Preeclampsia testing with Elecsys® sFlt-1/PIGF
Short-term prediction and diagnosis
sFlt-1/PIGF ratio provides peace of mind for physicians to timely and correctly diagnose preeclampsia…

- a disease where the clinical picture is not always clear
- a disease where the onset is unpredictable
- a disease where the assessment of the severity/prognosis is difficult
- a disease where timely decision can be critical both for mother and fetus

Angiogenic factors are proven to play an important role in the pathogenesis of preeclampsia\textsuperscript{15}

**sFlt-1 concentrations increase approximately 5 weeks before the onset of preeclampsia\textsuperscript{15}**

- Controls
- Women with clinical PE

**PIGF concentrations have a substantial decrease 5 weeks before onset of preeclampsia\textsuperscript{15}**

- Controls
- Women who had PE > 5 wk later
- Women who had PE < 5 wk later

\textit{PE = preeclampsia}
Clinical management can be challenging due to:

- A lack of effective treatment options other than delivery\(^6\)
- The necessity of a reliable tests to predict preeclampsia and related complications and to assess disease severity and progression\(^6,7\)
- The necessity to balance maternal and fetal risks\(^1\)

Preeclampsia is defined as new-onset of hypertension and proteinuria after 20 weeks of gestation.\(^3\)

Preeclampsia is one of the leading causes of maternal and perinatal morbidity and mortality worldwide.\(^4\)

Between 2006 and 2008 in the UK, 20 out of 22 deaths linked to preeclampsia involved substandard care.\(^5\)
Elecsys® sFlt-1/PlGF for short-term prediction and diagnosis of preeclampsia

Early-onset preeclampsia – gestational week 20 – 33+6 days

<table>
<thead>
<tr>
<th>sFlt-1/PlGF ≥ 85</th>
<th>Diagnosis</th>
<th>99.5% specificity (the woman has preeclampsia)</th>
<th>Sensitivity: 88.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>sFlt-1/PlGF &lt; 85</td>
<td>Prediction rule-in within next 4 weeks</td>
<td>38.6% PPV (the woman is at high risk to develop preeclampsia within the next 4 weeks)</td>
<td></td>
</tr>
<tr>
<td>sFlt-1/PlGF &lt; 38</td>
<td>Prediction rule-out for the next 1 week</td>
<td>99.1% NPV (the woman will not develop preeclampsia for the next 1 week)</td>
<td></td>
</tr>
</tbody>
</table>

Late-onset preeclampsia – gestational week 34 to end of pregnancy

<table>
<thead>
<tr>
<th>sFlt-1/PlGF ≥ 110</th>
<th>Diagnosis</th>
<th>95.5% specificity (the woman has preeclampsia)</th>
<th>Sensitivity: 58.2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>sFlt-1/PlGF &lt; 110</td>
<td>Prediction rule-in within next 4 weeks</td>
<td>38.6% PPV (the woman is at high risk to develop preeclampsia within the next 4 weeks)</td>
<td></td>
</tr>
<tr>
<td>sFlt-1/PlGF &lt; 38</td>
<td>Prediction rule-out for the next 1 week</td>
<td>99.1% NPV (the woman will not develop preeclampsia for the next 1 week)</td>
<td></td>
</tr>
</tbody>
</table>

Improve the management of suspected preeclampsia patients

Patients with signs and/or symptoms of preeclampsia are sometimes difficult to be managed. Often, a suspicion of preeclampsia triggers escalation to a higher level of care. In fact, appropriate and timely referral to specialized centers reduces perinatal morbidity and mortality by 20%.8

The prognostic performance of the current diagnostic standard in determining which women will develop preeclampsia and how the disease will progress, is quite poor.5 As a consequence, many pregnant women with signs and/or symptoms of preeclampsia are often unnecessarily hospitalized for observation, resulting in stress for the expectant woman and significant additional costs to pregnancy care.

The measurement of the Elecsys sFlt-1/PlGF ratio is a reliable tool in women with suspected preeclampsia to identify the women being at high risk to develop preeclampsia within the next 4 weeks requiring a closer monitoring. On the other hand, the Elecsys sFlt-1/PlGF ratio test allows you to confidently send home women with suspected preeclampsia that are not going to develop the disease for one week.16,17

Improve outcome for mother and child through effective clinical management

In addition to supporting the prediction of preeclampsia, Elecsys sFlt-1 and PlGF immunoassays help to diagnose the disease in unclear clinical situations.8,9,10 The sFlt-1/PlGF ratio aids in the differential diagnosis of preeclampsia: it can be used to differentiate preeclampsia/HELLP from different forms of hypertensive pregnancy disorders.8,11

Following the diagnosis of preeclampsia an assessment is needed to grade the severity of the disease and to determine whether conservative or active management is appropriate. With the Elecsys sFlt-1 and PlGF immunoassays the physician does not just have to rely on the degree of hypertension, the degree of proteinuria and the presence or absence of symptoms.

Clinical criteria alone may be inadequate to predict adverse outcomes. Recent studies showed that a high sFlt-1/PlGF ratio is associated with a significantly increased risk for an immediate delivery.2,6
The use of the sFlt-1/PIGF assays could allow cost-savings
An improved prediction and diagnosis of preeclampsia can allow a reduction of inappropriate discharges as well as a reduction of unnecessary hospitalizations, therefore a reduction of the health care burden. Adding the sFlt-1/PIGF ratio to the standard diagnostic method improves risk stratification with a significant reduction of false positive and false negative diagnosis. This could enable reductions in direct hospital costs and resource use with savings of 540-1,215 USD per patient. By using the sFlt-1/PIGF test in the UK, the NHS could save GBP 730 million annually and in Germany, national savings could reach EUR 436 million annually.
References

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Roche Diagnostics International Ltd
CH-6343 Rotkreuz
Switzerland
www.cobas.com