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ORIGINAL PAPER

EARLY PREGNANCY PRE-ECLAMPSIA SCREENING USING FETAL MEDICINE FOUNDATION FORMULA: A LONGITUDINAL STUDY

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Abstract

Background. Pre-eclampsia and eclampsia are major obstetric disorders that complicate 2–10% of pregnancies. The current management focuses on early detection, prevention, monitoring, and timely delivery.
The objective of the study was to evaluate the effectiveness of the Fetal Medicine Foundation (FMF) early pregnancy screening model and to identify the risk factors for pre-eclampsia.
Material and methods. This longitudinal study was conducted on 1,650 pregnant women during their first trimester, from June 2021 to November 2022. The participants underwent medical history review, blood pressure measurement, uterine artery Doppler ultrasound, and pregnancy-associated plasma protein A (PAPP-A) and placental growth factor (PlGF) testing per FMF criteria. High-risk women received aspirin prophylaxis and were monitored until delivery, with pre-eclampsia onset recorded. The study also examined the risk factors in this cohort.
Results. Among 1,650 pregnant women, 163 (9.9%) had high-risk of pre-eclampsia, and 22.6% developed pre-eclampsia. Of those who developed pre-eclampsia,

Résumé

Dépistage de la pré-éclampsie précoce de grossesse à l'aide de la formule de la Fetal Medicine Foundation: une étude longitudinale

Introduction. La pré-éclampsie et l'éclampsie sont des troubles obstétricaux majeurs qui compliquent 2 à 10% des grossesses. La direction actuelle se concentre sur la détection, la prévention, la surveillance précoce et la livraison en temps opportun.
L'objectif de l'étude était d'évaluer l'efficacité du modèle de dépistage de la grossesse précoce de Fetal Medicine Foundation (FMF) et d'identifier les facteurs de risque de pré-éclampsie.
Matériel et méthodes. Cette étude longitudinale a été menée sur 1650 femmes enceintes au cours de leur premier trimestre, de juin 2021 à novembre 2022. Les participants ont subi une revue des antécédents médicaux, une mesure de la pression artérielle, une ultrasonographie Doppler de l'artère utérine et un test de facteur de croissance placental par critère de FMF. Les femmes à haut risque ont reçu une prophylaxie de l'aspirine et ont été surveillées jusqu'à l'accouchement,

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14.3% had severe evolution. The mean gestational age at diagnosis was 36.6 weeks, 10.7% before 34 weeks, 21.4% between 34–37 weeks, and 67.9% at/after 37 weeks. Women with education below high school had a 5.9-fold higher pre-eclampsia risk (95% CI: 2.1–16.6). A history of hypertension led to a 22.8-fold higher risk (95% CI: 2.3–223.6).

Conclusions. FMF-based early screening should be implemented to enable timely low-dose aspirin prophylaxis, reducing pre-eclampsia incidence. Low education and hypertension increase pre-eclampsia risk, even with aspirin prophylaxis.

Keywords: pre-eclampsia, first trimester, screening.

List of abbreviations:
FMF = Fetal Medicine Foundation
MAP = mean arterial pressure
MoM = multiples of the median
UTPI = uterine artery pulsatility index
PAPP-A = pregnancy-associated plasma protein A
P1GF = placental growth factor
NICE – National Institute for Health and Care Excellence
ACOG – American College of Obstetricians and Gynecologists

avec le début de la pré-éclampsie enregistrée. L'étude a également examiné les facteurs de risque dans cette cohorte.

Résultats. Parmi 1650 femmes enceintes, 163 (9,9%) avaient un risque élevé de prééclampsie et 22,6% ont développé une prééclampsie. Parmi ceux qui ont développé une pré-éclampsie, 14,3% ont eu une grave évolution. L'âge gestationnel moyen au diagnostic était de 36,6 semaines, 10,7% avant 34 semaines, 21,4% entre 34 et 37 semaines et 67,9% à / après 37 semaines. Les femmes ayant une éducation en dessous du lycée avaient un risque de pré-éclampsie de 5,9 fois plus élevé (IC à 95%: 2,13–16,6). Des antécédents d'hypertension ont entraîné un risque de 22,8 fois plus élevé (IC à 95%: 2,3–223,6).

Conclusions. Un dépistage précoce basé sur la FMF doit être mis en œuvre pour permettre une prophylaxie en temps opportun à faible dose d'aspirine, réduisant l'incidence pré-éclampsie. La faible éducation et l'hypertension augmentent le risque de pré-éclampsie, même avec la prophylaxie de l'aspirine.

Mots-clés: pré-éclampsie, premier trimestre, dépistage

Introduction

Pre-eclampsia and eclampsia affect 2–8% of pregnancies worldwide, posing serious maternal and fetal health risks that require stringent clinical management[1]. Current management emphasizes early detection, prevention, monitoring, and timely delivery[2].

Several key factors contribute to the development of pre-eclampsia, including maternal age, mean arterial pressure (MAP), uterine artery pulsatility index (UTPI), and a variety of biochemical markers such as pregnancy-associated plasma protein A (PAPP-A), placental growth factor (PlGF), and soluble fms-like tyrosine kinase-1 (sFlt-1). Various predictive algorithms, based on these factors, estimate pre-eclampsia risk with varying sensitivity and specificity[2,3].

Among predictive models, the Fetal Medicine Foundation (FMF) early pregnancy screening formula, based on Bayes' theorem, is widely recognized. It integrates four key indices—MAP, UTPI, PAPP-A, and PlGF—alongside maternal history and clinical factors. The FMF test has demonstrated 90% accuracy for early pre-eclampsia, 75% for preterm delivery, and a 10% false positive rate. Detection rates for early preterm, and term pre-eclampsia were 90%, 75%, and 41%, respectively[2]. Given its higher accuracy, the FMF formula is preferred over National Institute for Health and Care Excellence (NICE) and the American College of Obstetricians and Gynecologists (ACOG) guidelines for identifying high-risk pregnancies eligible for low-dose aspirin prophylaxis[1,3,4]. Hence, this study assessed the FMF screening model's effectiveness and identified the risk factors for pre-eclampsia to improve prevention and management strategies.

Materials and methods

Subjects

A descriptive longitudinal study was conducted on 1,650 pregnant women attending antenatal care during their first trimester, from June 2021 to June 2023. These women were considered eligible for the study if they met the following criteria: gestational age between 11 weeks and 13 weeks 6 days, the presence of singleton pregnancy, a viable fetus, and the provision of signed informed consent. Exclusion criteria encompassed the detection of any fetal anomalies during the first or second trimester screenings. This study was approved by the Biomedical Research Committee of Can Tho University of Medicine and Pharmacy, Vietnam (approval no. 095/PCT- HĐĐĐ, dated March 30, 2021).

Table 1. General characteristics of study subjects (n=1650)

Characteristics		*Low risk n=1487 (percent)*	*High risk n=163 (percent)*	*Overall n=1650 (percent)*
Maternal age	< 35 years old	1259 (84.7)	104 (63.8)	1363 (82.6)
	≥ 35 years old	228 (15.3)	59 (36.2)	287 (17.4)
	Mean ± SD (Min-Max)		28.9±5.5 (16 – 47)	
Parity	Primigravida	814 (54.7)	114 (69.9)	928 (56.2)
	Multigravida	673 (45.3)	49 (30.1)	722 (43.8)
Occupation	Housewife	655 (44.0)	61 (37.4)	716 (43.4)
	Officers	313 (21.0)	30 (18.4)	343 (20.8)
	Workers, farmers	401 (27.0)	52 (31.9)	453 (27.5)
	Others	118 (7.9)	20 (12.3)	138 (8.4)
Education level	≤ High school	499 (33.6)	56 (34.4)	555 (33.6)
	> High school	988 (66.4)	107 (65.6)	1095 (66.4)

Data are presented by n (percent) and mean ± SD.

Sample size

The sample size for the study was determined using the Cochran formula with $Z_{1-\frac{\alpha}{2}}$ value of 1.96; confidence coefficient of 0.95; a margin error of 0.015; the percentage of high-risk pregnancies for pre-eclampsia using FMF screening (p) was set at 0.105 based on the ASPRE trial in 2017[5]. The required sample size was calculated to be 1,604.5. Ultimately, 1,650 samples were included in the study.

Study procedures

Pregnant women between 11 weeks and 13 weeks 6 days of gestation were assessed through interviews regarding their medical and obstetrical history, blood pressure measurements, Doppler ultrasound of the uterine arteries, and testing for PAPP-A and PlGF. The FMF formula was applied to evaluate the risk of pre-eclampsia. Women identified as high-risk (FMF value > 1/100) were prescribed 162 mg of aspirin daily until 36 weeks of gestation or until pregnancy termination if it occurred earlier. These women were monitored through regular antenatal visits, with pre-eclampsia occurrence documented. For cases diagnosed with pre-eclampsia, gestational age at diagnosis (<34 weeks, 34-37 weeks, or ≥37 weeks), severity, and pregnancy complications were recorded. Additional interviews explored factors contributing to pre-eclampsia development or the lack thereof.

Pre-eclampsia diagnosis criteria

The diagnosis was based on hypertension (blood pressure ≥ 140/90 mmHg) occurring after 20 weeks of gestation in women without pre-existing hypertension, accompanied by one or more of the following:

- Proteinuria (≥ 300 mg/24 hours, proteins/creatinine ratio ≥ 0.3, ≥ 1+ on dipstick, or 0.3 mg/dL in a random sample);
- Platelet count < 100,000/μL;
- Renal impairment (serum creatinine ≥ 1.1 mg/dL or twice the normal level in women without prior renal disease);
- Elevated liver enzymes (AST or ALT levels twice the normal);
- Central nervous system symptoms (headache, visual disturbances);
- Pulmonary edema.

Statistical analysis

Data analysis was conducted using SPSS software version 20 (SPSS Inc., USA). Categorical variables were presented as frequencies and percentages. Continuous variables were expressed as mean and standard deviation if normally distributed or median (minimum and maximum) if not normally distributed. Data were analyzed using c2 and non-parametric tests (Mann-Whitney U-test and Wilcoxon-test). All tests were 2-tailed and a p-value <0.05 was considered statistically significant. Multivariate logistic regression analysis was used to determine the association between variables that were statistically significant in univariate analysis with p < 0.05 and 95% CI not containing the value 1.

Results

A total of 1,650 pregnant women underwent pre-eclampsia screening during their first trimester. Among them, 163 (9.9%) were classified as high risk based on the FMF formula. Table 1 presents the baseline characteristics of the participants. The majority (82.6%) were under 35 years old, and more than half (56.2%) were experiencing their first pregnancy. In terms of occupation, housewives made up the largest group (43.4%), followed by workers, farmers, and

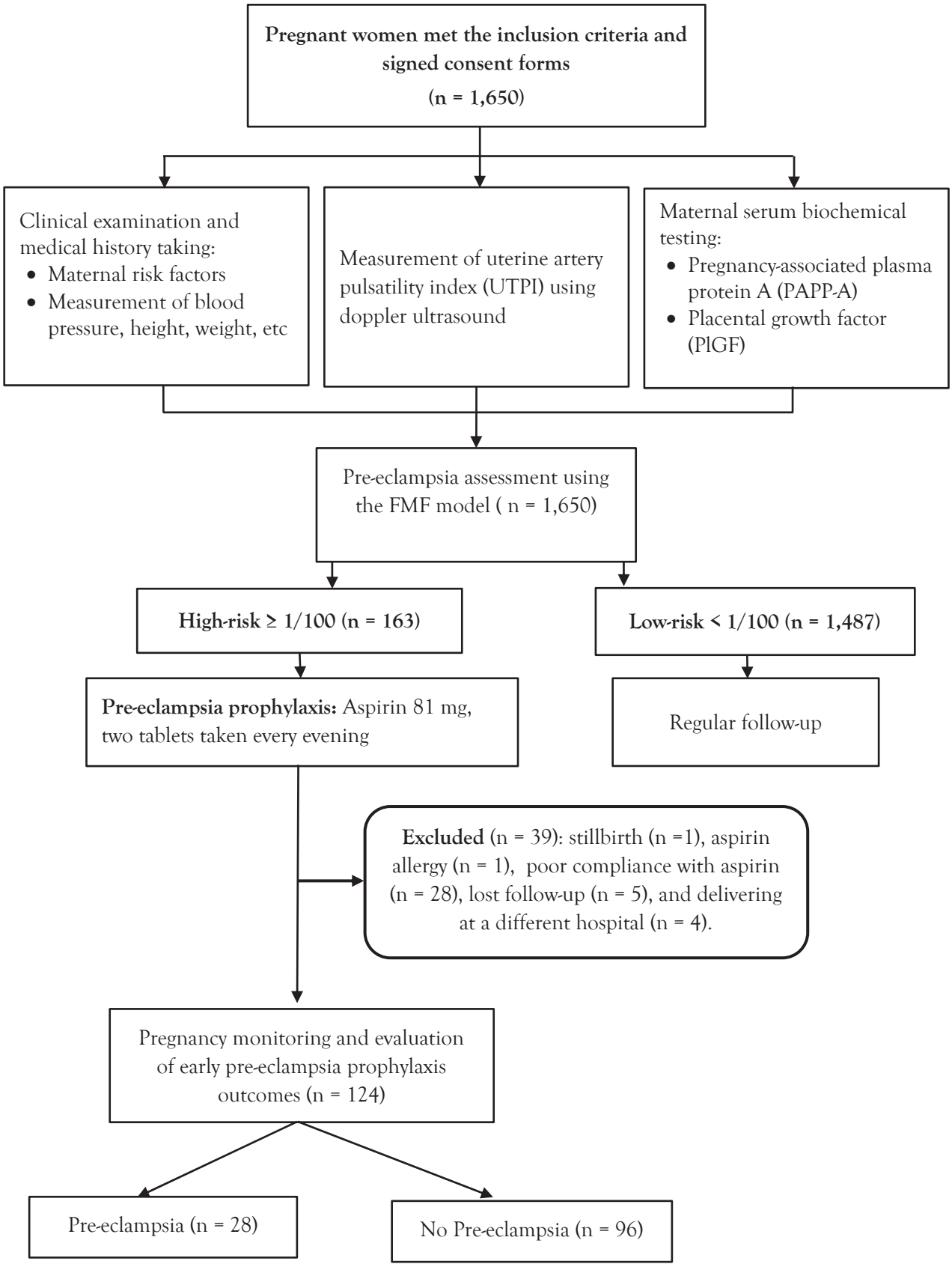


Figure 1. Flow of study

Table 2. Characteristics used in FMF pre-eclampsia screening (n=1650)

Characteristics	*Low risk*	*High risk*	*General*	*p*
Mean Arterial Pressure (MAP) mmHg	83.8±8.1	95.2±9.1	84.9±8.9	< 0.01
Uterine Artery Pulsatility Index (UTPI)	1.75±0.5	2.0±0.5	1.78±0.5	< 0.01
Pregnancy-Associated Plasma Protein-A (PAPP-A)	4554.1±2776.9	2450.1±1701.1	4346.3±2761.7	< 0.01
Placental Growth Factor (PlGF)	45.2±24	21.7±10.3	42.9±24.1	< 0.01

Data are presented by mean ± SD

Table 3. Pre-eclampsia outcomes (n=124)

Groups	*Frequency*	*Rate (%)*
Pre-eclampsia	28	22.6
Severe pre-eclampsia	*4*	*14.3*
Non-severe pre-eclampsia	*24*	*85.7*
No pre-eclampsia	96	77.4
Total	**124**	**100**

Table 4. Pre-eclampsia diagnosis time (n=28)

Pre-eclampsia diagnosis time	*Severe pre-eclampsia, n (%)*	*Non-severe pre-eclampsia, n (%)*	*Total, n (%)*
< 34 weeks	2 (67.7)	1 (33.3)	3 (10.7)
34 – 37 weeks	0	6 (100.0)	6 (21.4)
≥ 37 weeks	2	17 (100.0)	19 (67.9)
Total	4 (14.3)	24 (85.7)	28 (100)

Data are presented by n (%)

Table 5. Factors associated with pre-eclampsia in high-risk pregnant women (n=124)

Characteristics		*cOR (95% CI)*	*p*	*aOR (95% CI)*	*p*
Education	< High school	5.3 (2.0-13.7)	<0.01	5.9 (2.1 – 16.6)	<0.01
	≥ High school				
Weight	< 65 kg	2.56 (0.97 – 6.72)	0.05	–	
	≥ 65 kg				
History of hypertension	Yes	20.7 (2.3 – 185.4)	0.01	22.8 (2.3 – 223.6)	0.01
	No				
Interval between pregnancies	≤ 10 years	25.88 (4.1 – 166.9)	<0.01	–	
	> 10 years				
MAP	< 95 mmHg	2.8 (1.2 – 6.7)	0.02	2.0 (0.8 – 5.2)	0.17
	≥ 95 mmHg				

cOR – crude Odds ratio; aOR – adjusted Odds ratio

traders (27.5%), while officers accounted for 20.8%. Notably, a substantial proportion (66.4%) had an educational level above high school.

During the follow-up period, one participant experienced stillbirth, another developed aspirin allergy, five either did not adhere to or did not receive prophylactic aspirin treatment, and 28 women discontinued prenatal care, delivering at a different hospital. Consequently, 39 participants were excluded from the final analysis, leaving 124 women who met the study criteria and were monitored until delivery (Figure 1).

Table 2 illustrates differences in key clinical characteristics between high-risk and low-risk groups, these values were statistically significantly different, with $p < 0.01$. Notably, the mean arterial pressure and uterine artery pulsatility index were elevated in the high-risk group, whereas PAPP-A and PlGF levels were lower compared to the low-risk group.

Following low-dose aspirin prophylaxis in the high-risk group, 28 women (22.6%) developed pre-eclampsia, with 14.3% (4 women) classified as severe (Table 3). The timing of pre-eclampsia onset varied: 10.7% (3 women) of cases were diagnosed before 34 weeks, 21.4% (21.4 women) between 34-37 weeks, and 67.9% (19 women) at term (Table 4).

Despite screening with the FMF model and aspirin prophylaxis, some risk factors remained influential. Multivariate logistic regression analysis identified two statistically significant predictors of pre-eclampsia: low educational attainment (below high school) and a history of hypertension (Table 5).

Discussion

Among 1,650 women, 17.4% were primigravid and ≥ 35 years old, with 20.6% at high risk for pre-eclampsia. In contrast, only 7.6% of women < 35 years old had high risk. Additionally, 56.2% were primigravid, with 12.3% at high risk. These findings align with the elevated pre-eclampsia risk in older mothers.

Rezende et al. found that 23% had preterm pre-eclampsia, mainly among the white subgroup[6].

In our study, 163 out of 1,650 women (9.9%) were at high risk by FMF screening, consistent with studies like the ASPRE trial (10.5%)[5]. The study of Rezende et al. found 11.9% after adjusting for ethnicity[6]. The comparison of the 2012 FMF model's initial and recalculated risk showed no significant differences in sensitivity or area under the curve, but a significant difference in the false positive rate[6]. The proportion of high-risk pre-eclampsia cases identified through FMF depends on population risk factors. Women with a history of pre-eclampsia have a higher risk of recurrence[7].

Of the 165 high-risk women, 39 were excluded because of stillbirth, drug allergies, non-compliance, or inadequate monitoring. Non-compliance among hypertensive patients is high, ranging from 8.8% to 30% due to forgetfulness, feeling well, or schedule issues[8]. Among 124 high-risk women receiving 162 mg of aspirin daily, 28 (22.6%) developed pre-eclampsia, 14.3% severe, similar with the results of a study of 138 high-risk women (21.7%), though aspirin regimen details were unspecified[9]. In contrast, the ASPRE study reported a pre-eclampsia rate of 11.1%[5]. Our study included many cases of chronic hypertension (64.3%) and a history of pre-eclampsia in previous pregnancies (85.7%). Zwertbroek's study on 362 high-risk women reported a 10.7% pre-eclampsia rate[7]. The pre-eclampsia rate based on the identified high-risk group (9.9%) and the total screened population (1.73%) indicates that having more risk factors increases the likelihood of developing pre-eclampsia.

In our study, the results of aspirin treatment were similar to other studies, despite limited interventions. Most severe cases were early-onset pre-eclampsia, but the small sample size (two cases) limits the conclusions. Studies on high-risk pregnant women with a history of hypertension found no significant reduction in pre-eclampsia rates (p=0.2) but improved neonatal outcomes (p = 0.002), especially in 5-minute Apgar scores (p = 0.009)[10]. Other studies comparing 60-100 mg/day aspirin to placebo found no significant difference (p = 0.06), though aspirin showed beneficial outcomes[11]. A study on 150 mg aspirin vs. placebo found higher pre-eclampsia rates before 34 and 37 weeks in the placebo group, though not statistically significant[12].

First-trimester screening studies for pre-eclampsia commonly compare women with pre-eclampsia to control groups without distinguishing between high- and low-risk groups. However, studies consistently highlight the predictive value of MAP in assessing pre-eclampsia risk. Women with pre-eclampsia or high risk showed higher MAP levels than control groups. For example, Poon et al. found the MAP multiples of the median (MoM) for early-onset pre-eclampsia to be 1.14 (94.5 mmHg) and for late-onset 1.09 (93.8 mmHg), both higher than the control group's 1.0 MoM (84.3 mmHg)[13]. Gallo et al. found MAP values for pre-eclampsia (1.055 MoM, 92.5 mmHg) higher than normal pregnancies (0.995 MoM, 84.7 mmHg), consistent with our findings. The detection rates for early preterm and overall pre-eclampsia were 74.3%, 62.9%, and 49.3%, respectively, with a 10% false-positive rate[14]. The MAP for the pre-eclampsia group was 93.2±4.6 mmHg compared to 85.3±4.2 mmHg in the non-preeclampsia group[15]. Women with pre-eclampsia tend to have higher blood pressure during the first and second trimesters, making accurate blood pressure measurement essential for early diagnosis[16].

Significant differences exist between high- and low-risk groups for UtA-PI and PlGF at 11–13 weeks. Combining PlGF thresholds with UtA-PI and MAP can predict pre-eclampsia[17].

In the pre-eclampsia group, PAPP-A and PlGF were lower, while free beta human chorionic gonadotropin and UtA-PI were higher. The clinical examination showed that PAPP-A is lower in the first trimester, while sFlt/PlGF increases during later trimesters for pre-eclampsia. MAP remains significantly higher across all trimesters compared to women without pre-eclampsia ($p < 0.001$), although UtA-PI levels show no significant differences ($p > 0.05$). Thus, the FMF formula for first-trimester screening reliably predicts pre-eclampsia[9,15].

Through univariate analyses, we identified four factors associated with the development of pre-eclampsia in the high-risk group of pregnant women. These factors are an educational level below high school, a pregnancy interval of over 10 years, a personal history of hypertension, and a MAP ≥ 95 mmHg. Since the variable "pregnancy interval of over 10 years" only applied to multigravida women, we conducted multivariate analysis with the remaining three variables. This analysis revealed two significant factors related to the development of preeclampsia in this population: an educational level below high school, with an OR of 5.9 (95% CI: 2.1 – 16.6), and a history of hypertension prior to pregnancy, with an OR of 22.8 (95% CI: 2.3 – 223.6). These results present novel findings compared to previous studies.

The univariate analysis identified four factors associated with pre-eclampsia in high-risk women: educational level below high school, pregnancy interval >10 years, a history of hypertension, and MAP ≥ 95 mmHg. The multivariate analysis of the remaining factors revealed that an educational level below high school (OR 5.9) and a history of hypertension (OR 22.8) were significant predictors of pre-eclampsia. These findings are novel compared to previous studies. Prior research has

also identified risk factors for preeclampsia based on demographics, epidemiology, and medical history. The key factors linked to preeclampsia include adolescent age, obesity, chronic hypertension, pre-existing diabetes, severe anemia, previous history of PE, and fetal chromosomal abnormalities[18].

Studies of first-trimester screening also identified factors such as Afro-Caribbean origin, chronic hypertension, history of preeclampsia and ovulation stimulation for early-onset preeclampsia, and maternal age, body mass index, family history, and personal history for late-onset preeclampsia[19]. Late-onset preeclampsia was also more frequent in Afro-Caribbean and South Asian descent (OR 2.66–3.31)[19].

Conclusions

The early pregnancy screening for pre-eclampsia using the FMF formula identified 9.9% of pregnant women as high risk. Among those who received prophylactic aspirin treatment, 22.6% developed pre-eclampsia, with 10.7% of these cases detected before 34 weeks of gestation. Two factors associated with the development of pre-eclampsia in the high-risk group were identified: an educational level below high school, with an OR of 5.95, and a history of hypertension prior to pregnancy.

Author Contributions:

L.M.D., N.Q,B., V.H.L conceived the original draft preparation. L.M.D., N.Q,B., V.H.L, D.L.T, T.T.T.L were responsible for conception and design of the review. L.M.D., N.Q,B., V.H.L, T.Q.D were responsible for the data acquisition. L.M.D., N.Q,B., V.H.L. T.Q.D, T.T.T.L, D.L.T were responsible for the collection and assembly of the articles/published data, and their inclusion and interpretation in this review. All authors contributed to the critical revision of the manuscript for valuable intellectual content. All authors have read and agreed with the final version of the manuscript.

Compliance with Ethics Requirements:

"The authors declare no conflict of interest regarding this article"

"The authors declare that all the procedures and experiments of this study respect the ethical standards in the Helsinki Declaration of 1975, as revised in 2008(5), as well as the national law. Informed consent was obtained from all the patients included in the study"

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Data availability

The data that support the findings of this study are available from the corresponding author Q.N.B. (i.e., upon reasonable request).

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