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#### Abstract

**Objective:** To identify the risk factors associated with Premature Rupture of Membranes (PROM) at the General Hospital of La Huasteca in patients who requested obstetric medical care during the 2020 - 2021 period.

**Material and Method:** Case-control study, from January 2020 to December 2021. The cases were patients with PROM. The variables were grouped into three types: socioeconomic, maternal and perinatal. In addition, the characteristics of the newborns were analyzed. The information was captured in an automated way, the data was analyzed with descriptive and analytical statistics. The statistical significance value was set at  $\alpha$  = 0.05.

**Results:** During the study period, 2,075 patients attended medical care for their pregnancy, of which 48 had PROM (2.3%). The factors associated with PROM were: urban environment OR = 2.5 (95% CI 1.2 - 5.1; p = 0.0094), single marital status OR = 2.8, 95% CI 1.3 - 5.8; p < 0.0042. Preterm birth OR = 4.7 (95% CI 1.7 - 12.8; p = 0.0012). They started their sexual life before the age of 18, OR = 3.6 (95% CI 1.7-7.5; p = 0.00036). Primiparous OR = 12.6 (95% CI 4.3 - 36.7; p = 0.000051). Multiparous, OR = 20.7 (95% CI 7.2 - 17.3; p = 0.00031). Overweight and obesity OR=3.4, CI95% (1.6 - 7.1; p < 0.000096). While obesity OR=5.0 CI95% (1.1 - 21.0; p = 0.018). Urinary infection OR = 17, CI95% (4.8 - 61.9; p = 0.000012). Cervicovaginal infection OR = 8.6 95% CI (4.2 - 17.4; p = 0.000012). Prenatal Control OR = 3.1 (95% CI 2.6 - 178.9; p = 0.000081). History of PROM OR = 21.9, (95% CI 2.6 - 178.9; p < 0.0039). In relation to the PROM latency hours, the average was  $16.2 \pm$  S.D. hours. Less than 12 hours were 19 (39.5%), from 12 to 23 hours 22 (43.8%) and more than 24 hours 7 (14.5%). Lower gestational age and lower birth weight were statistically significant. Respiratory depression at minute (Apgar 1') was statistically significant.

Conclusions: Some risk factors associated with PROM could be identified, which can be used in subsequent studies.

Keywords: PROM; Risk Factors; Perinatal Morbidity; Cases and Controls

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#### Introduction

Premature Rupture of Membranes (PROM) is the loss of continuity of the ovular membranes with the consequent leakage of amniotic fluid (AF) [1], which increases the risk of perinatal morbidity and mortality [2]. PROM can occur during a term (PT) or preterm birth (PP, < 37 weeks of gestation) [3] in both cases the risk of damage to the mother-product binomial is increased with respect to a rupture during labor or in the expulsive period [1]. It is not known still the cause of premature rupture of the membranes, although there are many and varied factors that can cause PROM; [3] what has been widely documented in the international literature is a correlation between the presence of PROM in a preterm birth (PP) or term and complications for the mother and the product of conception, the risk being greater for a PP with PROM than for a PT [4,5]. According to McKenzie [6] PROM exerts an important influence on the prognosis of the emba reason, since it is the cause of more than 40% of all PP and the most frequent maternal complications, of which 22.9% were chorioamnionitis.

Likewise, Günay [8]., *et al.* document a frequency of maternal complications in 41.4%, of which 33.3% corresponded to Chorioamnionitis and 25.0% to endometritis. Regarding complications in fetuses, Jung [2]., *et al* found a higher frequency of fetal complications in the presence of PROM. Similarly, Günay in his study [8] found fetal complications in 72.9%, of which 52.1% presented respiratory problems, and Knippel documented an early neonatal mortality of 5.6%.7 Several studies have estimated the frequency of PROM, thus, Meller in Argentina [9] calculates a frequency of 3%; in Peru, Gutiérrez reports a similar frequency, 2%. [10] Other authors, such as Etsay in Ethiopia, [11] document a frequency between 5 and 10%.

The variation in this frequency has much to do with the diagnostic method used, as well as the measurement of the hours elapsed between the rupture event, gestational age and at the time of delivery.

However, one of the highest frequencies reported is that of Di Mascio [12] with 20.7%, although this measurement was carried out in the context of the current pandemic of Severe Acute Respiratory Syndrome due to New Coronavirus 2 (SARS-CoV2), patients with this infection presented a high frequency of PROM, so this prevalence should be taken with caution. There are multiple risk factors associated with PROM, several authors have evaluated in different parts of the world the participation of risk factors related to PROM, these factors have been arbitrarily classified as sociodemographic, maternal and perinatal. The sociodemographic factors [13,14] evaluated are: age, low socioeconomic level, rural origin, marital status, smoking and drug use. Maternal factors: 10 [15]. Beginning of active sexual life, number of sexual partners, history of urinary tract infection and/or cervical-vaginal infection, body mass index (< 18.0 or > 25.0), primigravida, multiple gestation (> 3), anemia. The perinatal factors [6,16] evaluated have been: Poor Prenatal Control, gestational age, short intergenic period, history of abortion, PROM, use of intrauterine device, multiple pregnancy. Other studies using logistic regression analysis have evaluated the association between PROM and the type of delivery: PP and PT and have found a greater relationship between PROM and PP (66.3% vs. 39.9%, p < 0.05) [17] and in relation to PROM latency, it presents greater complications as the duration of PR is greater than 15 hours (OR = 7.2) [18]. The detection of factors associated with PROM can contribute to improving the quality of care provided to the obstetric patient, since their identification allows their monitoring and facilitates the evaluation of modifiable factors to establish strategies aimed at their modification, and eventual elimination, with which the rate of perinatal complications would decrease, thereby improving the quality of care provided to patients using our hospital, in addition, it would contribute to reducing care costs since the days of hospital stay and the supplies required for their care would be much lower [19,21]. Risk factors associated with PROM have not been detected in the General Hospital of La Huasteca, so the objective of this study is to identify the factors Sociodemographic, maternal and perinatal risk factors associated with PROM in patients using hospital obstetric health services. The objective of the study was to identify the risk factors associated with PROM at the Huasteca General Hospital in patients who requested obstetric medical care during the 2020 - 2021 period.

#### **Material and Method**

An observational, analytical, retrospective cohort study, with a case-control design, was carried out with the clinical records of patients who attended the Huasteca General Hospital in Huejutla de Reyes, Hidalgo, Mexico, for delivery care, in the period from January 2020 to

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December 2021. The inclusion criteria were: going for delivery care and having had a PROM regardless of gestational age and for controls was attending delivery without premature rupture of membranes. The study was carried out with all patients who were diagnosed with PROM (cases) and were compared with patients who did not have PROM (controls) to identify associated risk factors. The variables of interest were grouped into three types of factors: socioeconomic, maternal and perinatal, and data on newborns were also collected.

Socioeconomic factors: Non-reproductive age (< 18 years and > 35 years) socioeconomic level, classified as low level (levels 1 - 3) high level (levels 4 and 5). Place of origin, urban or rural (according to the classification of the National Population Council 33), Marital Status, single or Free Union and Married, Status of tobacco and drug use.

Maternal Factors: Premature Birth (< 37 Weeks of Gestation, SDG), Number of Sexual Partners, Age of onset of active sexual life, Number of births (primiparous, multiparous). Nutritional status weight for gestational age (According to the tables of weight gain in pregnancy of the World Health Organization 34). Presence of anemia (Hemoglobin level < 11.6 mg/dl), presence of a Urinary Infection and/or Cervical-Vaginal Infection.

The Perinatal Factors were: Inadequate Prenatal Control (Medical Consultations < 5), Intergenesic Period < 2 years, History of PROM in previous pregnancies, History of Abortion, Multiple Pregnancy and use of Intrauterine Device (IUD) in the current pregnancy. Likewise, the average PROM hours were evaluated and classified into three groups: less than 8 hours, from 8 to 12 hours and more than 12 hours (Prolonged Rupture) 35,36.

The characteristics of the newborns studied were: Gestational age, type of prematurity, [22-26,27]. Birth weight, Apgar at one minute and at five minutes, admission to the Neonatal Intensive Care Unit (NICU), reason for admission, days of stay Hospital and hospital discharge condition.

The Statistical Area provided the information of the ICD-10 codes: 0410, 0411, 0418 and 0419 with such information, the Clinical Files were requested from the Clinical File area, two Undergraduate Medical Interns filled out the Data Collection Sheet, designed by researchers. Once the information was captured in the spreadsheet, one of the researchers validated the information that was later captured in an Excel<sup>®</sup> spreadsheet from the Microsoft<sup>®</sup> 2010 Windows Office Package for analysis. The database was exported to the EPI-INFO Program ver. WHO 7.0 for analysis. Statistical analysis was descriptive, for qualitative variables: rates, ratios and proportions; for the numerical ones, calculation of measures of central tendency and dispersion. The variables of interest (Risk Factor) will undergo a bivariate analysis, for the qualitative ones, calculation of OR, 95% CI, X2 and p value. The statistical significance value was set at  $\alpha = 0.05$ . The Research Protocol was validated and authorized (02/02/2022) by the Teaching, Research, Training and Ethics Committee of the Hospital.

#### Results

In the study period (January 2020 to December 2021, 2,075 patients attended the Huasteca General Hospital for medical care during their pregnancy, of which 48 had PROM (2.3%), these were compared with a random sample of 144 patients pregnant women without PROM, with a 1:2 ratio. Sociodemographic factors.

Regarding the non-reproductive age of < 18 and > 35 years, there were 9 (18.7%) in the cases and 17 (17.7%) in the controls, p > 0.05. Of the Socio-economic Level, lower (2 and 3) the cases were 38 (79.1%) and the controls 64 (66.6%) the difference was not statistically significant. In relation to the origin of the municipality where the patient lives, 30 (62.5%) cases come from the urban environment 30 (62.5%) controls 38 (39.5%), with an OR = 2.5 (95% CI 1.2 - 5.1; p = 0.0094) and single marital status 24 (50%) was associated with a higher risk of suffering PROM compared to controls 25 (26.4%) with an OR = 2.8, CI95% 1.3 - 5.8; p < 0.0042.

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Factor	Number	Percent	Or <sup>1</sup> (Ci <sup>2</sup> )	Р
AGE				
	9	18.8		
<18 and >35	39	81.2		N.S.*
From 18 to 35				
SOCIOECONOMIC LEVEL				
	38	79.2		
Level 2 and 3	10	20.8	1.9 (0.48-5.87)	N.S.*
Level 4 and 5				
ORIGIN	30	62.5		
			2.5 (1.2-5.1	0.0094
Urban Rural	18	37.5		
CIVIL STATUS				
	24	50		
Single woman		= -	2.8 (1.3-5.8)	0.0042
Married	24	50		

 Table 1: Sociodemographic factors associated with PROM of the pregnant women studied. 2020-202

 1.- Odds Ratio. 2.- Confidence Interval. \*.- Not significant.

Factor	Number	Percent	Or <sup>1</sup> (Ci <sup>2</sup> )	Р
EARLY LABOR	13	27.1	4.7 (1.7-12.8)	0.0012
YES NO	35	72.9		
NUMBER OF SEXUAL PART-				
NERS	44	91.7		
1	4	8.3	0.78 (0.2-2.6)	N.S.*
>1				
BEGINNING OF SEXUAL LIFE (BEFORE 18 YEARS OLD)	31	64.5	3.6 (1.7-7.5)	0.0003
YES NO	17	35.5		
PARITY	26	54.2		
PRIMIPARA MIILTIPARA TWO	17	35.4	12.6 (4.3-36.7)	0.00005
BIRTHS	5	10.4	20.7 (7.2-17.3)	0.0003
BMI <sup>3</sup>				
OVERWEIGHT AND	34	70.8	3.4 (1.6-7.1	0.00096
OBESITY	14	29.2		
NORMAL				
OBESITY	5	26.3	5.0 (1.1-21.0	0.0181
NORMAL	14	73.7		
ANEMIA	9	18.7	1.3 (0.5-3.3	N.S.*
YES NO	39	81.3		
URINARY INFECTION	17	35.5	17.0 (4.0, (4.0)	0.00000
YES NO	31	64.5	17.0 (4.8-61.9)	0.00002
CERVICO-VAGINAL INFECTION	4	8.4	8.6 (4.2-17.4)	0.0242
YES NO	44	91.6		

**Table 2:** Maternal factors associated with PROM of the pregnant women studied. 2020-2021.

 1.- Odds Ratio. 2.- Confidence Interval. 3.-Body Significant Index. \*-. Not significant.

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Factor	Número	Porciento	Or <sup>1</sup> (Ci <sup>2</sup> )	Р
INADEQUATE PC <sup>3</sup>				
(< 5 QUERIES)				
YES	13	27.1	3.1 (1.2-7.9)	0.010
NO	35	72.9		
PROM				
BACKGROUND				
YES	9	18.7	1.07 (2.6-178.9)	0.00008
NO	39	81.3		

Table 3: Perinatal factors associated with PROM of the pregnant women studied. 2020-2021.

 1.- Odds Ratio. 2.- Confidence Interval. 3.- PC.- Prenatal Control \*.- Not significant.

#### **Maternal factors**

Premature delivery occurred in 13 cases (27%) and in 7 (7.3%) of the controls, OR = 4.7 (95% CI 1.7 - 12.8; p = 0.0012). Thirty-one (64.5%) of the cases began their sexual life before the age of 18, while in the controls this condition was present in 32 (50.1%), with an OR = 3.6 (95% CI 1.7 - 7.5; p = 0.00036 In relation to the Number of Sexual Partners, 4 (8.3%) of the cases have more than one partner and 10 (10.4%) of the controls had this condition (OR = 0.78; CI95% 0.2 - 2.6; p = 0.6908. Regarding the primiparas, in the cases there were 26 (83.8%) and in the controls 25 (14.0%) the OR value was 12.6 (CI95% 4.3 - 36.7; p = 0.000051. While in the multiparous women, the cases were 17 (35.4%) and controls 10 (10.4%), with an OR = 20.7 (95% CI 7.2 - 17.3; p = 0.00031). In relation to weight gain in pregnancy, cases with overweight and obesity there were 34 (70.8%), while in the controls, this same category showed 40 (41.6%) patients (OR = 3.4, 95% CI 1.6 - 7.1; p < 0.000096). While in the obesity category, the cases were 5 (26.3%) and in 14 (14.5%) of the controls (OR = 1.3, CI95% 0.5 - 3.3; p = 0.52). Urinary infection was present in 17 (35.4%) of the cases and in 3 (3.2%) of the controls (OR = 17, CI95%) 4.8 - 61.9; p = 0.000012).

#### **Perinatal factors**

Inadequate Prenatal Control occurred in 13 (27%) of the cases and in 10 (10.4%) of the controls (OR = 3.1 CI95% 2.6 - 178.9; p = 0.0000081. The history of PROM in a previous pregnancy showed a strong association with the PROM in the present pregnancy, since the cases were 9 (24.3%) and the controls only 1 case (1.04%) presented this history (OR = 21.9, CI95% 2.6 - 178.9; p < 0.0039). in no case of patients with an Intergenic Period < 2 years, history of abortion, carrying an IUD or multiple pregnancy. In relation to the hours of latency of the PROM, the average was 16.2 ± SD hours. Less than 12 hours were 19 (39.5%), from 12 to 23 hours 22 (43.8%) and more than 24 hours 7 (14.5%). The average number of days of hospital stay in the cases was 3 days while in the controls it was 1.3 days (p = 0.000005). The reason for hospital discharge in the cases, 45 (93.7%) was due to improvement and 3 (6.2%) due to death, while in the controls, 93 (96.8%) due to improvement and 2 (2.0%) due to death. Regarding this last indicator (deaths), the difference between both groups was

#### **Characteristics of newborns**

Gestational Age was lower in cases, 36 SDG than, in controls, 38 SDG (p < 0.0012) and in relation to birth weight, the proportion of newborns with lower birth weight (< 2,500 g) was in cases 13 (86.4%) compared to controls 11 (22.9%), significant difference (p < 0.00015). The 13 preterm infants were classified according to the WHO prematurity typology: Extremely Premature 2 (15.3%), Severely Premature none, Moderate Premature 1 (7.7%) and Mild Premature 10 (76.9%). Respiratory depression at one minute occurred in 12 (24.3%) of the

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cases and in 9 (9.4%) of the controls (p < 0.0122). 100% of these patients recovered within 5 minutes. Of the 48 cases, 4 were admitted to the NICU, 8.3% of the controls, no newborn was admitted to intensive care. Of the 4 who were admitted to the NICU, all were admitted for pneumonia. Regarding mortality, 2 of the 48 cases (4.2%) and 3 of the 96 controls (3.1%) died (p > 0.05), the difference was not significant.

#### Discussion

PROM continues to be a frequent and serious complication for the binomial in general hospitals that care for obstetric patients. Much progress has been made in diagnostic methods, beyond direct observation and crystallography. Similarly, there is much progress in treatment protocols for this type of patient. However, analytical studies to identify risk factors have been mostly case-control studies, as an attempt to modify them, but analytical cohort studies to modify them are relatively few.

There are many and very varied risk factors associated with PROM analyzed. To simplify their analysis, some authors have arbitrarily divided them into three types: socioeconomic, maternal, and perinatal, in an attempt to understand the dynamics of these factors and their relationship with PROM. However, a limitation in our study is the fact that it is a retrospective study, but despite this, the design is the most convenient to explore the relationship of certain factors with PROM. We studied 20 risk factors, 6 socioeconomic, 8 maternal and 6 perinatal.

In this sense, our results are different from those of Ramos in Peru, who published his study in 2020 and found that age < 18 and > 35 years and Socioeconomic Level are factors associated with PROM; we were unable to associate these factors.

In relation to the marital status Bendezú in Peru [16] finds an association with the married marital status, contrary to our data in which the single marital status was associated with a greater risk of suffering PROM. We found no association with smoking and drug use.

Regarding maternal factors, our results coincide with those of Assefa [11], where it is found that multiparous women have a higher risk of suffering from PROM. Likewise, we agree with the findings of Morgan [14] and Ramos [15] who find an association with obesity, the presence of urinary tract infection and cervical-vaginal infection.

Our results are similar to those reported by Gutiérrez., et al [10], in which inadequate Prenatal Control and a history of PROM in previous pregnancies are related to PROM.

The mechanism by which some factors can cause PROM remains unclear. In the case of urinary and cervical-vaginal infections, the mechanism is better understood, however, how do socioeconomic factors affect pregnant women? For example, how is the municipality of urban origin and the single marital status associated with a greater risk of suffering from PROM? And in the case of perinatal factors, such as Prenatal Control, how does an inadequate control influence the development of an PROM?

These are questions that begin to have an answer with the epidemiological analysis of such factors, in our case, a second analysis of the data will be made through logistic regression to identify that group of women with the highest risk of having an PROM, useful information for the doctor of first contact detect those patients with higher risk, establish a timely management plan that helps reduce perinatal complications of PROM and contribute to improving the quality of care. Because the study is a retrospective study, there are methodological limitations that must be considered; however, these limitations are inherent to the design of this type of study.

In a second investigation, a prospective cohort study will be designed to identify those patients with a higher risk of suffering from PROM, establish more timely management at the second level of care, and in a third experimental investigation, modify the risk factors that help reduce the Frequency of PROM and its complications in patients using the Health System of our state.

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