

## The Value of Actim Partus Test in Women Presented Clinically with Spontaneous Preterm Delivery: A Cross-Section Cohort Study

**Zeena Helmi\***

*Department of Obstetrics and Gynecology, College of Medicine University of Mustansiriyah, Baghdad, Iraq*

**\*Corresponding Author:** Zeena Helmi, Department of Obstetrics and Gynecology, College of Medicine University of Mustansiriyah, Baghdad, Iraq.

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### Abstract

Preterm delivery (PTD) is generally referred to childbirth before 37 weeks of pregnancy. It accounted around 10% and associated with a high percentage of perinatal mortality. This cross sectional cohort study was done in the Department of Obstetrics and Gynecology in the College of Medicine, Al-Mustansiriyah University in Baghdad-Iraq from August 2016 to December 2017. This study included 63 women recruited from the Department of Obstetrics and Gynaecology at Al-Yarmouk Teaching Hospital. The women were grouped into Group I (n = 20) women without clinical evidence of spontaneous premature labour and served as control; and Group II (n = 43) women with clinical evidence suggested a spontaneous premature labour. Anthropometric measurements, blood group testing and the cervical levels of using phIGFBP actim partus.

**Results:** Twenty three women (53.5%) of Group II had positive phIGFBP test and their characteristics did not show significant difference from the other twenty women (46.5%) with negative phIGFBP test. Women with positive phIGFBP test were significantly had short gestational age at the time of delivery, wide cervical dilatation and low birth weight of new born with low Apgar score.

**Conclusion:** Actim partus test is positive in 53.5% of women presented clinically with spontaneous preterm delivery and associated with cervix dilatation. This test serves as a good predictor of the unfavorable newborn baby outcome

**Keywords:** Labour; Preterm; Contraction; phIGFBP; Women; Spontaneous; Fetus; Birth

### Introduction

Preterm delivery (PTD) is generally referred to childbirth before 37 weeks of pregnancy. It accounted around 10% and associated with a high percentage of perinatal mortality [2-4]. There is evidence that placentation disorders that involved the vascular component of the placenta is one cause of preterm delivery [1]. Because Spontaneous preterm labour is a syndrome that caused by multiple pathologic processes, the current research tries to establish several laboratory methods in order to predict the preterm delivery via using the serological and cervico-vaginal sample assays. Cervical phosphorylated insulin-like growth factor binding protein-1 (phIGFBP-1) test is proposed to predict symptomatic and asymptomatic preterm delivery women. The principle of this test that phIGFBP-1 is an important factor of the development of the placenta and fetal growth that synthesised in the endometrium decidua. In preterm labour, the uterine contractions caused disruption of the decidua and leaking of the phIGFBP-1 into the cervical secretion [5,6]. Symptomatic women at risk of preterm birth have significant high levels of cervical phIGFBP-1, and it can accurately predict preterm birth in women with intact membranes [7,8]. A recent meta-analysis concluded that cervical phIGFBP-1 test is of limited predictive value in identification the asymptomatic and symptomatic women at risk of PTD [3]. The rationale of this study that there are several limitations of this test, which can reduce the predictive ability, therefore, this study takes these limitations in the interpretation of the test. This cohort study aimed to clarify the importance of determining the cervical levels of phIGFBP-1 in women at risk of an episode of labour.

### Patients and Methods

This cross sectional cohort study was done in the Department of Obstetrics and Gynaecology in the College of Medicine, Al-Mustansiriyah University in Baghdad-Iraq from August 2016 to December 2017. The study was conducted according to the ethical guidelines constructed by the Scientific Committee of the Institute in which the treatment or using device should not be harmful to the patient and

the patient is free to decline from the study or to refuse for study admission. The criteria of inclusion were women with uterine contraction suggestive of premature labour at the third trimester of pregnancy. Women with current antepartum haemorrhage or preeclampsia were excluded from the study. Each patient was examined by consultants of Obstetrics and Gynaecology prior to the inclusion into the study and the data that included the characteristics of the patients, previous and current obstetrics history were collected. The clinical diagnosis of spontaneous premature labour achieved by using the Creasy and Herron criteria (in which the contraction should be at least 4 in 20 minutes or 8 in 60 minutes associated with either PROM or dilatation of the cervical canal exceeds two cm or effacement that is more than 50% or changes associated with periodic examination of effacement or cervical dilatation with a gestational age at least 20 weeks to 36 weeks and 6 days [9].

This study included 63 women recruited from the Department of Obstetrics and Gynaecology at Al-Yarmouk Teaching Hospital. The women were grouped into Group I (n = 20) women without clinical evidence of spontaneous premature labour and served as control; and Group II (n = 43) women with clinical evidence suggested a spontaneous premature labour. Anthropometric measurements, blood group testing and the cervical levels of phIGFBP using (actim partus, Medix Biochemica, Finland) for each patient and before digital examination a sterile speculum inserted in the vagina and a Dacron swab inserted to the external cervical os and left there for 10 seconds then it is withdrawn and inserted in a tube with few cc of buffered solution kept there for 15 second and again removed to insert a dipstick in the tube for 20 seconds then its remove to put on a table waiting for the result within 2 - 5 minutes two blue lines considered as positive, one blue line considered as negative.

Each woman was followed up until delivery and both the woman and her new born were examined in an attempt to link the outcome of pregnancy with the results of the phIGFBP testing.

### Statistical analysis

The data were presented as number (percentage), and whenever possible as mean  $\pm$  SD (median). Two tailed, one paired student's (t), and difference between percentage tests were used to analyse the significant difference taking the probability (p)  $\leq$  0.05 as the lowest limit of significance.

### Results

The characteristic features of women included in this study showed that the mean  $\pm$  SD of the age and educational status in Group II women were significantly differed from corresponding values of Group I (Table 1). The gestational age of Group II women at the time of the study was significantly more than corresponding value of Group I whereas the gestational age at the time of the delivery was significantly less than that of Group I (Table 2). Cervical dilatation was significantly larger among Group II women which amounted 3.6 times of the corresponding value of Group I (Table 2). The mean weight of the new born baby delivered from Group II women was less than that of Group I women by 0.744 kg (Table 2).

Twenty three women (53.5%) of Group II had positive phIGFBP test and their characteristics did not show significant difference from the other twenty women (46.5%) with negative phIGFBP test (Table 3). Women with positive phIGFBP test were significantly had short gestational age at the time of delivery, wide cervical dilatation and low birth weight of new born with low Apgar score (Table 4). There was non-significant difference between the studied groups in the distribution of the blood group (Table 5).

### Discussion

The results of this study highlights the importance of determination the cervical level of phIGFBP-1 in order to anticipate the unfavorable pregnancy outcome that will happen in women with phIGFBP-1 and provide an appropriate management. The current finding that showed an association of positive actim partus test with the dilatation of the cervix is agreed with the recent study that a combination of the cervical length and the actim partus test is a suitable test for prediction of spontaneous preterm delivery and it can substitute the fatal fibronectin test [10]. Positive Actin partus test was detected in 53.5% of women with suggestive clinical signs and symptoms of spontaneous preterm delivery and this finding is approximately similar to other study conducted in Egypt which accounted 50.9% [11]. The

	Group I (n = 20)	Group II (n = 43)	P value
Age (Year)	24.2 ± 5.9 (23)	29.04 ± 6.4 (31.0)	0.004*
Gravida	1.8 ± 1.4 (1.0)	2.5 ± 1.8 (2.0)	0.062
Spontaneous abortion	0.05 ± 0.2 (0)	0.1 ± 0.4 (0)	0.410
History of preterm delivery	1.0 (5.0)	4.0 (9.3)	0.556
Body mass index	22.0 ± 3.3 (21.5)	24.9 ± 4.5 (24.0)	0.005
Gestational diabetes	1.0 (5.0)	1.0 (2.3)	0.564
<b>Vaginal bleeding</b>			
1 <sup>st</sup> trimester	0 (0)	1 (2.3)	0.492
2 <sup>nd</sup> trimester	0 (0)	0 (0)	-
3 <sup>rd</sup> trimester	0 (0)	1 (2.3)	0.492
<b>Smoking</b>			
Current	1 (5.0)	0	0.139
Ex-smoker	0 (0)	0	-
Passive	5 (25.0)	6 (14.0)	0.282
<b>Education</b>			
Illiterate	0 (0)	7 (16.3)	0.056
Primary school	4 (20.0)	1 (2.3)	0.016*
Secondary school	3 (15.0)	8 (18.6)	0.726
Higher	13 (65)	15 (34.9)	0.025*

**Table 1:** Maternal obstetric and the demographic characteristics.

The results are expressed as mean ± SD (median) and number (%). \*: Probability of significant difference.

	Group I (n = 20)	Group II (n = 43)	P value
Gestation age at enrollment (week)	31.1 ± 1.8	33.1 ± 5.6	0.0005
Gestation age at birth (week)	39.1 ± 1.0	36.6 ± 2.0	0.0000
Birth weight (Kg)	3.479 ± 0.334	2.735 ± 0.435	0.0000
Cervical dilatation (cm)	0.39 ± 0.5	1.4 ± 0.9	0.0000

**Table 2:** Comparison of obstetric variables.

The results are expressed as mean ± SD. \*: Probability of significant difference.

patients that included in the study were symptomatic women and this observation allows the actin partum test to be valid as this test is not a good predictor of pre-term birth in high-risk asymptomatic women [12]. This study adds new information to other studies which include first: the characteristic of the patients have no role in the spontaneous preterm delivery and thereby the validity of actim partus test as a predictor will be high [13]. Second; there is no evidence that showed an association between the spontaneous preterm delivery and diabetes [14]. In addition, there is no evidences that false positive actin partum test was reported in diabetes. Therefore, the validity of this test remains high even in the presence of concomitant illnesses and it is useful to predict the latent diabetes in the new born babies [14].

	phIGFBP-1 (+) (n = 23)	phIGFBP-1 (-) (n = 20)	P value
Age (Year)	29.2 ± 7.1 (30)	28.9 ± 5.6 (31)	0.851
Gravida	2.6 ± 1.9 (2)	2.4 ± 1.7 (2)	0.710
Parity	1.4 ± 1.75 (1)	1.4 ± 1.7 (1)	0.874
Spontaneous abortion	0.17 ± 0.49 (0)	0.05 ± 0.22 (0)	0.285
Preterm delivery	3 (13)	1 (5)	0.365
<b>Body mass index</b>			
< 19.6 kg/m <sup>2</sup>	1 (4.3)	1 (5)	0.920
>26.0 kg/m <sup>2</sup>	9 (39.1)	8 (40)	0.954
Gestational diabetes	0 (0)	1 (5)	0.278
<b>Vaginal bleeding</b>			
1 <sup>st</sup> trimester	1 (4.3)	0 (0)	0.345
2 <sup>nd</sup> trimester	0 (0)	0 (0)	-
3 <sup>rd</sup> trimester	1 (4.3)	0 (0)	0.345
<b>Smoking</b>			
Current	0 (0)	0 (0)	-
Ex-smoker	0 (0)	0 (0)	-
Passive	5 (21.7)	1 (5)	0.114
<b>Education</b>			
Illiterate	2 (8.7)	4 (25)	0.286
Primary school	8 (34.8)	5 (25)	0.486
Secondary school	5 (21.7)	3 (15)	0.571
Higher	8 (34.8)	7 (35)	0.988

**Table 3:** Maternal obstetric and the demographic characteristics of Group II in respect to the result of phIGFBP-1 reactivity test.

The results are expressed as mean ± SD (median) and number (%). \*: Probability of significant difference. PhIGFBP-1: Phosphorylated Insulin-Like Growth Factor Binding Protein-1.

	phIGFBP-1 (+) (n = 23)	phIGFBP-1 (-) (n = 20)	P value
Gestation age at enrollment (week)	33.3 ± 2.5	32.1 ± 2.1	0.1
Gestation age at birth (week)	35.2 ± 1.5	37.7 ± 1.2	0.0000*
Birth weight (kg)	2.505 ± 0.33	3.018 ± 0.842	0.0005*
Cervical dilatation (cm)	1.98 ± 0.68	0.79 ± 0.63	0.0000*
Apgar score	5.66 ± 0.65	6.25 ± 0.88	0.031*

**Table 4:** Comparison of obstetric and neonatal parameters in phosphorylated insulin-like growth factor binding protein-1 (+) and (-) subgroups.

The results are expressed as mean ± SD. \*: Probability of significant difference.

	phIGFBP-1 (+) (n = 23)	phIGFBP-1 (-) (n = 20)	P value
Group A+	5 (21.7)	2 (10)	0.298
Group A-	1 (4.3)	0 (0)	0.345
Group B+	4 (17.4)	7 (35)	0.189
Group B-	1 (4.3)	1 (5)	0.920
Group AB+	3 (13)	5 (25)	0.315
Group AB-	0 (0)	0 (0)	-
Group O+	6 (26.1)	4 (20)	0.638
Group O-	3 (13)	1 (5)	0.365

**Table 5:** Comparison of phenotype blood groups in phosphorylated insulin-like growth factor binding protein-1 (+) and (-) subgroups.

The results are expressed as mean ± SD.

Thirdly; positive actin partum test is not only a useful predicting investigation of the spontaneous preterm delivery but also provides a good predictor of newborn outcome as the birth weight and Apgar scores were low in women with positive test. This observation is reported for the first time as the previous studies did not highlight the difference between women with actin partum test positive and negative but mentioned that woman with spontaneous preterm delivery had small birth weight baby [15].

The non-significant difference between women with positive and negative actin partum test is due to the small sample size which can consider it a limitation of the study. ABO blood group phenotype showed that 25.8% of women had blood group B+ and this finding is agreed the other study [16].

### Conclusions

Actin partus test is positive in 53.5% of women presented clinically with spontaneous preterm delivery and associated with cervix dilatation. This test serves as a good predictor of the unfavorable newborn baby outcome.

### Conflict of Interest

No conflict of interest.

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