

# The proteinuria/creatinuria index is unrelated to signs of severity in patients with pre-eclampsia. A single-center observational study. A single-center observational study.

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## Abstract


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**Introduction:** Preeclampsia is a common hypertensive disorder in pregnant women, and its impact varies depending on its severity and can affect target organs such as the kidneys. The proteinuria/creatinuria index is a test that can be performed in pregnant patients to confirm the presence of significant proteinuria, which can be detected within the diagnosis of preeclampsia. This study aimed to determine the association between the proteinuria/creatinuria index and preeclampsia severity in pregnant women.

**Methods:** Observational, analytical, retrospective study. The data were taken from the José Carrasco Arteaga Specialty Hospital database in Cuenca-Ecuador between January 2017 and December 2021. The statistical analysis used the SPSS 25 program and Microsoft Excel 2018. The associations between variables were evaluated with the chi-square test, and odds ratios were calculated.

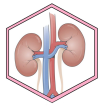
**Results:** A total of 149 patients were included; the mean age was  $31.9 \pm 5.5$  years, 49% were married, and 64.4% were from urban areas. A total of 35.7% were nulliparous, with an average gestational age of  $34.6 \pm 4.2$  weeks. The sample consisted of 149 preeclamptic patients, 86.6% ( $n = 129$ ) of whom presented with severe symptoms. The median proteinuria/creatinuria ratio was 0.58 (0.26-1.66) mg/dL. The proteinuria/creatinuria index was not associated with preeclampsia severity ( $X^2 = 2.161$ ; OR = 2.547; 95% CI = 0.706-9.186;  $P = 0.153$ ).

**Conclusion:** The proteinuria/creatinuria index in this study was not associated with the severity of preeclampsia.

## Keywords:

Proteinuria/creatinuria ratio, Preeclampsia, Severity criteria.

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**P**reeclampsia is a gestational hypertensive disorder that has a significant impact on maternal and child health and complicates 2 to 8% of pregnancies; it is widely associated with adverse maternal and perinatal outcomes and is one of the top three causes of maternal death worldwide, but it is not an economic problem [1-3].

This disease is defined by the presence of systolic blood pressure (SBP)  $\geq 140$  mmHg or diastolic blood pressure (DBP)  $\geq 90$  mmHg after the twentieth week of gestation and may be associated with signs of severity such as proteinuria, thrombocytopenia, increased values of liver enzymes, creatinine, pulmonary edema or alterations of the central nervous system [1]. In addition, pregnant women with early-onset preeclampsia are more susceptible to severe complications, such as acute renal failure, respiratory morbidities, cardiomyopathies, sepsis, and a ninefold greater chance of maternal death [4].

Among the essential paraclinical for the study of this disorder, proteinuria is an indicator of kidney injury due to glomerular endotheliosis, and it can take up to two years to resolve, remaining a subclinical renal disorder after the event; however, its significant values ( $\geq 300$  mg) in 24-hour urine have shown several changes as a result of inadequate collection and discomfort due to the time involved, which leads to delays in decision-making and higher costs for the health system. For this reason, the proteinuria/creatinuria index is a simpler and faster method that, although it may vary during the day, has a strong correlation with 24-hour proteinuria in predicting significant proteinuria. Based on the data above, this study aimed to determine the associations between the proteinuria/creatinuria index and preeclampsia severity [1,5].

Hypertensive disorders are common conditions during pregnancy, and preeclampsia occurs in approximately 2 to 10% of all pregnancies worldwide [6]. An observed peculiarity is that it is seven times more common in developing countries (2.4%) than in first-world countries (0.4%) [7].

However, the most significant problem is that preeclampsia is a complication that increases maternal deaths worldwide, representing 14% of mortality from this cause [8]. Annually, there are 50,000 maternal deaths and 90,000 perinatal deaths from these hypertensive disorders [9]. In Latin America, preeclampsia is the leading cause of maternal mortality and complicates 25.7% of pregnancies [9]. In 2018, 28.7% of maternal deaths occurred in Peru [8], while in Brazil, 56 deaths occurred per 100,000 live births [10]. In Ecuador in 2019, preeclampsia was the leading cause of direct obstetric death, which was observed in 20.3% of patients [11]. Finally, at the José Carrasco Arteaga Specialty Hospital in the city of Cuenca, maternal mortality from preeclampsia reached 4.30% during the period from 2018–2019 [12].

Preeclampsia is a challenging problem with significant social repercussions and extensive implications for public health. For this

reason, early diagnostic identification through assessing signs, symptoms of severity, and laboratory criteria is essential.

Clinically, the parameters used to determine preeclampsia severity are based on target organ damage, including blood pressure, platelet count, altered kidney or liver function values, and involvement of the lung parenchyma or the central nervous system [13].

24-hour proteinuria has been the gold standard for paraclinical patients for many years. Still, it is not feasible because it requires extensive collection time and the difficulties of hospitalized patients [1]. Thus, the proteinuria/creatinuria index is a quick alternative and can predict significant proteinuria in terms of suspicion of preeclampsia, in addition to being a low-cost and easily accessible diagnostic method [13].

This research aimed to determine whether the proteinuria/creatinuria index is associated with preeclampsia severity in patients treated at a Public Hospital of Reference in Cuenca, Ecuador.

## Materials and methods

### Study design

An observational, analytical, and retrospective study was carried out.

### Study area

This research was carried out at the José Carrasco Arteaga Specialty Hospital located between Popayán and Pacto Andino on the way to Rayoloma.

### Universe and sample

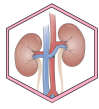
The population consisted of all patients with preeclampsia treated in the Department of Gynecology and Obstetrics of the Hospital de Especialidades José Carrasco Arteaga from January 2017 to December 2021. No sample size calculation was performed because the sample ( $n = 149$ ) satisfied the selection criteria.

### Inclusion criteria

- Data from patients diagnosed with preeclampsia according to the criteria of the Guide for Hypertensive Disorders of Pregnancy of the American College of Gynecology and Obstetrics.
- Data from patients with preeclampsia who underwent paraclinical tests for proteinuria and creatinuria.

### Exclusion criteria

- Data from preeclamptic patients in whom proteinuria and creatinuria were not tested as complementary tests.
- incomplete Data.



## Variables

The following variables were included in the research: sociodemographic, gynecological-obstetric, dependent, and independent variables on details of the operationalization of the variables.

## Technical methods and instruments for data collection

### Methods

The observational method was used, starting from the review of an anonymized database.

### Techniques

- The data is from an anonymized database provided by the statistics department of the Hospital de Especialidades José Carrasco Arteaga.
- The information was collected through a digital form.
- A database was created in Excel.
- The information obtained was validated.
- The data were analyzed through statistical programs.

### Instruments

The authors built a digital form in Excel.

Procedures

### Authorization

Approval was requested from the University of Cuenca, the highest authority of the Hospital de Especialidades José Carrasco Arteaga, and the Department of Gynecology and Obstetrics for access to the information in the anonymized databases that were used in this research.

### Training

Consultations with experts on the subject were attended, such as teachers from the University of Cuenca and doctors from the José Carrasco Arteaga Specialty Hospital.

### Supervision:

Dr. Julio Cárdenas, a Department of Gynecology and Obstetrics professor at the University of Cuenca, supervised this research.

### Statistical analysis

- In presenting the results, simple, composite, and double-entry tables were used with the respective sociodemographic, clinical, and gynecological-obstetric variables.
- To summarize the information, the following variables were used: the arithmetic mean ( $\bar{x}$ ) and the standard deviation ( $S$ ) for normally distributed quantitative variables or the median ( $Me$ ) and interquartile range ( $Q1 - Q3$ ) for nonnormally distributed qualitative variables and the frequencies ( $F$ ) and percentages (%) of qualitative variables. The normality of the data distribution was evaluated using the Kolmogorov–Smirnov test.
- In the comparison of variables and to verify differences between groups (proteinuria/creatinuria index in patients with

preeclampsia with signs of severity), hypothesis testing was used: the chi-square test ( $X^2$ ), considering statistically significant differences at values with  $P < 0.05$ .

- To measure the intensity of association, the odds ratio (OR) with its 95% confidence interval (95% CI) was used.
- SPSS 25 (trial version), Microsoft Excel 2018, and Microsoft Word 2018, all licensed, were used for data management, presentation, and analysis.

## Results

### Study participants

A total of 149 patients were included in the study; 129 patients had severe disease, and 20 patients had no severe disease.

### Characteristics of the study group

A total of 149 pregnant patients with preeclampsia whose mean age was  $31.9 \pm 5.5$  years were included in the study. Participants aged 31 and 40 comprised the most common age group, representing 58.4% ( $n = 87$ ) of the patients. Similarly, 49% ( $n = 73$ ) of the pregnant women were married, 40.9% ( $n = 61$ ) had a higher education level, 30.9% ( $n = 46$ ) were professionals and 64.4% ( $n = 46$ ) were professionals. % ( $n = 96$ ) resided in urban areas ([Table 1](#)).

### Characteristics of the group with signs of severity

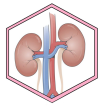
Among the 129 patients with severe preeclampsia, 64.3% ( $n = 83$ ) were multiparous. However, when breaking down parity according to the number of pregnancies, primiparous women predominated in 35.7% ( $n = 46$ ) of the pre-gestational age of the participants was  $34.6 \pm 4.2$  weeks, and the mean maternal weight was  $71.83 \pm 13.41$  kg ([Table 2](#)).

Of the 149 patients with preeclampsia included in the study, 86.6% ( $n = 129$ ) presented signs of severe disease. In addition, 69% of the subjects with severe disease had a proteinuria/creatinuria index  $\geq 0.3$  mg/dL ( $n = 89$ ). The results indicate that not all preeclamptic patients with severe disease had a proteinuria/creatinuria index  $\geq 0.3$  mg/dL, and approximately 7 out of the 10 patients studied were positive for this relationship ([Table 3](#)).

Among pregnant women with severe preeclampsia, the mean levels of proteinuria and creatinuria were  $157.52 \pm 312.77$  mg/dL and  $90.42 \pm 60.63$  mg/dL, respectively. Similarly, the median proteinuria/creatinine index was 0.58 (0.26-1.66) mg/dL ([Table 4](#)).

### Main results

[Table 5](#), there was a more significant proportion of pregnant preeclamptic women with severe disease who presented a proteinuria/creatinuria index  $\geq 0.3$  mg/dL than those who had an index  $< 0.3$  mg/dL (69.0% vs. 31.0%, respectively). A statistically significant association was not found when evaluating the relationship between these two variables ( $X^2 = 2.161$ ;  $P = 0.141$ ).



**Table 1.** Sociodemographic characteristics of pregnant women with preeclampsia in the Department of Obstetrics, Hospital de Especialidades José Carrasco Arteaga, period 2017-2021.

	n=149	%
<b>Age groups (years)</b>		
≤ 20	2	1.3
21-30	53	35.6
31-40	87	58.4
> 40	7	4.7
<b>Marital status</b>		
Single	34	22.8
Married	73	49.0
Free union	34	22.8
Divorced	8	5.4
<b>Level of instruction</b>		
Primary	31	20.8
Secondary	57	38.3
Superior	61	40.9
<b>Occupation</b>		
Student	2	1.3
Professional	46	30.9
Employee	45	30.2
Housewives	27	18.1
Other	29	19.5
<b>Residence</b>		
Rural	53	35.6
Urban	96	64.4
<b>Age (mean ± SD)</b>	31.9	5.5

SD: Standard deviation.

**Table 2.** Gynecological-obstetric characteristics of preeclamptic pregnant women with signs of severity in the Obstetrics department of the José Carrasco Arteaga Specialty Hospital, period 2017-2021.

	n=129	%
<b>Parity</b>		
Nulliparous	46	35.7
Multiparous	83	64.3
<b>Gestures</b>		
First	46	35.7
Second	38	29.5
Third	27	20.9
Fourth	11	8.5
Fifth	4	3.1
Sixth	1	0.8
Seventh	2	1.6
<b>Gestational Age (mean ± SD)</b>	34,6	4.2
<b>Weight (mean ± SD)</b>	71.83	13.41

SD: Standard Deviation.

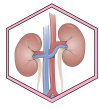
**Table 3.** Frequency of preeclampsia with signs of severity in preeclamptic pregnant women in the Department of Obstetrics of the Hospital de Especialidades José Carrasco Arteaga, period 2017–2021.

	n=149	%
<b>Preeclampsia</b>		
With signs of gravity	129	86.6
No signs of gravity	20	13.4
<b>n=129</b>		
<b>Proteinuria/Creatinuria Index ≥0.3 mg/dL</b>		
≥0.3 mg/dL	89	69.0
<0.3 mg/dL	40	31.0

**Table 4.** Proteinuria/creatinuria index of preeclamptic pregnant women with signs of severity in the Obstetrics department .

	Medium	Of
<b>Proteinuria</b>	157.52	312.77
<b>Creatinuria</b>	90.42	60.63
<b>Proteinuria/Creatinuria Index *</b>	0.58	0.26-1.66

\* Median and interquartile range. SD: Standard Deviation.

**Table 5.** Association between the proteinuria/creatinuria index and preeclampsia with signs of severity in preeclamptic pregnant women in the Department of Obstetrics of the Hospital de Especialidades José Carrasco Arteaga, period 2017–2021.

	Preeclampsia				Total		X <sup>2</sup> (P)	OR (IC95%) (P)
	With signs gravity		No signs gravity		n	%		
	n	%	n	%				
<b>Proteinuria/Creatinuria Index</b>							2.161	2.547 (0.706-9.186)
≥0.3 mg/dL	89	69.0	17	85.0	106	71.1	(0.141)	(0.153)
<0.3 mg/dL	40	31.0	3	15.0	43	28.9		
<b>Total</b>	129	100.0	20	100.0	149	100.0		

X<sup>2</sup>: Chi Square; OR: Odds Ratio; CI: Confidence Interval.

## Discussion

Preeclampsia is a clinical syndrome that affects multiple organs and systems, with a prevalence of up to 7% in pregnant women. It is responsible for 500,000 fetal deaths and more than 70,000 maternal deaths each year worldwide [14]. It has been hypothesized that this disorder arises due to an imbalance between anti- and proangiogenic factors in maternal circulation. This alteration affects the kidney more importantly and frequently, with 24-hour proteinuria being the method of choice for evaluating kidney damage [15,16]. However, more practical, quick, and simple diagnostic procedures have been designed, such as the proteinuria/creatinuria index, strongly correlated with 24-hour proteinuria [17].

However, preeclampsia is known to cause significant clinical damage that is severe, so timely diagnosis is essential for obtaining better perinatal results. In this regard, little is known about the usefulness of the proteinuria/creatinuria index in identifying preeclampsia with signs of severity, so this study aimed to determine the association between the proteinuria/creatinuria index and preeclampsia with signs of seriousness at the José Carrasco Arteaga Specialty Hospital from January 2017–December 2021.

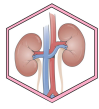
The participants who were cared for in the gynecology and obstetrics department of the José Carrasco Arteaga Hospital were characterized mainly by being pregnant for 31-40 years, having an average age of 31.9 ± 5.5 years, being married, having higher education, being professionals, being employees and having lived in urban areas. Other authors have also reported means of age similar to those observed in our study; for example, Xiao et al. [18] reported that their sample of 961 pregnant patients with gestational hypertension had an average of 30.95 ± 4.51 years; Pasternak et al. [19] reported a mean of 32.9 ± 5.8 years in their population of 463 pregnant women with suspected preeclampsia; and Waugh et al. [20] reported that the median age of 959 pregnant women was 30 (25-34) years.

These findings indicate that although pregnant patients at an optimal fertile age were included, both in this and the other studies cited, the participants were already approaching an age considered

extreme in obstetrics (≥35 years). Therefore, the risk of developing a complication was greater. Interestingly, none of the studies or reports reviewed for comparing our data reported sociodemographic data of their participants to compare the results.

About the obstetric characteristics of the participants, it was observed that the majority were multiparous; however, when the parity decreased according to the number of gestations, it was found that the primigravida were the group that predominated, followed by those who were in their second feat. The average gestational age of the participants was 34.6 ± 4.2 weeks, and the mean weight was 71.83 ± 13.41 kg. Similarly, in the study by Xiao et al. [18], the sample consisted of between 71% and 84% gilts. Similarly, in a report by Pasternak et al. [19], 65% of the admitted patients were nulliparous, while 20% were multi-pregnant, with a median of 2 pregnancies (1–3). Furthermore, the average gestational age was 34.0 ± 3.4 weeks, similar to our study's reported findings. By these data, Waugh et al. [20] reported that their sample was predominantly composed of primiparous women (65-69%), with a median gestation of 37 (36-39) and a median weight of 76 (65-91) kg. Leiva-Hernández [21] divided 100 pregnant patients into two cohorts and reported that 52% were primiparous. The previously reported findings may be because some morbid obstetric states, such as preeclampsia, tend to be more frequent in nulliparous or primiparous patients in the third trimester of pregnancy. Concerning anthropometric findings, it is expected that, during pregnancy, patients will gain weight, so we expected to find higher values for these anthropometric parameters.

The frequency of severe preeclampsia in the participants in the present study was greater than 85%. In comparison, 69% of the participants in the same study group had a proteinuria/creatinuria index ≥ 0.3 mg/dL. In addition, the median proteinuria/creatinuria index in patients with severe disease was 0.58 (0.26-1.66) mg/dL. In the study by Xiao et al. [18], a prevalence of preeclampsia of 27.2% was reported, while that of severe preeclampsia was 41.9%. These same authors noted that the median index in patients with severe preeclampsia was 1.44 (0.42–2.69) mg/dL, a value greater than that in our study. For their part, Pasternak et al. [19] reported that the



median index in their sample was 0.5 (0.3–1.0), with 73.2% of the pregnant women having a proteinuria/creatinuria index value  $\geq 0.3$  mg/dL. At the same time, the study by Leiva-Hernández [21] found that only 39% of the sample had an index  $\geq 0.3$  mg/dL. Waugh et al. [20] reported that 43% of their population had severe preeclampsia, presenting a median index of 0.52 (0.25–1.48), a value very similar to that observed in our sample. In the study by Cade et al. [22], which included 141 patients with preeclampsia, 15 patients (10.6%) had a proteinuria/creatinuria index  $< 0.3$  mg/dL, while 126 (89.4%) had an index  $\geq 0.3$  mg/dL. Likewise, this group of researchers reported a mean proteinuria/creatinuria index of  $0.72 \pm 0.40$  mg/dL. In their study of 200 women with preeclampsia, Nigam et al. [23] reported an index  $\geq 0.3$  mg/dL in 159 patients (79.5%) and an index  $< 0.3$  mg/dL in 41 (20.5%). Furthermore, Nischintha et al. [24] studied 75 pregnant women with preeclampsia and reported that the proteinuria/creatinuria index was  $< 0.3$  mg/dL in nine (12%) women, while it was  $\geq 0.3$  mg/dL in 66 (87.7%) patients. The findings previously presented suggest that the majority of patients with preeclampsia with signs of severity have a proteinuria/creatinuria index  $\geq 0.3$  mg/dL, which is a reflection of the kidney damage that occurs in this disease.

Finally, when evaluating the proteinuria/creatinuria index  $\geq 0.3$  mg/dL according to the presence or absence of preeclampsia with signs of severity, it was found that although there was no statistically significant association between these variables, a greater proportion of pregnant women with preeclampsia with signs of severity had a higher rate of preeclampsia than did those with an average rate. Xiao et al. [18] sought to determine the optimal cutoff point of the index for their sample. They reported that a value of 0.625 mg/dL had 68.8% sensitivity and 84.2% specificity for the diagnosis of severe preeclampsia, a diagnosis that increased the possibility of severe adverse perinatal outcomes by up to two times (OR = 2,185; 95% CI = 1,568–3,045). Similarly, Pasternak et al. [19] reported that a cutoff point of 0.3 mg/dL for the index had a sensitivity of 90% and a specificity of 63.3% for the identification of preeclampsia with proteinuria, that the index was positively correlated (0.843,  $P < 0.001$ ) with proteinuria levels within 24 hours, and that having a proteinuria/creatinuria index  $\geq 0.3$  mg/dL increased the risk of preeclampsia by up to 16 times (OR = 16.58; 95% CI = 10.12–27.19). Similarly, Leiva-Hernández [21] reported that the 0.3 mg/dL cutoff point had a sensitivity of 73% and a specificity of 100% for the identification of proteinuria in patients with preeclampsia, which was significantly associated with signs of severity. Similarly, Bhadarka et al. [25] and Stefańska et al. [26] reported that in pregnant patients with preeclampsia, the proteinuria/creatinuria ratio was firmly, positively, and significantly correlated with 24-hour proteinuria.

Although in our study, the proteinuria/creatinuria index was not significantly associated with the presence of preeclampsia with signs of severity, the more significant proportion of patients with this morbid state who had a high index is evidence that the majority of the participants with preeclampsia probably have a proteinuria/creatinuria index  $\geq 0.3$  mg/dL. This, together with the findings of the other

studies cited, suggest that, due to its precision, reproducibility, accessibility, and excellent correlation with 24-hour proteinuria, the proteinuria/creatinuria index is a practical, fast and reliable method for the prediction of proteinuria in pregnant patients with preeclampsia.

The strength of this study is that the sample was taken from a single hospital. The limitations of the study are related to the retrospective nature of the study design, which prevents us from identifying potential confounders that could interfere with the results. In this sense, data on clinical variables and personal history were not collected, nor was the use of any drug considered during the study. In addition, the levels of the proteinuria/creatinuria index were not compared or correlated with the results of a 24-hour proteinuria test, nor were the percentages of sensitivity and specificity of the cutoff point of 0.3 mg/dl of the index determined, so it is not possible to infer that this is the best cutoff point for the sample.

## Conclusion

The proteinuria/creatinuria index was not significantly associated with the presence of severe preeclampsia in pregnant patients at the José Carrasco Arteaga Specialty Hospital between January 2017 and December 2021. The participants were mainly pregnant individuals aged 31–40 years who were married, had a higher education level, were professionals, were employed, and lived in urban areas. Most of the patients were pregnant first or second. The average gestational age of the sample was  $34.6 \pm 4.2$  weeks. The frequency of preeclampsia with signs of severity in the population was 86.6%. In comparison, the proteinuria/creatinuria index frequency in patients with preeclampsia with signs of severity  $\geq 0.3$  mg/dL was 69%. The median proteinuria/creatinuria index was 0.58 (0.26–1.66) mg/dL.

## Abbreviations

OR: odds ratio.

## Supplementary information

The supplementary materials have not been included.

## Acknowledgments

Does not apply.

## Authors' contributions

Gema Marianela Cedeño Farías: Data curation, Formal analysis, Fund acquisition, Research, Methodology, Project management, Resources, Software, Writing - original draft.

Marcel Isaías Merchán Coyago: Conceptualization, Supervision, Validation, Visualization, Writing: review and edition.

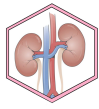
Julio César Cárdenas Mateus: conceptualization, supervision, validation, and visualization.

Adrián Sacoto: Formal analysis, Research, Methodology.

All the authors have read and approved the final version of the manuscript.

## Financing

The study was self-financed by the authors.



### Availability of data or materials

The datasets generated and analyzed during the current study are not publicly available but can be shared with an academic request.

## Declarations

### Ethics committee approval and consent to participate

This study was approved by the Research Bioethics Committee of the University of Cuenca Health Area (COBIAS-UCUENCA). The authors sent the journal editors a copy of the study approval letter.

### Consent for publication

Studies that do not publish photographs of patients, CT scans, or X-ray studies are unnecessary.

### Conflicts of interest

The authors declare that they have no conflicts of interest.

### Author information

Does not apply.

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