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CERVICOVAGINAL PLACENTAL ALPHA MICROGLOBULIN-1 FOR THE PREDICTION OF PRETERM BIRTH IN WOMEN WITH SUSPECTED PRETERM BIRTH

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ABSTRACT

Background: Preterm birth is one of the most challenging and critical issues in obstetrics. Despite decades of study and therapeutic progress, roughly 10% of neonates are born prematurely. Early prediction of preterm labor allows for timely intervention (e.g. drug administration, neonatal intensive care unit preparation). One potential marker is placental Alpha microglubolin-1. It is a specific α-1 globulin secreted by decidual cells and amniotic epithelial cells early in pregnancy. It is associated with physiological changes occurring in the cervix and fetal membranes during labor and is predominantly found in high concentrations in amniotic fluid. **Aim of study:** To evaluate the role of cervicovaginal placental alpha microglobulin-1 for the prediction of the timing of spontaneous preterm birth. **Patients and methods:** This is an analytic cohort study that included 90 pregnant women presented with a suspicion of preterm labor and was conducted at the Gynecology and Obstetrics department of Baghdad Teaching Hospital/ Medical City, Baghdad. The study duration was from 1st of February 2024 to the end of November 2024. Inclusion criteria involved singleton pregnancy with intact membrane and cervical dilatation of ≤3 cm of gestational age (28 – 36 weeks + 6 days). Patients were categorized into four groups according to the time of delivery: Group I (preterm delivery within one week), group II (preterm delivery within two weeks), and group III (delivery after two weeks). All patients were test for placental alpha microglobulin-1 at time of admission. **Results:** Statistical analysis revealed that cervical placental alpha macroglobulin – 1 was a significant predictor of preterm delivery within 1 week, and 2 weeks. For predicting spontaneous preterm labor within 7 days, the optimal cut-off point was determined to be 6.46 ng/ml, resulting in a sensitivity of 98.6%, specificity of 88.9%, positive predictive value of 97.2%, and negative predictive value of 94.1%. Finally, the optimal threshold for predicting preterm labor within 14 days was established at 5.54 ng/ml, demonstrating a sensitivity of 96.2%, specificity of 100%, positive predictive value of 100.0%, and negative predictive value of 78.57%. **Conclusion:** Cervical placental alpha macroglobulin - 1 was shown to be a reliable predictor of the timing of spontaneous preterm birth in women suspected of preterm labor. Notably, it showed highest sensitivity and specificity within 1 week; and thus, effectively risk stratifying women who would be at risk of spontaneous preterm delivery within one week of symptom onset.

KEYWORDS: One potential marker is placental Alpha microglubolin-1.

INTRODUCTION

Preterm labor (PTL) is defined as the onset of labor before 37 weeks.[1] It is responsible for a large number of infant deaths and a wide range of newborn morbidities such as retinopathy, bronchopulmonary dysplasia and cerebral palsy.[2] Around 25% of PTLs are for maternal or fetal reasons, 50% are for spontaneous PTL, and 25% are for preterm premature rupture of the membrane. PTLs are more common in African or Afro-Caribbean women.[1] **Suspected preterm labor** is the condition in

which the woman has reported symptoms of preterm labor and has had a clinical assessment (including a speculum or digital vaginal examination) that confirms the possibility of preterm labor, but rules out established labor.[3]

Placental Alpha Microglubolin I (PAMG-1) is a specific α-1 globulin secreted by decidual cells and amniotic epithelial cells early in pregnancy, beginning with forming decidual cells and developing the amniotic sac during the first trimester. It is first isolated from human amniotic fluid in the 1970s. It is a glycoprotein with a molecular weight of approximately 34 kDa. This protein is present in high concentrations in amniotic fluid—up to 10,000 times higher than in cervicovaginal secretions—making it a valuable biomarker for clinical assessments related to pregnancy. PAMG-1 is primarily detected in cervicovaginal secretions, amniotic fluid and Decidua and Placental Tissues.[4,5][6] PAMG-1 is not typically found in significant concentrations in maternal blood. Its high concentration is restricted to the amniotic fluid, where levels range **from 2,000 to 25,000 ng/mL**. By contrast, its presence in vaginal secretions and other fluids, including maternal blood, is minimal or negligible, often below the threshold required for diagnostic relevance.[7]

This study aims to evaluate the role of cervicovaginal placental alpha microglobulin-1 for the prediction of the timing of spontaneous preterm labor.

PATIENTS AND METHODS

Study place and time

The study has been conducted at the Gynecology and Obstetrics department at Baghdad Teaching Hospital/ Medical City, Baghdad. The data was collected from 1st of February 2024 to the end of November 2024.

Study design

An analytic cohort design has been chosen for this study.

Approval, official permission, and ethical consideration

Verbal consent has been obtained from all participants before data collection. An official letter of approval has been obtained from the scientific committee of the local scientific council of Obstetrics and Gynecology – Iraqi Board for Medical Specializations \ Iraq and Baghdad Teaching Hospital.

General work-up and data collection

A total of 90 pregnant women (gestational age: 28 weeks – 36 weeks + 6 days) suspected of preterm labor were enrolled in this study. Participants provided information on their demographic and obstetric characteristics, such as age, residency, occupation, parity, and gravidity. Gestational age was determined based on the last menstrual period and confirmed through fetal crown-rump length measurements during the first-trimester ultrasound. Patients were categorized into four group, as follows.

Group I: Delivered within one week.
Group II: Delivered within two weeks.
Group III: Delivered after two weeks.

All participants underwent a comprehensive evaluation, including detailed history, clinical Examination, abdominal Examination, pelvic **examination.** After obtaining informed consent, a vaginal examination was conducted to assess cervical readiness using the Bishop score, and speculum examination.

1. **Obstetric Ultrasound:** All participants underwent ultrasound examinations to confirm fetal viability, assess placental location, and measure amniotic fluid index. These examinations were performed using a Samsung HS70A Ultrasound System at the outpatient clinic of the Gynecology and Obstetrics Department.
2. Investigations were done for all patients including CBC, GUE, and rectovaginal swab for beta-hemolytic streptococci.

The suspicion of preterm labor was established based on clinical manifestations, including frequent uterine contractions, abdominal pain, and back pain. All patients were admitted to the hospital.

The management upon admission was as follows.
- The patients were sampled for placental α-microglobulin-1.
- progesterone suppositories
- a bolus dose of magnesium sulfate (MgSO4) of 4 grams, followed by a maintenance dose of 1 gram per hour for a duration of 24 hours.
-steroid was provided as dexamethasone 6 mg IM in four doses

All patients were kept for in-hospital monitoring until either delivery or resolution of symptoms occurred. Patients whose symptoms resolved were requested to provide their contact information (phone number) to facilitate follow-up until delivery.

The Patients were categorized based on the timing of delivery as follows: those who delivered preterm within 7 days, within 14 days, beyond 14 days, and those who delivered at term.

Inclusion Criteria

1. Single fetus.
2. Intact membranes.
3. Cervix 2 - ≤ 3 cm.
4. Gestational age (28 – 36 weeks + 6 days).

Exclusion Criteria

Pregnant women with the following conditions were excluded: Vaginal bleeding**, f**etal distress**, p**olyhydramnios**,** drug abuse, chorioamnionitis, previous

caesarian section, diabetes mellitus, preeclampsia, multiple gestation, ruptured membrane, and previous cervical surgery.

Procedure for Sample Collection and Preparation of Placental α-microglobulin-1

- Patient put in lithotomy position
- PV speculum examination to assess membrane status and dilatation of cervix and membrane status.
- Measurement of Cervical vaginal fluid for PAMG was don as follow:
  - A sterile cotton swab was inserted into the posterior vaginal fornix for one minute
  - Remove swab and put in tube containing 1 ml of PBS (pH 7.2-7.4) solution.
  - Shake vigorously for 1 minute.
  - Remove cotton swab from solution, then solution centrifuge for 20 min at 3000 RPM
  - Then the solution will Store in the refrigerator at -80 °C of the hospital.
  - When all Take to the private laboratory for measurement of placental alpha macroglobulin-1 levels.

Test Principle

The test use enzyme linked immunosorbent assay. Kit property: Catalogue number (YLA421 4HU), origin (Shanghai YL Biont/ China).

Data Analysis

Data entry was done using Microsoft Excel 2019. Data was recorded into different quantitative and qualitative variables for the purpose of analysis. Analysis was done using statistical package for social sciences (SPSS version 26). A two-tailed p value of less than or equal to 0.05 was assigned as a criterion for declaring statistical significance. ROC analysis was conducted in order to evaluate the role of Placental α-microglobulin-1 for the prediction of preterm labor.

RESULTS

The study sample

A total number of 90 pregnant women suspected of preterm labor were included in the study sample. As illustrated in Figure 1, the distribution of delivery times among these women was as follows: 72 (80%) delivered within one week days, 7 (7.8%) within two weeks, and 11 (12.2%) after more than two weeks. Of the 11 women who delivered after a period exceeding two weeks, eight experienced preterm labor, while three delivered at term.

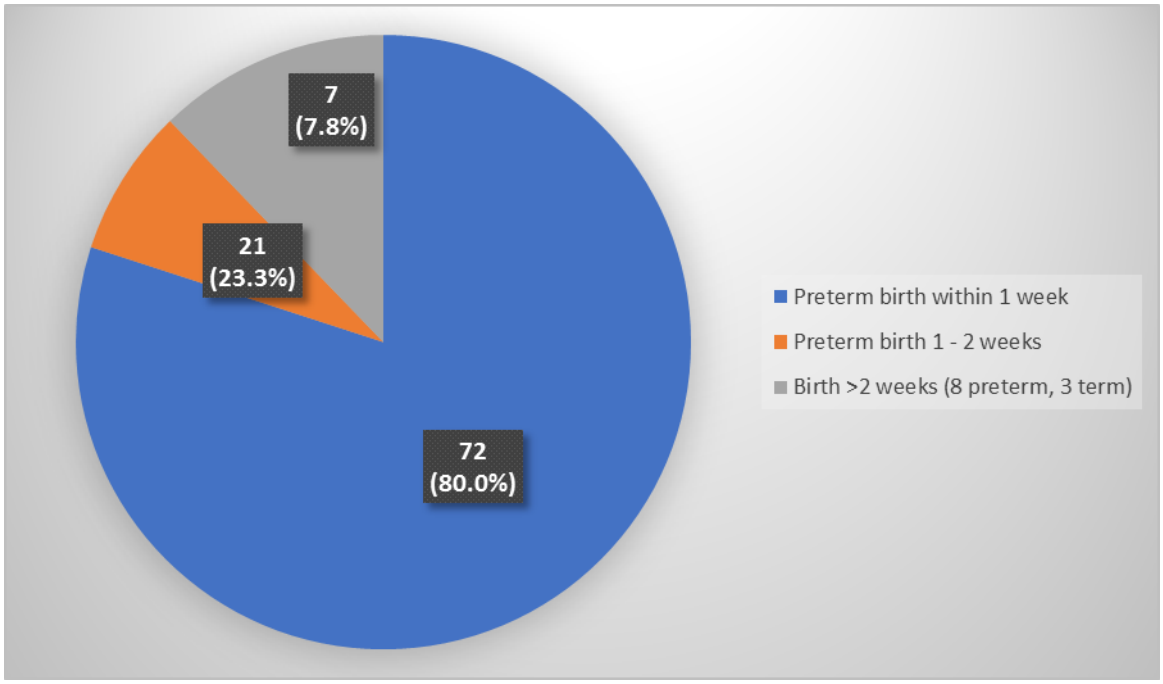


Figure 1: The study sample.

Basic characteristics of the studied sample

No significant difference was detected between the 4 study groups regarding age, gestational age at time of assessment, parity, and history of preterm birth; as shown in table (1).

Table 1: Basic characteristics of the studied sample.

Parameter	Group				P value
	Group I N = 51	Group II N = 21	Group III N = 7	Group IV N = 11	
Age					
<30 years	24	8	3	5	0.943
	47.1%	38.1%	42.9%	45.5%	
≥30 years	27	13	4	6	
	52.9%	61.9%	57.1%	54.5%	
Gestational age at time of assessment					
Mean ± SD	32.4 ± 2.1	32.9 ± 1.8	32.1 ± 1.1	33.0 ± 1.4	0.756
Range	28 w – 34 w + 5 d	29 w + 3 d – 34 w + 1 d	29 + 6 – 33 + 6	28 + 5 – 33 + 1	
Parity					
Primiparous	21	13	2	7	0.156
	41.2%	61.9%	28.6%	63.6%	
Multiparous	30	8	5	4	
	58.8%	38.1%	71.4%	36.4%	
History of preterm birth					
Yes	14	6	1	3	0.959
	27.5%	28.6%	14.3%	27.3%	
No	37	15	6	8	
	72.5%	71.4%	85.7%	72.7%	

Comparison of PAMG-1 levels among the three study groups

The comparative analysis of PAMG-1 levels across the four study groups indicated that Group I exhibited significantly elevated levels relative to Group II. Furthermore, Group II demonstrated significantly higher levels than Group III, as illustrated in Table 2.

Table 2: Comparison of PAMG-1 levels among the four study groups.

Group	Mean ± SD	P value
Group I (<1 week)	12.56 ± 4.43	Group I vs. group II: P = 0.022
Group II (1-2 weeks)	7.22 ± 3.99	Group II vs. group III: P = 0.009
Group III (>2 weeks)	2.65 ± 1.47	Group I vs. group III: P <0.001

Efficiency of PAMG-1 for the prediction of preterm labor within 1 week of symptoms

The ROC analysis revealed that PAMG-1 was a significant predictor of preterm delivery within 1 week of symptoms (AUC = 0.960, P value <0.001); as shown in **Figure 3.** The optimum cut-off point with the highest (sensitivity + specificity) was determined to be 6.46 ng/ml; as it had a sensitivity of 98.6%, specificity of 88.9%, PPV of 97.2%, NPV of 94.1%; as shown in **Table (4).**

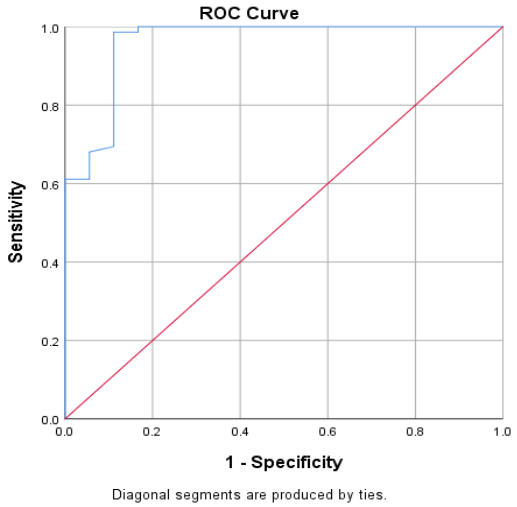


Figure (3): ROC analysis diagnostic indices of PAMG-1 for prediction of preterm labor within 1 week.

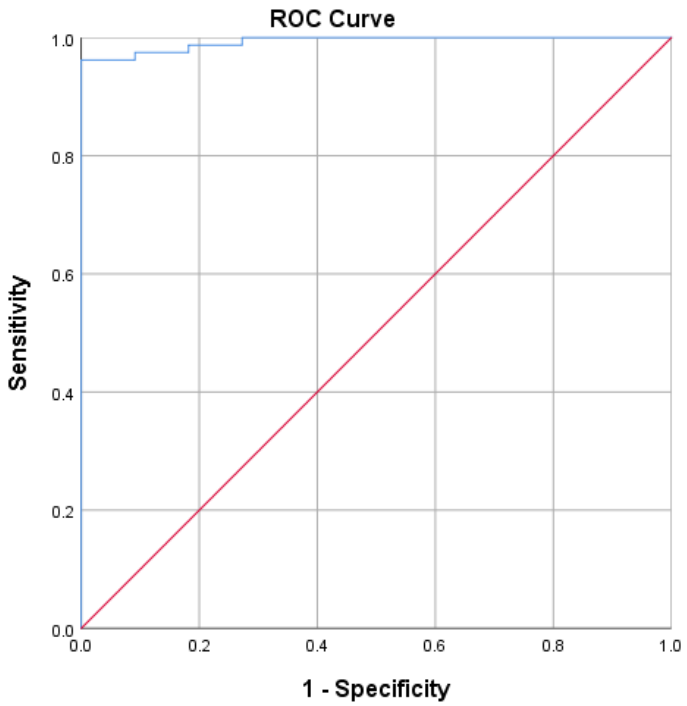
Table (4): Efficiency of 6.46 ng/ml as a cut-off point of PAMG-1 in the prediction of preterm labor within 1 week.

PAMG-1 level	Preterm labor <1 week		Total
	Yes	No	
≥6.46 ng/ml	71 (TP)	2 (FP)	73
<6.46 ng/ml	1 (FN)	16 (TN)	17
Total	72	18	90

PAMG-1: placental alpha microglobulin-1, TP: true positive, FN: false negative, FPL false positive, TN: true negative.

Efficiency of PAMG-1 for the prediction of preterm labor within 2 weeks of symptoms

The ROC analysis revealed that PAMG-1 was a significant predictor of preterm delivery within 1 week of symptoms (AUC = 0.993, P value <0.001); as shown in **Figure 3.** The optimum cut-off point with the highest (sensitivity + specificity) was determined to be 5.54 ng/ml; as it had a sensitivity of 96.2%, specificity of 100%, PPV of 100.0%, NPV of 78.57%; as shown in **Table (4).**



ROC: Receiver operator characteristics.

Figure (3.4): ROC analysis diagnostic indices of PAMG-1 for prediction of preterm labor within 2 weeks.

Table (5): Efficiency of 5.54 ng/ml as a cut-off point of PAMG-1 in the prediction of preterm labor within 2 weeks.

PAMG-1 level	Preterm labor <2 weeks		Total
	Yes	No	
≥5.54 ng/ml	76	0	76
<5.54 ng/ml	3	11	14
Total	79	11	90

DISCUSSION

Preterm birth is a serious obstetric problem accounting for 11% of pregnancies worldwide. It is associated with significant neonatal morbidity and mortality. Predictive tests for preterm birth are incredibly important, given the huge personal, economic, and health impacts of preterm birth. They can provide reassurance for women who are unlikely to deliver early, but they are also important for highlighting those women at higher risk of premature delivery so that we can offer prophylactic interventions and help guide antenatal management decisions.[8]

In the current study, no significant difference was detected between the four study groups regarding age, gestational age at time of assessment, parity, and history of preterm birth. This indicates that these factors could not predict the exact time of preterm delivery.

A notable finding of the current study is that extending the prediction window to 1 week, a cutoff of 6.46 ng/ml achieved a high sensitivity of 98.6% and specificity of 88.9%. In Turkey, the study by (**Gokce et al., 2022)** included 287 women with singleton pregnancies between 24th and 34th gestational weeks, who had preterm labor symptoms (regular uterine contractions in tococardiography, contractions felt by the mother, abdominal or back pain, pelvic pressure), transvaginal cervical length <25mm, and clinically intact membranes. Their study revealed that a positive Partosure PAMG-1 test could predict spontaneous preterm delivery within 1 week with a sensitivity of 52.94%, specificity of 98.84%, PPV of 91.4%, and NPV of 90%.[9]

In Iran, the study by (**Kashanian et al., 2022)** that a positive Partosure PAMG-1 could predict spontaneous preterm delivery within 7 days with 50.6% sensitivity and 91.2% specificity.[10]

The study by (**Nikolova et al., 2018)** included 383 patients with intact amniotic membranes and cervical dilation ≤ 3 cm, without recent intercourse or cerclage, between gestational weeks of 20+0 and 36+6. The study reported that Partosure PAMG-1 could significantly predict spontaneous preterm delivery within 7 days (69.2% sensitivity and 96.6% specificity).[11]

The study by (**Cnota et al., 2022)** included 46 women with singleton pregnancies between 24 + 0/7 and 33 + 6/7 weeks of gestation who presented with symptoms of threatened preterm labor, with cervical dilatation of < 3 cm, cervical length (CL) of < 30 mm and clinically intact fetal membranes. The study reported that the Partosure PAMG-1 test predicted spontaneous preterm labor within 7 days with 50% sensitivity, 80.56% specificity, 12.5% PPV and 96.67% NPV.[12]

The study by **(Lega et al., 2017)** included 96 women with singleton gestation, symptoms of preterm labor, gestational age 22 - 35. Recruited patients had intact membranes and a cervical dilatation of ≤3 cm. The study found that for the prediction of spontaneous preterm delivery within 7 days of admission, the Partosure PAMG-1 test showed a sensitivity of 100%, specificity of 83.3%, PPV of 71.4%, and NPV of 100%.[13]

In the study by (**Haverhagen et al., 2015)** patients with symptoms of preterm labor between 24 and 37 weeks of gestation were included into the study group. The research revealed that Partosure PAMG-1 predicted delivery within 7 days with a PPV of 100% and NPV of 69.5%.[14]

Finally, a cutoff of 5.54 ng/ml exhibited a sensitivity of 96.2% and specificity of 100% for predicting preterm birth within 2 weeks. The study by (**Haverhagen et al., 2015)** revealed that Partosure PAMG-1 predicted delivery within 14 days with a PPV of 100% and an NPV of 42.8%.[14] The study by (**Nikolova et al., 2018)** reported that Partosure PAMG-1 could predict delivery within 14 days with 53.9% sensitivity and 97.4% specificity.[11]

A case-control study conducted by **(AbdelGaied et al., 2021)** included 90 pregnant women, divided into two equal cohorts: group A consisted of 45 women between 24+0 and 36+6 weeks gestation exhibiting threatened preterm labor and a shortened cervix, while group B included 45 women of the same gestational age without symptoms of threatened preterm labor and possessing normal cervical measurements. They found that cervical Partosure PAMG 1 exhibited a sensitivity of 71.11%, a specificity of 100.0%, a positive predictive value of 100%, a negative predictive value of 77.59%, and an accuracy of 85.56%. Additionally, a significant link existed between positive PAMG and the timing of delivery, with 18.8% of births occurring within the first 48 hours, 50.0% between 2 and 7 days, and 31.3% beyond 7 days. Conversely, all women with negative PAMG-1 delivered after a duration of 7 days.[15]

The rationale behind PAMG-1 predicting timing of preterm labor is due to its association with physiological changes occurring in the cervix and fetal membranes during labor. PAMG-1 is predominantly found in high concentrations in amniotic fluid. During labor, especially when uterine contractions occur, PAMG-1 can transudate through the chorioamniotic membranes into the cervicovaginal fluid. This transudation may be facilitated by the degradation of the extracellular matrix of fetal membranes during inflammatory processes associated with labor.[16] Therefore, the detection of PAMG-1 in cervicovaginal secretions indicates that there is a physiological process underway that could lead to imminent delivery.[5]

In the present study, no significant difference was detected between various PAMG-1 cutoffs regarding maternal age, gestational age at time of assessment, and parity. This is in concordance with (**Kashanian et al., 2022)** who reported that there was no significant difference between positive PAMG-1 and negative PAMG-1 tests for maternal age, gravidity, parity, and gestational age at recruitment.[10] This effectively excludes the role of these factors as potential confounders that may impact the levels of cervical PAMG-1.

CONCLUSION

Cervical PAMG-1 was shown to be a reliable predictor of the timing of spontaneous preterm birth in women suspected of preterm labor. Notably, it showed highest sensitivity and specificity within 1 week; and thus, effectively risk stratifying women who would be at risk of spontaneous preterm delivery within one week of symptom onset.

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