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Comparison of conservative & aggressive management of PPROM at 34-36 weeks gestation in terms of development of neonatal sepsis & RDS

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Abstract
Objective: To compare the conservative and aggressive management of Preterm prelabor rupture of membranes (PPROM) at 34-36 weeks gestation in terms of development of neonatal sepsis and respiratory distress syndrome (RDS).

Method: 194 pregnant women with PPROM at gestational age 34-36 weeks admitted in labour ward were included in the study conducted from 2009-2010 in department of Obstetrics & Gynaecology, SMS Medical College, India. Random allocation to conservative & aggressive management group was done by offering Chit Box Method assigning 97 cases in each group. In conservative management cases were hospitalised & provided bed rest, Daily fetal monitoring, Maternal vitals monitoring, Oral tab erythromycin 500 mg T.D.S for 7 days, Daily WBC count and c-reactive protein estimation. Expectant management was abandoned if there was clinical evidence of labour, infection or fetal distress. In aggressive management induction of labour was done by Tab Misoprostol 25 μg orally, at 4-6 hour intervals, for a maximum of 5 doses. Caesarean delivery was performed for standard obstetrical indication and for failed induction. After delivery neonatal care was provided by neonatologist.

Results: Out of 97 cases in aggressive management group 4 (4.12%) newborn babies suffered from neonatal sepsis and out of 97 newborn babies in conservative management group 14 (14.43%) babies had neonatal sepsis. Out of 97 cases in aggressive management group 15 (15.46%) newborn suffered from RDS and out of 97 cases in conservative management group 12 (12.34%) newborn suffered from RDS.

Conclusion: Rate of neonatal sepsis was higher in conservative management group than aggressive management group. Thus there was significant association observed for neonatal sepsis in between aggressive management and conservative management group. The rate of RDS was lower in conservative management group as compared to aggressive management group. But there is no significant association were observed between RDS in both conservative and aggressive management group.

Keywords: PPROM, conservative, aggressive, neonatal sepsis, Respiratory distress syndrome

1. Introduction
Preterm prelabor rupture of fetal membranes (PPROM) is defined as rupture of fetal membranes prior to the onset of labour at less than 37 weeks of gestation. The fetal membranes serve as a barrier to ascending infection. Once the membranes rupture, both the mother and fetus are at risk of infection and of other complications. Most women with PPROM go into spontaneous labour within 24 hours of rupturing their membranes, but 6% of women will not be in spontaneous labour within 96 hours. However earlier in gestation the rupture occurs, the less likely that the onset of labour will be within a specified time period. PPROM occurs in 2 to 3% of all pregnancies and proceeds 1/3 of preterm births and 18 to 20% of perinatal deaths. PPROM is largely a clinical diagnosis characterised by a history of watery vaginal discharge. Prolonged rupture of membrane (PROM) is an important risk factor for early onset neonatal sepsis and RDS, which is associated with increased neonatal morbidity and mortality.

Conservative versus aggressive management of PPROM is amongst the most controversial issue and still remains a major dilemma to the obstetricians. Present study is intended to compare the conservative and aggressive management of PPROM at 34-36 weeks gestation in terms of development of neonatal sepsis and respiratory distress syndrome (RDS).
2. Material and methods

This prospective randomized clinical trial study was conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur during the year 2009-2010. 194 pregnant women with PPROM at gestational age 34-36 weeks admitted in labour ward were recruited in the present study. Written informed consent by each subject was sought before the study. Random allocation to both the management groups was done by offering Chit Box Method to eligible patients assigning 97 cases to each group. Inclusion Criteria were pregnant women with PPROM at 34-36 weeks of gestation. Exclusion Criteria were cases requiring delivery viz. labour, infection, fetal distress, lethal fetal anomalies / fetal demise, Maternal medical disorders, Non-vertex presentation, Antepartum haemorrhage, absolute indication for caesarean section.

PPROM was confirmed by sterile speculum examination, single digital examination, USG for AFI. Eligible women were assigned to either the conservative management or aggressive management group.

1. Group A (Conservative Management) - 97 cases
2. Group B (Aggressive Management) - 97 cases

Women of both groups were subjected to general physical examination, per abdomen examination Per speculum / Pervaginal examination, sterile single digital examination to exclude occult cord prolapse and to assess cervical score.

Conservative management was consist of Hospitalised bed rest, Daily Foetal Movement count, Intermittent FHS auscultation, NST, Maternal vitals monitoring every 8 hourly, Digital vaginal examination – Prohibited, Oral antibiotics - Tab Erythromycin 500 mg TDS for 7 days, Daily leucocyte count and CRP estimation. Expectant management was abandoned if there is clinical evidence of labour, infection or fetal distress.

In aggressive management group induction of labour was done by Tab Misoprostol 25 µg orally, at 4-6 hour intervals, for a maximum of 5 doses. (ACOG Recommendation) or caesarean delivery was performed for standard obstetrical indication and for failed induction.

After Delivery neonatal care was provided by neonatologist. Neonatal outcome variables of interest e.g. RDS, neonatal sepsis and other neonatal complications were noted.

2.1 Statistical methods

All the data was entered in Excel Sheet and the data was analysed statistically using XL Stat and Statcal Software. Quantitative data was summarized in the form of Mean ± SD and the difference in mean value of both the groups were analysed using Student’s ‘t’ test. Qualitative data was summarized in the form of proportions and difference in proportion was analysed using Chi Square test. All the statistical analysis was done at 95% confidence level and 80% power.

3. Results

Out of total 97 cases in aggressive management group 4 (4.12%) newborn babies suffered from neonatal sepsis and out of total 97 newborn babies in conservative management group 14 (14.43%) babies had neonatal sepsis. Rate of neonatal sepsis were higher in conservative management group than aggressive management group. Thus there was significant association observed for neonatal sepsis in between aggressive management and conservative management group as shown in Table-1 and figure-1.

Out of total 97 cases in aggressive management group 15 (15.46%) newborn suffered from RDS and out of total 97 cases in conservative management group 12 (12.34%) newborn suffered from RDS. The rate of RDS was higher in aggressive management group as compare to conservative management group. But there is no significant association were observed between RDS in both conservative and aggressive management group as shown in Table-1 and figure-1.

Table 1: Distribution of cases according to complication in neonates in aggressive & conservative management group

<table>
<thead>
<tr>
<th>Neonatal Complications</th>
<th>Aggressive Management</th>
<th>Conservative Management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Cases (%)</td>
<td>No. of Cases (%)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>4 (4.12)</td>
<td>14 (14.43)</td>
</tr>
<tr>
<td>RDS</td>
<td>15 (15.46)</td>
<td>12 (12.34)</td>
</tr>
</tbody>
</table>

$\chi^2$(Sepsis) = 4.960

$\chi^2$(RDS) = 0.387

Figure 1: Distribution of cases according to complication in neonates in aggressive & conservative management group
4. Discussion

The present study showed that chances of neonatal sepsis are higher in cases of conservative management of PPROM while there is no significant increase in chances of RDS with conservative management which is similar to the findings of B M Mercer et.al [1] which showed immediate induction of labour reduces the duration of hospitalization and infection in both mothers and neonates.

This is in accordance to the study of Buchanan et al [2] study which shows that in pregnancies complicated by PPROM between 34 and 37 week of gestation, Induction of labour does not substantially reduce the incidence of neonatal sepsis compared to expectant treatment. The number of neonates with respiratory distress was comparable in induction as well as expectant management.

This is also in concordance to the study of Khashoggi et al [3] which shows increased maternal and neonatal infection rates with prolonged latency of labour.

This is contrary to the study of Hájek et al [5] which showed that acute management increases the number of operative deliveries and respiratory distress syndrome (RDS) in the infants.

5. Conclusion

Rate of neonatal sepsis were more in conservative management than aggressive management group and results were statistically significant. Whereas rate of development of RDS were lower in conservative management group but results were not statistically significant.

Thus to prevent neonatal sepsis induction of labour should be preferred over caesarean section in cases of PPROM.

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