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Different Treatment Modalities And Perinatal Outcome In Prelabor Rupture Of Membranes In A Tertiary Care Center – A Comparative Study.

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Abstract:
The etiology of prelabor rupture of membranes (PROM) is unknown in majority of cases though bacterial infection, cervical incompetence, hypertensive disease, recent coitus, malpresentation, antepartum hemorrhage (APH), malnutrition are recognized causes of PROM. A study was conducted in our institution Bankura Sammilani Medical College and Hospital, Bankura, West Bengal, India for six months during April to September in 2018, where 478 cases presented with PROM. Spontaneous rupture of membranes after 28 weeks of gestation before the onset of labor is called PROM. When it occurs before 37 completed weeks of gestation it is called preterm PROM (pPROM). The term PROM cases were induced after waiting for 24 hours for a spontaneous onset of labor. The preterm population were divided in ***three groups*** *and were given treatment as;* ***Group A****: with beta-mimetic, antibiotic, steroid, iron and folic acid (IFA);* ***Group B****: With steroid, antibiotic, natural progesterone and IFA;* ***Group C****: With only steroid, antibiotic and IFA. Observed neonatal mortality in the very preterm group (<34 weeks) was 10% as compared to 5.8% in preterm (34-37 weeks) and nearly 3% among term pregnancies. Treatment of pPROM cases with steroid and antibiotic compared with addition of natural progesterone with or without beta-mimetic did not show any significant difference in terms of Apgar score, need for resuscitation in absence of maternal infection. Elective lower segment cesarean section (LSCS) showed a zero neonatal mortality, better Apgar score and significantly lesser requirement of neonatal resuscitation compared to emergency LSCS. It was concluded that gestational age at the time of delivery is the main determinant of neonatal birth weight as well as survival among PROM cases. Beta-mimetics and progesterone showed no role to prolong pregnancy in PROM cases.*

Keywords: *PROM, pPROM, Apgar score, neonatal resuscitation, neonatal mortality.*

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I. Introduction

Prelabor rupture of membranes (PROM) is defined as spontaneous rupture of membranes any time beyond 28th week of pregnancy but before the onset of labor**(1).** Preterm prelabor rupture of membranes (pPROM) is defined as spontaneous rupture of membranes during the period from viability to 37 completed weeks prior to the onset of labor**(2).** PROM complicates 5-10% of all pregnancies. At least 60% cases of PROM occurs at term**(3).**

PROM is one of the important causes of preterm labor and prematurity. Chance of ascending infection in PROM is more if labors fails to start within 24 hours**(1).** Chorioamnionitis, cord prolapse, dry labor and neonatal respiratory distress syndrome (RDS) are the complications of PROM. Fetal pulmonary hypoplasia, especially in preterm PROM is a real threat when associated with oligohydramnios**(1).**

The current study was conducted to investigate the efficacy of three different management protocols in cases with pPROM and to know the perinatal outcome in PROM.

II. Review of Literature

Review of available literature shows that rupture of membranes is related not only to bacterial infection but also to cervical incompetence, hypertensive disease, recent coitus, malpresentation, antepartum hemorrhage (APH) and inappropriate nutrition. PROM is also found more commonly in low socioeconomic class with inadequate prenatal care and inadequate weight gain during pregnancy**(4).**

The etiology of pPROM is uncertain though probably multifactorial. The final common pathway usually involves a subclinical chorioamnionitis, which is facilitated via cervical changes leading to a loss of integrity of the canal or particular organisms being present in the vagina allowing overgrowth of unwanted organisms. The effect is a cascade of biochemical changes in the fetal membranes and decidua which ultimately lead to prostaglandin and cytokine release and up regulation of intracellular messengers. In turn these changes lead to cervical ripening and membrane disruption. Increased uterine activity is often not far behind**(3).**

The history of leaking fluid or gushing of water from vagina is diagnostic in over 90% cases. Different tests like nitrazine test, fern test, evaporation and diamine oxidase tests are done to confirm PROM. Now-a-days, ultrasound examination is also a popular method of diagnosis of PROM**(4).** On examination, the fetal presentation needs to be assessed as there is high chance it may not be cephalic. A sterile speculum examination should be performed and high vaginal swab (HVS) to be taken. Per vagina (PV) examination should be avoided. Liquor is usually clear and colorless, though it may be pink. White cell count and C-reactive protein (CRP) have been investigated as possible better predictors of evolving chorioamnionitis but are not reliable**(3).**

The microorganisms most commonly identified in the membranes and amniotic fluid of pregnancies complicated with spontaneous preterm labor with intact membranes are *Ureaplasma urealyticum*, M*ycoplasma hominis, Gardnerella vaginalis*, Mobiluncus, and bacteroides. The microorganisms most commonly associated with clinical chorioamnionitis and fetal infection after rupture membrane are Group B-streptococci (GBS) and *Escherichia coli*. However, the association between preterm labor and lower genital tract colonization with these organisms is less clear. Upto 30% of pregnant women are colonized with GBS. GBS is the leading cause of neonatal sepsis and a substantial number of neonatal sepsis occurs among preterm infants**(5).**

Birth asphyxia is the most common neonatal morbidity seen among PROM and reaches upto 40% followed by RDS seen nearly among 28% cases. The incidence of neonatal morbidity increases as duration of PROM increases. Apart from infection (pneumonia, meningitis, sepsis), pulmonary hypoplasia, limb and body deformities, umbilical cord compression or prolapse and abruptio placentae are occasional complications of PROM**(4).**

The optimum management of PROM would be that, which minimizes the risk of both RDS and maternal and perinatal infection. The Cochrane review of over 6,000 randomized women shows that there is no difference in neonatal outcome from immediate induction of labor or waiting upto four days.

There is no evidence that routine use of antibiotics improve neonatal outcome in absence of an indication for GBS prophylaxis**(3).** Random treatment of pregnant women of third trimester with oral erythromycin or placebo continuously for 10 weeks to treat GBS colonization, chlamydia and *U. urealyticum* resulted in no significant improvement of preterm delivery in pPROM. Majority of randomized control trials with antibiotic treatment of lower genital tract infections in cases of bacterial vaginosis (BV) have failed to show any significant benefit in terms of preterm labor and neonatal birth weight. However, there is significant heterogeneity between studies. The Center for Disease Control (CDC) in USA notes in its guideline that evaluation of BV be conducted at the first prenatal visit for asymptomatic woman who are at risk of preterm labor. But current evidence does not support routine testing for BV**(5).** The practice in our center is to treat an woman with PROM with antibiotics e.g. amoxycillin, which aims at preventing neonatal sepsis and maternal postnatal morbidity.

The use of progesterone administration to improve pregnancy outcome in threatened preterm labor dates back to as early as 1950s. The results of these early trials were summarized in two meta-analyses published in 1989 and 1990. One of these meta-analyses found positive efficacy of progesterone in reducing preterm delivery; whereas, the other did not find any. Erny et al in 1986 used 400 mg of micronized progesterone orally or a placebo in their patients with 30-36 weeks of gestation who were at risk of preterm labor. After one hour all their patients received intravenous ritodrine for tocolysis. The frequency of uterine contractions decreased in 76% of the progesterone group and 43% of the placebo group. Although progesterone treatment to prevent preterm delivery is not considered standard of care now-a-days, many clinicians may, in their wisdom decide to use this drug for these specific groups of women**(5).**

Although it is generally accepted that antenatal glucocorticoids reduce RDS in preterm pregnancies with intact membranes, their use in pregnancies with PROM has been studied in limited number of prospective trials with conflicting results**(6,7).**

In absence of fetal and maternal compromise, where the presentation is cephalic, vaginal delivery is usually indicated. Where the presentation is breech there is no evidence to suggest that cesarean section improves neonatal outcome. Generalization is difficult and decision needs to be individualized. Generally, outcome is related to the period of gestation, birth weight and fetal sex as with all preterm births. In pPROM particularly, fetal/neonatal sepsis will result in worse outcome**(3).**

III. Aims and Objectives

The objectives of the study were

- To observe the perinatal outcome in pPROM treated with
- Isoxsuprine + antibiotic + steroid + iron and folic acid (IFA)
- Natural progesterone + antibiotic + steroid +IFA
- Only antibiotic + steroid+ IFA
- To note the perinatal outcome in different modes of delivery in PROM cases, e.g.
- Elective lower segment cesarean section (LSCS)
- Emergency LSCS after a failed induction of labor after six hours
- Vaginal delivery.

IV. Material and Methods

The study was conducted at Bankura Sammilani Medical College and Hospital, Bankura which is a tertiary care center in a district town in West Bengal, India. The duration of the study was six months during April to September,2018. All the patients presented with PROM to the Dept. of Obstetrics and Gynecology, during that period were admitted. Then considering the previously set criteria mothers suitable for the study were included in the study population. The exclusion criteria were

- Patient in labor
- Pregnancy-induced hypertension (PIH)
- Multiple pregnancy
- Patients already suffering from fever
- Intrauterine fetal death
- Diagnosed cases of placenta previa and accidental hemorrhage
- Fetal congenital anomaly

As per the said design we got 478 pregnant mothers complicated with PROM. All the participant mothers gave informed consents. Detailed history was taken from every case and period of gestation was noted. On clinical examination, we noticed maternal height, weight, pulse, blood pressure, temperature and condition of heart, lung, liver and spleen. We also noticed fetal heart rate and whether patient was in labor or not by per abdominal and per vaginal examination. Internal examination was done by a consultant or a senior resident to exclude any cord prolapse. A high vaginal swab was taken for bacteriological examination. Hematological investigations were done for Hb%, TC, DC, ESR, Platelet, ABO and Rh-typing. Blood sugar estimation and VDRL, HIVI & II testing were also done. Routine and microscopic urine examinations were also performed. Anaerobic culture specific for GBS is not a routine practice in our institution. Hence special arrangements to do the same failed due to official delay in face of a short notice and also prohibitive cost of the detection kit. Ultrasonography was prescribed in every case to determine feto-placental profile and liquor volume.

Regarding treatment, we waited for 24 hours for spontaneous onset of labor in term PROM cases (e.g. 37 weeks of gestation). But in preterm cases (pPROM) we divided the study population in **three groups for three different management protocols** as namely

- **Group A:** Isoxsuprine (10 mg TDS) + antibiotic (cap amoxycillin 500 mg TDS) + betamethasone (12mg IM 12 hourly two such for 24 hours) + IFA.
- **Group B:** Natural progesterone (200 mg orally at bed time) + betamethasone (12 mg IM 12 hourly two such for 24 hours) + antibiotic (amoxycillin 500 mg cap TDS) + IFA.
- **Group C:** Only betamethasone (12 mg IM 12 hourly two such for 24 hours)+ antibiotic (amoxycillin 500 mg cap TDS) + IFA.

  But most of the consultants working here disagreed to prescribe isoxsuprine and natural progesterone and preferred only antibiotic and steroid.

We followed up the cases till the onset of labor or termination by induction and subsequent events. The different modes of delivery i.e., spontaneous vaginal delivery, vaginal delivery following induction of labor and LSCS were noted in each case. Birth weight of the babies and Apgar score were recorded. Birth weight < 2 kg and/or Apgar score <7 babies were sent to sick neonatal care unit (SNCU) attached to the same building. Any resuscitation measure undertaken on the neonate was recorded. We followed the mothers and their babies for two days following vaginal delivery and for seven days following cesarean section. Categorical data was described as frequency and percentage.

V. Results and Analysis

During our study, 478 mothers were included as they fulfilled the inclusion criteria.30 mothers were in between 28-34 weeks; 34 mothers were in between 34-37 weeks and finally 414 mothers presented beyond 37 completed weeks. The neonates born to first group mothers had birth weight ranging from 0.7 to 2.6 kg. The second group of mothers had the neonates ranging from 2.2 kg to 3.1 kg and finally the third group had their neonatal birth weight ranging in between 2.75 kg to 3.3 kg. Neonatal resuscitation was necessary in 27 cases in 1st group; 21 cases in 2nd group and 49 cases in 3rd group. There was three neonatal deaths in 1st group; 2 neonatal deaths occurred in 2nd group and 13 deaths occurred in 3rd group**(Table1, Fig1).**

Table 1: Perinatal Outcome of Different Gestational Periods

Gestational Age	28-34weeks(n=30)	34-37weeks(n=34)	>37weeks(n=414)
Birth weight (kg)	0.7-2.6	2.2-3.1	2.75- 3.3
Resuscitation required	27(90%)	21(61.7%)	49(11.8%)
Neonatal mortality	3(10%)	2(5.8%)	13(3.14%)

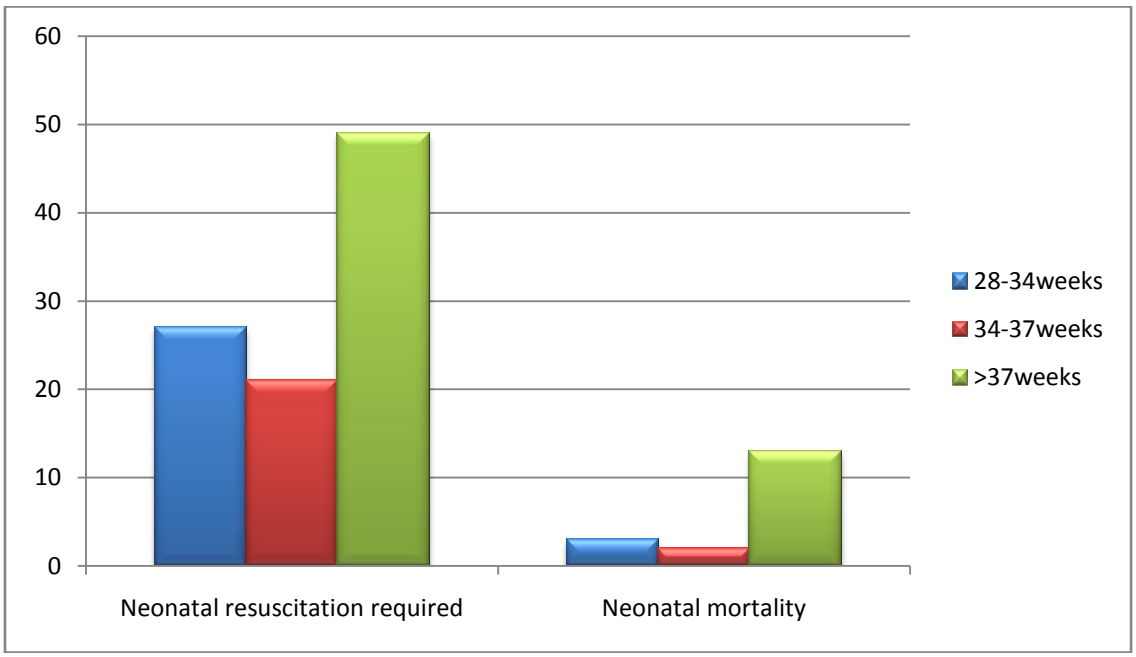

Figure 1: showing perinatal Outcome of Different Gestational Periods

(Table 2, Fig 2) shows the perinatal outcomes among the 64 mothers who had pPROM and received treatment according to previously set protocol, e.g.

- **Group A:** Treated with isoxsuprine + antibiotic+ steroid + IFA
- **Group B:** Treated with natural progesterone + antibiotic + steroid + IFA
- **Group C:** Treated with only antibiotic+ steroid+ IFA

Group A consisted of 10 cases; their neonatal birth weight varied in between 1.5-2.6 kg. Apgar score varied in between 4-7. Baby resuscitation was necessary in nine cases with bag mask ventilation (BMV) and oxygen inhalation. There were two neonatal deaths. **Group B** consisted of 14 cases with pPROM; their baby weights were in between 2.3-3 kg; Apgar score in between 4-8 and four babies required resuscitation in the form of BMV and oxygen and there was no perinatal mortality. **Group C** consisted of 40 cases, where the birth weights were in between 0.7-3.1 kg; Apgar scores between 2-9; baby resuscitation was necessary in 28 cases and there were nine neonatal deaths.

Table 2. Perinatal Outcomes Among Mothers Who Received Treatment For pPROM

Treatment Protocol Groups	GroupA	GroupB	GroupC
No. of cases	10	14	40
Birth weight (kg)	1.5-2.6	2.3-3.0	0.7-3.1
Apgar score	4-7	4-8	2-9
Resuscitation required	9	4	28
Neonatal mortality	2(20%)	-	9(22.5%)

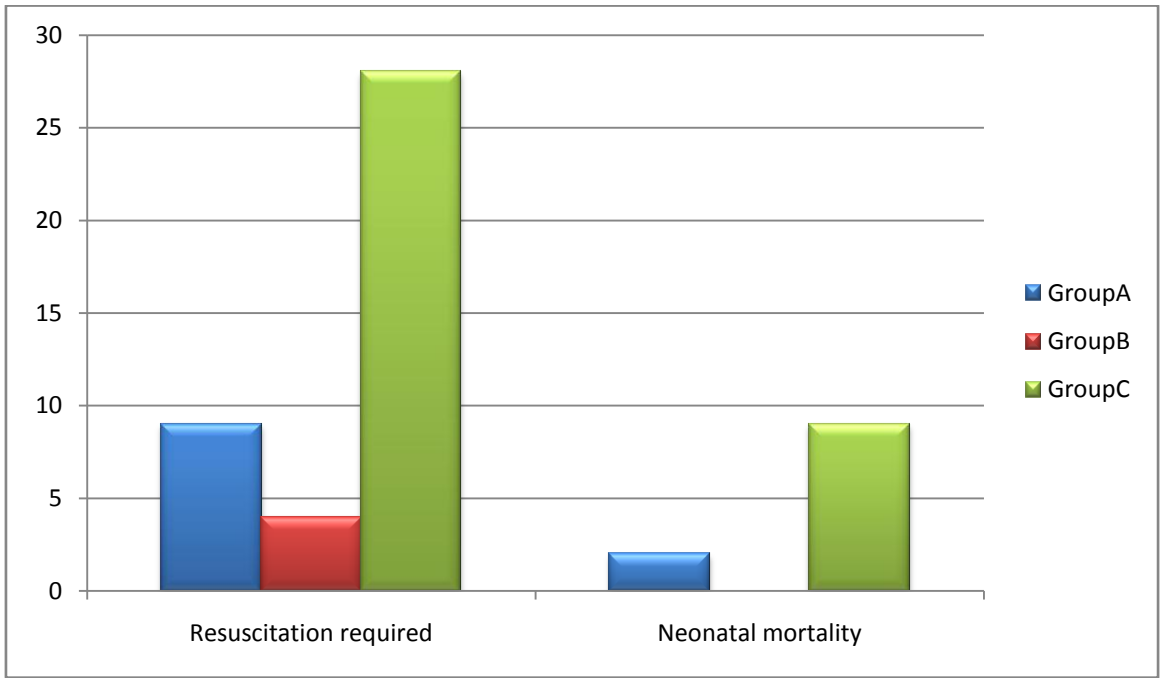

Fig 2 : showing perinatal Outcomes Among Mothers Who Received Treatment For pPROM

Total number of vaginal delivery performed were 351 among 478 study cases (73.4%) and rest (i.e., 127 among 478 cases) had been delivered by LSCS. Among these 127 cases, 46 mothers had been operated electively (36.22%) and rest 81 mothers had undergone emergency LSCS. The electively operated mothers had their neonatal birth weight ranging between 1.75-3.1 kg, Apgar scores varied between 4-7 and 13 neonates in this group required resuscitation in the form of BMV and/or oxygen inhalation. There was no neonatal mortality. In emergency LSCS cases, neonatal birth weight varied in between 1.2-3.0 kg, Apgar scores varied in between 2-7 and 32 neonates required resuscitation measures. There were eight neonatal deaths in this group. On the other hand, the 351 mothers who delivered vaginally had their babies with birth weight ranging in between 0.7-3.3 kg, Apgar scores in between 2-10 and 48 newborns among them required neonatal resuscitation. Twenty neonatal death were recorded in this group**(Table3, Fig3)**

Table 3: perinatal outcome in different modes of delivery

Perinatal Outcome in different modes of Delivery	Elective Cesarean Section (n = 46)	Emergency Cesarean Section (n = 81)	Vaginal Delivery (n = 351)
Birth weight (kg)	**1.75-3.1**	**1.2-3.0**	**0.7-3.3**
Apgar score	**4-7**	**2-7**	**2-10**
Resuscitation required	**13(28.3%)**	**32(39.5%)**	**48(13.6%)**
Neonatal mortality	**-**	**8(9.8%)**	**20(5.71%)**

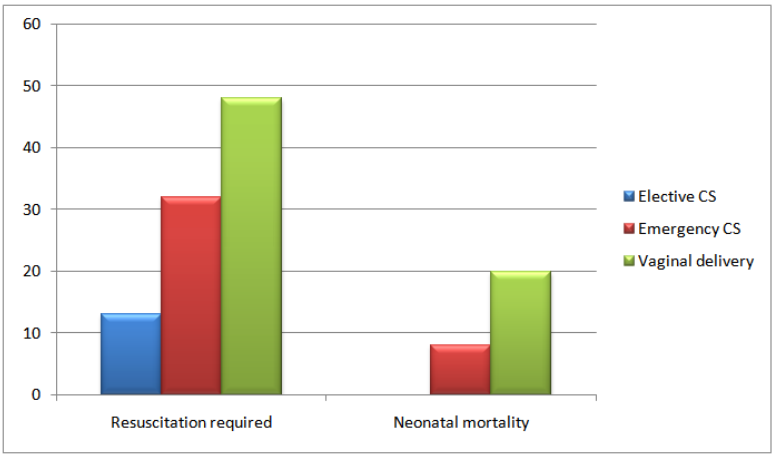

Fig 3: showing perinatal outcome in different modes of delivery

VI. Observations and Discussion:

Table 1 shows the distribution of neonatal body weights at different gestational ages. The number of cases under the term PROM (414) was considerably larger than the other two groups e.g. preterm (34-37 weeks-34 cases) and very preterm (<34 weeks - 30 cases only). It is also obvious that gestational ages at delivery has shown the main impact on neonatal birth weight, neonatal mortality and need for neonatal resuscitation.

Observed neonatal mortality of 10% in the very preterm group against 5.8% in preterm and nearly 3% among term pregnancies when compared in pairs did not show any significance but there was much higher incidence of neonatal resuscitation among preterm neonates against their term counterparts - 90% in very preterm, 62% in preterm and only 11.8% among term neonates. One reason for this might be nonavailability of electronic fetal monitoring (EFM) in all cases, which could have indicated the optimum timing for a caesarean section. Morales et al in their study, observed neonatal mortality of 5%-12% among preterm rupture of membrane below 34 weeks**(7).**

Table 2 shows that addition of isoxsuprine with steroid and antibiotic **(Group A)** or natural progesterone with steroid and antibiotic **(Group B)** did not show any significant benefit in terms of Apgar score, need for neonatal resuscitation. There was no incidence of neonatal mortality in the natural progesterone group, which was obviously due to higher birth weights (2.3-3.0 kg) as compared to other two groups-the finding that reinforces our claim that it is the birth weight in absence of maternal infection that is the major determinant of neonatal survival. Paul J Meis and Ngina Connors in their review "Progesterone Treatment to Prevent Preterm Birth" have concluded that all the successful trials reported have indicated Progesterone therapy relatively early in gestation (at <24 weeks) in women who showed no symptoms of preterm labor. Trials of progesterone compounds to aid in halting the progression of labor have not been successful and the use of progesterone in women who have had symptoms or signs of labor should be discouraged**(5).**

Table 3 indicates that planned elective LSCS showed a zero neonatal mortality, better Apgar score and significantly lesser requirement of neonatal resuscitation compared to emergency LSCS (28.3% against 39.5%). Hassan et al in their study at Lahore found nearly 30% neonatal intensive care admission after emergency LSCS and nearly 13% after elective LSCS**(8).** Compared to this a mild but significant higher resuscitation rate in our study may allude to greater degree of prematurity and lack of universal EFM.

VII. Conclusion

The study clearly indicates that gestational age at the time of delivery is the main determinant of neonatal birth weight as well as survival among PROM cases. Having said that obstetrician should consider elective LSCS in appropriate cases to avoid unnecessary emergencies to save a valuable child. Thanks to NICU support and antibiotic prophylaxis. Beta-mimetics and progesterone have no role to prolong pregnancy in PROM cases. Continuous EFM can help to decide an optimum timing of LSCS terminating a trial of vaginal delivery.

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