



STUDY SUMMARIES

Actim[®] Partus

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CERVICAL PHOSPHORYLATED INSULIN-LIKE GROWTH FACTOR
BINDING PROTEIN-1 FOR THE PREDICTION OF PRETERM DELIVERY IN
SYMPTOMATIC CASES WITH INTACT MEMBRANES

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“The study showed that phIGFBP-1 had sensitivity, specificity, PPV and NPV of 70%, 74%, 48% and 89% respectively for predicting deliveries at less than 34 weeks’ gestation. For predicting deliveries within 7 days of admission, the corresponding figures were 93%, 79%, 56% and 97%. The high negative predictive value of this test, especially for delivery within seven days, may aid the clinician to avoid unnecessary and potentially hazardous medications.”

Method

This study was a part of fibronectin study for preterm labor assessment that included a total 121 pregnant women. From this cohort, 68 symptomatic pregnant women, with a gestational age of 24-37 weeks, with <3 cm cervical dilatation and intact membranes provided informed consent for enrollment in this study. The diagnosis of preterm labor on clinical grounds included the following: (1) contractions that are painful, palpable, last longer than 30 s and occur at least four times per 20 min; (2) evidence of a change in the position, consistency, length and/or dilatation of the cervix. Symptoms suggestive of preterm labor included regular uterine contractions (>10/h) low back pain, minimal vaginal bleeding and increased vaginal discharge.

Sterile speculum examination was performed to check for signs of infection and to take two cervical swab samples for an assay of phIGFBP-1 (Actim Partus, Medix Biochemica) and also of Actim PROM test (Medix Biochemica) to exclude rupture of membrane. Actim Partus and PROM dipsticks were tested according to user instructions. Results were blinded to managing obstetricians during the study. Decision on tocolytic and steroid use after specimen collection were made by managing physicians. Test (+) and (-) were evaluated in terms of maternal demographic characteristics.

Results

The phIGFBP-1 positivity (Actim Partus positive) cases had high Bishop scores on admission and a smaller gestational age at delivery and a smaller neonatal birthweight. The strongest predictors of preterm delivery before 34 weeks of gestation were a history of preterm delivery and the presence of cervicovaginal phIGFBP-1 (Actim Partus positive). For predicting deliveries within 7 days of admission phIGFBP-1 positivity (Actim Partus positive), Bishop score and cervical dilatation on admission were found to be statistically significant.

The sensitivity, specificity, positive and negative predictive values of the Actim Partus test are shown in Table 1 for predicting deliveries at less than 34 weeks' gestation, within 7 days of admission and within 14 days.

TABLE 1. Sensitivity, specificity, PPV and NPV of cervicovaginal phosphorylated IGFBP-1 for predicting the deliveries < 7 days, < 14 days of admission and < 34 weeks' gestation

		Prediction of deliveries within					
		< 7 days	> 7 days	< 14 days	> 14 days	< 34 weeks	> 34 weeks
Actim Partus test	pos	14	11	17	11	12	13
	neg	1	42	8	32	5	38
Sensitivity		93.3 %		60.7 %		70.5 %	
Specificity		79.2 %		80.0 %		74.5 %	
PPV		56.0 %		68.0 %		48.0 %	
NPV		97.6 %		74.4 %		88.8 %	

Conclusion

The results show that detection of phIGFBP-1 in cervicovaginal secretions of pregnant women (Actim Partus positive) with signs and symptoms suggestive of preterm labor may confer a high-risk of preterm delivery. Finding is consistent with previous studies showing that a bedside phIGFBP-1 test (Actim Partus test) may be valuable in predicting premature delivery in women with premature contractions. There was also an association between cervical length and gestational age at delivery in patients with a positive phIGFBP-1 test (Actim Partus positive). The high negative predictive value (NPV) of this test may aid the clinician to avoid unnecessary and potentially hazardous medications.

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