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Gynecology

# External validation of the preeclampsia predictive model of the Hospital Clinic of Barcelona in a second-level unit in Guayaquil, Ecuador.

Kevin David Dickens Warrior [1] ID *, Pilar Maricela Díaz Abadie [1] ID.

1. Gynecology and Obstetrics Service, General Hospital of Northern Guayaquil Ceibos, Ecuadorian Social Security Institute, Guayaquil, Ecuador.
2. Gynecology Service, Clinical Surgical Center, South Valdivia Day Hospital, Ecuadorian Social Security Institute, Guayaquil, Ecuador.

## Summary

**Introduction**: The objective of the present study was to evaluate the operational capacity of the Hospital Clinic of Barcelona's predictive algorithm for detecting the risk of preeclampsia (PE) in a cohort of women treated at a secondary level in Guayaquil, Ecuador.

**Methods:** A cohort study of 304 pregnant women between August 2018 and August 2019. The algorithm was applied without angiogenic biomarkers, evaluating sensitivity, specificity, area under the curve (AUC), predictive values, and likelihood ratio. Data were analyzed based on the algorithm's ability to predict PE in resource-limited settings.

**Results:** The algorithm showed a high predictive capacity with an AUC of 0.924, a sensitivity of 88.46%, and a specificity of 91.37%. Implementing the cut-off point at 0.75 optimized the identification of PE cases. Without using biomarkers, it was detected that between 10 and 15% of cases could not be identified in high-risk patients.

**Conclusions**: The predictive algorithm is effective for detecting PE in secondary care settings in Ecuador. Stratified screening with biomarkers in high-risk subgroups is suggested to optimize accuracy without universal screening, thus adapting resources to local needs.

## Keywords :

Preeclampsia, Predictive algorithm, Screening, Biomarkers, Maternal health.

## Abbreviations

AUC: Area under the curve.
BMI: Body mass index.
MAP: mean arterial pressure.
PE: Pre-eclampsia.

## Additional information

No supplementary materials were declared.

## Acknowledgments

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## Authors' contributions

Kevin Dickens: Conceptualization, data curation, formal analysis, funding acquisition, investigation, writing – original draft.
Pilar Díaz Abadie: Funding acquisition, Research, Methodology, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review and editing.
All authors read and approved the final version of the manuscript.

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## Availability of data and materials

The datasets used and analyzed during the present study are available from the corresponding author upon reasonable request.

# Introduction

Preeclampsia (PE) is a gestational complication characterized by hypertension and systemic damage. It affects between 2% and 10% of pregnant women worldwide [1]. In Ecuador, it is one of the three leading causes of preventable maternal death, which demonstrates its impact on public health [2]. The consequences of PE are severe, with a significant increase in maternal-perinatal morbidity and mortality. Complications associated with this condition include HELLP syndrome, seizures, maternal death, intrauterine growth restriction (IUGR), preterm birth, and neonatal mortality [3].

In response to this global public health problem, the Hospital Cliníc de Barcelona team has developed predictive algorithms to identify pregnant women at high risk for PE. These models use demographic data and biomarkers to identify these women and act promptly [4- 10].

In the context of countries with health systems, mainly due to low budgets, such as Ecuador, angiogenic factors are usually not considered as part of the screening, so it is essential to know the operational capacity of the model without taking into account the angiogenic factors [5 - 6].

The Hospital Cliníc de Barcelona's predictive model is robust in developed countries; however, in contexts such as Ecuador, validation is required to ensure its effectiveness and viability in predicting PE. In addition, its capacity and accuracy in risk stratification should be evaluated, as should the opportunity to perform prophylaxis with acetylsalicylic acid (ASA) (up to week 16 of gestation) [7- 12].

The timely identification of pregnant women at risk remains a challenge for Ecuador due to the lack of trained personnel, infrastructure problems, and technology, in addition to public health policies [5- 6].

This study aims to determine the operational capacity of the algorithm in predicting the risk of preeclampsia in a cohort of pregnant women treated at the secondary care level in Guayaquil, Ecuador.

# Materials and methods

## Study design

This study is retrospective, longitudinal, and analytical. The source is retrospective.

## Scenery

The study was conducted at the Hospital General del Norte de Guayaquil Ceibos-IESS, Guayaquil, Ecuador, from August 1, 2018, to August 31, 2019.

## Participants

The records of pregnant women over 18 years of age with a single pregnancy with a live fetus and a cranial-caudal length (CCL) between 45 and 84 mm on first-trimester ultrasound were included. Women with multiple pregnancies, structural abnormalities and aneuploidies, cases of late abortion or stillbirth, patients without subsequent prenatal check-ups in the unit, patients with previous regular use of acetylsalicylic acid before screening, patients with prolonged use of non-steroidal anti-inflammatory drugs and patients with participation in other scientific studies in the last 28 days were excluded.

## Variables

The variables were:

1. Maternal characteristics: age, ethnicity, weight, and height at the consultation, medical history (parity, history of preeclampsia in previous pregnancies, chronic hypertension, thrombophilia, pregestational diabetes, nephropathies, and collagenopathies), and type of fertilization.
2. Biophysical parameters:

- Average uterine artery pulsatility index (PI): Measured by transabdominal Doppler ultrasound with the Medison Accuvix A30 equipment.
- Mean arterial pressure (MAP): Measured with an electric blood pressure monitor recommended in the ASPRE7 study. The formula is (systolic pressure + 2 x diastolic pressure) /3.

## Data sources/measurements

The source was indirect; an electronic form was filled out from the MIS-AS 400 institutional clinical history data. The predictive models used [4- 11] were the following:

1. Early preeclampsia

*A priori risk:*

Y= -7.703 + (0.086 x BMI) + (1.708 if chronic hypertension) + (4.033 if kidney disease) + (1.931 if multiparous, previous PE) + (0.005 if multiparous, no previous PE).

*A posteriori risk:*

21.999 + (12.251×a priori risk) + (11.516×MoM PAM) + (3.784×MoM average IP).

2. Late preeclampsia

*A priori risk:*

Y = −6.135 + (2.124 if previous PE) + (1.571 if chronic hypertension) + (0.958 if diabetes mellitus) + (1.416 if thrombophilia) − (0.487 if multiparous) − (0.093 × BMI).

*A posteriori risk:*
14.315 + (8.864 × a priori risk) + (7.429×MoM PAM) + (2.447×MoM average IP).

### Biases

Applying the participant selection criteria avoided observation and selection bias. To avoid possible interviewer, information, and memory biases, the principal investigator kept the data at all times using a guide and records approved in the research protocol. Two researchers independently analyzed each record in duplicate, and the variables were recorded in the database once their concordance was verified.

### Study size

The sample was probabilistic. According to INEC data, there are 1.4 million women in Guayas, of which 53.2% are of childbearing age (744,800). A fertility rate of 42.8 per 1000 women in Ecuador corresponds to 31,877 possible pregnancies as a universe. With an expected frequency of pre-eclampsia of 27.1%, a confidence limit of 5%, and a confidence interval of 95%, the sample size was 301 cases. The EPI info™ program (Version 7.2.5, CDC, Atlanta, USA, September 2022) was used for the sample calculation.

### Quantitative variables

Descriptive statistics were used. Results are expressed as frequency and percentage. Categorical variables were not converted into quantitative variables.

### Statistical analysis

1. Descriptive Statistics: Qualitative variables were analyzed with frequency and percentages, while quantitative variables were described using central tendency and dispersion measures.
2. ROC curve and Youden Index: The algorithm's predictive capacity was calculated, and the optimal cut-off point of 0.75 was selected.
3. Sensitivity and Specificity: Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy for late preeclampsia were evaluated at the cut-off point 0.75.
4. Inferential Statistics: Clinical characteristics were compared between the groups with and without preeclampsia using the chi-square test for categorical variables and the Mann-Whitney test for non-normal continuous variables, with a significance level of $P$ <0.05. The statistical package used was IBM Corp., Released in 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.

# Results

## Participants

The study included 304 cases.

## Main characteristics of the study group

Of the 304 patients, 8.55% (26 patients) presented with preeclampsia (Figure 1). Table 1 contains the cohort's epidemiological, clinical, and biophysical data, providing additional context on the sample's characteristics.

**Figure 1.** Pie chart, distribution of patients with pre-eclampsia.

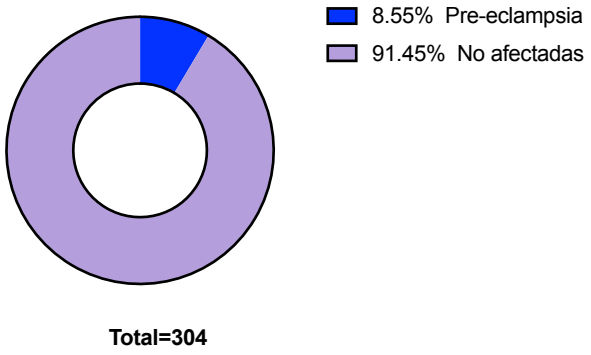
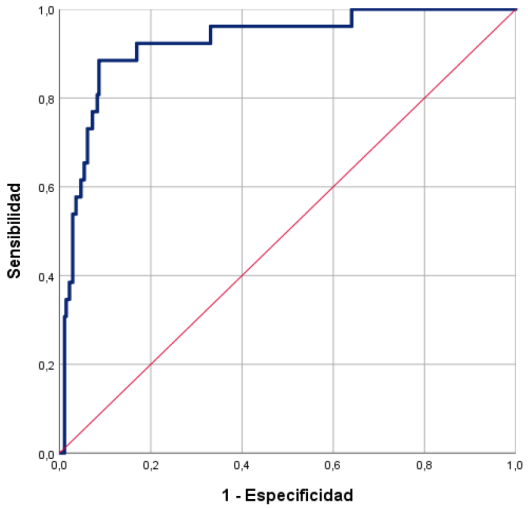



**Figure 2.** Test of the area under the ROC curve for the risk prediction algorithm for late-onset preeclampsia at the Hospital Clinic of Barcelona.




Note: a: Null hypothesis: true area = 0.5; *statistical significance with H0≠ 0.05.

**Table 1.** Demographic and clinical characteristics of the study group.

| Clinical features | Cluster | | *P* - value |
|---|---|---|---|
| | Preeclampsia | Not affected | |
| Age (median (IQR)) years 1/ | 30 (24-34) | 30 (23-34) | 0.835 |
| Size (median (IQR)) cm 1/ | 162 (157-166) | 163 (159-166) | 0.550 |
| Weight (median (IQR)) kg 1/ | 65 (60-70) | 66 (60-70) | 0.892 |
| BMI (median (IQR)) kg/m2 1/ | 25.0 (22.8-26.3) | 24.9 (22.8-26.5) | 0.883 |
| CRL (median (IQR)) mm 1/ | 68 (58-74) | 68 (60-74) | 0.593 |
| Family history of preeclampsia (n (%)) 2/ | 3 (11.5%) | 48 (17.3%) | 0.590 |
| Twin pregnancy (n (%)) 2/ | 0 (0 %) | 9 (3.24%) | 1.000 |
| Chronic hypertension (n (%)) 2/ | 2 (7.69%) | 11 (3.96%) | 0.307 |
| Type I diabetes (n (%)) 2/ | 0 (0 %) | 4 (1.44%) | 1.000 |
| Type II diabetes (n (%)) 2/ | 1 (3.85%) | 9 (3.24%) | 0.597 |
| Systemic lupus erythematosus (n (%)) 2/ | 0 (0%) | 4 (144%) | 1.000 |
| Nulliparous (n (%)) 2/ | 13 (50.0%) | 134 (48.20%) | 0.861 |
| History of preeclampsia (n (%)) 2/ | 7 (26.9%) | 13 (4.7%) | 0.001* |
| SBP (median (IQR)) mmHg 1/ | 100 (100-116) | 100 (100-110) | 0.798 |
| PAD (median (IQR)) mmHg 1/ | 70 (60-80) | 60 (60-70) | 0.012** |
| PAM (median (IQR)) mm 1/ | 80 (76-87) | 77 (73-80) | 0.054 |
| IPm-AUt (median (IQR)) 1/ | 4.15 (3.55-4.38) | 2.40 (1.96-2.78) | <0.001** |

Note: 1/ based on Mann-Whitney test; 2/ based on chi-square test; * significant differences in proportion p-value<0.05; ** significant differences in means p-value<0.05; IQR=Interquartile Range.

## Diagnostic tests

The point estimate of the area under the curve (AUC) for predicting preeclampsia was 0.924 (95% CI 0.87-0.98), being this area significant with *P* -value <0.001 (Figure 2). Using the Youden index (Figure 3) the cut-off point for the risk prediction algorithm for late-onset preeclampsia of the Hospital Clinic of Barcelona was determined. The cut-off point value for risk measured by the algorithm was 0.75 (3/4), where for this value, the Youden index reached its maximum value (0.798); the prediction of preeclampsia will be for values greater than or equal to 0.75 (3/4).

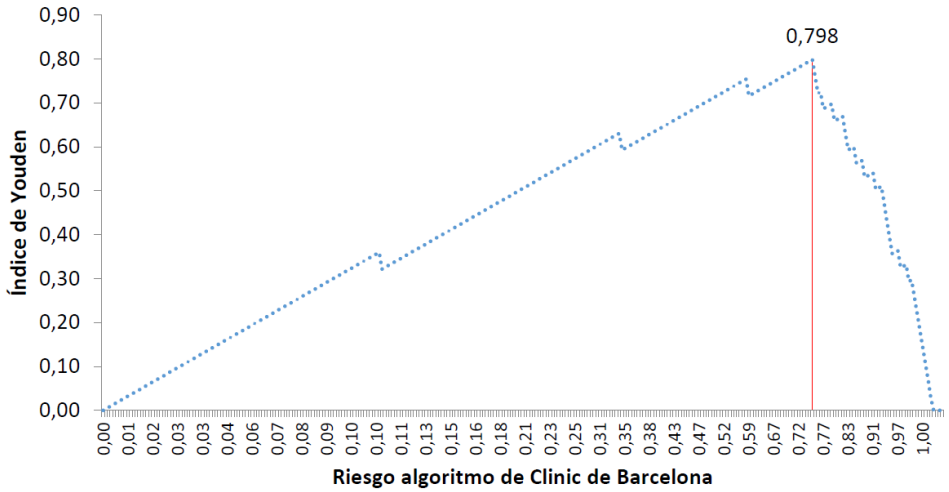
Using the cut-off point 0.75 (3/4) of the Hospital Clinic of Barcelona's late-onset preeclampsia risk prediction algorithm, the sensitivity was 88.46%, specificity 91.37%, Pand PV 48.94%, NPV 98.83%, with a false positive rate of 8.63% (Table 2).

The test accuracy value was 91.12%; the correct prediction was achieved in 91.12% of the cases analyzed. This result, together with the sensitivity and specificity, which were high, shows that the model based on the cut-off point is quite good.

The positive likelihood ratio was 10.25, which is greater than one (1), indicating that there is a high probability that patients present preeclampsia for values greater than or equal to the selected cut-off point, while the negative likelihood ratio was 0.13, which is less than one (1), that is, there is a high probability that patients will not be affected for values less than the selected cut-off point.

When comparing the incidence of preeclampsia, significant differences were observed *P* -value <0.05, where the incidence was 48.94% for values ≥0.75 (3/4) vs. 1.17% for values <0.75 (3/4), where patients with values ≥0.75 (3/4) are 81 times more likely to present preeclampsia.

**Figure 3.** Test of the area under the ROC curve for the risk prediction algorithm for late-onset preeclampsia at the Hospital Clinic of Barcelona.




Note: a: Null hypothesis: true area = 0.5; *statistical significance with H0≠ 0.05.

**Table 2.** Diagnostic test studies for cytology and colposcopy.

| Variable | Result |
|---|---|
| Cut-off points | ≥ 3/4 or 0.75 |
| Sensitivity | 88.46% |
| Specificity | 91.37% |
| VPP | 48.94% |
| VPN | 98.83% |
| False positive rate | 8.63% |
| Accuracy | 91.12% |
| Positive likelihood ratio | 10.25 |
| Negative likelihood ratio | 0.13 |
| Incidence of preeclampsia | ≥ 3/4 = 48.94*<br><3/4 = 1.17%* |
| OR (95%CI) | 81 (23 - 290) |

PPV=Positive predictive value, NPV=Negative predictive value; * significant difference in incidence of preeclampsia between groups ≥ or < the cut-off point *P*-value<0.05, based on chi-square; ** Odds Ratio (OR) significant risk factor for preeclampsia for cut-off points ≥.

## Discussion

This study aimed to determine the operational capacity of the PE predictive model developed by the Hospital Cliníc of Barcelona, Spain. The results show that the algorithm has a high discriminative capacity, with an AUC of 0.924 and high sensitivity and specificity values. These findings suggest that the model is effective in resource-limited settings, allowing the identification of patients at risk of developing PE without requiring angiogenic biomarkers.

The high operational capacity of the model remains consistent with other studies that have evaluated algorithms without including angiogenic factors. Wright D et al. (2019) [12] have shown that models based solely on demographic characteristics, clinical history, and biophysical data achieve up to 85% sensitivities and specificities more significant than 85%, supporting their use in low-resource settings. This suggests that the algorithm from the Hospital Cliníc in Barcelona, Spain, with comparable and, in some cases, superior operational capacity, may be effective in similar situations.

The omission of angiogenic biomarkers such as sFlt-1 and PlGF may lead to a lower detection of positive cases, especially with early PE, where biomarkers show their highest accuracy. Crovetto et al. (2014) [4] found that combining these biomarkers with uterine artery Doppler significantly increases the prediction of early PE, reaching a detection rate of 91.2% for early-onset PE with a false positive rate of 10%. However, although these biomarkers improve their accuracy, their universal implementation in low-resource countries may need to be revised. The results of this study indicate that, in the absence of these factors, the algorithm maintains a good performance in the detection of PE, which makes its use feasible in these contexts [12].

Crovetto et al. [4] and Stepan et al. [9] propose that biomarkers such as sFlt-1 and PlGF and uterine artery Doppler be applied in a selective screening focused on high-risk subgroups. Stepan et al. suggest that a stratified screening approach increases accuracy and reduces the false positive rate by up to 60%, minimizing hospitalizations and costs. This strategy would allow for optimizing the use of resources in low-income contexts, implementing the quantification of angiogenic factors only in patients preselected by clinical risk factors without extending screening to the entire population.

The work of Kienast et al. [8] in Ecuador also evaluated the use of biomarkers and uterine artery Doppler for the prediction of PE and intrauterine growth restriction (IUGR), finding that the combination of these angiogenic factors and Doppler significantly improved predictive accuracy. In particular, Kienast et al. [ 8 ] observed an AUC of 0.85 in the second trimester and 0.89 in the third trimester when combining the sFlt-1/PlGF ratio with uterine artery Doppler. Although these results suggest that the inclusion of biomarkers improves accuracy, the clinical context of this study demonstrates that a model without biomarkers can also be effective, provided that they are adapted to local conditions and stratified screening is considered in high-risk patients.

This study supports the feasibility of using the prediction algorithm from the Hospital Cliníc de Barcelona, Spain, in a developing country context such as Ecuador, where its operational capacity allows identifying patients at risk without the need for advanced biomarkers. However, limitations in the sample size and the low incidence of early-onset PE in these years suggest that future research should include larger samples to confirm these findings and assess the accuracy of specific high-risk subgroups. Furthermore, stratified screening with angiogenic biomarkers in selected patients could provide an intermediate and effective strategy in contexts with limited resources, improving screening accuracy without universal biochemical screening.

Consequently, although studies such as those by Crovetto et al. [4], Stepan et al. [9], Binder et al., and Kienast et al. [8] suggest that angiogenic biomarkers improve the accuracy in PE detection and monitoring in specific subgroups the findings of this study indicate that the Hospital Clinic de Barcelona algorithm is a viable and effective alternative in second-level settings. The stratified strategy could be a solution to improve PE detection in high-risk patients, optimizing resources and maintaining a cost-effective approach in resource-limited settings.

The present study evaluated the operational capacity of the PE risk prediction algorithm from the Hospital Clinic de Barcelona in Guayaquil, Ecuador. The results indicate that

the algorithm has a high predictive capacity, with an AUC of 0.924 and high levels of sensitivity and specificity. This supports its use as an effective tool for the early identification of patients at risk of PE in resource-limited settings.

While the omission of angiogenic biomarkers, such as sFlt-1 and PlGF, may lead to the loss of some favorable cases, the clinical model analyzed is a viable and accessible alternative in settings where the cost and infrastructure required to implement these biomarkers represent a significant limitation. This study also suggests that a stratified screening approach, in which biomarkers are used exclusively in high-risk subgroups, could improve the accuracy of PE screening without the need to implement universal screening, thus optimizing available resources.

Limitations of this study include the small sample size and low incidence of early-onset PE, which underscore the need for future research to validate these findings in larger samples and in diverse clinical settings. Additionally, assessing the impact of stratified biomarker screening in high-risk subgroups could provide valuable information for designing more cost-effective screening programs in primary and secondary care settings.

## Conclusions

In conclusion, this study provides evidence on the applicability of the PE prediction algorithm in the population of Guayaquil, Ecuador, highlighting its potential as an accessible and effective tool in the early detection of PE. The stratified screening strategy, supported by recent studies, represents a promising way to maximize screening accuracy in high-risk patients while reducing costs in low-resource settings, thus contributing to the improvement of prenatal care in vulnerable populations.

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## Statements

### Ethics committee approval and consent to participate

The bioethics committee of the Faculty of Medical Sciences of the University of Guayaquil approved the study.

### Consent to publish

It was not required because the present study does not publish images, radiographs, or specific patient studies.

### Conflicts of interest

The authors declare that they have no conflicts of interest.

### Author information

**Kevin David Dickens Guerrero,** Physician from the University of Guayaquil (Guayaquil, 2006). Specialist in Gynecology and Obstetrics from the Catholic University of Santiago de Guayaquil (Guayaquil, 2012). Master in Management of Health Service Centers from the University of Barcelona (Barcelona, 2021). Professor, University of Guayaquil, Faculty of Medical Sciences; Rotating Internship - Gynecology and Obstetrics Service, General Hospital of the North of Guayaquil Ceibos - IESS, Guayaquil, Ecuador.
Email: infor@drkevindickens.com
ORCID https://orcid.org/0000-0003-0349-8169

**Pilar Maricela Díaz Abadie,** Physician from the University of Guayaquil (Guayaquil, 2003). Specialist in Gynecology and Obstetrics from the Catholic University of Santiago de Guayaquil (Guayaquil, 2008). Specialist in Management and Strategic Planning in Health from the Technical University of Loja (Loja, 2007). Professor, University of Guayaquil, Faculty of Medical Sciences; Gynecology, Surgical Clinical Center Hospital del Día Sur Valdivia - Gynecology and Obstetrics Service, IESS, Guayaquil, Ecuador.
ORCID https://orcid.org/0009-0004-1137-4507

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**Correspondence:** Kevin David Dickens Guerrero. Email: info@drkevindickens.com
Address : R492+MJF, Av. Kennedy, Guayaquil CP 090514, Guayaquil. Medical School, Faculty of Sciences Medical, University of Guayaquil. Telephone : (04) 228-1148.