Cervical phIGFBP-1 indicates preterm delivery

Preterm birth (earlier than 37 weeks of gestation) is the leading cause of neonatal morbidity and mortality, necessitating accurate predictive and preventive measures. An elevated cervical concentration of the highly phosphorylated isoform of insulin-like growth factor binding protein 1 (phIGFBP-1) is an early predictor of preterm or imminent delivery.1,2

The phIGFBP-1 phosphoisoform is produced by the decidua3,4,5 and leaks into the cervix following the detachment of the decidua and chorion in the early stages of labor. The presence of phIGFBP-1 in cervical secretions predicts premature or imminent delivery in expectant mothers with intact fetal membranes, even before the occurrence of visible symptoms.1,6

The concentration of cervical phIGFBP-1 can be quantified using the immunochromatographic dipstick test Actim® Partus 1ngenii (Figure 1).7,8

Materials & Methods

The clinical performance of Actim Partus 1ngenii – a quantitative test employing monoclonal antibodies specific for decidual phIGFBP-1 – was evaluated retrospectively. phIGFBP-1 concentration in 120 frozen cervical swab samples from pregnant women at different gestational ages, with or without symptoms of preterm labor, was quantified using an automated Actim 1ngenii System (Figure 2).

Differences in phIGFBP-1 concentration between the clinical groups were analyzed by ANOVA, and the correlation between phIGFBP-1 level and cervical length by two-tailed Pearson correlation using IBM SPSS Statistics 22.0.
HIGH CERVICAL PHIGFBP-1 CONCENTRATION IN ACTIM® PARTUS 1NGENI TEST IS A RELIABLE INDICATOR OF PRETERM DELIVERY WITHIN 7 DAYS

Positive Actim Partus 1Ingeni test reliably predicts delivery within 7 days

The median cervical phIGFBP-1 concentration quantified by Actim 1Ingeni System with Actim Partus 1Ingeni test was significantly higher in women who delivered within 7 days of sample collection as compared to women who delivered beyond the 7-day period (p=0.011).

The median cervical length was significantly shorter in women who delivered within 7 days of sample collection, as compared to women who delivered later in the pregnancy (p=0.001). Moreover, an elevated cervical phIGFBP-1 concentration correlated with a shorter cervical length in women who delivered within 7 days of sample collection (r=0.421; p=0.05). Clinical outcomes of the quantitative Actim Partus 1Ingeni analysis are summarized in Table 1.

TABLE 1. High cervical phIGFBP-1 concentration in Actim Partus 1Ingeni and shortened cervical length predict preterm delivery within 7 days of sample collection. IGFBP-1, insulin-like growth factor-binding protein 1; r, Pearson correlation coefficient; n=120.

<table>
<thead>
<tr>
<th>CLINICAL OUTCOMES</th>
<th>DAYS UNTIL DELIVERY</th>
<th>MEDIAN PHIGFBP-1 CONCENTRATION (μG/L)</th>
<th>MEDIAN CERVICAL LENGTH (MM)</th>
<th>CORRELATION PHIGFBP-1 VS. CERVICAL LENGTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINICAL GROUPS</td>
<td>≤7</td>
<td>15.0</td>
<td>15.0</td>
<td>r=–0.421*</td>
</tr>
<tr>
<td></td>
<td>&gt;7</td>
<td>4.0</td>
<td>30.0</td>
<td>r=0.076</td>
</tr>
<tr>
<td>Statistical signif.</td>
<td>between clinical groups</td>
<td>p=0.011</td>
<td>p=0.001</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

Preterm delivery is associated with a high risk of severe neonatal complications. Therefore, accurate identification of pregnant women who are at risk for preterm delivery is crucial for commencing treatment strategies that accelerate fetal pulmonary maturation and delay birth.

In this quantitative retrospective analysis, a positive Actim Partus 1Ingeni result and a shortened cervical length reliably predicted delivery within 7 days of cervical sample collection in women with intact fetal membranes. Actim Partus 1Ingeni is therefore a valuable clinical tool for the fast and accurate identification of women at high risk for imminent delivery. Moreover, Actim Partus 1Ingeni identifies patients that are highly unlikely to give birth in the next 7 days and helps to avoid overtreatment and unnecessary medications.

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References


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