under antibiotic regimen that helps in combating the infection and preventing vertical transfer to the infant.

Conservative management results in a longer stay of the mother in the hospital that might cause additional issues for the family. Also a complete bed rest for the mother for days on end may be a health concern for the mother herself that might complicate things further. Moreover the chances of the mother as well as the fetus contacting infections increases that makes the rate of morbidity and mortality even higher. There has been an increasing trend shifting towards the active management due to the complications that the conservative management brings with it. Many are of the view to not prolong the latency and the pregnancy further once the uterine contractions start after the amniotic membrane ruptures remote to term. Conservative does bring a number of complications with it but there is an increased chance that the fetus delivered prematurely might not be able to survive due to the neonatal morbidities and the complications that come with them.

With conservative management, the risks of infection in the placenta increases, as well as that of chorioamnionitis for which it is advised to opt for the active management and deliver the infant soon after the contractions start or even with the artificial induction of the uterine contractions. However, if there is no sign of active infection in the mother, conservative management is usually a better option if the fetal tests for pulmonary maturity come out as negative. In case of fetal

immaturity, the risks of RDS and other complications rises exponentially if active management is done to deliver the infant. They lead to neonatal morbidities and hence the death of the infant. For the periods of gestation from 34 to 37 weeks, the fetus usually has achieved pulmonary maturity and is able to avoid the complications that can arise due to RDS. Prolonging the latency is not advised if there is no longer the need for fetus to develop any further. Doing so will only put the fetus under a higher risk of infection. Therefore, literature suggests that in case where the fetal maturity is reached, active management should be commenced to avoid unnecessary complications. Choice between active & conservative management in this duration remains controversial & no study provides a conclusive answer. Owing to increased incidence of lung problems seen at 34 weeks of gestation in our study, our opinion is that active management should be delayed at least until 35 weeks of gestation.

The small number of cases, the comparison of results in three different centers were the main limitations of our study.

Conclusion

Conservative management of premature preterm rupture of membranes is more appropriate choice of management than active management in terms of better maternal and fetal outcomes, if decided earlier.

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