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Inpatient vs. Outpatient Management of Uncomplicated Preterm Premature Rupture of Membranes: A Clinical Trial

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Abstract

Background: Preterm premature rupture of membranes (PPROM) is spontaneous rupture of fetal membranes before 37 weeks of gestation. PPROM cases that are clinically stable with no sign or symptom of intrauterine infection and normal fetal assessment are usually managed expectantly in hospital settings or at home. This study aimed at comparing the inpatient and outpatient management among women with uncomplicated PPROM.

Methods: This non-randomized clinical trial was performed in an academic hospital, Mashhad University of Medical Sciences in 2017-2018. Women with confirmed PPROM who received initial treatments during the primary 72 hours of hospitalization were assigned into inpatient (n=45) or outpatient (n=35) management groups according to the patient's decision. The obstetrical, maternal and neonatal outcomes under the focus of this study included latency period, gestational age at delivery, delivery route, delivery reason, WBC and neutrophil count, neonates' weight, Apgar score, NICU admission, and death in the first 28 days after delivery. Data were analyzed by Statistical Package for Social Science (IBM SPSS) version 23. $P<0.05$ was considered statistically significant.

Results: Among 120 patients assessed for eligibility criteria, 80 patients were enrolled and the data of 68 participants was analyzed. Women in outpatient group had significantly longer latency period than women in inpatient group (18.7±12.9 vs.7.1±5.8days, $p<0.001$). The rate of vaginal delivery was 77.5% (n=31) in inpatients group vs.57.1% (n=16) in the outpatient group ($p=0.1$), no significant difference was found regarding cesarean indications, pregnancy termination indication, GA at delivery and WBC or neutrophil count ($p>0.05$). Neonatal Apgar score, death, and NICU admission rate or period were not significantly different between the two groups ($p>0.05$).

Conclusion: Homecare for the selected PPROM women could be a suitable expectant strategy without compromising neonatal or maternal outcomes.

Key Words: Fetal membrane, Hospitalization, outpatient, Pregnancy outcome, Premature rupture of membrane.

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1- INTRODUCTION

Preterm premature rupture of membranes (PPROM) is the spontaneous rupture of the fetal membranes before 37 weeks of gestation that precedes labor, with unknown causes in most cases (1). PPROM complicates up to 3% of all pregnancies and accounts for nearly one third of all preterm births (1, 2). Accordingly, of 14.8 million live preterm births worldwide in 2014, about 5 million were due to PPROM (3).

Prematurity and intra-uterine infection as the two main complications of PPROM, increase perinatal morbidity and mortality as much as the intrauterine infection can lead to early neonatal sepsis, necrotizing enterocolitis and in utero fetal death (4-6). Respiratory distress, sepsis, and intraventricular hemorrhage as the prematurity complications (7), are reported to be the leading cause of death among children younger than 5 years old (8). Additionally, prematurity constitutes heavy economic burden on healthcare system and financial and psychological trauma on the mothers and the family of the preterm infants (3, 9, 10).

PPROM does not necessarily result in immediate labor and more than 40% of cases deliver subsequent to the first week after PPROM, hence the pregnancy may last for several days (1, 11). Induction of labor and expectant management are the two possible PPROM management options; however, the proper treatment strategy is a clinical controversy. The treatment decision is generally made according to the risk benefit assessment of complications followed by early delivery (e.g. prematurity) against the expectant management (e.g. infection, abruption placenta, and umbilical cord accident) considering the gestational age and the fetal and maternal clinical status (7, 12).

PPROM cases who are clinically stable with no sign or symptom of intrauterine infection and normal fetal assessment, are usually managed expectantly and the pregnancy continues under close monitoring (5, 13, 14). Expectant management can be implemented either in a hospital setting or at home (5). Hospitalization is the conventional expectant policy recommended by various guidelines until the delivery, in order to closely monitor maternal and fetal clinical status (7, 12, 15, 16). In view of the fact that during the inpatient follow-up, the hospitalization period is indefinite and daily professional examinations are required, high health system costs and poor maternal compliances are presumable (17).

On the other hand, outpatient care in eligible PPROM patients seems to be a safe, low-cost and acceptable substitute for inpatient care that is reported to be associated with a relatively longer latency period without increasing neonatal or maternal adverse outcomes (17-23). Despite the growing evidence regarding the benefits of outpatient care, it is not recommended by practice guidelines yet due to the limited supportive evidence to confirm its safety (7, 15). Moreover, it is possible that the PPROM cases develop uncommon but serious obstetric emergencies at any time during the conservative management period; hence, outpatient management is cautiously avoided by some obstetricians (23, 24). Choosing between inpatient and outpatient strategy during expectant management period in a way that both mother and fetus benefit from it, continues to pose a clinical dilemma.

Given the maternal and neonatal complications of PPROM and their significant psychologic and economic burden, clinical management of patients with PPROM is a vitally important and a tricky decision, especially when considering the patient`s compliance and the limits of health service’s resources in

developing countries. Furthermore, no straightforward guideline is available regarding outpatient and inpatient management and the safety of home management has not been established yet (24). This study is therefore aimed to compare the obstetrical and neonatal outcomes of inpatient and outpatient management among women with uncomplicated PPROM prior to 34 weeks of gestation.

2- METHODS

This non-randomized clinical trial was carried out in an academic hospital, Mashhad University of Medical Sciences, Mashhad, Iran, during December 2017 and August 2018. Based on local evidence and the clinician`s consensus, a maximum number of 10 patients per month were predicted to present to our study referral center and all eligible patients were recruited during the enrollment period. Women with confirmed PPROM who received initial treatments during a primary 72-hour hospitalization period and did not have any spontaneous delivery signs, were assigned into inpatient (n=45) or outpatient (n=35) management groups according to the patient`s own decision.

The study flow chart is shown in figure 1.

Of 80 participants who had the eligibility criteria, 68 women finished the trial.

All participants provided oral and written informed consent after receiving thorough information about the pros and cons of each management strategy. The ethical approval for this trial was received from the ethics committee of the Mashhad University of Medical Sciences (ID: IR.MUMS.fm.REC.1396.640) and it was registered at http://www.irct.ir (Registration ID: IRCT20181115041666N1).

2-1. Participants

After the primary 72-hour inpatient assessments, eligible participants were assigned into inpatient or outpatient management groups according to their own decision. The inclusion criteria included singleton pregnancy with gestational age of 25+0 to 33+6 weeks, live fetus, confirmed PPROM, cephalic presentation, no clinical or laboratory sign of chorioamnionitis, absence of labor signs (regular uterine contractions, dilation > 3 cm or effacement ≥80%) within the first 3 days after membrane rupture, rapid accessibility to the hospital facilities, presence of vertical amniotic fluid pocket >2cm.

The rupture of amniotic membranes was confirmed by direct observation of leakage, Nitrazine or AmniSure test under the sterile speculum examination. Chorioamnionitis symptoms were defined as fever (>38°C persisting more than 1h or any fever ≥38.5°C), uterine tenderness, maternal (>100/min) or fetal tachycardia (>160/min), purulence or foul odor vaginal discharge, or leukocytosis (WBC>15000), and the presence of a left shift or bandemia (>9%). Additionally, having a caregiver at home and short distance between the patient's house and the hospital (<60 min) were necessary for those who were assigned into outpatient care.

Women with vaginal bleeding, fetal malformation or distress signs, and those who were unwilling to continue the study, were excluded from the trial.

2-2. Intervention

During the primary 3-day hospitalization period, all participants received the following regimen; Ampicillin (IV, 2 g, every 6 hours, for 2 days), Betamethasone (IM, 12 mg, 2 doses, 24 hours apart), Amoxicillin (oral, 500 mg, TID, for 5 days), Erythromycin (oral, 400 mg, QID, for 5 days). The patients were assessed regularly as their vital signs were controlled every 6 hours, ultrasonography was conducted weekly, besides Non-stress

Test (NST) and CBC were performed twice a week.

The inpatient group participants were examined through daily vital sign check, weekly ultrasound tests, and twice-a-week NST and CBC tests. On the other hand, the outpatient group women and their caregivers were fully educated and informed about the chorioamnionitis signs (fever, tachycardia, purulence or foul odor vaginal discharge, dyspnea, decreased fetal movements, pain, vaginal bleeding) and in case of any alarm sign, they were warned to refer to the nearest hospital as soon as possible.

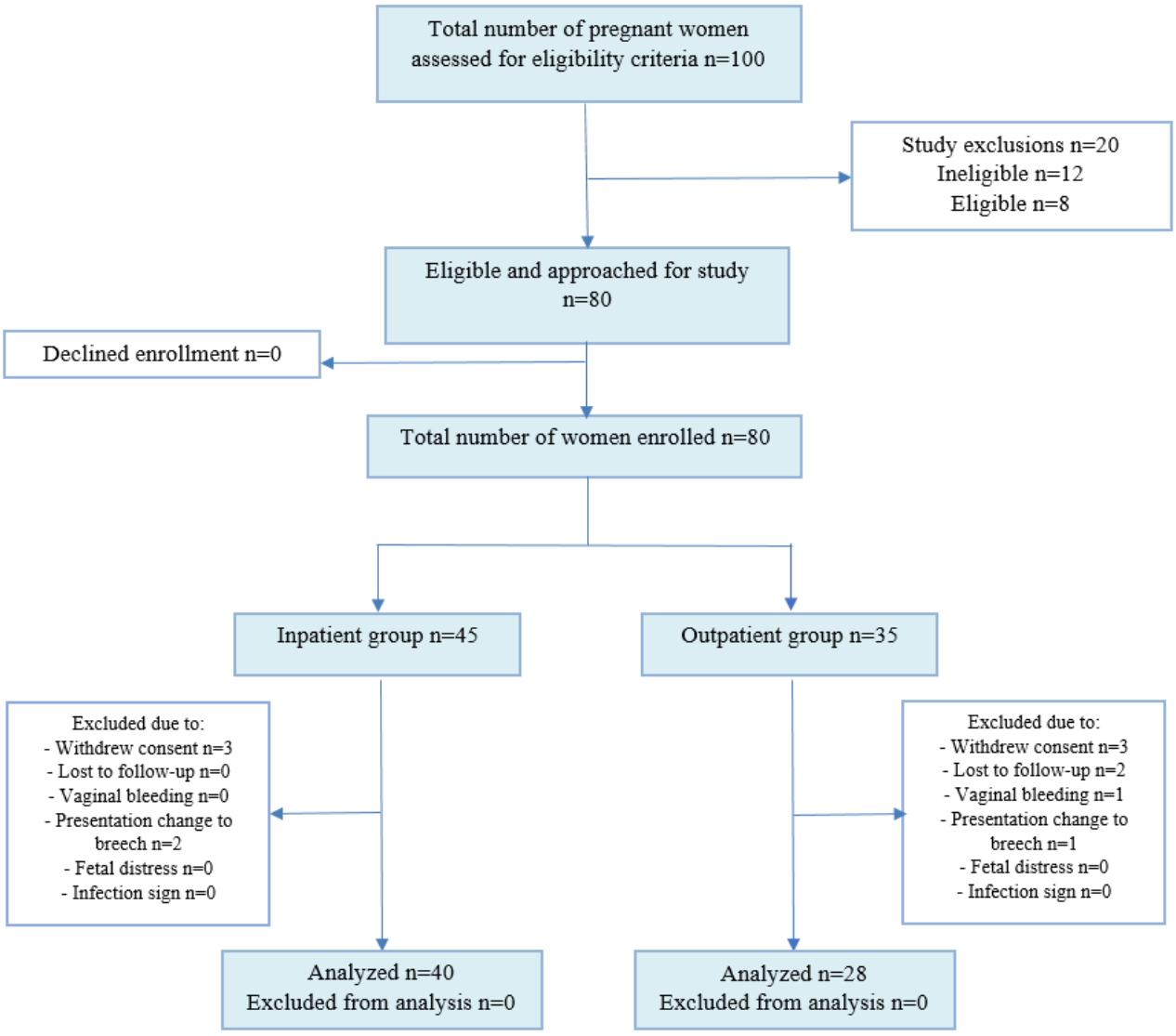

Fig. 1: Recruitment, assignment, and flow of the participants through the trial

Additionally, these women were asked to check and record their temperature and pulse rate to be reported to the clinician daily. NST and CBC tests were also applied twice per week along with weekly biophysical profile tests.

All participants were managed expectantly until the sign of spontaneous labor or chorioamnionitis occurred and NST abnormalities or acute complications (e.g., placental abruption, cord prolapse) were detected. Due to the fact that spontaneous

labor did not happen during the study period for any of the participants, their pregnancy was terminated through labor induction or cesarean section, at the end of the 34 weeks of gestation. We recorded maternal and fetal complications including chorioamnionitis, cesarean deliveries, cord prolapse, NICU admission, and death.

2-3. Outcome measurements

The obstetrical, maternal and neonatal outcomes under the focus of this study included: latency period, gestational age at the delivery, delivery rout, delivery reason, WBC and neutrophil count, neonates' weight, Apgar score, NICU admission, and death in the first 28 days after delivery. Latency period was defined as the period of time from membrane rupture to the delivery.

2-4. Statistical analysis

Data were collected and entered to the Statistical Package for Social Science (IBM SPSS) version 23. Means, standard deviations (SD) and percentages were used in the descriptive analyses. We checked normality distribution of the variables with Kolmogorov–Smirnov test. Analyses were performed by independent t-test, Mann–Whitney U test, Chi-square test, and Fisher's exact test. P<0.05 was considered as the significant level.

3- RESULTS

Among 120 patients who were assessed for eligibility criteria, 80 patients were enrolled and the data of 68 participants was analyzed (figure 1).

Demographic and clinical characteristics were similar among the two groups including maternal age, BMI, smoking and parity as shown in **Table 1**.

The maternal and obstetrical outcomes are demonstrated in **Table 2**. The women in the outpatient group had a significantly longer latency period than those in the inpatient group (18.7±12.9 vs. 7.1±5.8 days, p<0.001). The rate of vaginal delivery was 77.5% (n=31) in the inpatients group vs. 57.1% (n=16) in the outpatient group (p=0.1).

Table-1: Baseline clinical characteristics of inpatient and outpatient PPROM groups

Variables	Inpatient group n=40	Outpatient group n=28	P-value [a]:
Maternal age,mean (SD), years	28.4±5.6	26.9±5.8	0.38
Gestational age at admission, weeks of gestation median [interquartile range]	29+2 [26+3 –31+4]	29+6 [27+2 –31+6]	0.14
BMI**,mean (SD), $^{kg}/_{m^2}$	27.7±4.6	26.5±2.4	0.23
Smoking (%)	2(5%)	1(3.57%)	2.00
Multliparity(%)	30(75%)	20(71.42%)	0.18
History of PPROM(%)	6(15%)	4(14.2%)	1

[a] Categorical variables were compared with chi-square or Fisher Exact tests and continuous variables were compared with Mann – Whitney U tests.
Abbreviations: BMI = Body Mass Index

Moreover, no significant difference was found regarding cesarean indications, pregnancy termination indication, GA at delivery and WBC or neutrophil count (p>0.05). Among the participants of both groups, the most common indications for cesarean section and terminating the pregnancy were fetal distress and spontaneous uterine contractions, respectively.

The neonatal weight was higher among inpatient treatment group as compared to the outpatient group; however, the difference was not significant (1729±530.7 vs. 1680±558.7, p=0.72).The neonatal Apgar score, death, and NICU admission rate or period were not significantly different between the two groups (p>0.05), as demonstrated in **Table 3**.

Table-2: Comparing obstetrical outcomes between inpatient and outpatient PPROM groups

Variables	Inpatient group n=40	Outpatient group n=28	P-value
GA at delivery, Gestational age at delivery, weeks of gestation median [interquartile range	31+5[28+6–33+6]	32+2 [29+5 –34+0]	0.09[a]
Indication for pregnancy termination: n (%)			
Spontaneous contractions	27(67.5)	19(67.9)	0.99[b]
Infection	3(7.5)	2(7.1)	
GA $> 34^{+6}$	10(25.0)	7(25.0)	
WBC count mean (SD), cell	12025±4663.6	11004.2±2980.4	0.43[a]
Neutrophil count mean (SD), cell	76.9±8.2	75.4±5.9	0.34[a]
Delivery rout:			
-Vaginal Delivery n (%)	31(77.5)	16(57.1)	0.1[c]
-Cesarean Delivery n (%)			
placental abruption	0(0)	4(14.2)	
Cord prolapse	2(5.0)	0(0)	
Fetal distress	5(12.5)	6(21.4)	
Induction Failure	2(5.0)	2(7.1)	
Latency Period mean (SD),day	7.1±5.8	18.7±12.9	<0.001[a]

Abbreviations: WBC = white blood cell, GA = gestational age
[a] Mann – Whitney U test [b] Fisher's exact test [c] Chi-square test

Table-3: Comparing neonatal outcomes between inpatient and outpatient PPROM groups

Variables	Inpatient group n=40	Outpatient group n=28	P-value
Neonatal weightmean (SD), g:	1729±530.7	1680±558.7	0.72[a]
Apgar Score n (%):			0.93[a]
10	20(50.0)	15(53.5)	
9	8(20)	5(17.8)	
8	3(7.5)	4(14.2)	
7	5(12.5)	1(3.5)	
5	1(2.5)	0(0.0)	
3	1(2.5)	0(0.0)	
0	2(5.0)	1(3.5)	
NICU Admission n (%):	21(52.2)	17(60.7)	0.62[b]
NICU Admission period mean (SD), day	20.2±24.8	19.9±18.5	0.76[a]
Neonatal death during first 28 days n (%):	2(5.2)	1(3.7)	0.99[c]

Abbreviations: NICU= Neonatal Intensive Care Unit, RDS=Respiratory Distress Syndrome
[a] Mann –Whitney U test [b] chi-square test [c] Fisher's exact test

4- DISCUSSION

In this clinical trial, there was no significant difference in terms of the Obstetrical and neonatal outcomes between women with uncomplicated PPROM in inpatient and outpatient expectant management groups; however, the women who were treated at home tended to have longer latency periods in comparison to the hospitalized women. Nevertheless, the hospitalized participants had lower cesarean rates than women who received home care, but it was not statistically significant.

Various retrospective studies have outlined the safety of outpatient management and considered it as an alternative to hospitalization after primary assessments (19-23, 25). It has been proposed that only patients with specific criteria are eligible for outpatient management (26, 27); and clinical trials are required to conclude its safety (19, 25). In a retrospective cohort study by Catt and coworkers, the obstetrical and neonatal outcomes of 122 hospitalized PPROM cases were compared to the 133 outpatient cases (28). Their results underlined the significantly longer latency periods among outpatient cases (18 vs. 11 days, $P<0.001$) and the comparable neonatal and obstetrical outcomes between groups, which are consistent with our findings. There are several hypotheses to explain this difference in latency periods. First, inpatient care may increase the likelihood of earlier delivery by increasing the risk of hospital acquired infections. Second, the high stress condition which associated with prolonged antenatal hospitalization may have a negative psychological impact which might indirectly decrease the latency period. Third, hospitalization may play an important role on the occurrence of more interventions (i.e., vaginal examination).

Results of a previous research, in line with those of the current study, indicated no significant neonatal or maternal complication in outpatient strategy; however, cesarean section rates were higher among outpatient women (29). Likewise, a Cochrane review which compared maternal and neonatal outcomes between PPROM cases who received inpatient and outpatient care showed similar findings to those of ours; this review concluded that neonatal morbidity and mortality did not differ between the two strategies. Our findings manifested that clinically stable PPROM patients with GA of 25+0 to 33+6 weeks can benefit from longer latency period followed by outpatient management while the infection risk remains unchanged.

This study adds to the current knowledge on antenatal monitoring from home during low-risk pregnancy as social changes are demanding a shift to home-based patient-centered care. Outpatient care provides flexibility to both physicians and patients, decreasing the need for interventions or clinic space with the same safety & efficacy as hospital care management.

As strength of the current study, to the extent of our knowledge, this is one of the first clinical trials performed in this field on the Iranian women population. However this trial has several limitations; this study was not randomized or blinded, we enrolled patients from a single hospital so differences between socioeconomic features of patients from other health centers may restrict the generalizability of our findings.

5- CONCLUSION

This trial showed that homecare for the selected PPROM women could be a suitable expectant strategy without compromising neonatal or maternal outcomes.

6- ACKNOWLEDGEMENT

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