



“A NOVEL BEDSIDE TEST-ACTIM PARTUS FOR PREDICTION OF PRETERM DELIVERY”

Dr. Snehal Wamanrao Pakhale, Dr. Angela Sehra, Dr. RAHUL PATIL
Maharaja Agrasen Hospital, Punjabi Bagh West, New Delhi



INTRODUCTION:

Preterm labour refers to the onset of labour after fetal viability but before 37 completed weeks of gestation. The incidence of Pre-term labour remains constant over recent years, varying from 5%-10% in different populations. In India, the incidence of preterm birth is approximately 13%, being the most common cause of perinatal morbidity and mortality. A bedside test-kit for pHIGFBP-1 has been developed and is commercially available under the trade name Actim Partus. The principle of the test is that pHIGFBP-1 is an important factor of the development of the placenta and fetal growth that synthesised in the endometrium decidua. 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.

AIM & OBJECTIVE:

To assess efficacy of presence of of Phosphorylated IGFBP-1 (pHIGFBP-1) in cervical secretions as a predictor in Threatened Preterm labour

METHODS:

Design: Prospective observational study

Methodology:

Study included 36 women between 28 to 37 weeks of gestation, singleton pregnancies with intact fetal membranes and spontaneous pain in abdomen. We used commercially available one step immuno-enzymatic dipstick test (Actim Partus) for detection of presence of pHIGFBP1 in cervical secretion by monoclonal antibody 6303 as detecting antibody specific for pHIGFBP-1 with threshold of 10µg/L. The kit contains sterile Dacron swab, test tube with 0.5 ml of extraction buffer solution and test dipstick. A strong positive result corresponds with sample extract that contains 30µg/L or more of pHIGFBP-1. A weak positive result corresponds to a level of 10-30µg/L of pHIGFBP-1 in cervical secretions. Management was individualized as per standard treatment protocol. Data was entered and analysed with Epi Info Software.

P value of < 0.05 will be considered to be statistically significant. Diagnostic value of test was interpreted by calculating sensitivity, specificity, positive predictive value and negative predictive value. Cohen's kappa was used to find degree of agreement.

OBSERVATION AND RESULTS:

1. GESTATIONAL AGE WISE DISTRIBUTION:

We observed majority 20(55.6%) of the women who underwent pre-term labour were in the ≥34 weeks of gestational age whereas 16(44.4%) were <34 weeks of gestational age. Mean gestational age was 33.2 weeks (±1.7) within a range of 29-35 weeks of gestation

GESTATIONAL AGE	Frequency	Percent
<34 WEEKS	16	44.4
≥34 WEEKS	20	55.6
Total	36	100

2. Efficacy of the Test: In the present study, we observed sensitivity of pHIGFBP -1 Test as 68.1%, specificity of 64.2%, Positive Predictive Value 75% and Negative Predictive Value 56.2%. Positive likelihood ratio was 1.9(1.2-3.03) and negative likelihood ratio of 0.49 (0.3-0.73). Diagnostic accuracy was 66.6% and degree of agreement was seen by computing Cohen's kappa which was 0.31 i.e. fair degree of agreement.

pHIGFBP -1 Test	Birth Before <48 Hrs	Birth After >48 Hrs	Total
Positive	15	05	20
Negative	07	09	16
Total	22	14	36

3. CORRELATION OF EFFICACY OF pHigfbp-1 TEST WITH GESTATIONAL AGE: In the study participants with gestational age<34 weeks, we observed sensitivity of pHIGFBP -1 Test as 90.9%, specificity of 60%, Positive Predictive Value 83.3% and Negative Predictive Value 75 %. Whereas ≥ 34 weeks of gestation sensitivity of pHIGFBP -1 Test was 45.5%, specificity of 66.6%, Positive Predictive Value 62.5% and Negative Predictive Value of 55 %.

Gestational Age	pHIGFBP -1 Test					
	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy	Cohen's Kappa
<34 Weeks	90.9 %	60%	83.3%	75%	81.2%	0.53
≥34 Weeks	45.5%	66.6%	62.5%	50%	55%	0.11

4. ACCURACY OF THE TEST: In the present study, we observed sensitivity of pHIGFBP -1 Test as 68.1%, specificity of 64.2%, Positive Predictive Value 75% and Negative Predictive Value 56.2%. Concurrent studies have also shown similar type of results. Vishwekar et al observed sensitivity of 73.3% and specificity of 64.8%. Whereas, Singh et al noted sensitivity of 72.2% and specificity if 90.6% in their study.

Study	Year	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
Ting et al	2007	69	78	39	92
Tanir et al	2009	93.3	79.2	56	97.6
Singh et al	2013	72.2	90.6	81.3	85.3
Vishwekar et al	2017	73.3	64.3	68.8	69.2
Present Study	2021	68.1	64.2	75	56.2

CONCLUSION:

In present study, we observed role of cervical IGFBP-1 test in management of suspected preterm labour and sensitivity of test to be higher in women with gestational age <34 weeks compared to overall sensitivity. It signifies that detection of cervical IGFBP-1 can be a good screening tool in diagnosing pre-term labour. The limitation of our study was small sample size. So, more randomized multicentric studies of cervical IGFBP-1 are needed to replace cervical ultrasonography and fetal fibronectin in future or to serve as a useful adjunct to these tests.

REFERENCES:

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