



STUDY SUMMARIES

Actim[®] PROM

Kubota, T.
EVALUATION OF INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1 AS
A DIAGNOSTIC TOOL FOR RUPTURE OF THE MEMBRANES

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J Obstet Gynecol Res (1998) 24:411-417.

“The sensitivity and specificity of the [Actim] PROM test were 94.7 % and 93.1%, respectively, showing the highest performance among the 4 methods tested in the present study. Measurement of IGFBP-1 with [Actim] PROM test is unaffected if the vaginal fluid is contaminated by nonamniotic body fluid, if the cervix has been dilated, or if uterine contraction has been established.”

Method

First, the IGFBP-1 concentrations were measured on 42 paired cervicovaginal samples before and after membrane rupture, using an immunoenzymatic assay to find the optimal cutoff value of IGFBP-1 concentration.

Second, the [Actim] PROM test, a BTB test, a ROM-Check and a fern test were compared in diagnosing rupture of the membranes in 48 patients. BTB test is a widely used test in Japan. It tests acidity or alkalinity of the vaginal fluids (principle is the same as in the Nitrazine test). The ROM-Check Membrane Immunoassay uses a monoclonal antibody that specifically recognizes an epitope of fibronectin present in fetal, but not adult, tissue or plasma. Fern test is a conventional method in which a test results is positive when microscopic examination of a vaginal sample on a slide reveals a fern pattern of crystallization.

Results

The [Actim] PROM test, with cutoff value 25 µg/l, had the highest sensitivity (94.7%) and highest specificity (93.3%). See table 1 to see the sensitivity and specificity of other three tests.

TABLE 1. Sensitivity and specificity of PROM, BTB, ROM-Check and fern test.

	PROM test	BTB test	ROM-Check test	Fern test
Sensitivity	94.7	73.3	84.2	42.1
Specificity	93.1	72.4	82.9	75.9

Unlike other tests, the PROM test is unaffected by contamination, cervical dilatation, or uterine contraction. Also, no significant different in specificity of [Actim] PROM test was noted between the laboring and non-laboring groups.

Conclusion

The study shows that with 42 paired vaginal samples, by setting the cutoff value of IGFBP-1 at 25 µg/l, a sensitivity of 95.2% and a specificity of 90.5% were attained. No significant difference in the sensitivity and specificity between the preterm group and the term group was observed with the [Actim] PROM test whose cutoff value was 25 µg/l.

The measurement of IGFBP-1 in vaginal fluids is useful for the diagnosis of ruptured fetal membranes. The sensitivity and specificity of the [Actim] PROM test were 94.7 % and 93.1%, respectively. The result of the [Actim] PROM test was not influenced by blood contamination in the vaginal fluid. There was no significant difference noted in specificity of [Actim] PROM test between the laboring and non-laboring groups.

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