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The diagnostic value of spot urine protein-to-creatinine ratio in the diagnosis of proteinuria severity; a diagnostic cross-sectional study

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Abstract

Introduction: Proteinuria is a key marker of renal dysfunction, yet its accurate quantification traditionally relies on 24-hour urine collection, a method that is time-consuming and often impractical in routine clinical settings. The spot urine protein-to-creatinine ratio (P/CrR) has emerged as a potential alternative, offering a simpler and more accessible approach for assessing protein excretion.
Objectives: This study aimed to evaluate the diagnostic value of spot urine P/CrR in identifying and stratifying the severity of proteinuria.
Materials and Methods: This diagnostic cross-sectional study enrolled 87 individuals with confirmed proteinuria who were referred to the outpatient clinics or inpatient wards of Qazvin hospitals between March and August 2020. Following informed written consent, spot urine samples and 24-hour urine collections were obtained under sterile laboratory conditions. The diagnostic utility of the spot urine P/CrR for identifying and stratifying proteinuria severity was evaluated in comparison with the 24-hour urine protein measurement as the reference standard.
Results: The study demonstrated that the spot urine P/CrR was strongly associated with proteinuria severity. Logistic regression showed that each unit increase in P/CrR increased the odds of moderate proteinuria, with unadjusted and adjusted odds ratios (ORs) of 1.05 and 1.06, respectively, and similarly increased the odds of severe proteinuria, with corresponding OR of 1.07 and 1.08. Diagnostic analysis indicated that a spot P/CrR threshold of 200 mg/g provided good discriminatory performance, yielding a sensitivity and specificity of 81% and 74% for moderate proteinuria and 91% and 74% for severe proteinuria.
Conclusion: Spot urine P/CrR showed a strong and graded association with proteinuria severity, with meaningful increases in odds across both moderate and severe categories and good diagnostic performance at the 200 mg/g threshold. These findings support its value as a simple and reliable marker for identifying and stratifying proteinuria severity.

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Introduction

Proteinuria is a hallmark of chronic kidney disease (CKD) and a strong, independent predictor of renal function decline and cardiovascular events (1-3). The magnitude of urinary protein excretion reflects the severity of glomerular injury and contributes directly to tubulointerstitial inflammation and fibrosis, so that reductions in proteinuria translate into slower CKD progression in both diabetic and non-diabetic kidney disease (1,2). In clinical practice, proteinuria severity is usually graded on the basis of 24-hour urinary protein excretion, ranging from sub-nephrotic to nephrotic-range proteinuria, with nephrotic-range proteinuria commonly defined as ≥3–3.5 g/24 h in adults (4,5). Although 24-hour urine protein remains the reference standard for quantifying proteinuria, incomplete or inaccurate collections and the inconvenience for patients limit its routine use, especially in outpatient settings (6-8).

To overcome these limitations, random or spot urine protein-to-creatinine ratio (P/CrR) has been adopted as a convenient surrogate for 24-hour urinary protein, assuming that creatinine excretion normalizes for urine concentration (2,9). Multiple studies in diverse CKD populations have shown strong correlations between spot urine P/CrR and 24-hour protein excretion, particularly at low to moderate proteinuria levels, supporting

Key point

The findings showed that higher spot urine protein-to-creatinine ratio (P/CrR) values were strongly linked to greater proteinuria severity, with odds ratios of 1.05 and 1.06 for moderate proteinuria and 1.07 and 1.08 for severe proteinuria in unadjusted and adjusted models, respectively. A diagnostic threshold of 200 mg/g demonstrated solid performance, yielding sensitivity and specificity of 81% and 74% for detecting moderate proteinuria and 91% and 74% for severe proteinuria. Collectively, these results highlight the spot urine P/CrR as a practical indicator for both predicting and distinguishing levels of proteinuria severity.

its use for screening and follow-up (2,9). However, other investigations report substantial dispersion and only moderate agreement when proteinuria increases, with urine P/CrR tending to misestimate 24-hour excretion in the nephrotic range (1,10). In IgA nephropathy, for example, spot urine P/CrR tracks 24-hour protein reasonably well, whereas in minimal-change disease or membranous nephropathy, discrepancies are larger and may be clinically important (5,10). These data indicate that the diagnostic performance of urine P/CrR may vary according to both the level of proteinuria and the underlying glomerular pathology.

Emerging evidence further suggests that pre-analytical factors, such as urine concentration, can systematically bias urine P/CrR values, with dilute samples overestimating and concentrated samples underestimating true daily protein excretion (1). Cross-sectional studies comparing 24-hour urine protein with spot urine P/CrR have proposed that the ratio is reliable mainly for lower proteinuria thresholds, whereas 24-hour collections remain necessary for accurate quantification at higher excretion rates and for treatment monitoring (2). Nevertheless, there is still no consensus on the optimal spot urine P/CrR cut-offs to classify proteinuria severity categories based on 24-hour protein, particularly in unselected CKD populations (1,2,9). The present diagnostic cross-sectional study, therefore, aims to evaluate the diagnostic value of spot urine P/CrR in defining proteinuria severity, using 24-hour urinary protein excretion as the standard reference.

Objectives

This study aimed to evaluate the diagnostic utility of the spot urine P/CrR in estimating and stratifying proteinuria severity by comparing its performance with the 24-hour urine protein excretion, which serves as the clinical reference standard.

Materials and Methods

Study design and participants

This study was conducted on a cohort of 87 individuals with confirmed proteinuria who were referred to the outpatient clinics or admitted to the inpatient wards of Qazvin hospitals during the period from March to August 2020. All eligible participants underwent standardized clinical evaluation and laboratory testing as part of routine care, and only those with complete urine analyses and demographic data were included in the final dataset.

Inclusion and exclusion criteria

The study included adult patients with confirmed proteinuria who provided informed written consent and were able to undergo both spot urine sampling and 24-hour urine collection under sterile laboratory conditions. Participants were eligible if they had complete demographic and clinical data, including age, gender, and laboratory-measured spot urine P/CrR and 24-hour urine protein values. Patients were excluded if they had incomplete urine samples, missing demographic or laboratory information, or were unable to complete the 24-hour urine collection. Individuals with conditions that could compromise the accuracy of proteinuria assessment, such as contaminated samples or improperly collected urine, were also excluded to ensure the reliability of protein measurements.

Data collection

Data were collected from 87 participants after obtaining informed written consent. Spot urine samples and 24-hour urine collections were obtained under sterile laboratory conditions to ensure accurate measurement of protein excretion. The spot urine P/CrR was analyzed for all patients, and proteinuria severity was categorized into normal-to-mild, moderate, and severe groups based on the amount of protein excretion in the 24-hour urine sample. Demographic data, including age and gender, were recorded for each participant from medical documents and participants' interviews.

Proteinuria classification

Amount-based proteinuria is classified into three main categories: normal to mild (protein loss <150 mg/day), moderate (150–500 mg/day), and severe (>500 mg/day) (11).

Outcome measurement

The primary outcome of this study was the assessment of 24-hour urine protein excretion, which served as the reference standard for determining daily proteinuria severity, along with the spot urine P/CrR obtained from a single random urine sample and evaluated for its ability to estimate and discriminate proteinuria severity. The secondary outcome was the diagnostic performance of the spot urine P/CrR, specifically its accuracy in predicting moderate and severe proteinuria when compared with the 24-hour urine protein measurement.

Statistical analysis

Data were analyzed using SPSS version 27 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was assessed using the Kolmogorov–Smirnov

test, and descriptive statistics were generated to summarize baseline demographic and clinical characteristics. Group comparisons across proteinuria-severity categories were performed using one-way analysis of variance (ANOVA) with post-hoc least significant difference (LSD) testing for quantitative variables, while categorical variables, such as gender distribution, were compared using the chi-square test. Binary logistic regression models, both unadjusted and adjusted for age and gender, were applied to evaluate the association between spot urine P/CrR and the likelihood of moderate or severe proteinuria using odds ratios (ORs). Diagnostic performance was assessed using the receiver operating characteristic (ROC) curve analysis to determine the discriminatory ability of P/CrR and to estimate sensitivity and specificity at the optimal cut-off value, and reporting an area under the curve (AUC) for proteinuria severity.

Results

The study enrolled 87 participants, with a mean age of 47.91 ± 17.27 years. A substantial proportion of the cohort exhibited markedly elevated protein excretion, as reflected by a mean spot urine P/CrR of approximately 216 mg/g, indicating that most patients had severe proteinuria at baseline (Table 1).

The distribution of demographic and clinical characteristics showed broadly similar patterns across the three proteinuria-severity groups, with no meaningful differences in gender composition or age, as the proportions of males and females and the average age range were comparable between categories. In contrast, the urine P/CrR demonstrated a clear stepwise increase from the normal-to-mild group to the moderate and severe groups, reflecting progressively higher protein excretion with increasing severity. Post-hoc LSD comparisons further indicated that each successive category exhibited distinctly greater proteinuria than the preceding one, underscoring a consistent gradient in urinary protein burden across severity levels (Table 2).

The binary logistic regression analysis demonstrated a consistent positive association between the spot urine P/CrR and increasing proteinuria severity. For the comparison of moderate versus normal proteinuria, both the unadjusted and age- and gender-adjusted models showed OR 1.05 and 1.06, indicating that higher urinary protein levels were associated with a greater likelihood of being classified in the moderate category rather than the normal group, with each mg/g increase of spot urine P/CrR was accompanied by an increase of 5% and 6% risk of moderate proteinuria occurrence probability. A similar pattern was observed for severe versus normal proteinuria, where the ORs were 1.07 and 1.08 in univariate and multivariate models, reflecting an even stronger association between elevated spot urine P/CrR and the occurrence probability of severe proteinuria (Table 3).

The diagnostic performance analysis ROC curve indicated that the spot urine P/CrR demonstrated strong discriminatory ability for identifying both moderate and severe proteinuria. At the threshold of 200 mg/g (as a normal range), the test achieved a high area under the curve for both moderate and severe proteinuria categories, indicating good overall accuracy. For moderate proteinuria, the cut-off of 200 mg/g provided a balanced combination of sensitivity and specificity, supporting its usefulness in correctly identifying individuals with intermediate levels of protein excretion. The diagnostic value was even more pronounced for severe proteinuria at 200 mg/g, where the test showed markedly higher sensitivity while maintaining comparable specificity (Table 4 and Figure 1).

Discussion

Our results indicated that spot urine P/CrR showed a strong

Table 1. Baseline characteristics of participating patients

Qualitative variable		Frequency	Percent
Gender	Male	42	48.3
	Female	45	51.7
	Total	87	100
Proteinuria severity	Normal to mild	26	29.9
	Moderate	27	31
	Severe	34	39.1
	Total	87	100
Quantitative variable		**Mean**	**SD**
Age (y)		47.91	17.27
Spot urine P/CrR (mg/g) in all patients		216.15	26.78

P/CrR: Protein-to-creatinine ratio, SD: Standard deviation.

Table 2. The frequency distribution of demographic profile and clinical data based on proteinuria severity

Variable		Proteinuria severity			*P* value
		Normal to mild (n = 26)	Moderate (n = 27)	Severe (n = 34)	
Gender n (%)	Male	9 (34.6)	14 (51.9)	19 (55.9)	0.238*
	Female	17 (65.4)	13 (48.1)	15 (44.1)	
Age (year; mean ± SD)		52.69 ± 19.03	45.44 ± 13.49	46.23 ± 18.27	0.241**
Spot urine P/CrR (mg/g)		195.13 ± 24.51	216.37 ± 16.01	232.06 ± 24.56	<0.001**
		Proteinuria level		**Mean difference**	***P* value****
Spot urine P/CrR (mg/g)	Normal to mild		Moderate	21.24	<0.001
			Severe	36.93	<0.001
	Moderate		Severe	15.69	0.008

P/CrR: Protein-to-creatinine ratio, SD: Standard deviation *Chi-square, **One-way ANOVA, ***Post hoc LSD.

Table 3. The correlation between Spot urine P/CrR and the severity of proteinuria using binary logistic regression

Spot urine P/CrR (mg/g)	Proteinuria severity		
	OR	95% CI	*P* value
Moderate compared to normal			
Unadjusted	1.05	1.02 – 1.09	0.002
Adjusted*	1.06	1.02 – 1.10	0.003
Severe compared to normal			
Unadjusted	1.07	1.03 – 1.11	<0.001
Adjusted*	1.08	1.03 – 1.12	<0.001

P/CrR: Protein-to-creatinine ratio, OR: Odds ratio, CI: Confidence interval, *Adjusted for age and gender.

Table 4. Diagnostic value of Spot urine P/CrR in the diagnosis of proteinuria severity

Proteinuria severity	Spot urine P/CrR (mg/g)						
	Cut off (mg/g)	AUC (0-1)	95% CI		*P* value	Sensitivity (%)	Specificity (%)
			Lower	Upper			
Moderate	200	0.806	0.685	0.927	<0.001	81	74
Severe	200	0.899	0.813	0.986	<0.001	91	74

P/CrR: Protein-to-creatinine ratio; AUC: area under curve; CI: confidence interval.

association with proteinuria severity, with increasing odds across both moderate and severe categories and good diagnostic performance at the 200 mg/g threshold. This pattern supports the concept that spot urine P/CrR can reflect the magnitude of urinary protein loss in a clinically meaningful way, while offering a simpler alternative to 24-hour urine collection. The graded relationship observed in this study is important because it suggests that spot urine P/CrR may be useful not only for identifying proteinuria but also for stratifying its severity. The present results are consistent with prior studies reporting that spot urine P/CrR correlates well with 24-hour urine protein excretion. In a diagnostic utility review by Kamińska et al, spot urine P/CrR thresholds around 0.2 mg/mg have commonly been used to detect proteinuria, while higher cutoffs have been proposed for nephrotic-range proteinuria (12). Likewise, earlier clinical studies have shown that random or spot urine P/CrR can estimate proteinuria severity with reasonable sensitivity and specificity across clinically relevant ranges (13-15). Kosmadakis et al assessed the quantitative reliability of the spot urine P/CrR across different times of day in patients with proteinuria in the diagnosis of proteinuria severity. In their cohort of 45 adults, the spot urine P/CrR measured in morning and midday samples showed strong concordance with 24-hour protein excretion across all levels of proteinuria severity and renal function strata. Sensitivity and specificity values were consistently high for detecting mild, moderate, and severe proteinuria, indicating robust diagnostic performance. Only the late-afternoon sample demonstrated a weaker association. Overall, the authors concluded that the spot urine P/CrR, particularly when collected from morning to midday, provides an accurate estimate of 24-hour proteinuria and can effectively replace the cumbersome 24-hour urine collection in routine clinical practice (15). Biradar et al examined the diagnostic performance of the spot urine P/CrR among adults with type 2 diabetes mellitus, comparing it directly with 24-hour urinary

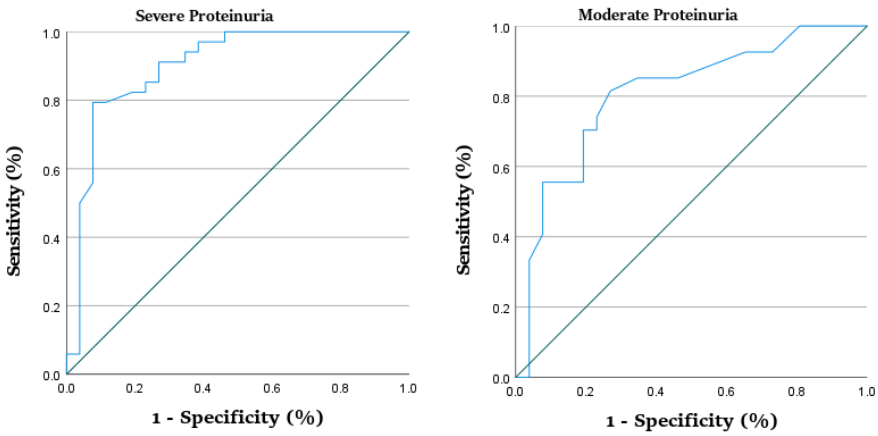

Figure 1. Spot urine P/CrR as a predictor of proteinuria severity by using ROC curve analysis.

protein excretion, and concluded that the random urine P/C ratio provides a reliable and rapid estimate of daily protein excretion and may serve as an effective substitute for the more cumbersome 24-hour urine collection in diabetic populations (13). Kucukgoz et al evaluated the diagnostic performance of the spot urine P/CrR across a spectrum of hypertensive disorders of pregnancy, including gestational hypertension, preeclampsia, and severe preeclampsia. In this large prospective cohort of 205 women, the spot urine P/CrR showed meaningful ability to reflect the magnitude of proteinuria, with its predictive accuracy improving as disease severity increased. Although the authors emphasized that 24-hour urine collection remains the most reliable method for quantifying total protein excretion, their findings indicate that spot urine P/CrR can provide a reasonable estimation, particularly in cases of severe preeclampsia where proteinuria is more pronounced (14). Wahbeh et al reported a strong correlation between the spot urine P/CrR and 24-hour urine protein in 68 nephrology patients. The ROC-derived spot urine P/CrR thresholds accurately predicted clinically relevant proteinuria cut-offs, particularly at lower levels of protein excretion. However, the analysis showed widening limits of agreement as proteinuria increased, indicating reduced reliability in heavier proteinuria. The authors suggested that spot urine P/CrR is an accurate and convenient estimator of 24-hour protein excretion, but its clinical precision is best maintained when proteinuria is relatively low (9).

In contrast, Sahu et al compared spot urine P/CrR with 24-hour urine protein in 72 patients with kidney disease. The spot urine P/CrR showed acceptable correlation only in those with low-grade proteinuria, while agreement with 24-hour measurements declined as proteinuria increased. In moderate and heavy proteinuria, correlations were weak or no significant. The authors concluded that spot urine P/CrR may be useful for initial screening, but for follow-up assessment and for proteinuria >0.5 g/day, 24-hour urine protein remains the most accurate method (2). Durnwald et al prospectively evaluated whether the urine P/CrR could reliably estimate 24-hour urine protein excretion in women with suspected preeclampsia. Unlike several other studies demonstrating a strong correlation between the two measures, their findings showed that the protein/creatinine ratio lacked sufficient accuracy to either exclude clinically significant proteinuria or predict severe proteinuria, and the authors suggested that the ratio should not replace 24-hour urine collection when confirming or quantifying proteinuria in this population (16). From a clinical perspective, the main value of spot urine P/CrR lies in its simplicity and convenience compared with 24-hour urine collection. The graded association seen in this study suggests that it may help clinicians quickly identify patients with more severe proteinuria and support decision-making when timely assessment is needed.

Overall, spot urine P/CrR showed a significant association with proteinuria severity. These results are consistent with previous literature, indicating that spot urine P/CrR correlates well with 24-hour urine protein excretion and can assist in identifying clinically important proteinuria categories. In conclusion, spot urine P/CrR appears to be a practical marker for identifying and stratifying proteinuria severity, although its use should be considered in the context of clinical judgment and reference-standard testing when precise quantification is required.

Conclusion

This study demonstrates that the spot urine P/CrR is a reliable and clinically meaningful indicator of proteinuria severity. Higher spot urine P/CrR values were consistently associated with increased odds of both moderate and severe proteinuria, and a diagnostic threshold of 200 mg/g showed strong discriminatory performance with high sensitivity and acceptable specificity. These findings support the use of spot urine P/CrR as a prompt, practical, non-invasive tool for stratifying proteinuria severity and guiding clinical assessment.

Limitations of the study

This study has several limitations that should be considered when interpreting the findings. Although urine samples were collected under sterile conditions, the accuracy of 24-hour urine collection may still be affected by patient adherence and collection errors. Additionally, potential confounders such as hydration status, dietary protein intake, and timing of urine sampling were not controlled, which may influence protein excretion measurements. Further multicenter studies with larger cohorts and longitudinal follow-up are needed to validate and extend these findings.

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Authors' contribution

Conceptualization: Sepideh Hajian and Pourya Ebizadeh Tourabifard.
Data curation: Sepideh Hajian and Pourya Ebizadeh Tourabifard.
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Project management: Sepideh Hajian
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Supervision: All authors.
Validation: Arian Ghannadi Karimi and Mehran Ebrahimi Varkiani.
Writing–original draft: All authors.
Writing–review and editing: All authors.

Conflicts of interest

The authors declare no conflict of interest.

Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of generative artificial intelligence (AI) and AI-assisted technologies in the writing process

While preparing this work, the authors utilized AI (Grammarly, Perplexity, and Copilot) to refine grammar points and language style. Subsequently, they thoroughly reviewed and edited the content as necessary, assuming full responsibility for the publication's content.

Ethical issues

The research was conducted in accordance with the principles outlined in the Declaration of Helsinki. Informed written consent was taken from all participants or their legally authorized representatives. This study was conducted at outpatient clinics or admitted to the inpatient wards of Qazvin hospitals and was derived from the thesis work of Pourya Ebizadeh Tourabifard (Thesis#14004083), approved by the ethics committee of Qazvin University of Medical Sciences, Tehran, Iran, under the ethical code (IR.QUMS.REC.1398.334; https://ethics.research.ac.ir/form/y2cm3zq634f88l0z.pdf) registered on November 29, 2022. Besides, the authors have ultimately observed ethical issues (including plagiarism, data fabrication, and double publication).

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