Summary of post-market study results

Real-world evidence for utility of serum sFlt-1/PlGF test for routine clinical evaluation of hospitalized women with hypertensive disorders of pregnancy[1]

Study: BEACON (Biomarker (sFlt-1/PlGF) Examination and Analysis for Clinical Obstetrical Navigation)

Study objective

The study objective was to generate real-world evidence for the clinical use and impact of the sFlt-1/PlGF test when made available to physicians within 24 hours as an aid in risk assessment for development of sPE within two weeks of testing in hospitalized patients with HDP.

Study participants

Hospitalized patients with HDP between 23 weeks to 34 weeks and 6 days of gestation were prospectively studied from June 2023 to Jan 2024. This included 58 eligible patients, 7 of whom were re-enrolled for a total of 65 patient encounters (or data points).

Background

What is the sFlt-1/PlGF biomarker test?

The sFlt-1/PlGF biomarker test received FDA clearance in May of 2023 to aid in the risk assessment and clinical management of preeclampsia with severe features (sPE), a worsening form of preeclampsia that can affect multiple organ systems. It is a blood test that can be administered to patients hospitalized for a hypertensive disorder of pregnancy* (HDP; characterized by high blood pressure) between 23 weeks and 34 weeks and 6/7 days of gestation for singleton pregnancies.

How does the test work?

The test measures two proteins found in the blood called soluble fms-like tyrosine kinase 1 (sFlt-1) and placental growth factor (PlGF) that are associated with the development of preeclampsia. A ratio of the two measurements is calculated to produce a numeric value that determines high or low risk for the pregnant woman to progress to sPE within the next two weeks.

How has this test been proven to be effective?

The PRAECIS pre-market study[2] was conducted to determine the ratio value that separates women at high risk from those who are at low risk of developing sPE and adverse pregnancy outcomes among a U.S.-based population. This study determined a value of 40 to be predictive of sPE. The BEACON post-market study[1] reported real-world evidence of clinical utility following implementation of the sFlt-1/PlGF biomarker test into routine clinical management according to the FDA intended use.

Key results of the BEACON study

Dependable test for improved clinical decision making

This test is especially helpful in situations involving uncertainty, unclear symptoms, or non-specific laboratory results. The test has the potential to greatly benefit the health of the mother and baby without causing harm or unintended consequences to either.

Optimizing the use of treatments

Patients with a ratio of less than 40 were less exposed to corticosteroids and magnesium sulfate; in part, due to the fact that there was lower concern for delivery in immediate future.

The ratio can help optimize administration of treatments like these to the most appropriate patients.

Safely prolonging pregnancy WITHOUT adverse outcomes

Pregnancy may be prolonged for patients with a low ratio, which can result in better neonatal outcomes by reducing the risk of admission to the neonatal intensive care unit (NICU) and also the days spent in the NICU.

*As defined by the American College of Obstetrics and Gynecology (ACOG)

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Study data shows the biomarker test helped safely prolong pregnancies and prevent possible adverse outcomes

In the BEACON study, 34 encounters showed an sFlt-1/PlGF ratio of less than 40, which is considered low risk for progression to sPE. However, of those 34, 22 (65% of the group with a low-risk result) had clinical signs and symptoms that resemble sPE. According to the study, these patients were clinically defined as presenting with sPE and, without the biomarkers, would have otherwise been delivered.* **Of the 22 encounters that were managed expectantly with the knowledge of biomarkers, there were no maternal or fetal adverse outcomes.**

The table (right) shows patient encounters with atypical PE or suspected sPE where the sFlt-1/PlGF ratio was less than 40 and who were managed expectantly, showing the extension of each pregnancy.

Demonstrated benefits

This study shows the value of using a quantifiable test in the form of the sFlt-1/PlGF ratio to determine if pregnancies are at low or high risk of developing preeclampsia with severe features within the next two weeks, and that pregnancies at low risk can be safely prolonged to achieve better outcomes for the fetus without harm to the mother.

	Enrollment gestation (weeks+days)	Latency (days pregnancy prolonged)	Delivery gestation (weeks+days)	sFlt/PlGF ratio	Adverse outcome Maternal	Adverse outcome Fetal
1	32+6	+24	36+2	23	No	No
2	31+4	+47	38+2	2	No	No
3	29+3	+57	37+3	2	No	No
4	34+4	+27	38+3	5	No	No
5	34+3	+27	38+2	5	No	No
6	31+2	+21	34+2	31	No	No
7	32+5	+18	35+2	4	No	No
8	30+1	+49	37+1	1	No	No
9	34+4	+5	35+2	6	No	No
10	32+0	+36	37+1	2	No	No
11	34+2	+26	38+0	1	No	No
12	31+2	+51	38+4	3	No	No
13	32+6	+29	37+0	22	No	No
14	27+6	+44	34+1	2	No	No
15	28+3	+46	35+0	1	No	No
16	30+4	+25	34+1	3	No	No
17	34+3	+19	37+1	23	No	No
18	29+5	+53	37+2	1	No	No
19	31+4	+17	34+0	27	No	No
20	32+3	+33	37+1	6	No	No
21	31+0	+21	34+0	1	No	No
22	25+4	+32	30+1	15	No	No

37 weeks

This table was adapted from the BEACON study manuscript (Table 5B) and correlates with number of patient counters, not patient identifiers used in the study. Note: not all medical information and clinical assessments are shown in this table.

*FDA intended use states the sFlt-1/PlGF biomarker test must be used in combination with other laboratory tests and clinical assessments; delivery decisions are not based on the biomarker ratio results alone. ACOG Clinical Practice Update. June 2024- "If the sFlt-1:PlGF ratio is used for hospitalized patients admitted between 23 and 35 weeks of gestation with hypertensive disorders, the test is a complementary risk-stratification screen to add to the diagnostic work-up of preeclampsia with severe features."

1. Burns L, Potchileev S, Mueller A, Azzi M, Premkumar A, Peterson J, Rausch A, Gonzalez M, Silasi M, Karumanchi SA, Thadhani R, Rana S. Real-world evidence for the utility of serum soluble fms-like tyrosine kinase 1/placental growth factor test for routine clinical evaluation of hospitalized women with hypertensive disorders of pregnancy. American Journal of Obstetrics and Gynecology. 2024:0002-9378; https://doi.org/10.1016/j.ajog.2024.07.015.
2. Thadhani R, Lemoine E, Rana S, et al. Circulating Angiogenic Factor Levels in Hypertensive Disorders of Pregnancy. NEJM Evid. 2022 Dec;1(12).

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