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Diagnostic utility of urine protein-to-creatinine ratio for identifying proteinuria in pregnancy

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Abstract

Objective—To evaluate urine protein-to-creatinine ratio (UPC) alone and with uric acid and clinical factors to predict or exclude significant proteinuria in preeclampsia evaluations.

Methods—Retrospective cohort study patients undergoing evaluation for preeclampsia. Greater than 300 mg of protein in a 24-h collection was the gold standard defining proteinuria against which UPC performance was measured. Bivariable, multivariable, and Receiver Operating Characteristic Curve (ROC) analyses were performed. Sensitivity, specificity, predictive values, and likelihood ratios were calculated for multiple cut-points of UPC alone and with uric acid.

Results—In a cohort of 356 patients, the area under the curve for UPC in the diagnosis of proteinuria was 0.81. No single cut-point of UPC was diagnostic of preeclampsia. UPC values 0.08 or 1.19 have useful negative or positive predictive values of 86% and 96%. Uric acid and clinical factors did not improve the detection of significant proteinuria.

Conclusion—Extreme values of UPC ratio 0.08 or 1.19 have favorable predictive values, which could enable the rapid diagnosis of preeclampsia without a 24-h urine collection.

Keywords

Urine protein-to-creatinine ratio; proteinuria; preeclampsia; uric acid; prediction

Introduction

Preeclampsia, defined by hypertension and proteinuria, complicates ~5–8% of pregnancies [1] and is responsible for 18% of maternal deaths in the United States [2]. Preeclampsia is classified as mild or severe based on several clinical criteria, but both require identifying significant proteinuria (>300 mg) in a 24-h urine collection. Severe preeclampsia with evidence of end organ involvement including neurologic, hematologic, pulmonary, hepatic,

and renal systems is easily identifiable during clinical evaluation. However, mild preeclampsia is still associated with morbidity and mortality but may not be as obvious during clinical evaluation. Similarly, the identification of superimposed preeclampsia in women with baseline chronic hypertension may be difficult to distinguish from the physiologic rise of blood pressure typical of later pregnancy. Especially in preterm patients rapid, accurate diagnostic classification is important for management decisions since maternal risks are balanced against neonatal prematurity risks. The distinction between mild preeclampsia, gestational hypertension without proteinuria, or worsening chronic hypertension often relies on and is deferred for the results of a 24-h urine collection.

Because of the inherent 24-h delay in diagnosis, the cost of testing, and difficulties with diagnosis related to noncompliance or poor collection technique, prior studies have evaluated spot urine protein-to-creatinine ratio (UPC) as a possible surrogate test to identify proteinuria in the workup of preeclampsia. However, despite the hope of a rapid test to streamline the diagnosis of preeclampsia, no consensus exists regarding the utility of or optimal cutoff value for UPC in identifying proteinuria. Similarly, it has been shown that uric acid is often elevated in women with preeclampsia, and is commonly measured as a part of routine laboratory evaluation during the workup for suspected preeclampsia. However, the predictive ability and clinical utility of serum uric acid in patients suspected to have preeclampsia have been limited [3–5].

The purpose of this study is to estimate test characteristics of UPC in predicting significant proteinuria and thus preeclampsia, and to assess whether or not the combination of UPC with other variables can correctly identify patients with preeclampsia. Specifically, we sought to evaluate whether certain UPC cutoffs alone or in combination with uric acid may accurately differentiate between patients with and without preeclampsia, obviating the need for a 24-h urine collection and shortening the time to establish a diagnosis.

Methods

We designed a retrospective cohort study of pregnant women from a single academic medical center undergoing evaluation for suspected preeclampsia between 2005 and 2007. The study was approved by the School of Medicine human studies review board before initiation. Routine clinical practice during the study period dictated that all patients with signs or symptoms concerning for the diagnosis of preeclampsia who were seen in the obstetrical triage unit and underwent blood pressure monitoring and laboratory evaluation, which included UPC ratio assessment prior to initiation of a 24-h urine collection for total protein. According to clinical practice at our institution, the vast majority of patients with concern for preeclampsia in the second and third trimester are evaluated in our obstetrical triage unit and not as outpatients. Patients were identified for inclusion in the cohort by searching a hospital database using the CPT code for 24-h urine collection (84156). Only pregnant women after 20 weeks gestation who underwent evaluation for suspected preeclampsia were included in the final cohort. Patients with proteinuria ≥ 300 mg in 24 h before 20 weeks of gestation were excluded. The first preeclampsia evaluation and 24-h urine collection was used for each patient. Laboratory methodology during the study time frame remained constant and involved end-point assay colorimetric (benzenethonium

chloride) technique for 24-h urine protein and random urine protein and enzymatic creatinase for random urine creatinine.

Prior to the study we calculated a sample size estimate. Assuming a prevalence of proteinuria in women who undergo UPC testing of 20% [6], an α error of 0.05 and β error of 0.1 we estimated that we would need a minimum of 240 patients to detect a clinically significant twofold increase in proteinuria risk with an abnormal UPC and to estimate the sensitivity and specificity of UPC to detect proteinuria. We increased our sample size from the calculated minimum to allow concurrent analysis of other predictors in multivariable models, based on the detectable difference of area under the ROC curve among prediction models.

Using a structured data form we collected information on maternal baseline characteristics, obstetric history, including prior preeclampsia (based on available medical records from prior pregnancy or patient self-report of receiving magnesium sulfate), medical history of chronic morbid conditions that increase preeclampsia risk, baseline physical examination, laboratory data obtained from the prenatal record, clinical data from the time of evaluation for preeclampsia (gestational age, first five blood pressures recorded, subjective symptoms, laboratory values, in-patient or out-patient management, final diagnosis), and delivery data (gestational age at delivery, magnesium sulfate use, mode of delivery). Two investigators abstracted data retrospectively from written prenatal records and hospital electronic medical records (C.M.S. and M.J.S.).

We defined preeclampsia based on the American College of Obstetricians and Gynecologists (ACOG) diagnostic criteria including hypertension (systolic blood pressure ≥ 140 mm Hg, diastolic blood pressure ≥ 90 mm Hg) persisting for at least 6 h and significant proteinuria defined as greater than or equal to 300 mg in a 24-h urine collection [1]. Descriptive statistics were used to estimate the frequency of significant proteinuria and diagnosis of preeclampsia within the study population. To identify potential predictors of the diagnosis of preeclampsia, women who had evidence of significant proteinuria on 24-h collection who were subsequently given the diagnosis of preeclampsia were compared to those women who were not diagnosed with preeclampsia using χ^2 or Fisher exact tests for categorical variables and Student *t*-test for continuous variables. We performed stratified and multivariable logistic regression analytic methods to assess for multiple predictors of preeclampsia, and to identify confounding and interaction. Because UPC and serum uric acid were both associated with the diagnosis of preeclampsia on univariate analysis, we used Receiver Operating Characteristic Curve (ROC) analysis to evaluate the test characteristics for various cutoffs of each of these variables. Sensitivity, specificity, predictive values, likelihood ratios and percent correctly classified were calculated for each of the UPC cutoffs alone and in combination with uric acid values. Sub-analyses were performed to assess predictive performance of UPC in women with severe proteinuria (defined in two separate analyses as either ≥ 3 g or ≥ 5 g in a 24-h urine collection). UPC test characteristics for severe proteinuria were assessed using the same methods as described above. All statistical analyses were performed using STATA 10, special edition (STATA, College Station, TX, USA).

Results

We identified 369 women in the 2-year period that underwent 24-h urine collection as part of an evaluation for suspected preeclampsia after 20 gestational weeks. Thirteen women were excluded secondary to the presence of proteinuria >300 mg before 20 weeks gestation, leaving 356 women in the final cohort. Of the 356 women in the cohort, 144 (40.5%) of them had >300 mg of protein in a 24-h urine collection and met criteria to be diagnosed with preeclampsia. Within the cohort, 93.7% had a 24-h collection performed as an in-patient. Women with confirmed proteinuria presented at an earlier gestational age for evaluation for preeclampsia, had higher mean diastolic blood pressure and mean arterial pressure at the time of evaluation for preeclampsia, and had higher serum uric acid compared to women without proteinuria. Women with confirmed proteinuria did not differ from those without proteinuria with respect to maternal age, parity, black race, and tobacco or other substance use, multiple gestations, chronic hypertension, diabetes mellitus, blood pressure at first prenatal visit, or in the rate of prior preterm delivery secondary to preeclampsia. Women with proteinuria had significantly lower platelet counts, higher serum creatinine and higher aspartate aminotransferase (AST) compared to women with no proteinuria, however the values for both groups were within the normal range (Table I).

ROC analysis was used to evaluate the predictive ability of UPC to detect proteinuria in the cohort of hypertensive women. The area under the curve was 0.82, with no clearly diagnostic cut-point with favorable trade-off between sensitivity and specificity (Figure 1). Since there was no single influential cut-point for prediction, we calculated sensitivity, specificity, predictive values, and likelihood ratios for multiple UPC cutoff values, maximizing either sensitivity or specificity (Table II). A UPC value of 0.08 maximized sensitivity at 97%. A modest decrease in sensitivity was noted to 90% with a UPC of 0.12, while maintaining a similar negative predictive value of 86%. The most specific cutoffs for UPC were 0.45 and 1.19 with specificities of 96% and 99% respectively. Using the most specific cutoff of 1.19, only 72% of the patients were correctly classified as having or not having proteinuria and the diagnosis of preeclampsia.

A logistic regression model was developed to evaluate the relationship among potential associated variables and confounders for predicting significant proteinuria (Table III). UPC was significantly associated with proteinuria (adjusted odds ratio (aOR) 10.3, 95% confidence interval (CI) 4.4–23.8 $p < 0.01$) after controlling for pertinent covariates. Uric acid was also significantly associated with proteinuria > 300 mg (aOR 1.4, 95% CI 1.0–1.9, $p = 0.03$). A prior history of preeclampsia was negatively associated with proteinuria (aOR 0.3 95% CI 0.1–0.7, $p < 0.01$). In the multivariable analysis, no other clinical factors were associated with or predictive of proteinuria on 24-h urine collection. ROC analysis used to assess the diagnostic utility of combining UPC and uric acid for detection of proteinuria revealed the combination of the two tests had a moderate ability to predict proteinuric preeclampsia. The area under the curve for a model with both UPC and uric acid was 0.79. Several cutoff values using combinations of UPC and uric acid levels to optimize sensitivity and negative predictive value resulted in reasonable sensitivity and negative predictive value but consistently poor positive predictive value and high false positive rate (Table IV). No combination of UPC and uric acid improved specificity beyond that achieved with UPC

alone. Negative predictive value was improved when combining UPC and uric acid as compared to UPC alone, and was optimized with a UPC cutoff of 0.12 and uric acid of 4.5. In addition, a stratified analysis according to preeclampsia in a prior pregnancy improved negative predictive values for a UPC cutoff of 0.12–100% if the patient had no history of prior preeclampsia. Other test characteristics were not significantly improved after stratifying by presence or absence of prior preeclampsia.

We examined extremes of UPC values to determine whether there was a level below which significant proteinuria could be ruled out and, above which proteinuria could be ruled in. In our cohort 10% ($n = 37$) of the patients had a UPC value of <0.08 . Of those with UPC values <0.08 only five patients had a false negative with 24 h protein results >300 mg, ranging from 321 to 532 mg, and none of these women had severe range proteinuria. Thirteen percent of women in our cohort had UPC of ≥ 1.19 and only 2 ($<1\%$) were false positives with actual 24 h urine results of <300 mg. Thus, 23.5% ($n = 84$) women would have avoided a 24-h urine collection by ruling out proteinuria with UPC <0.08 and ruling in proteinuria with UPC ≥ 1.19 .

In the subgroup analysis for severe proteinuria, 22 (6.2%) women had severe proteinuria defined as ≥ 5 g in 24 h and 30 (8.4%) had proteinuria ≥ 3 g. None of these patients had a UPC value <0.08 (i.e. a false negative result). Similar to the prediction of mild proteinuria, the area under the ROC curve for UPC in predicting proteinuria ≥ 5 g and ≥ 3 g was 0.78 and 0.84, respectively with no clearly diagnostic cut-point. A UPC cut-point ≥ 0.08 has 100% sensitivity and 10% specificity for 3 g of protein and 100% sensitivity and 6.8% specificity for 5 g of protein in 24 h. Increasing the cut-point to ≥ 0.12 , 1 patient with severe proteinuria was missed. A cut-point of <0.12 had 98.9% sensitivity and 11% specificity for the detection of 3 g of proteinuria and 98.9% sensitivity and 8.1% specificity for 5 g of protein.

Discussion

Hypertensive disorders remain a leading cause of pregnancy-related mortality [2]. Prompt diagnosis and aggressive therapy of hypertensive disease during pregnancy can reduce maternal and perinatal risks. A 24-h urine collection is the gold standard to quantify proteinuria and diagnose preeclampsia in hypertensive pregnant patients. However, the collection of 24-h urine samples is cumbersome, time intensive and often requires an admission to the hospital. We sought to evaluate whether UPC alone or in combination with other clinical predictors could streamline the diagnosis of proteinuria and preeclampsia by using the test to triage a patient to therapy or further evaluation. Ideally, we sought to validate a rapid test to obviate the need for a 24-h urine collection in a significant proportion of patients. In this cohort of more than 300 women, our results demonstrate no single cut-point of the UPC value to be diagnostic for preeclampsia. However, a sufficiently low UPC value ≤ 0.08 or sufficiently high value ≥ 1.19 are associated with favorable negative and positive predictive values, which could allow the option of diagnosing preeclampsia without a 24-h urine collection in that subset of patients. Addition of uric acid or other clinical predictive factors to UPC did not enhance the ability to identify significant proteinuria. Analysis stratified by presence or absence of prior preeclampsia demonstrated improved negative predictive value in women without any history of preeclampsia, typical of negative

predictive value trends in a population with decreased disease prevalence. However, other test characteristics were not significantly improved by considering presence or absence of preeclampsia in a prior pregnancy. In this cohort, prior preeclampsia appeared to be negatively associated with proteinuria, possibly due to provider selection bias by having a lower threshold for pursuing clinical evaluation in a patient with history of prior preeclamptic disease.

The use of UPC to quantify proteinuria has been used for nonpregnant patients since the 1980s [7,8]. However, the utility of UPC in pregnant patients to accurately predict proteinuria has been mixed. Several studies have found excellent correlation between UPC values and 24-h urine protein results in cohorts of hypertensive women [9–12]. However, rigorously tested cut-points of UPC values to confidently exclude the need for a 24 h urine have not been thoroughly validated and UPC has not been evaluated as part of a multivariable diagnostic tool. Rodriguez- Thompson and Lieberman reported on a cohort of 138 hypertensive women and report an area under the ROC curve of 0.91, slightly better than the results of this study. They suggest the optimal cutoff from their dataset was 0.19 with a sensitivity of 90% and that a cutoff below 0.14 confidently ruled out proteinuria [11]. The use of UPC to rule out significant proteinuria has been suggested based on negative predictive values of >90% [6,10], however the negative predictive values we present in this study are not as high as those previously reported with a maximum value of 86%. Other studies have demonstrated poorer correlations of 0.4 and 0.5 between UPC and 24-h urine protein and areas under the ROC curves of ~0.8 with no clear diagnostic cut-point [6,13]. A recent systematic review of the use of UPC in preeclampsia suggests that there is no single UPC value to identify proteinuria, but that the use of a “two-cut-point” system with high values of UPC maximizing specificity and low values maximizing sensitivity may have clinical utility [14].

We evaluated a two cut-point system in the clinical application of UPC for the diagnosis of preeclampsia. We sought to define both a UPC value that maximizes sensitivity, below which the risk for significant proteinuria is quite low and, and a value that maximizes specificity, above which the presence of significant proteinuria can be assumed and the diagnosis of preeclampsia confirmed. Using a cutoff of 0.08 to rule out proteinuria, 10% of 24-h urine collections would have been avoided. Using a cutoff of 1.19 above which proteinuria can be assumed, 12% of 24-h urine collections would be avoided. A total of 84 women (23.5% of the cohort) would have avoided a 24-h urine collection, and the ensuing delay in diagnosis and therapy, based on the UPC results using the two cut-point strategy. Using this strategy, 7 women (1.9%) would have been misclassified, missing only 5 women (1.4%) who truly had disease and missing no women with severe proteinuria. The addition of a uric acid measurement to UPC to exclude proteinuria did not improve the ability to confidently rule in or out proteinuria.

Strengths of this study include a large cohort of women with comprehensive follow-up and clinical data. Risk factors and clinical outcomes were defined strictly and objectively and were identified using a standardized data collection process. In addition, this study was performed in a population of women at high risk for preeclampsia allowing sufficient preeclampsia cases to evaluate test characteristics and performance. More than 90% of the

24-h urine collections were obtained on an in-patient basis and therefore the reliability of the results is high. The risk characteristics of this patient population should be considered when interpreting test performance. This cohort included all hypertensive women with suspicion for preeclampsia, regardless of other risk factors, which allows the findings to be generalizable to obstetric patients that are being evaluated for gestational hypertension. Our logistic regression analysis did not suggest that typical risk factors for preeclampsia were differentially associated with subgroups of patients stratified on UPC level and did not enhance the performance of UPC in predicting preeclampsia.

Our study is not without limitations. The retrospective nature of this study limits what data are available for the cohort; however the hospital electronic medical record allowed collection of thorough clinical data without relying on patient recall or report. Although selection bias and misclassification bias are always possible in retrospective study designs, significant differential bias is unlikely since all patients who presented for possible preeclampsia in the study window and met the strict inclusion criteria were included and all patients underwent the same “gold standard” 24-h urine test. In addition, the sub-analyses of severe preeclampsia had restricted power due to the low case numbers. Lastly, although ACOG definition of preeclampsia includes proteinuria, there are known non-proteinuric phenotypes of severe preeclampsia and HELLP syndrome. These data do not address the diagnosis of non-proteinuric preeclampsia phenotypes, as patients with lab abnormalities suggestive of HELLP syndrome are typically delivered without continuation of a 24-h urine collection.

In conclusion, very high or very low values of UPC may be useful to discern between hypertensive patients with or without proteinuria and thus, preeclampsia. The UPC ratio at either very high (1.19) or very low (0.08) levels, is clinically useful, providing data that is rapidly available to clinicians to improve selection of those women who do or do not need to undergo a 24-h urine collection, thus, minimizing delay in the diagnosis or exclusion of preeclampsia. Further studies are needed to evaluate the cost-effectiveness of routine use of UPC. Before adopting this diagnostic approach universally, we recommend that our estimate of UPC diagnostic accuracy be validated prospectively in an independent cohort and that cost-effectiveness be formally evaluated. Validation should be performed with the knowledge that the majority of the population will fall in the less-predictive mid-range values, but UPC testing may still result in overall cost savings or improved health outcomes by obviating the need for a 24-h urine collection, consequential delays in diagnosis and the expense of an in-patient admission for a substantial proportion of patients.

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Figure 1.
Receiver Operating Characteristic Curve for urine protein-to-creatinine ratio (UPC) to predict proteinuria.

Table I

Baseline socioeconomic and demographic characteristics of women with proteinuria compared to those without proteinuria.

Characteristic	Proteinuria (n = 144)	No proteinuria (n = 212)	p
Maternal age (mean years)	27.5 ± 6.7 (26.4–28.6)	26.8 ± 6.5 (26.0–27.7)	0.35
Black race (%)	59.9	68.7	0.09
Gravidity	2.8 ± 1.9 (2.4–3.0)	3.1 ± 2.3 (2.8–3.4)	0.10
Parity	1.2 ± 1.6 (0.9–1.5)	1.4 ± 1.8 (1.2–1.6)	0.27
Tobacco use (%)	15.3	18.4	0.4
Alcohol use (%)	3.5	1.0	0.09
Drug use (%)	6.9	4.7	0.37
Multiple gestation	11.2	8.5	0.29
Gestational age at presentation for study workup (weeks)	31.3 ± 3.8 (30.7–31.9)	32.2 ± 3.8 (31.8–32.8)	<0.01
Chronic hypertension (%)	21.1	25.9	0.3
Current gestational hypertension (%)	1.7	2.2	0.7
Current diabetes mellitus (%)	21.0	15.6	0.2
Systolic BP at first visit (mm Hg)	120.9 ± 18.4 (115.2–126.7)	117.8 ± 14.8 (113.3–122.3)	0.4
Diastolic BP at first visit (mm Hg)	71.3 ± 16.5 (66.2–76.5)	71.1 ± 12.6 (67.3–75.0)	1.0
Preeclampsia in prior pregnancy (%)	30.6	52.4	<0.01
Prior preterm delivery Secondary to Preeclampsia (%)	12.9	14.2	0.80
BMI	35.4 ± 9.0 (33.9–37.0)	35.5 ± 9.4 (34.2–36.8)	0.99
Mean systolic blood Pressure (mm Hg) ^a	147.5 ± 13.0 (145.3–149.6)	143.1 ± 29.8 (139.0–147.1)	0.10
Mean diastolic blood Pressure (mm Hg) ^a	89.4 ± 10.9 (87.6–91.2)	85.9 ± 10.4 (84.5–87.3)	<0.01
Mean arterial pressure (mm Hg) ^a	106.8 ± 13.7 (105.1–108.6)	103.0 ± 13.4 (101.2–104.9)	<0.01
Serum uric acid (mg/dL)	5.2 ± 1.4 (5.0–5.5)	4.5 ± 1.2 (4.4–4.7)	<0.01
Hemoglobin (g/dL)	11.4 ± 1.5 (11.2–11.7)	11.2 ± 1.4 (11.0–11.4)	0.22
Platelets (x1000/mL)	241.2 ± 75.7 (228.7–253.7)	258.6 ± 73.2 (248.7–268.6)	0.03
Serum creatinine (mg/dL)	0.64 ± 0.13 (0.62–0.66)	0.60 ± 0.19 (0.60–0.62)	0.02
Serum AST (U/L)	27.9 ± 16.0 (25.2–30.5)	23.9 ± 13.6 (22.0–25.7)	0.01
24-h urine collection performed as in-patient (%)	96.5	92.0	0.08

^a Obtained from first five values measured at time of workup for preeclampsia.

Table II

Test characteristics of urine protein-to-creatinine ratio to predict proteinuria using various UPC cutoffs.

UPC cutoff (>)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+LR	-LR	Percent correctly classified
0.08	97	15	44	86	1.14	0.23	60
0.12	90	39	50	86	1.48	0.25	60
0.19	78	70	64	82	2.60	0.31	73
0.40	50	92	81	74	7.08	0.53	75
0.45	47	96	88	73	11.0	0.56	76
1.19	31	>99	96	67	33.1	0.70	72

LR, likelihood ratio; NPV, negative predictive value; PPV, positive predictive value; UPC, urine protein-to-creatinine ratio.

Table III

Logistic regression model for covariates associated with significant proteinuria.

Variable	Adjusted odds ratio (95% CI)	<i>p</i> value
Proteinuria	—	—
UPC	10.3 (4.4–23.8)	<0.01
Uric acid	1.4 (1.0–1.9)	0.03
Black race	0.6 (0.1–1.3)	0.15
Nulliparity	0.6 (0.2–2.0)	0.5
Prior preeclampsia	0.3 (0.1–0.7)	<0.01
Chronic Hypertension	1.1 (0.5–2.4)	0.7
Mean systolic BP at presentation	1.0 (0.9–1.0)	0.5
Mean diastolic BP at presentation	1.0 (0.9–1.0)	0.2

BP, blood pressure; CI, confidence interval; UPC, urine protein-to-creatinine ratio.

Table IV

Test characteristics for models using both UPC and uric acid for the predication of significant proteinuria.

Model	UPC cutoff ()	UA cutoff ()	Screen + rate (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+LR (%)	-LR (%)
	0.12	UPC only	73	90	39	50	86	1.48	0.3
1	0.12	3.9	92	98	13	43	93	1.1	0.1
2	0.12	4.5	84	97	25	47	94	1.3	0.1
3	0.19	3.9	85	97	22	46	92	1.3	0.1
4	0.19	4.5	73	93	41	51	90	1.6	0.2

LR, likelihood ratio; NPV, negative predictive value; PPV, positive predictive value; UPC, urine protein-to-creatinine ratio.