



## **PROGNOSIS Asia: PRediction of short-term Outcome in preGNant wOmen with Suspected preeclampsia Study using the sFlt-1/PIGF ratio in an Asian population**

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### **Objective**

Current criteria for diagnosis of preeclampsia have limited clinical value for prediction of the onset of preeclampsia. PROGNOSIS, a prospective, multicenter study (14 Western countries) in pregnant women with suspected preeclampsia, demonstrated that a serum sFlt-1/PIGF ratio  $\leq 38$  rules out preeclampsia within 1 week with a 99.3% negative predictive value (NPV). PROGNOSIS Asia was designed to validate the performance of this cut-off in the short-term prediction of preeclampsia in pregnant women in Asia.

### **Methods**

PROGNOSIS Asia was a prospective, multicenter, blinded, non-interventional study including pregnant women at gestational week 20+0 days (18+0 days in Japan) - 36+6 days with suspected preeclampsia, conducted at 25 sites in Asia. The primary objectives were to validate the sFlt-1/PIGF ratio of  $\leq 38$  to predict the absence of preeclampsia within 1 week, and the sFlt-1/PIGF ratio of  $> 38$  to predict the presence of preeclampsia within 4 weeks.

### **Results**

764 subjects were enrolled and data from 700 subjects (91.6%) were evaluable for primary endpoint analysis. The prevalence of preeclampsia in this cohort was 14.4%. An sFlt-1/PIGF ratio of  $\leq 38$  had an NPV of 98.6% (95% confidence interval [CI], 97.2–99.4) for ruling-out preeclampsia within 1 week with 76.5% sensitivity (95% CI, 58.8–89.3), 82.1% specificity (95% CI, 79.0–85.0) and area under the curve (AUC) of 84.3% (95% CI, 75.6–91.4). The positive predictive value (PPV) of an sFlt-1/PIGF ratio  $> 38$  for the diagnosis of preeclampsia within 4 weeks was 30.3% (95% CI, 23.0–38.5), with 62.0% sensitivity (95% CI, 49.7–73.2), 83.9% specificity (95% CI, 80.8–86.7) and AUC of 81.2% (74.8–86.6).

### **Conclusion**

The clinical performance of the sFlt-1/PIGF ratio cut-off of 38 was validated in an Asian population. This study confirms the clinical utility of the sFlt-1/PIGF ratio to aid in the short-term prediction of preeclampsia in conjunction with other diagnostic and clinical information.