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Effect of Bed Rest on Prepartum Premature Rupture of Membrane: A Randomized Controlled Trial.

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Abstract:
Introduction: *Preterm premature rupture of membranes (PPROM) i.e. rupture of membranes before 37 weeks of gestation occurs in 3% of pregnancies. The management generally include bed rest in cases of PPR0M, though the guidelines do not mention about the antepartum bed rest, however the general practice is to put the patients on bed rest. As there was no prospective study with role of bed rest in cases of PPROM at that time, our study was planned to evaluate the role of bed rest on outcome in pregnancies complicated by PPROM.*
Methods: *The present study was randomized controlled trial. Study subjects were pregnant women with 26-34 weeks of gestation with PPROM. In addition to routine investigations, complete blood count, urine for culture/sensitivity and high vaginal swabs were taken. All the patients were managed as per hospital protocol and admitted till delivery. Patients were randomized into two groups i.e. bed rest and activity group by computer generated random numbers.*
Results: *Mean AFI at the time of admission in bed rest and activity group was. 7.38±3.39 and 6.63±2.63 cm (p-value=0.34). Mean BPS at the time of admission in bed rest and activity group was 7.47±0.90 and 7.60±0.81respectively (p=0.55). Mean AFI after the intervention in bed rest and activity group was. 7.59±0.95 and 7.57±0.81cm (p-value=0.29). Mean BPS after the intervention in bed rest and activity group was 7.59±0.95 and 7.57±0.81 respectively (p=0.93).*
Conclusion: *Present randomized controlled trial of effect of bed rest on preterm premature rupture of membrane revealed that bed rest have no role in prolongation of pregnancy and activity does not affect latency period too.* ***Keywords:*** *Preterm premature rupture of membrane, Bed rest,Perinatal morbidity, Preterm births, Maternal morbidity.*

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I. Introduction

Preterm premature rupture of membranes (PPROM) i.e. rupture of membranes before 37 weeks of gestation occurs in 3% of pregnancies and is responsible for 1/3rd of preterm births.[1] It can lead to significant perinatal morbidity and is associated with 18-20% of perinatal deaths.[2]

Perinatal morbidity results due to infection, cord compression, placental abruption and prematurity. It is also associated with maternal morbidity due .to chorioamnionitis (37%), postpartum endometritis (11%) and sepsis (1%).[3-6]

The majority of pregnancies with PPROM (56%) deliver within one week of membrane rupture. In a randomized trial of PPROM at 24-32 weeks, group B streptococcal negative patients managed expectantly with prophylactic antibiotics, the median time to delivery was 6.1 days.[7 8]

Management of PPROM is a challenging problem and it depends on the gestational age and fetal status. Termination of pregnancy is advised in gestation <24 weeks and >34 weeks. However, in gestation between 24-34 weeks, expectant treatment is offered.[4]

During expectant management, patients are hospitalized and admitted till delivery for maternal & fetal monitoring. The aim of expectant management is to prolong the pregnancy and improve the neonatal outcome without compromising maternal health. The recommended treatment is antibiotic course and steroid coverage for lung maturity.[4 5] The management generally include bed rest in cases of PPR0M, though the guidelines do not mention about the antepartum bed rest, however the general practice is to put the patients on bed rest. Fox NS, et al's study enquired the practice patterns regarding bed rest in

women with PPROM and found that 87% of practitioners would recommend bed rest.[9] Bed rest in cases of PPROM might help in reduction of uterine contractions, prolongation of pregnancy and prevention of cord prolapse. It may also enhance the amniotic fluid reaccumulation and decrease the stress, and increase the blood flow to the placenta.[9] However these benefits have never been proved by the controlled trials.

Bed rest, though currently prescribed in regarding the PPROM , but no benefits have been observed.[10] On the other hand bed rest represents significant change in lifestyle and causes the risk of thromboembolism, muscle atrophy and emotionally distressing to the patients and her family.

The Chochrane review in 2005, evaluated the role of bed rest in preterm labor and author concluded that there is no evidence, either supporting or refuting the use of bed rest in prevention of preterm birth.[11] As there was no prospective study with role of bed rest in cases of PPROM at that time, hence the present study was planned to evaluate the role of bed rest on outcome in pregnancies complicated by PPROM.

Aim: To evaluate the role of bed rest in pregnancies complicated by preterm prematurerupture of membrane (PPROM).

Objective: To compare the latency period i.e. days gained till delivery in women withPPROM receiving bed rest with the women receiving activity and to compare antepartum and postpartum events in both the groups.

II. Materials And Methods

The present study was randomized controlled trial, protocol of which was approved by the Institutional Ethical committee of the medical college. Written informed consent was taken from all study subjects before collection of data. The study was carried out in the Department of Obstetrics & Gynaecology, UCMS & GTB Hospital, Delhi from November 2013 to 30 July 2016. Study subjects were Pregnant women with 26-34 weeks of gestation with PPROM and recruited from the labour room of Department of Obstetrics & Gynaecology. Inclusion Criteria were pregnant women between 26-34 weeks gestation with PPROM, Vertex presentation and Singleton pregnancy. Exclusion Criteria were multiple gestation, malpresentation, any maternal or fetal indication for immediate delivery and active herpes simplex genital infection. Patients were randomized in 1:1 ratio with the help of centralized computer randomization into bed rest group and activity group.

Methodology

Subjects fulfilling the inclusion criteria were recruited for the study. Detailed history pertaining to risk factors were taken. Diagnosis of PPROM was confirmed by sterile speculum examination. If pooling of fluid in the posterior vaginal fornix was not seen then actim PPROM test or AFI on ultrasonography was used to substantiate the diagnosis. Digital examination was avoided. Maternal examination was done for signs of chorioamnionitis, i.e. maternal pyrexia, tachycardia, uterine tenderness, offensive vaginal discharge. In addition to routine investigations, blood for complete blood count, urine forculture/sensitivity and high vaginal swabs were taken. All the patients were managed as per hospital protocol and admitted till delivery. They were given erythromycin 250 mg qid for 10 days, betamethasone (12 mg) IM stat and then same dose was repeated after 24 hours. TPR was recorded 6 hourly for first 48 to 72 hours and then twice a day. There after BPS was done twice weekly. Mother was observed for signs of clinical chorioamnionitis. Patients were randomized into two groups by computer generated random numbers·

Group I: Patients were put on bed rest i.e. patients spent majority of their days in their hospital bed usuaUy in reclined or lying position. Subjects abstained frorn walking or engaging in any extraneous activity including lifting or spending any extended period of time out of bed. Subjects were allowed to use the bathroom privilege.

Group II: Patients were allowed activity and did minimum one hour walking per day in addition to the toilet privileges like women walked to fetch her meals/to gel ultrasound done etc. Subjects were permitted more activity as desired. Maternal monitoring was done till the time of delivery. Latency period, i.e. days gained till delivery was monitored.

The sample size calculation has not been done as this is an exploratory trial. Since test to be applied is t-test, which is based on the assumption of normality, sampleof 30 in each group will be taken.

Maternal demographic and obstetrics data were compared between groups using independent t-test, Fisher's exact test, and Chi-square test. Latency period i.e. days gained till delivery was evaluated using Mann-Whitney test. p-value <0.05 was considered significant.

III. Results

During the study period total 124 women with PPROM were randomly considered for inclusion in the study. Out of 124 women, 64 were excluded due to the exclusion criteria like period of gestation <26 weeks (18 cases), >34 weeks (14 cases), women PPROM with breech (11 cases),

women PPROM with multiple gestation (3 cases), immediate delivery (latency period<48 hours) (18 cases)

A total of 60 women with PPROM included in our study which met the minimum sample size criteria for the study. They were randomized into 2 groups i.e. Group I= bed rest and Group II= activity, 30 patients in each group completed the study & were evaluated for the analysis.

Table 1. Comparison of baseline characteristics in bed rest and activity group.

Demographic characteristics		Bed rest N (%)	Activity N (%)	p-value
Age (years) (mean±S.D.)		25.20±3.70	25.40±4.02	0.84
Parity	0	10 (33.33)	18 (60.00)	0.05
	1	15 (50.00)	06 (20.00)	
	2	05 (16.67)	05 (16.67)	
	3	00 (00)	01 (03.33)	
Religion	Muslim	9 {30%)	9 (30%)	
	Hindu	21 (70%)	21 (70%)	1.00
socioeconomicstatus	Upper	1 (3.33%)	0%	
	Upper middle	18 (60%)	22 (73.33%)	
	Lower middle	11 (36.67%)	8 (26.67%)	0.41
	Upper lower	0%	0%	
	Lower	0%	0%	
B.M.I. (mean±S.D.) (kg/m^2)		21.83±2.59	21.90±2.26	0.98

Sociodemographic profile was comparable in both the groups. Both groups had similar number of cases from different religions. Majority patients belonged to upper middle and lower middle socioeconomic status with mean B.M.I. of 21.83±2.59 and 21.90±2.26 in bed rest and activity group respectively. In bed rest group, the age of subjects ranged from 20 to 35 years and in actiVity group, ranged from 20 to 41 years. The mean age in bed rest group was 25.20±3.70 years and in activity group was 25.40±4.02 years. The difference was statistically non significant (p-value= 0.84) Parity was non equally distributed in both groups as shown in Table 2. In bed restgroup 10 women were nullipara while in activity group 18 (60%) cases were nulliparous women. There was only one grand multipara which was in activi group. The difference was statistically non significant (p=0.05) (Table 1)

Table 2. Comparison of various pregnancy parameters in bed rest and activity group at baseline.

Parameter	Bed rest N (%)	Activity N (%)	p-value
TLC ($cells/mm^3$) Mean ± SD	10916.67±2009.82	10526.67±2260.44	0.48
Urine c/s	0	01 (03.33)	1.00
HVS c/s	02 (06.67)	0 (00)	0.49
CRP (>0.06)	01 (03.33)	0 (00)	1.00
AFI (cm) Mean ± SD	7.38±3.39	6.63±2.63	0.34
BPS (8/8) Mean ± SD	7.47±0.90	7.60±0.81	0.55

(HVS= High vaginal swab, C/s= Culture & sensitivity, CRP= C-reactive protein, TLC= Total leukocyte count, AFI= Amniotic fluid index, BPS= Biophysical score).

Mean of TLC at the time of admission in bed rest and activity group was 10916.67±2009.82 and 10526.67±2260.44 (p-value=0.48). Urine c/s was positive (E.coli) only in one case in activity group (p-value=1.00). HVS c/s was positive (E. coli and kleibsella) only in2 cases in bed rest group and none in activity group CRP was positive only in 1case inbed rest group and none in activity group. Mean AFI at the time of admission in bed rest and activity group was. 7.38±3.39 and 6.63±2.63 cm (p-value=0.34). Mean BPS at the time of admission in bed rest and activity group was 7.47±0.90 and 7.60±0.81respectively (p=0.55). Both the groups were comparable at the time of admission. (Table 2)

Table 3. Comparison of various pregnancy parameters in bed rest and activity group after intervention.

Parameter	Bed rest N (%)	Activity N (%)	p-value
TLC (cells/mm^3) Mean ± SD	10407.44±1989.55	10106.33±2211.23	0.58
Urine c/s	0	0	--
HVS c/s	03 (06.67)	1 (03.33)	0.3
CRP (>0.06)	02 (03.33)	1 (03.33)	0.55
AFI (cm) Mean ± SD	7.42±3.31	6.61±2.56	0.29
BPS (8/8) Mean ± SD	7.59±0.95	7.57±0.81	0.93

(HVS= High vaginal swab, C/s= Culture & sensitivity, CRP= C-reactive protein, TLC= Total leukocyte count, AFI= Amniotic fluid index, BPS= Biophysical score).

Mean of TLC after the intervention in bed rest and activity group was 10407.44±1989.55 and 10106.33±2211.23 (p-value=0.58). After the intervention no case had urine c/s positive for E.coli. HVS c/s was positive (E.coli and kleibsella) only in 3 cases in bed rest group and 1 case in activity group (p= 0.3). CRP was positive only in 2 cases in bed rest group and 1 case in activity group (p = 0.55). Mean AFI after the intervention in bed rest and activity group was. 7.59±0.95 and 7.57±0.81cm (p-value=0.29). Mean BPS after the intervention in bed rest and activity group was 7.59±0.95 and 7.57±0.81 respectively (p=0.93).

Table 4. Comparison of various antepartum and postpartum events in bed rest and activity group.

Parameter	Bed rest N (%)	Activity N (%)	p-value
Latency period from D.O.L. (in hours)	254.23 ± 258.32	402.43 ± 369.43	0.29
Latency period from D.O.A. (in hours)	216.60 ± 220.54	353.93 ± 369.1	0.39
Gestational age (days)	228.23 ± 15.19	227 ± 12.64	0.73

(D.0.A= Date of adm1ss1on, D.O.L=Date of leaking)

Maternal outcome included latency period (from D.O.L. and D.O.A.) and gestational age at the time of delivery. In bed rest group latency period (D.O.A.) ranged from 2 days to 45 days. In activity group latency period (D.O.A.) ranged from 12 to 52 days. Latency period of delivery from admission (D.0.A.) and also from the day of leaking (D.O.L.) was longer in activity group as compared to bed rest group. The mean of gestational age at the time of delivery in bed rest group was 228.23 ± 15.19 days and in activity group was 227 ± 12.64 days with no significant difference between the two (p=0.73).

Table 5. Comparison of various antepartum and postpartum events in bed rest and activity group.

APE & PPE	Bed rest N (%)	Activity N (%)	p-value
Chorioamnionitis	0 (00)	1 (03.33)	
Abruption	2 (06.67)	0 (00)	
PPFI	0 (00)	1 (03.33)	
Total	02(06.67)	02 (06.67)	

Chorioamnionitis only present in activity group i.e. in 1 case. Placental abruption occurred during intrapartum followed by normal vaginaldelivery among 2 cases in bed rest group. Postpartum febrile illness in 1 case in activity group. Difference of antepartum and postpartum event was statistically non-significant (p=0.49)

IV. Discussion:

In In PPROM any strong evidences or guidelines are not present regarding bed rest which is beneficial or harmful in PPROM women. According to hypothesis and assumption that bed rest enhances amniotic fluid reaccumulation and prolongs latency period.[11]

In our study total 60 subjects were selected for study. They were randomly assigned to two groups, group I- bed rest and group II- activity. All subjects were indoor patients in the department. Subjects in bed rest group were verbally instructed to spend the majority of their day in the hospital bed, usually in a reclined or sleeping position and given full bathroom privileges. In other studies on bed rest in pregnant women, similar criteria have been used for bed rest group.[12,13] Subjects in the activity group were verbally instructed. For activity group there was no limitation on activity and subjects were asked to walk for a minimum of 20 min. at least 3 times a day. Other researches also have used the similar criteria for evidence minimum activity.[13]

We diagnosed cases of PPROM on clinical examination that is the standard recommendation[2,8,14] In 3 cases when there was no certainty on clinical examination (per speculum) rupture of membrane were confirmed by actim PROM test. We

used actim PROM test because test is not affected by presence of infected vaginal secretion urine, semen, small amount of blood. The confirmation and sensitivity of test is 98% and 95-100%.o[3], [15]

Baseline parameters regarding age, parity, duration of LPV were comparable in both groups. In our study, age ranged from 20 to 41 years and which was similar to Bigelow CA, et al's[16] study. In our study, parity in both groups were non equally distributed.[9] 33.33% women were nullipara in bed rest group and 18 (60%) women were nulliparous in activity group. Bigelow CA, et ars study also found that majority of subjects were nulliparous.[16]

In our study, period of time from L.P.V. to D.O.A was comparable in both groups and difference was not significant statistically. In our study, period of gestation {by dates) were comparable in both groups. High risk factors related to PPROM were compared between both groups like past history of preterm birth, past history of miscarriages, and first trimester bleeding in ongoing pregnancy. Both the groups were comparable regarding this factor which could have effected the outcome of study. In Bigelow CA, et al's[16] study, they found higher incidence preterm birth {PTB) in their study subjects. Though there was no difference between groups. In our study past history of preterm birth (PTB) was seen in 3 {10%) pregnancies.

All 60 subjects were afebrile and their vitals were stable during admission.

In our study, after admission in both groups all cases were screened for infections and baseline USG was done. Their difference was not significant statistically.

In our study, primary outcome latency period i.e. days gained till delivery from dayof admission (D.O.A) and day of leaking (D.O.L.}. Latency period {from D.O.L. andD.O.A.) in bed rest group was shorter than activity group. Mean latency period (D.O.A.} in bed rest group was 9.02±9.18 days and in activity group was 14.75±15.37days and we found that difference in latency period (D.O.A.) was not statistically significant. Similar observations were made by w CA, et al[16] in their RCT, w h e r e in, they also did not find significant effect of rest in latency penod.

In our study, latency Period was shorter in bed rest group While Bigelow CA, et al[16] also had shorter POL in bed rest group but no significant difference in either of these studies. our study, gestational age at the time of delivery in bed rest and activity groups was 32.60±2.17 weeks and 32.42±1.80 week respectively but the difference was not statistically significant (p=0.73). This outcome was similar to the study reported by Bigelow CA.[16] We excluded cases who delivered within 48 hours of admission as the intervation would not have had effect latency period in this group. According to Dale PO, et al[17] and Bengtson JM[18], et al'sstudy found that in PPROM women remote from term 70 to 90 % women will go into labor within 7 days and 50% will go into labor within 24 to 48 hours.[37] In our study also majority of women in both groups went into spontaneous labor within 7 days (fig-13). In the Bigelow CA, et al[16] study they induced all subjects at 34 weeks they have not mention about spontaneous onset of labor in their subjects.[16]

Bed rest is hypothesised to improve outcome in PPROM by increasing AFI levels but we found that AFI was not affected by bed rest or activity. In the present study there was no effect of bed rest or activity on the AFI or biophysical profile.

Bigelow CA, et al[16] in their study they found that similar results as our study.

In our study, induction of labor in view of chorioamnionitis was only present in activity group i.e. 1 (3.33%) case [Table 8(a)]. Bigelow CA, et al's[16] study found high number of chorioamnioniotis in bed rest and activity group i.e. 3 (18%) cases and 4 (22%) cases respectively. Other causes of induction of labor (high TLC, poor BPS, gestational age >34 weeks) were also compared with both groups and difference was not significant statistically (p=0.643).

In our study majority of subjects had normal vaginal delivery in both groups i.e. (bed rest-86%, activity-SO%) and less number of subjects had LSCS in both groups i.e. (bed rest-13.33%, activity-20%) These observations compared with Bigelow CA, et al[16] study and in their study found that number of NVD and LSCS cases in bed rest group was 10 (56%) cases and 8(44%) cases respectively and number of NVD and LSCS cases in activity group was 5 (29%) cases and 12 (71%) cases respectively

As the limitation of our study was small size of subjects. In our study difference between mean latency period was 5.72±6.19 days to find a statistically significant difference between the activity and bed rest groups with 95% confidence and BO% power using a two-sided test, with equal numbers of patients in each group, 89subjects would be needed in each group, for a total of 178 study subjects. Similarly Bigelow CA et al also concluded that higher number (total 194 subjects) was needed for a significant difference between groups.

V. Conclusion

Present randomized controlled trial of effect of bed rest on preterm premature rupture of membrane revealed that bed rest have no role in prolongation of pregnancy and activity does not affect latency period too. Also bed rest does not have any effect on amniotic fluid index and biophysical profile. Activity does not have any complications like chord prolapse. There is no effect of bed rest or activity on antepartum and postpartum events like placental abruption, chorioamnionitis, postpartum febrile illness.

Declaration: There was no source of funding in our study hence there were no any conflict of interest.

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