EE302

IMPACT OF sFlt-1/PlGF RATIO TESTING FOR EARLY PREECLAMPSIA DETECTION ON HEALTHCARE RESOURSE UTILIZATION IN ROUTINE PREGNANCY MANAGEMENT

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BACKGROUND

- Preeclampsia (PE) is a severe complication affecting 2-8% of pregnancies[1].
- Using the sFlt-1/PlGF ratio test starting from the 24th week of pregnancy has shown high diagnostic and predictive value for the onset of PE. The screening is characterized by 66.2% sensitivity and 83.1% specificity[2].
- While improved diagnostic accuracy for PE does not reduce the overall incidence of PE cases, it can decrease the frequency of false-positive diagnoses, thereby reducing healthcare resource utilization (HCRU). Additionally, it increases the rate of early diagnoses before symptom onset, which may help prevent irreversible complications for both the patient and fetus.

OBJECTIVES

- This study aims to assess the impact of incorporating the sFlt-1/PlGF ratio test in routine pregnancy management on HCRU and clinical outcomes.

METHODS

- The study compared pregnancy management strategies without the sFlt-1/PlGF ratio testing to those with testing of women with high risk of PE.
- We developed a decision tree model (see Figure 1) using test sensitivity and specificity data from the PROGNOSIS[2] trial, along with statistical data on the number of pregnancies, PE severity, and the average number (N) of tests per pregnancy (N = 1; 1,45; 2; 3).
- It was assumed that all PE cases in the model develop within four weeks following testing, which is performed at the physician's discretion. Thus, increasing the average number of tests per pregnancy effectively extends the time window during which the condition can be reliably diagnosed before symptoms onset (i.e. 3 tests equal to 12 weeks).
- The probability of assigning patients to sFlt-1/PlGF groups (<38 and >38) was estimated using data from the PROGNOSIS[2] clinical study, which provided test sensitivity and specificity, as well as input from expert surveys that reflected the real-world likelihood of PE in both low- and high-risk patients. These estimates were then adjusted to align with actual statistical data on PE rates.

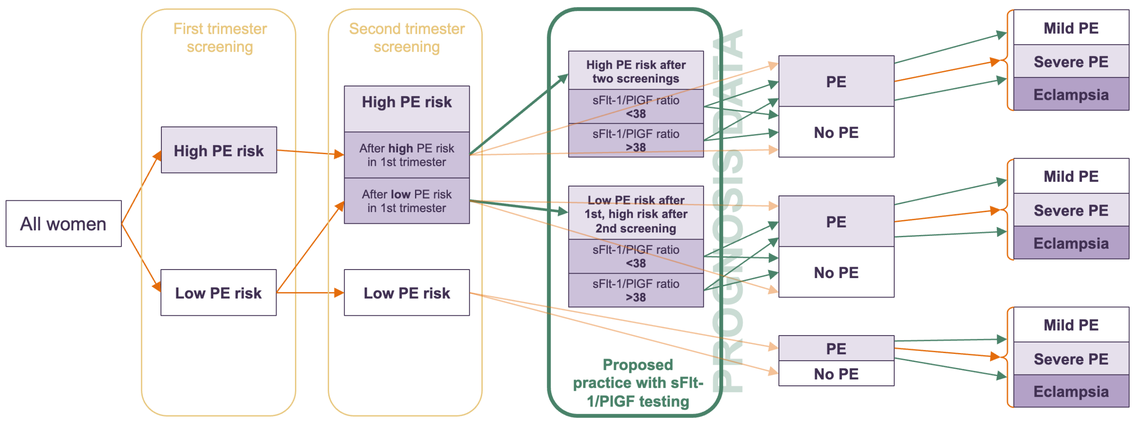

Figure 1. Patient management algorithm **with sFlt-1/PlGF** (with rates and probabilities based on PROGNOSIS data) testing and **without sFlt-1/PlGF** (with rates and probabilities based on RWD and panel board data) testing.

- The model categorizes pregnant women into risk groups with different management strategies, including standard and enhanced monitoring (inpatient hospitalization, or day hospital care, or additional outpatient visits), and inpatient hospitalization. Corresponding HCRU rates were defined by the panel board (see Table 1).

Type of healthcare	Current practice		Proposed practise			LL risk group
	HH risk group	HL risk group	sFlt-1/PlGF <38	sFlt-1/PlGF >38-85	sFlt-1/PlGF >85	
Inpatient hospitalization	16,67%	26,67%	2,67%	8,10%	76,67%	1,67%
Enhanced monitoring	56,67%	53,33%	9,00%	24,60%	16,67%	3,33%
Standard monitoring	26,67%	20,00%	88,33%	67,30%	6,67%	95,00%
Total	100,00%	100,00%	100,00%	100,00%	100,00%	100,00%

Note: HH – high PE risk after both screenings, LH – low PE risk after 1st screening and high PE risk after 2nd screening, LL – low PE risk after both screenings.

Table 1. HCRU for different PE risk groups.

- The model also considered adverse outcomes, which, according to expert opinion, occurred more frequently in cases of emergency childbirth compared to planned deliveries (Table 2). The expert panel indicated that mild PE was associated with a 30% chance of emergency childbirth, severe PE with a 96% chance, and eclampsia with a 100% chance.
- The model was validated on data from three Russian regions: Moscow suburb region (results presented below), Samara region, Republic of Bashkortostan.

Adverse outcome	In case of emergency childbirth, %	In case of planned hospitaliation, %	Δ, p.p.
Maternal mortality	0,04	0,01	0,03
Perinatal mortality	1,45	0,61	0,84
Stillbirth	1,35	0,45	0,90
Respiratory distress syndrome	17,00	6,50	10,50
Periventricular leukomalacia	7,50	2,00	5,50

Note: p.p. – percentage point.

Table 2. Frequency of adverse outcomes in case of an emergency childbirth and planned hospitalization.

RESULTS

- Upon validating the model using data from 70,162 pregnancies (with a PE frequency of 34.4 cases per 1,000 births), it is anticipated that without testing among women at high risk of PE, there would be 5,198 inpatient visits, 2,715 day hospital care visits, and 27,167 outpatient visits (Figure 2).

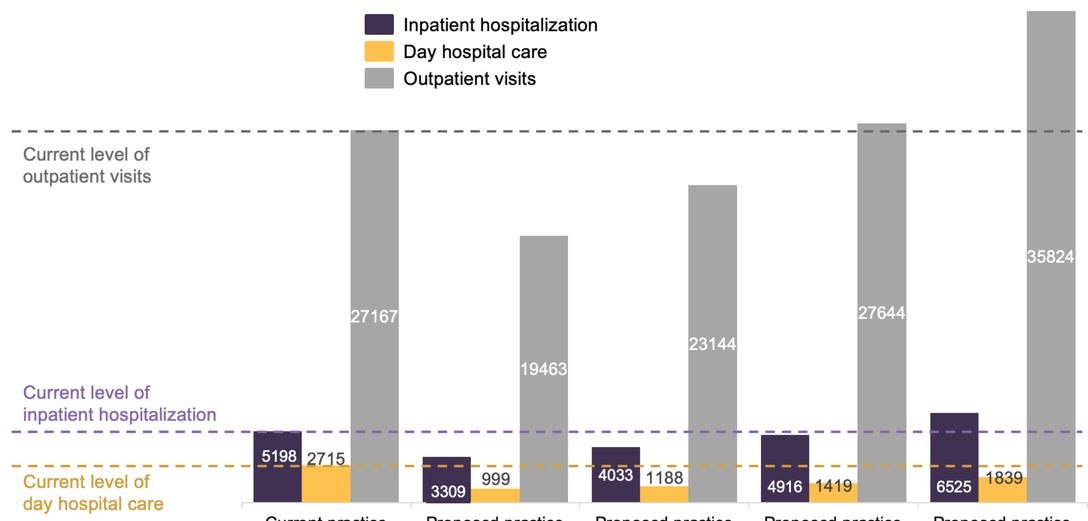

Figure 2. HCRU for different scenarios of proposed practice with varying number of sFlt-1/PlGF tests.

- With the implementation of one test per pregnancy, the number of inpatient hospitalizations would decrease to 3,309, day hospital care to 999, and outpatient visits to 19,463.
- With 1.45 tests per pregnancy, HCRU is higher than with a single test per pregnancy due to an increase in false-positive diagnoses. However, it remains lower compared to current practice. When the number of tests increases to two per pregnancy, the number of outpatient visits exceeds current practice levels, while other aspects of HCRU remain below these levels.
- Regardless of the number of sFlt-1/PlGF tests in the proposed practice, the number of emergency childbirths is expected to decrease to 664.3 cases. Additionally, perinatal mortality is projected to decline by 1.5 cases, stillbirths by 1.6 cases, instances of periventricular leukomalacia by 9.8 cases and respiratory distress syndrome by 18.7 cases (Table 3).

Event	Current practice (1)	Proposed practice (2)	Δ (2)-(1)
Number of emergency childbirth	842,7	664,3	-178,4
Number of associated adverse outcomes			
Maternal mortality	0,2	0,2	<0,1
Perinatal mortality	7,1	5,6	-1,5
Stillbirth	7,6	6,0	-1,6
Respiratory distress syndrome	88,5	69,8	-18,7
Periventricular leukomalacia	46,3	36,5	-9,8

Table 3. Number of adverse outcomes in case of current and propose practices (regardless of the number of sFlt-1/PlGF tests).

CONCLUSIONS

- Implementing routine sFlt-1/PlGF ratio testing in pregnancy management can enhance the diagnosis of PE, potentially reducing HCRU.

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