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THE RELATION BETWEEN LACTATE LEVEL IN VAGINAL FLUID AND LATENCY PERIOD OF LABOUR IN PRETERM PRELABOUR RUPTURE OF MEMBRANES

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ABSTRACT

Background: Preterm prelabour rupture of membranes occurs in 2-4% of pregnancies, characterized by the spontaneous rupture of membranes before 37 weeks. The literature discusses the relationship between vaginal fluid lactate levels and the latent phase of labor in these cases. **Aim:** The relation between lactate level in vaginal fluid and latency period of labour in preterm prelabour rupture of membranes. **Patients and Methods:** This is a prospective observational case series study included 100 pregnant patients with singleton viable fetus with gestational age ranged from 28-36 weeks of gestation included in the study which conducted in the Department of Obstetrics and Gynecology at Al-Batool Teaching Hospital during a period from 10th of February to 1st of June 2024. **Results:** Patients with a latency period within 48 hours exhibited significantly higher vaginal lactate levels (7.21 ± 2.59 mmol/L) compared to those with a latency period after 48 hours (4.57 ± 0.35 mmol/L), with a P-value of 0.001. A strong negative correlation exists between vaginal fluid lactate level and latency period (R = -0.614, P = 0.022), most pronounced in the very preterm group (R = -0.713, P = 0.001), followed by the moderate preterm group (R = -0.621, P = 0.022), and least in the late preterm group (R = -0.512, P = 0.041). **Conclusions:** Negative correlation between lactate level in vaginal fluid and the latency period, indicating that higher lactate levels were associated with a shorter latency period.

KEYWORDS: Lactate, Latency period, Preterm prelabour rupture of membranes, Vginal fluid.

INTRODUCTION

Prelabour rupture of membranes (PROM) is a significant clinical condition where the chorioamnionic membranes rupture, leading to the expulsion of amniotic fluid before active labor begins. PROM is classified based on gestational age: preterm prelabour rupture of membranes (PPROM) occurs before 37 weeks, while term prelabour rupture of membranes (TPROM) occurs at or beyond this gestational milestone. The interval between membrane rupture and the onset of active labor, known as the latent phase, can range significantly, and if it exceeds 12 hours, it is considered prolonged.[1]

PPROM is prevalent in 2-4% of all pregnancies and is responsible for approximately 25% of preterm births. The World Health Organization defines preterm birth (PTB) as any birth occurring before 37 completed weeks of gestation. It can be further categorized into extremely preterm, very preterm, moderate preterm, and late preterm.[2] Anatomically, the chorio-amniotic membranes consist of three layers: the amnion, chorion, and a mesenchymal layer. Amniotic fluid plays crucial roles in fetal protection, development, and immune defense. Pathological alterations in the membranes, particularly at the cervical area, predispose them to rupture, with factors such as mechanical stretch, inflammation, and matrix metalloproteinases (MMPs) contributing to the weakening of membrane structure.[3]

The epidemiology of PROM shows a worldwide prevalence variance, with PPROM accounting for significant preterm labor cases.[4] Various etiological factors linked to PROM include maternal conditions such as polyhydramnios, multiple pregnancies, uterine and cervical abnormalities, infections (including bacterial vaginosis and urinary tract infections), malnutrition, environmental factors like smoking, and genetic predispositions including syndromes like Ehlers-Danlos and Marfan.[5-7]

Diagnosis primarily relies on clinical evaluation, history taking, and physical examination. Speculum examinations, nitrazine and fern tests, and other biochemical marker assessments such as fetal fibronectin and insulin-like growth factor binding protein-1 are utilized for accurate diagnosis. Results influence management strategies that balance risks between maternal and neonatal health.[8]

Management modalities for PPROM include prophylactic antibiotic therapy and corticosteroids to minimize the risks of infection and enhance fetal lung maturity, respectively. The use of tocolytics remains subjective, with a focus on prolonging gestation enough for effective steroid treatment.[9]

Maternal complications frequently associated with PPROM include chorioamnionitis, puerperal infections, and necessitated operative deliveries, while fetal complications extend to increased morbidity and mortality rates, arising predominantly from prematurity. The condition can lead to severe neonatal outcomes including respiratory distress syndrome and neurodevelopmental delays.[10]

Lactate is a classical byproduct of glucose metabolism, and the main lactate production pathway depends on glycolysis and its production of lactate as fuel increases when the demand for oxygen and ATP exceeds the cellular supply, such as during strenuous exercise and infection.[11]

Emerging studies propose lactate as a significant biomarker in managing PROM and predicting labor onset, underlining the complex interplay of physiological processes governing PROM and PPROM dynamics throughout pregnancy. Lactate's role as both an energy substrate and signaling molecule underscores its relevance in fetal metabolism and potential clinical diagnostic applications.[12]

The current study aimed to find the relation between lactate level in vaginal fluid and latency period of labour in preterm prelabour rupture of membranes.

PATIENTS AND METHODS

A prospective observational case series involving 100 pregnant patients with premature rupture of membranes (PPROM). Conducted at Al-Batool Teaching Hospital between February 10th to June 1st 2024, the study specifically targeted patients aged between 28 to 36 weeks gestation, confirmed through regular menstrual cycles and/or early ultrasounds. Informed consent was obtained from all participants.

The inclusion criteria mandated that patients had a singleton pregnancy with viable fetuses and cervical dilatation of less than 4 cm, while the exclusion criteria eliminated those with multiple pregnancies, existing medical conditions (such as diabetes and hypertension), antepartum hemorrhage, and several other complications, including infections and congenital fetal abnormalities.

Ethical considerations were duly addressed, with approval obtained from both the Iraqi Board of Health Specialization and the Nineveh Health Directorate. Patient confidentiality was ensured by anonymizing data and employing secure methods for data storage.

Data collection involved a comprehensive, pre-designed questionnaire covering demographic factors and medical history. Parameters evaluated included patients' gravidity, parity, frequency of antenatal care visits, presenting complaints, past obstetrical histories, and vital signs, alongside a complete examination to assess the clinical status of the fetus and the mother. Specific assessments involved sterile speculum examinations to evaluate amniotic fluid loss and subsequent laboratory analyses for inflammatory markers, such as complete blood count and CRP levels.

Laboratory analysis included a sterile speculum examination where lactate levels were measured using a competitive ELISA method, with specific attention given to a cutoff value of more than 5 mmol/L as defined in previous research.

Statistical analysis was performed utilizing Microsoft Excel for data management and Minitab software for analytical purposes, with descriptive statistics presented as means and percentages. The analytical method included independent T-tests for quantitative comparisons, and Chi-square tests for categorical data, with a significance threshold set at p-values ≤ 0.05.

RESULTS

This is a prospective observational case series study that included 100 pregnant patients suffered from PPROM. Regarding sociodemographical characteristic, the mean age was 27.0 ± 4.1 years, ranging from 17 to 39 years. The average body mass index (BMI) was 24.8 ± 2.1 kg/m², with values ranging from 20.2 to 29.6 kg/m². Most of the participants were housewives (80.0%), and a smaller portion were employed (20.0%). The majority were illiterate (60.0%), while 19.0% had higher education, and 9.0% had a primary education level. Over half of the patients (60.0%) resided in rural areas. In terms of smoking, 31.0% were non- secondary smokers,

and 69.0% were secondary smokers. As shown in Table (1).

Table 1: Sociodemographical characteristics of studied patients.

Variables		**Mean ± SD**	**Range**
Maternal Age (years)		27.0 ± 4.1	17 – 39
Weight (kg)		63.1 ± 4.9	54 –78
Height (m)		1.6 ± 0.1	1.5 – 1.7
BMI (kg/m2)		24.8 ± 2.1	20.2 – 29.6
[total = 100]		No.	%
Occupation	Housewife	80	80.0
	Employee	20	20.0
Educational Level	Illiterate	60	60.0
	Primary	9	9.0
	Secondary	12	12.0
	Higher education	19	19.0
Residence	Urban	40	40.0
	Rural	60	60.0
Secondary Smoking	Yes	69	69.0
	No	31	31.0

Regarding obstetrical data, the average gravida number was 2.6 ± 1.6, the mean para was 1.5 ± 1.4. Abortion mean was 0.1 ± 0.4.The average gestational age at (PPROM) was 32.7 ± 2.0 weeks, while at the onset of labour was slightly higher, with a mean of 32.9 ± 2.0 weeks. The average latency period was 30.1 ± 16.9 hours. The majority (57.0%) had irregular antenatal care visits and (40%) of patients had an interpregnancy interval of less than 6 months. Cervical dilatation of 1 cm was observed in 50.0% of the cases and 1-2 cm in 31.0% as shown in Table (2).

Table 2: Obstetrical characteristic of studied patients.

Variables		**Mean ± SD**	**Range**
Gravida		2.6 ± 1.6	1 – 8
Para		1.5 ± 1.4	0 – 7
Abortion		0.1 ± 0.4	0 – 2
Gestational age at PPROM [Median]		32.7 ± 2.0 [33.0]	28.0 – 36.0
Gestational Age at Onset of labour [Median]		32.9 ± 2.0 [33.1]	28.3 – 36.2
Latency period [Median]		30.1 ± 16.9 [24.0]	14.0 – 72.0
total = 100]		No.[	%
Antenatal care visits in current pregnancy	No antenatal care	8	8.0
	Irregular	57	57.0
	Regular	35	35.0
Inter-pregnancy interval	Primi	19	19.0
	< 6 months	40	40.0
	6-12 month	30	30.0
	> 1 year	5	5.0
	> 2 years	6	6.0
Cervical dilatation	No dilatation	19	19.0
	1cm	50	50.0
	1-2 cm	31	31.0

Regarding patients who had latency period after 48 hours were more likely to be housewives (90.0%) and live in urban areas(75.0%) than those within 48-hour group (77.5%housewives, 31.2% urban residents), p-values=0.035, 0.001, respectively. Secondery smoking was more within 48-hour group(75.0%) than those after 48-hour group(45.0%), p-value=0.012. those after 48-hour group were more likely to have irregular or no antenatal care (60.0% and 25.0%, respectively) compared to the 48-hour group, which had more regular visits (40.0%), p-value=0.030. BMI differences were not statistically significant as shown in Table (3).

Table 3: Comparison of sociodemographic characteristics and latency period of studied patients.

Parameters		Latency Period within 48 hrs. [n=80]		Latency Period after 48 hrs. [n=20]		P-value*
		No.	%	No.	%	
Occupation	Housewife	62	77.5	18	90.0	0.035
	Employee	18	22.5	2	10.0	
Residence	Urban	25	31.2	15	75.0	0.001
	Rural	55	68.8	5	25.0	
Secondary Smoking	Yes	60	75.0	9	45.0	0.012
	No	20	25.0	11	55.0	
BMI	Normal (18.5-24.9)	42	52.5	15	75.0	0.057
	Overweight (25-30)	38	47.5	5	25.0	
Antenatal care visits	No antenatal care	3	3.8	5	25.0	0.030
	Irregular	45	56.2	12	60.0	
	Regular	32	40.0	3	15.0	

*Chi square test was used.

The mean vaginal fluid lactate level was 5.1 ± 2.2 mmol/L, with values ranging from 1.25 to 9.67 mmol/L. As shown in Table (4).

Table 4: Vaginal fluid lactate level at the onset of labor.

Variable	Mean ± SD	Range
Vaginal fluid lactate level (mmol/L)	5.1 ± 2.2	1.25 – 9.67

Regarding patients who had latency period within 48 hours had significantly higher vaginal lactate level (7.21 ± 2.59 mmol/L) compared to those who had latency period after 48 hours (4.57 ± 0.35 mmol/L), with a p-value of 0.001, showing statistical significance. As shown in Table (5).

Table 5: Difference between latency period concerning vaginal fluid.

Variable	Latency Period		P- value*
	≤ 48 Hours [n = 80]	> 48 Hours [n = 20]	
	Mean ± SD (Median)	Mean ± SD (Median)	
Vaginal fluid lactate level (mmol/l)	7.21 ± 2.59 (6.8)	4.57 ± 0.35 (4.2)	0.001

*Independent T-test of two mean was used.

Regarding patients who had lactate level ≥ 5 (mmol/L), 92.69% had latency period within 48 hours compared to patients who had lactate level < 5(mmol/L), 77.78%% had latency period after 48 hours with (P-value=0.001) showing statistical significance as shown in Table (6).

Table 6: Difference between lactate level cutoff value and latency period in studied patients.

Latency Period	Lactate level < 5 [mmol/L]	Lactate level ≥ 5 [mmol/L]	P-value*
≤ 48 hours	4/18 (22.22%)	76/82 (92.69%)	0.001
> 48 hours	14/18 (77.78%)	6/82 (7.31%)	

* Chi square-test was applied.

There is a negative correlation between lactate level in vaginal fluid and the latency period, indicating that higher lactate levels were associated with a shorter latency period. As shown in figure (1).

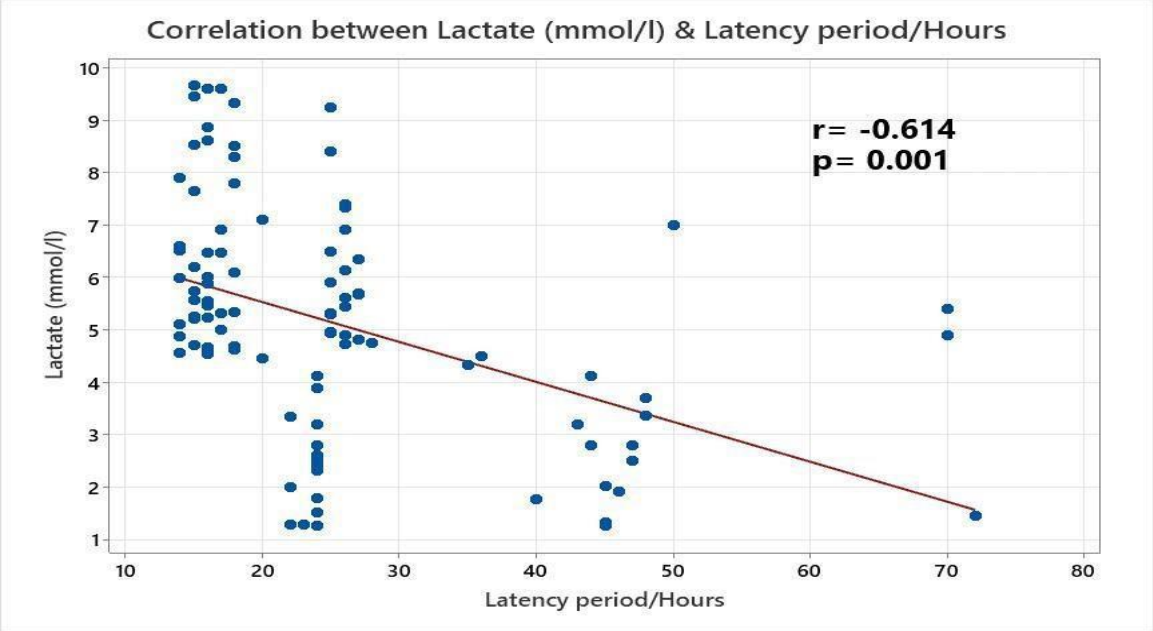

Figure 1: The correlation between lactate level and latency period.

The negative correlation between lactate level and latency period was strongest in patients with gestational ages between 28 to <32 weeks (r= -0.713, p = 0.001), followed by those between 32 to <34 weeks (r = -0.621, p = 0.022), and was weakest in the 34 to 36 weeks group (r= -0.512, p = 0.041). As shown in Table (7).

Table 7: Correlation between Latency Period and Vaginal Fluid Lactate level according to different gestational ages.

Vaginal fluid lactate level (mmol/L)	Latency Period		
	Very preterm GA at PPROM 28 - <32 weeks (n=30)	Moderate preterm GA at PPROM 32 - <34 weeks (n=30)	Late preterm GA at PPROM 34-36 weeks (n=40)
r *	- 0.713	- 0.621	- 0.512
P	0.001	0.022	0.041

*Pearson's correlation coefficient.

DISCUSSION

This study aimed to explore the relationship between lactate level in vaginal fluid and latency period in patients with preterm prelabour rupture of membranes (PPROM). Additionally, it sought to analyzes the socio-demographic characteristics and evaluates maternal and neonatal outcomes associated with PPROM. The findings provide valuable insights into the interplay between biochemical marker, patient characteristics, and clinical outcomes in this high-risk obstetric population.

The socio-demographical data revealed that the majority of participants were young patients, with a mean age of 27.0 years and with range(17-39) due to early marriage age onset, which is almost similar to the study by Zakaria et al.[13]

In pregnancy (81%) of them were housewives. Notably, over half (60%) of the participants resided in rural areas, reflecting the socioeconomic context of the study population. This finding aligns with a cross-sectional study conducted in Ethiopia by Addisu et al.,[14] which linked limited access to healthcare facilities with an increased risk of PPROM.

According to educational level, over half (60%) of the participants were illiterate, this finding aligns with study conducted by Kashif et al.,[15] who showed similar results, this may be related to low socioeconomic status and low level of antenatal care in patients make them more prone to PPROM.

Regarding secondary smokers, it was found in (69%) of the patients, therefore, emphasizes the effect of smoking on the risk of PPROM, the study by Rau et al.,[16] showed similar results this is because cigarete smoking induces oxidative stress and inflammation, both of them implicated in fetal membrane weakening which predispose PPROM.

The obstetrical characteristic data revealed the average gestational age at (PPROM) was 32.7 ± 2.0 weeks while the gestational age at the onset of labour was slightly

higher, with a mean of 32.9 ± 2.0 weeks. These findings were similar to the study by Abouseif et al.,[17] in Egypt.

The findings of latency period are 30.1 ± 2.0 hours with range (14.0- 72.0 hours) this results similar to study by Zakeria et al.[13]

Most of the participants had an interpregnancy interval of < 6 months (40%) and of 6_12 months (30%) made them more experiencing PPROM. This finding is similar to the study by Jena et al.,[18] which included IPI <_6 months was associated with an increased risk of developing PPROM compared with patients with IPI >24 months. This could be due to the hypothesis,[19] that short intervals between pregnancies cause cervical insufficiency or incompetency, abnormal remodeling of the endometrial blood vessels, and maternal nutrition depletion, as the time interval was not sufficient enough to recover from preceding pregnancy and childbirth conditions so it need more antenatal care.

The findings of cervical dilatation (50% of the cases showing 1 cm and 31% with 1-2 cm) are also in line with existing literature. Research has shown that cervical dilatation greater than 1-2 cm is typically associated with an increased likelihood of labour initiation within 24-48 hours after membrane rupture.[20]

Regarding sociodemographical characteistics and latency period of studied patients, a significantly higher number of housewives (90%) experienced longer latency after 48 hours compared to 77.5% in the early latency group with (P-value 0.035), suggesting employment might have an influence on labour timing by increase physical and mental stress which lead to shorter latency period.[21]

Urban patients constituent a higher number among patients who had latency period after 48 hours, indicating possible environmental or lifestyle influences. The findings of current study disagree with study conducted by Alom SMT et al.,[22] who found that a rural patients had longer latency peroid, this difference is due to different sample size. Exposure to secondary smoking is significantly associated with earlier latency (P-value 0.012), with 75% of patients had latency period within 48 hours, the study by Ilhan et al.,[23] who showed similar results this is because cigarete smoking induces oxidative stress lead to shorter latency period. Irregular antenatal care was significantly associated with longer latency period (P-value 0.030), with 25% of those with no care experiencing latency after 48 hours, this results similar to study by Kaur J et al.,[24] who found poor antenatal care associated with adverse maternal outcome.

Regarding the mean vaginal fluid lactate level (5.1 ± 2.2 mmol/L, range: 1.25–9.67 mmol/L) can be contextualized within existing research on lactate levels and their association with labour onset in prelabour rupture of membranes (PROM). Patients who had latency period within 48 hours had significantly higher vaginal lactate level (7.21 ± 2.59 mmol/L) compared to those who had latency period after 48 hours (4.57 ± 0.35 mmol/L), with (P-value 0.001). These findings are similar to Zakaryia et al.[13]

The current study's finding that a significantly higher numbers (92.69 %) of patients with a history of PPROM and lactate level ≥ 5 mmol/L had a latency period within 48 hours compared to (22.22%) of patients with lactate level <5 mmol/L had a latency period within 48 hours with (P-value 0.001). A study by Jaiswar et al.,[25] which found that the lactate level of ≥ 5 mmol/L, 81.0% of patients had a latency period within 48 hours after PROM, this variation is due to different gestational age included and sample size. Study indicate that elevated lactate level (≥5.0 mmol/L) are significantly associated with a shorter time to labour onset, with most patients going into labour within 48 hours at these levels. In contrast, lower lactate levels (<5.0 mmol/L) are associated with prolonged latency periods. This suggests lactate concentration may reflect the biochemical readiness of uterine tissues for labour onset.

The correlation between vaginal fluid lactate level and latency period in patients with PPROM has been investigated in various studies. The current findings align with some reports but differ from others. In current study, a significant negative correlation was observed between vaginal fluid lactate level and latency period, these findings are consistent with a study by Zakaria et al.,[13] that highlighted lactate levels as a marker for the timing of labour onset, where elevated lactate levels corresponded to shorter latency periods. Contrastingly, another study involving 70 women with PPROM (28–34 weeks gestation) conducted by Sariaslan et al.,[26] reported no significant correlation between vaginal lactate levels and latency period. The researchers noted a median lactate level of 3.81 mmol/L for patients with a latency ≤ 48 hours, which was not predictive of the duration of the latent phase (P-value 0.904). The variation in outcomes might stem from differences in sample size, gestational age ranges, and methodologies for lactate measurement.

The current study demonstrates a significant negative correlation between vaginal fluid lactate level and the latency period in women with PPROM, with the strength of this relationship varying by gestational age. The findings highlight that the correlation is strongest at earlier gestational ages, with the most significant association observed in pregnancies between 28 and <32 weeks. The study by Zakaria et al.,[13] corroborates the findings of the current study, demonstrating an even stronger negative correlation at earlier gestational age. Although the absolute values of the correlation coefficients differ slightly with different gestational ages, the trend remains consistent, underscoring that lactate level has a higher predictive value for shorter latency periods at lower gestational ages.

The observed trends may be explained by the inflammatory and biochemical changes in the amniotic and vaginal environment during labour. Elevated lactate level may reflect increased metabolic and inflammatory activity, particularly in cases of early gestation, where cervical and uterine readiness for labour are likely more sensitive to such changes. As gestational age advances, other factors such as fetal maturity, mechanical cervical changes, and hormonal shifts may play a more substantial role, potentially diminishing the relative impact of lactate level on latency.

From a clinical perspective, these findings suggest that measuring vaginal fluid lactate level can serve as a valuable tool for predicting the latency period in PPROM, particularly in pregnancies before 34 weeks of gestation. This predictive capability is critical for optimizing interventions such as the timing of corticosteroid administration, tocolysis, and NICU preparation, which are pivotal for improving neonatal outcomes.

CONCLUSION

The study on Preterm Premature Rupture of Membranes (PPROM) revealed that housewives with irregular antenatal care living in urban areas generally had a latency period of under 48 hours, which was statistically significant. Exposure to secondary smoke also correlated significantly with shorter latency periods. Patients with a history of previous PPROM, prematurity, cervical cerclage, preterm births, cesarean sections, and a family history of PPROM were more susceptible to PPROM. A strong negative correlation was found between vaginal fluid lactate levels and latency period, with higher lactate levels seen in patients with latency periods under 48 hours, particularly pronounced in those between 28 to less than 32 weeks gestation. The study also noted a higher number of NICU admissions associated with shorter latency periods but found no significant links between latency period and maternal age, parity, BMI, or gestational age at PPROM.

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