Evaluation of perinatal outcomes in pregnant women with preterm premature rupture of membranes

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Summary

Objective: To determine the association between amniotic fluid index (AFI) and perinatal outcomes in preterm premature rupture of membranes (PPROM).
Method: A retrospective cohort study was conducted between 2008 and 2012. 86 pregnant women were included, with a diagnosis of PPROM and gestational age from 24 to 35 weeks. Women who presented hypertensive disorders, diabetes, fetuses with birth defects and infection at admission were excluded. To determine the association between AFI and perinatal outcomes, chi-square and Fisher's exact test were used if necessary, as well as risk ratio (RR) and 95% confidence intervals (95CI). Correlation between AFI and perinatal outcomes was determined by using simple linear regression, and AFI progression during pregnancy was analyzed by Z-test.
Results: When comparing newborns presenting ultrasound with AFI<5cm and AFI>5cm, there was a higher frequency of perinatal mortality when the AFI was lower than 5 cm. However, when the oligohydramnios was diagnosed as severe (AFI<3cm), there was a higher frequency of Apgar scores less than seven at 1 minute, neonatal sepsis and early neonatal mortality compared to those presenting AFI>3cm. There was a positive correlation between AFI and gestational age at delivery, birth weight and Apgar scores at minutes 1 and 5. There was also a decrease in amniotic fluid volume with increased gestational age.
Conclusion: The presence of severe oligohydramnios after PPROM contributed to a higher frequency of perinatal complications and death.

Keywords: amniotic fluid, premature rupture of fetal membranes, neonatal intensive care units.

Introduction

Amniotic fluid (AF) provides a protective environment for the development of the fetus.[1] A decrease in its volume can occur due to premature rupture of membranes (PROM), and when this happens before the 37th week of pregnancy it is called preterm premature rupture of membranes (PPROM).[1,2]

The volume of amniotic fluid is an important parameter in the evaluation of fetal well-being.[3] The amniotic fluid index (AFI) ultrasound technique is one of the methods used, with oligohydramnios when the AFI is less than 5 cm and severe oligohydramnios when less than 3 cm.[4]

Severe oligohydramnios after PROM is associated with fetal abnormalities, pulmonary hypoplasia, intrauterine growth restriction, fetal distress, presence of meconium and an Apgar score lower than seven at five minutes.[3] In addition to the presence of chorioamnionitis, the long length of time of premature rupture of membranes and the oligohydramnios are risk factors for adverse perinatal outcomes.[5-8]

PPROM is one of the main causes of prematurity and its complications, such as newborn respiratory distress syndrome, neonatal sepsis, necrotizing enterocolitis, intraventricular hemorrhage, periventricular leukomalacia, varying degrees of hypoplasia and bronchopulmonary dysplasia, contributing greatly to an increase in neonatal morbidity and mortality.[7,8]

A prospective cohort study in women with PPROM verified the association of oligohydramnios, the lowest

latency period, and increase in adverse perinatal outcomes, such as an Apgar score lower than seven at five minutes after birth and increased rate of neonatal deaths,[8] unlike a different study.[9] Thus, the objective of our study was to determine whether there is an association of amniotic fluid index and perinatal outcomes in patients with preterm premature rupture of membranes.

Method

An observational, retrospective cohort study was conducted at the high-risk pregnancy ward at the Women's Center of the Instituto de Medicina Integral Prof. Fernando Figueira (Imip) from January 2008 to December 2012.

The study only began after approval by the Ethics Committee for research on human subjects at the Imip - CAAE - 0252.0.099.000-11.

Epi Info™ software version 7 (Centers for Disease Control and Prevention – CDC, Atlanta, GA, USA) was used for calculation of the sample size in order to verify that the sample had sufficient strength to observe differences between the groups. A percentage of 36% for chorioamnionitis was considered in pregnant women with oligohydramnios after PPROM, and 9% in pregnant women without oligohydramnios.[5] For a strength of 80% and a 95% confidence level, we found that the sample of our study of 86 pregnant women would be sufficient to provide us with an answer.

Pregnant women with a diagnosis of premature rupture of membranes from week 24 to week 35 of pregnancy hospitalized in the high-risk pregnancy ward were included. The exclusion criteria were: pregnant women with hypertensive syndromes, diabetes, diagnosis of fetal malformation found on ultrasound performed between weeks 20 and 24 of pregnancy, not having taken the AFI measurement, and diagnosis of infection at the time of hospitalization. The sample is characterized in Table 1.

The independent variable was the AFI, with cut-off points of 3.0 cm and 5.0 cm. The dependent variables were: length of neonatal hospital stay (<10 days and >10 days), birth weight (>2000 g and <2000 g), Apgar score at 1 and 5 minutes (<7 or >7), need for admission to the intensive care unit (ICU), perinatal complications, sepsis,[10] ventilatory assistance,[10] early (less than seven days) or late-onset mortality (more than seven days up to 28 days or hospital discharge) and intrauterine death.

All patients were subjected on admission to a new obstetric ultrasound to determine the amniotic fluid index (AFI). Subsequently, if necessary, other ultrasounds were performed upon request by the attending physicians. The amniotic fluid index was calculated in centimeters by following the technique of Phelan et al.[4] The last value measured was considered for AFI classification, divided into four groups for comparison (AFI < 5.0 cm *vs.* > 5.0 cm and AFI < 3.0 cm *vs.* AFI > 3.0 cm).

TABLE 1 Characteristics of pregnant women with a diagnosis of PPROM.

Characterization of the sample	Average ± SD	Median, IIQ	Variation
Mother's age (years)	25.4±6.1	-	14 – 40
Gestational age at admission (weeks)	31.9±2.8	-	25 – 35
AFI at admission (cm)	3.7±2.1	-	0 – 8
Previous gestations	-	2, 1-3	1 – 13
Previous parity	-	1, 0-2	0 – 12
BMI (kg/m^2)	27.0±5.1	-	18.2 – 40.8

The data was collected from medical records identified in the obstetric screening admissions record book. The medical records were filed at the institution with monitoring conducted from admission up to discharge or death of the newborn.

PPROM diagnosis was established using patient history and physical exam. The presence of amniotic fluid in the vaginal sack and/or viewing through the external cervical orifice using the Valsalva maneuver confirmed the clinical diagnosis. After diagnostic confirmation, these women underwent ultrasound in the Fetal Medicine sector to rule out the possibility of fetal malformation, and to measure the volume of amniotic fluid. The pregnant women were monitored daily by clinical and obstetric examination, as well as leukogram for screening of infections in the first three days and after, every three days.

The patients included in the study received care according to institutional protocol,[11] so that the pregnancy is interrupted around the 34th week, when there is no clinical and/or laboratory signs of infection. In the presence of preterm labor, a uterolytic agent was administered (nifedipine 20 mg, orally, loading dose – every 30 minutes up to three consecutive doses; and maintenance doses every 8 hours in the first 24 hours and, then, every 6 hours for another 24 hours), in order to inhibit labor and enable the use of corticosteroids. Corticosteroid therapy (betamethasone acetate 3 mg/mL, betamethasone disodium phosphate 3 mg/mL, via intramuscular injection, total dose of 24 mg, divided into two doses every 24 hours) for acceleration of lung maturity and the administration of prophylactic antibiotics (erythromycin 500 mg orally or ampicillin 1 g intravenously every 6

hours for 7 days, the latter associated with a 1g single dose azithromycin) is recommended for all patients under conservative conduct.

When the women went into labor, 5,000,000 IU (loading) or 2,500,000 IU (maintenance – repeated every 4 hours) of crystalline penicillin diluted in 100 ml of saline solution were administered until delivery of the child.

Statistical analysis was conducted using the public domain program Stata version 10.0. For categorical variables, frequency distribution tables were constructed. For the numerical variables, measures of central tendency and dispersion were calculated. To determine the association between the independent variables and perinatal outcomes, contingency tables were prepared using the chi-square test or Fisher's exact test, where appropriate, adopting a level of significance of 5%. Risk ratio (RR) was calculated and its 95% confidence interval (95CI) as a measure of the strength of the association, assigning the value of 1.0 to the reference category.

For comparison of the means between the two groups, we used Student's *t* test. A Z-test was used for comparison of the means of the AFI between the three times. Through simple linear regression analysis we determined the correlation between amniotic fluid index, birth weight and Apgar scores at 1 and 5 minutes.

Results

Data from the 124 patients who were admitted to the high-risk pregnancy unit diagnosed with PPROM were collected. However, only 86 of these pregnant women had been submitted to ultrasound with measurement of the AFI and had a gestational age between 24 and 35 weeks. The groups of pregnant women were then categorized based on AFI less than 3.0 cm and less than 5.0 cm, to observe whether variations in oligohydramnios would interfere in perinatal outcomes. We found 30 pregnant women with an AFI less than 3.0 (34.8%) and 48 with an AFI less than 5.0 cm (55.8%). Corticosteroid therapy for acceleration of pulmonary maturity was given to 96.5% (n=83) of the women, while prophylactic antibiotics were given to 91.9% (n=79) of them.

For the majority of the maternal characteristics studied, no significant differences were observed in the groups in the two analyses carried out. However, there was a difference in gestational age at diagnosis of rupture of membranes, both with AFI < 3.0 cm and AFI > 3.0 cm (63.3 *vs.* 30.4%; p=0.003) and an AFI < 5.0 cm and AFI > 5.0 cm (51.0 *vs.* 29.7%; p=0.04) (Table 2).

In relation to the perinatal results, when comparing the newborns in two groups with AFI < 5.0 cm and AFI > 5.0 cm, a statistically significant difference was not observed in relation to Apgar scores lower than seven at 1 and 5 minutes, need for admission to NICU, presence of any perinatal complications, sepsis and early or late neonatal mortality (Table 3). Although 64% of the newborns weighed less than 2000 g, there was no significant difference in weight in relation to the presence of an AFI lower or greater than five (Table 3). In relation to general mortality (early and late neonatal mortality and intrauterine death) it is important to highlight that this was significantly more frequent when AFI was less than 5.0 cm (32.7 *vs.* 10.8%; RR 3.02; 95CI 1.10-8.3; p=0.02).

We should emphasize that, comparing the neonatal outcomes in terms of severe oligohydramnios (AFI < 3.0 cm or ≥ 3.0 cm), a statistically significant association was observed for: AFI < 3.0 cm with a higher frequency of Apgar scores lower than seven at 1 minute (RR 2.09; 95CI 1.19-3.68), neonatal sepsis (RR 3.60; 95CI 1.01-13.3) and early neonatal mortality (RR 3.60; 95CI 1.18-10.9) and general mortality (RR 2.80; 95CI 1.29-6.09), with the strength of the association greater than the cut-off point used previously (AFI of 5.0 cm) (Table 4).

It should be noted that the average latency period was similar in the two analyses conducted: AFI < 5.0 cm or > 5.0 cm (9.9, 9.4 days *vs.* 10.0, 9.4 days; p=0.98); and AFI < 3.0 cm or > 3.0 cm (8.4, 7.9 days *vs.* 12.1, 10.7 days; p=0.07).

TABLE 2 Characteristics of the women according to amniotic fluid index (AFI) in preterm premature rupture of membranes.

Characteristics of the women	AFI < 3 cm		AFI > 3 cm		p*	AFI < 5 cm		AFI > 5 cm		p*
	n=30	%	n=56	%		n=48	%	n=38	%	
Age > 30 years	6	20.0	12	21.4	0.88	11	22.9	7	18.4	0.69
Gestational age at diagnosis < 30 weeks	19	63.3	17	30.4	0.003	25	52.1	11	28.9	0.04
Body mass index (BMI) > 30 kg/m^2	12	48.0	13	52.0	0.10	19	39.6	6	15.8	0.02
Formal education < 7 years	13	43.3	23	41.1	0.84	24	50.0	12	31.6	0.12
Previous gestations < 1	8	26.7	22	39.3	0.24	18	37.5	12	31.6	0.68
Recife and greater area	15	50.0	27	48.2	0.87	21	43.7	21	55.2	0.20

* Chi-square test

TABLE 3 Perinatal outcomes in pregnant women with a diagnosis of PPROM according to the presence of oligohydramnios.

Neonatal outcomes	AFI < 5 cm		AFI > 5 cm		RR	95CI	p
	n	%	n	%			
Neonatal hospitalization: > 10 days	13	36.1	13	38.2	0.94	0.51-1.73	0.85*
Birth weight: < 2.000 g	33	68.8	22	59.5	1.15	0.83-1.60	0.37*
Apgar score at 1 minute: <7	20	41.7	10	27.0	1.54	0.82-2.88	0.16*
Apgar score at 5 minutes: <7	9	18.8	3	8.1	2.31	0.67 – 7.9	0.16*
NICU hospitalization	29	61.7	18	48.6	1.27	0.85-1.89	0.23*
Perinatal complication	32	65.3	19	51.4	1.27	0.87 – 1.84	0.19*
Neonatal sepsis	6	12.8	3	8.1	1.57	0.42-5.88	0.37**
Ventilatory assistance	29	61.7	18	48.6	1.27	0.85-1.89	0.23*
Early mortality	9	19.1	3	8.1	2.36	0.69-8.10	0.15*
Late mortality	3	7.9	1	2.9	2.68	0.29 – 24.6	0.35**
Intrauterine death	4	8.2	0	0.0	-	-	0.10**
General mortality	16	32.7	4	10.8	3.02	1.10 – 8.3	0.02*

NICU: neonatal intensive care unit; AFI: amniotic fluid index; RR: risk ratio; 95CI: 95% confidence interval. * Chi-square test; ** Fisher's exact test.

TABLE 4 Perinatal outcomes in pregnant women with a diagnosis of PPROM according to the presence of severe oligohydramnios.

Neonatal outcomes	AFI < 3 cm		AFI > 3 cm		RR	95CI	p
	n	%	n	%			
Neonatal hospitalization: > 10 days	8	40.0	18	36.0	1.11	0.58-2.13	0.75*
Birth weight: < 2.000 g	22	73.3	33	60.0	1.22	0.90-1.66	0.22*
Apgar score at 1 minute: <7	16	53.3	14	25.5	2.09	1.19-3.68	0.01*
Apgar score at 5 minutes: <7	7	23.3	5	9.1	2.57	0.89-7.39	0.07**
NICU hospitalization	20	66.7	27	50.0	1.33	0.92-1.93	0.14*
Perinatal complication	20	66.7	31	55.4	1.20	0.85-1.70	0.31*
Neonatal sepsis	6	20.0	3	5.6	3.60	1.01-13.3	0.04**
Ventilatory assistance	20	66.7	27	50.0	1.33	0.92-1.93	0.14*
Early mortality	8	26.7	4	7.4	3.60	1.18-10.9	0.02**
Late mortality	3	13.6	1	2.0	6.81	0.75-61.9	0.08**
Intrauterine death	1	3.3	3	5.4	0.62	0.07-5.72	0.56**
General mortality	12	40.0	8	14.3	2.80	1.29-6.09	0.007*

NICU: neonatal intensive care unit; AFI: amniotic fluid index; RR: risk ratio; 95CI: 95% confidence interval. * Chi-square test; **Fisher's exact test.

It was also noted that the average amniotic fluid index was significantly lower in the group of infants who presented perinatal complications (3.20, 2.22 cm *vs.* 4.00, 2.18 cm; p=0.04).

After simple linear regression analysis a positive correlation was observed with gestational age in weeks (R^2=0.78; p<0.0001), birth weight (R^2=122.6; p<0.0001) and Apgar scores at 1 (R^2=0.55; p<0.0001) and 5 minutes (R^2=0.45; p<0.0001) (Table 5).

In relation to the mean AFI at the three times, there was a significant decrease in the volume of amniotic fluid with advancing gestational age between time 0 and 1 (Time 0: 3.48 cm *vs.* Time 1: 2.98 cm; p=0.04) and between times 0 and 2 (Time 0: 3.48 cm *vs.* Time 2: 2.54 cm; p=0.004). There is no significant difference between the means of times 1 and 2 (p=0.12).

Discussion

Studies report an association between PPROM and oligohydramnios and adverse perinatal outcomes,[3,5,6] similar to this study which observed an association mainly with severe oligohydramnios. Perinatal mortality was high (18.6%), double that found in a university hospital in Iran, which described a rate of 8.7%,[8] but lower than the 25.7% observed in a university hospital in the southeast of Brazil.[12] The differences in perinatal mortality rates may be

TABLE 5 Correlation between amniotic fluid and perinatal outcomes in pregnant women with a diagnosis of preterm premature rupture of membranes.

	Coefficient	95CI	Standard error	P
Gestational age at delivery (weeks)	0.78	0.47 – 1.09	0.15	< 0,0001
Birth weight (grams)	122.6	70.9 – 174.3	26.1	< 0,0001
Apgar score at 1 min	0.55	0.33 – 0.78	0.11	< 0,0001
Apgar score at 5 min	0.45	0.24 – 0.67	0.11	< 0,0001

Simple linear regression.

due to different conduct protocols for PPROM or even regional differences. It was also observed that when AFI was less than 5.0 cm the risk for perinatal mortality was three times higher. However, in the presence of severe oligohydramnios, we noted double the risk of an Apgar score < 7 at 1 minute and four times the risk of neonatal sepsis and early neonatal mortality.

Gestational age is of fundamental importance in the treatment of PROM. Expectant treatment favors corticosteroid therapy, for acceleration of fetal lung maturity,[1] and prophylactic antibiotics to increase the latency period.[1,13,14] What stands out in this study is that a high rate of neonatal respiratory assistance was found. This high rate probably resulted from prematurity and oligohydramnios, which may have favored pulmonary hypoplasia. This is especially true when the PPROM occurs before the 26th week of pregnancy, due to pulmonary underdevelopment, resulting from the scarcity of amniotic fluid with a prolonged latency period.[15] Tavassoli et. al. observed a frequency of 12.5% in the need for ventilatory assistance when the AFI was lower than 5.0 cm.[9]

The use of a routine uterolytic to inhibit premature labor in PPROM is controversial, as labor itself can be a sign of subclinical chorioamnionitis and may contribute to adverse perinatal outcomes.[16] It should be noted that many of the patients included used a uterolytic agent, waiting for spontaneous or induced labor up to week 34 in the inhibited pregnant women. It is important to note that it is only recently, in 2013, that the American College of Obstetricians and Gynecologists positioned itself against the routine use of a uterolytic to inhibit premature labor in pregnant women with PPROM.[1]

Corroborating data from the literature,[7,8] in this sample the neonatal outcomes were unfavorable when the AFI was less than 3.0 cm, leading us to question whether these pregnant women wouldn't benefit from an interruption of the pregnancy as of week 32. Another question is whether there is any benefit from cesarean section in cases of severe oligohydramnios. In this situation the adverse perinatal results might have been influenced by the compression of the umbilical cord. It is important to note that the patients were evaluated on a daily basis, when labor was absent, and fetal auscultation performed every 15/30 minutes during labor. Nevertheless, we must remember that cesarean sections can increase the risk of maternal infection and its complications, particularly in women at risk of developing chorioamnionitis.[5,7,12] Thus, given the rigorous monitoring of these patients it is likely that the rate of perinatal mortality was due to neonatal sepsis and not compression of the umbilical cord. Another point in favor of mortality, as a result of sepsis, is that the risk of neonatal sepsis was equal to the risk of early neonatal death. Thus, we can highlight the importance of conducting a study developed specifically to determine the factors associated with mortality and/or adverse neonatal outcomes.

Another major concern is the association of PPROM with oligohydramnios and chorioamnionitis.[3,7,8] The diagnosis of chorioamnionitis is based on monitoring of clinical signs and changes in the leukogram.[1,17] Chorioamnionitis was not the subject of this study, but its occurrence may probably have been high because neonatal sepsis was observed in nine newborns. Six of these were part of the group with severe oligohydramnios. One study found an association between AFI<5.0 cm and neonatal sepsis,[8] which could be due to ascending infection of the amniotic cavity by microorganisms *Escherichia coli* and Group B β-hemolytic streptococcus, the main cause of neonatal sepsis. Thus, it is not just PPROM that is associated with neonatal sepsis, but the decrease in the volume of AF also favors perinatal infection.[8,19,20] We can also point out the difficulty in diagnosing chorioamnionitis because adverse perinatal outcomes often occur without clinical or laboratory signs of infection.[1,17] Authors analyzing the placentas of puerperal woman who had PROM found a poor correlation between histological chorioamnionitis (59%) and clinical chorioamnionitis (42%).[18]

In the institution's routine, oral or intravenous hydration of the mother is performed in an attempt to preserve the volume of the amniotic cavity, although there

is no evidence to recommend the practice.[21] In our study a decrease in AFI was observed with the progression of gestational age, even with maternal hydration, and consequent risks for the development of adverse perinatal outcomes. It should be noted that this study was not designed to observe the effect of maternal hydration on amniotic fluid volume in patients with PPROM, and further studies are needed to determine this association.

This study presented some methodological limitations, as it is a retrospective study with a small sample size. Therefore, further studies are needed with a prospective design that can answer questions about severe oligohydramnios and its association with adverse perinatal outcomes.

Given all of the above, we can highlight the importance of amniotic fluid volume as an important parameter in the evaluation of fetal wellbeing and perinatal outcomes in preterm premature rupture of membranes. Oligohydramnios is associated with a poor fetal prognosis, with no consensus on the best moment to induce labor seeking a reduction of perinatal risks.[3] However, it can be said that AFI is a good indicator of fetal prognosis in the presence of PPROM.[5]

Conclusion

The unfavorable outcomes observed in this study justify reflection and reassessment of obstetric conduct. When PPROM is associated with severe oligohydramnios, increased surveillance of maternal infection and fetal vitality, early diagnosis of clinical chorioamnionitis becomes necessary, favoring the neonatal outcomes. However, the major benefit of this study was the recognition of the association of severe oligohydramnios and PPROM with adverse perinatal outcomes.

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Resumo

Avaliação dos resultados perinatais em gestantes com rotura prematura das membranas pré-termo

Objetivo: determinar a associação do índice de líquido amniótico (ILA) com os resultados perinatais na rotura prematura das membranas pré-termo (RPMPT).
Método: realizou-se um estudo de coorte retrospectivo, de 2008 a 2012. Foram incluídas 86 gestantes, com diagnóstico de RPMPT e idade gestacional entre a 24ª e 35ª semanas. Foram excluídas gestantes que apresentavam síndromes hipertensivas, diabetes, fetos com malformações fetais e infecção na admissão. Para determinar a associação entre ILA e desfechos perinatais, foram utilizados os testes qui-quadrado e exato de Fisher, quando pertinentes, além da razão de risco (RR) e seu intervalo de confiança a 95% (IC95%). A correlação entre ILA e desfechos perinatais foi determinada por regressão linear simples, e a evolução do ILA durante a gestação foi analisada pelo teste Z.
Resultados: quando comparados os recém-nascidos que apresentavam ultrassonografia com ILA<5 cm e ILA>5 cm, observou-se maior frequência de mortalidade perinatal nos casos de ILA<5 cm. Quando o oligo-hidrâmnio, porém, era diagnosticado como grave (ILA<3 cm), observava-se maior frequência de escore de Apgar <7 no 1º minuto, sepse neonatal e mortalidade neonatal precoce em relação aos que apresentavam ILA>3 cm. Observou-se uma correlação positiva entre ILA e idade gestacional no parto, peso ao nascer e escore de Apgar no 1º e 5º minutos, além de diminuição do volume do líquido amniótico com o avançar da idade gestacional.
Conclusão: a presença de oligo-hidrâmnio grave após a RPMPT contribuiu para uma maior frequência de complicações e mortalidade perinatal.

Palavras-chave: líquido amniótico, ruptura prematura de membranas fetais, unidades de terapia intensiva neonatal, unidades de cuidado intensivo neonatal.

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