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Research Article

Maternal and Neonatal Adverse Outcomes of Prelabor Rupture of Membranes: A Multicenter Clinical Controlled Study

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Abstract

Background: This study aims to assess the maternal and neonatal adverse outcomes in women with complicated Prelabor Rupture of Membranes (PROM).

Methods: This study is a multicenter clinical controlled trial and compared adverse outcomes between women with PROM and those without.

Results: From the assessment of 5457 women between June 2017 to July 2020, 331 and 354 women were assigned to the PROM and non-PROM groups respectively. The PROM group had longer total labor time than the non-PROM group (18.3±8.7 *vs.* 14.9±5.9, P<.01). Furthermore, the PROM group had a lower percentage of vaginal delivery and a higher proportion of cesarean delivery than the non-PROM group. The proportion of obstetric infection (41.9% *vs.* 12.7%; P<.01), severe postpartum haemorrhage (5.1% *vs.* 1.4%; P<.01), neonatal intensive care units' admissions (10.3% *vs.* 5.1%; P<.01), and percentage of neonate's sepsis (2.4% *vs.* 0.6%; P<.01) were significantly higher in the PROM group than in the non-PROM group. All these adverse outcomes were related to the longer duration from PROM onset to delivery.

Conclusion: Women with complicated PROM have a higher incidence of adverse maternal and neonatal outcomes. Prolonged labor time and a higher incidence of obstructed labor may be mechanism behind the induction of adverse maternal and neonatal outcomes. Taking valid steps to induce labor without delay, shortening labor, and timely correction of obstruction and dystocia maybe the useful measures to decrease the incidence of adverse outcomes.

Keywords: Adverse maternal and neonatal outcomes; Obstetric infection; PROM

Introduction

Prelabor Rupture of Membranes (PROM) refers to the rupture of membranes prior to the onset of labor, with approximately 8% of pregnancies having complicated PROM [1]. Its etiology is multifactorial reasons, but most cases can be attribute to Group B streptococcus or Escherichia coli infection and physiologic weakening of the membranes; however, in some cases, the disease etiology remains unclear [2-6]. PROM is related to a number of adverse maternal and neonatal outcomes. The most frequent maternal consequences associated with PROM are chorioamnionitis, wound infection, pelvic abscess, bacteremia, sepsis and postpartum hemorrhage [7-9]. An adverse neonatal outcome significantly correlated with fetal inflammatory response syndrome or early-onset neonatal infection [10-14]. To date, the optimal approach toward the clinical assessment and treatment of women with term PROM remains controversial.

This study aims to assess the maternal and neonatal adverse outcomes in women with PROM compared with women without PROM, furthermore, this study aimed to analyze the relative causes of these outcomes, and to provide valuable references for clinical practice and counselling.

Methods

Study Design and Randomized Strategy

This multicenter clinical controlled trial was conducted in the Department of Gynecology and Obstetrics of six different tertiary hospitals: Affiliated Guangren Hospital of Xi'an Jiaotong University, Shaanxi Provincial People's Hospital, First Affiliated Hospital of Xi'an Jiaotong University, Second Affiliated Hospital of Xi'an Jiaotong University, West Power Group Hospital and Northwestern Women's and Children's Hospital. The study was conducted from June, 2017 to July, 2020. All authors vouch for the accuracy and completeness of the data and for the fidelity of the trial protocol. Eligible women were assigned in a 1:1 ratio to PROM and non-PROM groups. Trained and certified research staff members from six different Department of Gynecology and Obstetrics collected information, including demographic information, and correlated outcome data. Participants were followed up with an interview performed 42 days postpartum.

Main Outcomes Measure

PROM was diagnosed according to the criteria listed in the ACOG practice guidelines [1]. PROM was diagnosed based on patient's history and physical examination, which included the visualization of amniotic fluid passing from the cervical canal and pooling in the

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vagina, and a pH test of the vaginal fluid ≥7. Clinical chorioamnionitis was diagnosed as the presence of maternal fever (temperature 38.0°C) with no evidence of an extra uterine cause accompanied by at least two of the following: fetal tachycardia, maternal tachycardia, leukocytosis, uterine tenderness, or new onset of foul-smelling vaginal discharge. Histological chorioamnionitis was diagnosed based on Redline's criteria using placental and fetal membrane pathological section. Bacteremia was diagnosed based on clinical presentation and blood culturing for bacteria, pertinent clinical symptoms include fever over 38.3°C, chills, and malaise. Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. The clinical criteria for sepsis include suspected or documented infection and an acute increase of two or more Sequential Organ Failure Assessment points as a proxy for organ dysfunction. Pelvic inflammatory disease includes endometritis, myometritis, salpingo-oophoritis, acute and chronic pelvic connective tissue inflammation, and pelvic abscess.

Inclusion criteria: nulliparous women, singleton pregnancy, gestational age equal or greater than 37 weeks, cephalic presentation.

Exclusion criteria: women with complicated disorders were excluded, multiparous pregnancy, multifetal gestation, insufficient cervical function, history of cervical knife cone biopsy, three or more previous abortions, severe preeclampsia, chronic hypertension requiring antihypertensive drugs, pre-pregnancy diabetes and gestational diabetes mellitus needing insulin therapy, cervical suture, fetal malformation; complicated renal disease; systemic lupus erythematosus or antiphospholipid syndrome, and estimated fetal weight ≥4000g.

Statistical Analysis

Statistical analysis was performed using SPSS (version 20.0) software according to the intention-to-treat principle. Categorical variables (reported as n) and the percentage of the categories were compared between the different study groups using the chi-square and Fisher's exact tests. Continuous variables were reported as mean and standard deviation and were compared using the Wilcoxon signed rank test Two-sided p-values of <0.01 were considered statistically significant.

Results

Characteristics of the Participants

From June 2017 to July 2020, a total of 5457 women were assessed and 817 women were recruited according to the set inclusion criteria for eligibility. After randomization, 393 and 424 women were assigned to the PROM and to non-PROM group, respectively. 56 women from PROM group and 62 women from non-PROM group were excluded from the study based on the exclusion criteria, detailed reasons for exclusion depicted in the enrollment flow chart. During the course of the study, 6 women in PROM group and 8 women from the non-PROM group were lost to follow-up. Finally, 313 women in the PROM group and 354 women in the non-PROM group provided written informed consent and their outcomes were analyzed (Figure 1).

Both groups exhibited similar baseline characteristics, with the exception of non-PROM group having fewer women with no complication of labor induction compared with the PROM group (40.4% *vs.* 52.9%, P<0.01) (Table 1).

Maternal Adverse Outcomes

Women in the PROM group had longer total labor time than women in the non-PROM group (18.3±8.7 *vs.* 14.9±5.9, P<.01) because of the longer time of the first stage of labor of women in the PROM group. The percentage of vaginal delivery was significantly lower in the PROM group than in the non-PROM group (74.3% *vs.* 83.9%; P<.01), in contrast, the percentage of women who underwent cesarean delivery was higher in the PROM group than in the non-PROM group (35.6% *vs.* 16.1%; P<.01). Additionally, the incidence of obstructed of labor was higher in the PROM group than in the non-PROM group (17.8% *vs.* 6.8%; P<.01). Chorioamnionitis, an obstetric infection, was observed as one of primary adverse maternal outcomes, pathologic diagnosis of chorioamnionitis includes both histological and clinical findings. The proportion of obstetric infection in the PROM group was significantly higher than in the non-PROM group (41.9% *vs.* 12.7%; P<.01). With respect to the clinical diagnosis of infection, the incidence of bacteremia incidence in women assigned to the PROM group was higher than the incidence seen in women assigned to non-PROM group (7.3% *vs.* 1.9%; P<.01). The incidence of other clinical signs and symptoms related to obstetric infection including puerperal sepsis, wound infection, and pelvic abscess, did not show a significant difference between the two groups. The percentage of postpartum hemorrhage was significantly higher in the PROM group than in the non-PROM group (11.5% *vs.* 5.9%; P<.01), the proportion of severe postpartum hemorrhage, which refers to the volume of blood lost greater than 1000mL, was significantly higher in the PROM group than in the non-PROM group (5.1% *vs.* 1.4%; P<.01). Two women in the PROM group underwent hysterectomy due to severe postpartum hemorrhage, while one woman in the PROM group was diagnosed with severe myometritis due to the observed massive myometrial granulocyte infiltration. The secondary maternal adverse outcomes in

Table 1: Baseline characteristics.

Variable	PROM	Non-PROM	*P value*
	n=331	n=354	
Age, y	27.6±4.8	28.1±5.4	.87[a]
Gestation, wk	38.5±6.1	39.8±5.5	.96[a]
BMI, kg/m^2	25.5±2.8	26.1±3.1	.94[a]
Smoke	18(5.4)	22 (6.2)	.99[b]
Spontaneous in labor	38(11.5)	37(10.5)	.97[b]
Induction of labor	238(71.9)	225(63.6)	.23[b]
No complications	175(52.9)	143(40.4)	<.01[b]
Post term pregnancy	11(3.3)	12(3.4)	1.0[c]
Preeclampsia	8(2.4)	12(3.4)	.98[c]
Gestational hypertension	15(4.5)	16(4.5)	1.0[c]
Gestational diabetes mellitus	28(8.5)	37(10.5)	.97[b]
Social psychological factor	1(0.3)	5(1.4)	.99[c]
Newborn weight, g	3225±613	3318±622	.97[a]

Data are mean±SD (range) or number (percentage). BMI, body mass index; Superscript "a" in table indicate that the data was analyzed in Wilcoxon rank sum test, superscript "b" indicate that the data was analyzed in Pearson Chi-square test, and superscript "c" indicate that the data was analyzed in Fisher's exact tests.

Table 2: Maternal adverse outcomes.

Variable	PROM	Non-PROM	P Value
	n=331	n=354	
The time of labor			
Total time of labor process, h	18.3±8.7	14.9±5.9	<.01[a]
The first stage of labor, h	15.6±4.1	11.6±3.6	<.01[a]
The second stage of labor, h	1.9±0.8	1.6±0.6	.86[a]
Vaginal delivery	246(74.3)	297(83.9)	<.01[b]
Spontaneous delivery	202(61.0)	267(75.4)	<.01[b]
Instrumental delivery	44(13.3)	30(8.5)	.75[b]
Cesarean delivery	85(25.6)	57(16.1)	<.01[b]
Blockage of labor	59(17.8)	24(6.8)	<.01[b]
Failure of forceps	4(1.2)	0	NA
Failure of labor induction	12(3.6)	10(2.8)	.95[b]
Fetal distress	7(2.1)	17(4.8)	.05[c]
others	3(0.9)	3(0.8)	.99[c]
Obstetric infection	139(41.9)	45(12.7)	<.01[b]
Chorioamnionitis-Clin	29(8.8)	8(2.3)	<.01[c]
Chorioamnionitis-Hist	110(33.3)	37(10.5)	<.01[b]
Clinical Diagnosis			
Bacteremia	24(7.3)	7(1.9)	<.01[c]
Puerperal sepsis	2(0.6)	0	NA
Wound infection	8(2.4)	5(1.4)	.93[c]
Pelvic abscess	2(0.6)	0	.NA
Postpartum haemorrhage	38(11.5)	21(5.9)	<.01[b]
≥500ml	21(6.3)	16(4.5)	.90[c]
≥1000ml	17(5.1)	5(1.4)	<.01[c]
Pelvic inflammatory disease	14(4.2)	3(0.8)	<.01[c]
Hysterectomy	2(0.6)	0	NA
Abruptio Placentae	1(0.3)	0	NA
Cord prolapses	1(0.3)	0	NA
Urine retention	41(12.4)	12(3.4)	<.01[b]
Stress incontinence	61(18.4)	25(7.1)	<.01[b]
Hospital stays, d	4.3±3.1	2.9±1.7	<.01[a]

Data are mean±SD (range) or number (percentage). Superscript "a" in table indicate that the data was analyzed in Wilcoxon rank sum test, superscript "b" indicate that the data was analyzed in Pearson Chi-square test, and superscript "c" indicate that the data was analyzed in Fisher's exact tests.

the study related to pelvic inflammatory disease, urine retention, and stress incontinence were noted 42 days postpartum. The percentage of pelvic inflammatory disease in the PROM group was higher than in the non-PROM group (4.2% *vs.* 0.8%; P<.01). The proportion of urine retention and stress incontinence was higher in PROM group than in the non-PROM group. Women with complicated PROM had a longer hospital stay than women in the non-PROM group (4.3±3.1 *vs.* 2.9±1.7; P<.01) (Table 2).

Neonatal Adverse Outcomes

Neonates born to women from the PROM group presented with a higher incidence of an Apgar score of ≤7 at 1min than in neonates born to women from the non-PROM group (8.1% *vs.* 2.8%; P<.01). The proportion of Neonatal Intensive Care Unit (NICU) admissions in PROM group was higher than in the non-PROM group (10.1% *vs.* 5.1%; P<.01). The percentage of neonatal sepsis was higher in the PROM group than in the non-PROM (2.4% *vs.* 0.6%; P<.01). Other neonatal adverse outcomes including respiratory distress syndrome, incubation, intraventricular hemorrhage, and necrotizing enterocolitis were similar between both groups (Table 3).

Table 3: Neonatal adverse outcomes.

Variable	PROM	Non-PROM	P-value
	N=331	N=354	
Apgar score			
1min ≤7	27(8.1)	10(2.8)	<.01[c]
5min ≤7	11(3.3)	8(2.3)	.95[c]
NICU admission	39(10.3)	18(5.1)	<.01[b]
Sepsis	8(2.4)	2(0.6)	<.01[c]
RDS	5(0.9)	1(0.3)	.97[c]
Intubation	6(1.8)	3(0.8)	.91[c]
IVH	5(1.5)	1(0.3)	.92[c]
NEC	2(0.6)	1(0.3)	1.0[c]
Neonatal death	2(0.6)	0	NA

Data are expressed as mean±SD (range) or number (percentage). Superscript "a" in table indicate that the data were analyzed using the Wilcoxon rank sum test, superscript "b" indicate that the data were analyzed using Pearson's Chi-square test, and superscript "c" indicate that the data were analyzed using Fisher's exact test. RDS: Respiratory Distress Syndrome, IVH: Intraventricular Hemorrhage, NEC: Necrotizing Enterocolitis. NICU: Neonatal Intensive Care Unit.

Subgroup Analyses

Bases on the results of this study, women and neonates in the PROM group presented with a higher incidence of adverse outcomes including obstetric infection, bacteremia, postpartum hemorrhage, pelvic inflammatory disease, urine retention, stress incontinence, Apgar score of 1min less than 7, NICU admission, neonatal sepsis, and neonatal death. To sufficiently analyze the reasons underlying the adverse maternal and neonatal outcomes, we stratified the PROM group into three subgroups according to the interval between PROM onset and delivery time, respectively was less and equal to 24 group, 24-48 group, 48-72 group. Comparison of the duration from PROM onset to delivery time between the ≤24 hours with 24-48 hours groups, revealed no significant difference in proportion of maternal and neonatal adverse outcomes. However, when the 24-48 group compared with the 48-72 group, women and neonates in the 48-72 group had a significantly higher incidence of obstetric infection, bacteremia, postpartum hemorrhage, pelvic inflammatory disease, urine retention, stress incontinence, Apgar score ≤7 at 1min, NICU admission, and neonatal sepsis (Table 4).

Discussion

Diagnosis and management of PROM have been thoroughly investigated in the literature, nevertheless, many decisions are still debatable. Most obstetricians seem paying more attention to the preterm premature rupture of membranes due to its adverse maternal and neonatal outcomes. Little emphasized the management of term pregnancy prelabor rupture of membranes because of its

Table 4: Relationship between the duration from PROM onset to delivery time and adverse maternal and neonatal outcomes of women with complicated PROM.

Variable	≤24h	24-48 h		48-72 h	
	N=85	N=202	P value	N=38	P-value
Obstetric infection	30(35.3)	78(38.6)	.99[b]	31(81.6)	<.01[b]
Bacteremia	0	6(2.9)	NA	21(55.2)	<.01[c]
Postpartum hemorrhage	5(5.9)	11(5.4)	.97[c]	21(55.2)	<.01[c]
Urine retention	2(2.4)	5(2.5)	.94[c]	31(81.6)	<.01[c]
Stress incontinence	9(10.6)	17(7.9)	.90[c]	35(92.1)	<.01[c]
Apgar score, ≤7 at 1min	2(2.4)	4(1.9)	.32[c]	21(55.3)	<.01[c]
NICU admission	3(3.5)	6(2.9)	1.0[c]	13(34.2)	<.01[c]
Neonatal sepsis	0	1(0.4)	NA	7(18.4)	<.01[c]
Neonatal death	0	0	NA	2(5.3)	NA

Data are expresses as mean±SD (range) or number (percentage). Superscript "a" in table indicate that the data were analyzed using the Wilcoxon rank sum test, superscript "b" indicate that the data were analyzed using Pearson's chi-square test, and superscript "c" indicate that the data were analyzed in using Fisher's exact test.

better maternal and neonatal prognosis. In fact, many severe adverse outcomes were reported involving inappropriate management of term pregnancy PROM such as severe postpartum hemorrhage induced emergency hysterectomy, infectious shock, sepsis, neonatal death, etc. [15-19]. This study focused on the adverse maternal and neonatal outcomes related to term pregnancy PROM. The results could be divided into four parts, the first was labor correlative adverse outcomes, the second part was postpartum infectious complications, the third part was pelvic floor dysfunction during postpartum recovery stage, and the fourth part was neonatal adverse outcomes.

Compared with non-PROM women, women complicated PROM presented longer time of latency duration from onset of membrane rupture to regular uterine contraction, lower incidence of vaginal delivery, higher percentage of cesarean section, and higher proportion of severe hemorrhage. Which may be due to the prolonged labor process and blockage of labor. For decreasing these adverse outcomes, care providers could take useful measure including taking appropriate induction of labor without delay, timely dealing with blockage of labor and dystocia, and taking proper measures to prevent severe hemorrhage. Meanwhile, timely dealing with blockage of labor and dystocia, shorten duration of labor, these measure also could decreased the incidence of postpartum pelvic floor dysfunction such as urine retention, stress incontinence [20,21].

For a long time, obstetrical infection induced by PROM was an intractable problem, mainly related chorioamnionitis, and secondary severe bacteremia, sepsis, intraperitoneal and pelvic abscess, even infectious shock. In the second part of results, the proportion of infection correlated complications in women with PROM were prominently higher than in women without PROM. Prophylactic antibiotics was recommended in multiple practice guidelines [1,22-24]. Except that what should we do? In this study, we stratified women with PROM into three subgroups according to time of labor process, the results showed that the incidence of severe maternal and neonatal adverse outcomes were significantly higher in women with time of labor process 48-72 hour group. In another words, timely induction of labor without delay, shorten duration of labor maybe the effective measures to lower the incidence of obstetrical infection induced by PROM.

It was known that prolonged labor process was of negative correlation with neonatal prognosis. This study presented on the higher incidence of Apgar score 1 min less and equal to 7 in PROM group, this result may be induced by maternal prolonged latency stage and blockage of labor. Furthermore, in the subgroup analysis, we observed the phenomenon that with the longer time of labor process, the higher incidence of Apgar score 1min less and equal to 7 in PROM group.

In conclusion, our study proposed that women complicated PROM have higher incidence of adverse maternal and neonatal outcomes. Prolonged labor process and higher proportion of labor blockage may be one kind of causes that induced adverse maternal and neonatal outcomes. Taking valid measure to induce labor without delay, shorten labor process, timely dealing with blockage and dystocia maybe the useful measures to decrease the incidence of adverse outcomes. This study conclusion will provide clinician counseling of women complicated PROM, the counseling includes anticipated maternal and neonatal outcomes, potential complications, precautions for patient, and management plan.

Limitations

Limitations of this study should be noted. Although its multicenter clinical controlled study, the study was not powered to detect differences in infrequent outcomes. Secondly, multifactor induced confound bias was possible in this study. Thirdly, our suggestions will need to be evaluated in a larger samples trial.

Declaration

Declaration is not applicable.

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Conflicts of Interest

The funding organization played no role in the study design, in the collection, analysis, and interpretation of data, in the writing of the article, or in the decision to submit the article for publication.

Author Contributions

Xiu Wang: Protocol development and manuscript writing; Li Xia: Data analysis and manuscript revising; Li Qin: Data collection, management and manuscript writing and manuscript revising; Chunfang Li:Protocol development and manuscript writing and manuscript revising; Qunchang Zhang: Data collection, management and manuscript writing and revising; Tongqiang He: Data collection, management and manuscript writing; Zhao Duan: Data collection, management; Jing Lei: Data collection, management.

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