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ORIGINAL ARTICLE

Different Management Strategies for Term Newborns Delivered with Premature rupture of membranes: Randomized Controlled Trial

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ABSTRACT

Background: Premature rupture of membranes (PROM) is a leading cause of neonatal morbidity and mortality.
Aim: To compare the outcomes of prophylactic versus selective antibiotics in term newborns born after PROM > 18 hours in terms of neonatal sepsis and resistance of neonatal.
Study design: Randomized controlled trial.
Methodology: This study enrolled (n=120) asymptomatic term (37^+ weeks) babies of either gender with PROM > 18 hours after ethical review committee's (ERC) approval. This study held at DHQ Hospital, Rawalpindi-Pakistan in 2019. Data was collected through a structured proforma with informed consent. Data was analyzed by SPSS, v-20. The study outcomes were neonatal sepsis and resistant neonatal flora. Chi-square test was applied with $p \leq 0.05$ taken as significant.
Results: The neonatal sepsis was diagnosed in 8 (13.3%) and 9(15%) babies in the prophylactic treatment group and the selective treatment group, respectively having statistically insignificant difference ($p>0.05$). Likewise, resistant neonatal flora between both groups showed statistically insignificant difference ($p>0.05$).
Conclusion: We concluded that there was insignificant difference in terms of rates of neonatal sepsis and resistant neonatal flora between two treatment groups. However, there is a need to conduct large sample size, multicentre studies to validate these results before making recommendations for routine treatment of full term babies with PROM >18 hours in our clinical settings.
Keywords: Neonates, Premature Rupture Of Membranes, Full Term, Neonatal Sepsis and Resistant Neonatal Flora.

INTRODUCTION

Premature rupture of membranes (PROM) is a leading cause of neonatal morbidity and mortality. PROM by definition occurs before the onset of labour[1]. When it lasts more than 18 hours before labour, it is defined as prolong rupture of membranes. PROM is associated with high rate (29%) of intrauterine infection or neonatal sepsis as revealed by many previous studies[2,3].

The incidence of PROM was high (19.53%) affecting various aspects of the neonatal health[4]. According to one survey, it was estimated that around 8% cases with PROM occur at term.[5] Various fetal and neonatal complications following PROM include prematurity, sepsis and respiratory distress syndrome (RDS) as major disorders[3]. This can lead to peri-natal death or death before discharge from hospital with longer ICU stays and different neonatal infection like pneumonia and necrotising enterocolitis requiring oxygen treatment greater than 36 weeks. Vertical transmission from mother to the fetus during perinatal period is usually observed for early onset infective patterns[6]. Thus, PROM is one of the main maternal condition and an important neonatal risk factor.

The management of the neonates born after PROM is intervention with appropriate antibiotics, however, it is controversial. A Cochrane Review revealed that there is insufficient data from RCTs to guide practice regarding use of antibiotics following PROM[7]. One study reported that clinical sepsis with positive blood culture accounted 16% of neonates in non treatment group vs. no evidence of sepsis in the treatment group[8]. Another study demonstrated 22% colonization of antibiotic resistant organism in rectal flora in treatment group vs. 5.4% in non-treatment group[9]. Though the use of antibiotic therapy after PROM > 18 hours is beneficial in reducing neonatal risk factors, its rationality remains unclear and many investigators believe that prophylactic therapy at times is not necessary and selective treatment should be given. Hence, in the light of above mentioned description, we planned current project to see management outcomes of PROM among two different groups.

The objective of the study was to compare the outcomes of prophylactic versus selective antibiotics in term newborns born after PROM >18 hours in terms of neonatal sepsis and resistance of neonatal.

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METHODOLOGY

This randomized controlled study enrolled (n=120) asymptomatic term (37^+ weeks) babies of either gender with PROM >18 hours after ethical review committee's (ERC) approval. This study held at DHQ Hospital, Rawalpindi-Pakistan in 2019. Data was collected through a structured proforma with informed consent. Neonates born after PROM <18 hours, having gross congenital anomalies, poor Apgar score (≤4/10) at 5 minutes and mothers with chorioamnionitis were ruled out. Neonates (60 each) were divided into prophylactic treatment (group-1) and selective treatment (group-2) respectively.

Data analyzed by SPSS version 20. The study outcomes were neonatal sepsis and resistant neonatal flora. Chi-square test was applied in order to compare study outcomes between both groups having p≤0.05 as significant.

RESULTS

Distribution of parameters like gender, body weight, blood cultures, Apgar score and clinical signs among enrolled babies in present study was presented as frequency and percentage in table-1. The distribution of clinical signs of all the enrolled babies in group-1 and group-2 were shown in table-2. Out of 60 babies in group I, 23(38.3%) babies had any clinical sign while babies in group II, 19(31.7%) babies had any clinical signs in the first 48 hours. Treatment outcomes like neonatal sepsis and resistant neonatal flora between both groups showed statistically insignificant difference (p>0.05) as shown in table-3.

Table-1: General Features Of Enrolled Babies (n=120)

Variables	Categories	Group-1	Group-2
Gender	Boys	42 (70%)	39(65%)
	Girls	18 (30%)	21(35%)
Birth Weight (Kg)	Less than 2.5	11 (18.3%)	09(15%)
	Equal or more than 2.5	49 (81.7%)	51(85%)
	Mean ± SD	2.7 ± 0.17	2.9±0.22
Apgar Score at 5 minutes	Score (5-7)	18 (30.0%)	19(31.7%)
	Score (8 or more)	42 (70%)	41(68.3%)
Clinical Signs	Yes	23 (38.3%)	19(31.7%)
	No	37 (61.7%)	41(68.3%)
Blood Culture Status	Positive	08 (13.3%)	9(15.0%)
	Negative	52 (86.7%)	51 (85%)

Table-2: Distribution Of Clinical Signs Among Babies In Both Groups (n=42)

Variables	Categories	Group-1 (n=23)	Group-2 (n=19)
Specific Clinical Signs	Respiratory distress	13 (56.5%)	14 (73.7%)
	Temp. instability	4 (17.4%)	2 (10.5%)
	Signs of shock	3 (13.0%)	zero
	Seizures	2 (8.7%)	1 (5.3%)
	Feed intolerance	1 (4.3%)	2 (10.5%)

Table 3: Comparison of Treatment Outcomes Among Enrolled Babies (n=120)

Variables	Categories	Group-1	Group-2	*P-value*
Neonatal sepsis	Yes	8 (13.3%)	9 (15.0%)	**0.07**
	No	52 (86.7%)	51 (85.0%)	
Resistant neonatal flora	Yes	3 (5.0%)	2 (3.3%)	**0.21**
	No	57 (95.0%)	58 (96.7%)	

DISCUSSION

Almost 8-10% of pregnancies at term are affected by premature rupture of membranes (PROM) according to one previous study[10]. Approximately 60-80% cases of PROM at term will enter spontaneous labour within 24 hours. Today, it denotes “rupture of membranes before the onset of labour”[11]. In the current study we randomized full term babies with PROM >18 hours into two groups, i.e. the prophylactic treatment group and the selective treatment group and compared the outcome in terms of neonatal sepsis and resistant neonatal flora.

In present study, findings of specific clinical signs were similar in both groups. The neonatal sepsis was diagnosed in 8(13.3%) and in 9(15%) babies in the prophylactic treatment group and the selective treatment group, respectively and this difference was not statistically significant (p=0.07). Likewise, resistant neonatal flora was present in 3(5%) and in 2(3.3%) babies in the prophylactic treatment group and the selective treatment group respectively and this difference was also not statistically significant (p=0.21). Hence, our study findings showed insignificant differences among both groups yet our findings were comparable with other previous studies.

One previous study conducted at Egypt enrolled 1,640 women with PROM at or beyond 36 weeks of pregnancy. They were randomized in order to receive a single dose treatment of prophylactic I/V antibiotics or placebo at time of admission. They found that early-onset neonatal sepsis appeared in 34(4.1%) involving antibiotics group whereas 24(2.9%) neonates had it in placebo group with p-value >0.05. Therefore, statistical insignificant difference was observed between the study groups[12]. Hence, it was concluded that prophylactic antibiotics use among women with PROM ≥ 36 weeks of pregnancy did not lessen the incidence of neonatal and maternal infection-related morbidity. Our study findings were in line with the above mentioned study.

In another previous study held at Spain enrolled 733 women in their study, antibiotic group (n=371) while control group (n=362). In their study, they observed reduction in the incidence of infections/ inflammatory conditions like chorioamnionitis and puerperal endometritis with statistically insignificant difference between both groups (p>0.05). However, antibiotics group showed decreased incidence of neonatal sepsis with statistically significant p-value (p<0.007*) among newborns in comparison to control group. Thus concluded that the use of prophylactic

antibiotics in PROM occurring at ≥ 36 weeks of gestation plays role in reducing the incidence of neonatal sepsis along-with maternal endometritis[13]. However, the findings of above mentioned study contradicted with the findings of present study that concludes antibiotics play no role in reducing neonatal sepsis.

CONCLUSION

We concluded that there was insignificant difference in terms of rates of neonatal sepsis and resistant neonatal flora between two treatment groups. However, there is a need to conduct large sample size, multicentre studies to validate these results before making recommendations for routine treatment of full term babies with PROM >18 hours in our clinical settings

Limitations: Our study had limitations like financial constraints, lack of resources and small sample size.

Authors' Contribution: JZ: Conception and design of work, MA: Collecting and analyzing the data, KF: Drafting the manuscript, TL: Drafting and revising the manuscript for intellectual content.

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