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Original Article

Diagnostic accuracy of urine dipstick for proteinuria in older outpatients



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ABSTRACT

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Background: The urine dipstick is widely used as an initial screening tool for the evaluation of proteinuria; however, its diagnostic accuracy has not yet been sufficiently evaluated. Therefore, we evaluated its diagnostic accuracy using spot urine albumin/creatinine ratio (ACR) and total protein/creatinine ratio (PCR) in proteinuria.

Methods: Using PCR ≥ 0.2 g/g or ≥ 0.5 g/g and ACR ≥ 300 mg/g or ≥ 30 mg/g as the reference standard, we calculated the diagnostic accuracy profile: sensitivity, specificity, positive and negative predictive value, and the area under the curve (AUC) of the receiver operating characteristic curve.

Results: PCR and ACR were available for 10,348 and 3,873 instances of dipstick testing. The proportions with PCR ≥ 0.2 g/g, ≥ 0.5 g/g and ACR ≥ 300 mg/g, ≥ 30 mg/g were 38.2%, 24.6% and 8.9%, 31.7%, respectively. The AUCs for PCR ≥ 0.2 g/g, ≥ 0.5 g/g, and ACR ≥ 300 mg/g were 0.935 (trace: closest to ideal point), 0.968 (1+), and 0.983 (1+), respectively. Both sensitivity and specificity were $> 80\%$ except for PCR ≥ 0.5 g/g with trace cutoff. For the reference standard of ACR ≥ 30 mg/g, the AUC was 0.797 (trace) and the sensitivity was 63.5%.

Conclusion: Urine dipstick test can be used for screening in older outpatients with ACR ≥ 300 mg/g or PCR as the reference standard for proteinuria. However, we cannot recommend the test as a screening tool with ACR ≥ 30 mg/g as the reference owing to its low sensitivity.

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Introduction

The prevalence of chronic kidney disease (CKD) is rapidly increasing worldwide, influencing public health by causing increasing risk of end-stage renal disease and broadening the range of complications including cardiovascular diseases [1]. Proteinuria is a cardinal manifestation of CKD. Its significance

as an independent risk factor for end-stage renal disease and cardiovascular disease has long been recognized, and is emphasized by several large cohort studies showing the prognostic value of even low-grade proteinuria [2–7]. However, proteinuria is usually silent and can be detected through medical screening.

Currently, the most accurate test for proteinuria is quantification using timed (usually 24 hours) urine collection [8]. However, this method is not only extremely cumbersome, the precision of urine collection is also questionable. Therefore, current clinical practice guidelines recommend “spot urine total protein or albumin” corrected for urine creatinine as the optimal method for the evaluation of proteinuria or albuminuria [8,9]. Recent

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research has focused on the outcome of albuminuria, a more sensitive marker of CKD attributable to diabetes, hypertension, and glomerular disease than total protein/creatinine ratio (PCR) [8]. However, quantifying albuminuria by spot urine albumin/creatinine ratio (ACR) is time-consuming and expensive.

The urine dipstick test is widely used as an initial screening tool for detecting proteinuria because of its low cost, wide availability, and ability to provide rapid information to clinicians and patients. The urine dipstick, however, has not been sufficiently evaluated for diagnostic accuracy. There have been a few studies concerning the diagnostic accuracy of urine dipstick for proteinuria in outpatients; however, most of these studies have been conducted on the general population. In addition, current clinical practice guidelines differ in their recommendations regarding the clinical utility of the dipstick for detecting proteinuria. We evaluated the diagnostic accuracy of urine dipsticks for proteinuria in outpatients at a single center using ACR and PCR as reference standards.

Methods

We collected data on urine dipstick, spot urine total protein, spot urine albumin, urine creatinine, and serum creatinine in patients who visited our center between January 1, 2012 and July 31, 2013. In the PCR group, urine dipstick (Clinitek Atlas 10 Reagent Pak; Siemens, Tarrytown, NY, USA), spot urine total protein (200 FR Neo, SIDAIA M-TP Kit; Toshiba, Tokyo, Japan), spot urine creatinine (Modular P/Modular D analysis, Jaffe kinetic colorimetric assay; Roche, Indianapolis, IN, USA) were all available, and the PCR (g/g) was calculated. In instances where the urine albumin (Nephelometer BN-II, N antiserum to human albumin; Siemens) was available, urine ACR (mg/g) was calculated (ACR group).

As a reference standard to evaluate the accuracy of urine dipstick for proteinuria, we used four different criteria: PCR ≥ 0.2 g/g or ≥ 0.5 g/g and ACR ≥ 300 mg/g or ≥ 30 mg/g. We calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of urine dipstick analysis for proteinuria using two cutoff values (trace or more, 1+ or more), and compared the area under the curve (AUC) of the receiver operating characteristic (ROC) curve. This study was approved by the Institutional Review Board of Veterans Health Service Medical Center.

We used Chi-square test for categorical variables. Data are expressed as mean \pm standard deviation. All statistical

analyses including the ROC curve were performed using STATA release 12 (StataCorp LP, College Station, TX, USA). A significant difference was defined as $P < 0.05$.

Results

PCR group

A total of 10,348 urine dipstick tests were conducted in 6,801 patients, and the PCR value was calculated. Of this total, 9,323 tests (90.0%) were performed in males. The average patient age was 68.2 ± 8.6 years, and 92.9% of the patients were older than 60 years. A negative dipstick result was obtained in 57.4% of tests and trace positive in 9.3%, 1+ in 10.6%, 2+ in 13.3%, and 3+ in 9.5%. In 38.2% of tests, PCR was ≥ 0.2 g/g. Six percent of patients with a negative dipstick result had a PCR ≥ 0.2 g/g, 41.9% of those with trace, 78.2% of those with 1+, and virtually 100% of those with either 2+ or 3+. A PCR ≥ 0.5 g/g was observed in 24.6% of all patients. The proportion of PCR ≥ 0.5 g/g was 0.6% for those with negative dipstick result, 8% for those with trace, 30% of those with 1+, 81.4% of those with 2+, and 100% of those with 3+ (Table 1).

When we set PCR ≥ 0.2 g/g as the reference standard for proteinuria, the AUC of the ROC curve was 0.935 [95% confidence interval (CI), 0.930–0.940], and the trace result was the closest to the ideal test point (Fig. 1). When trace or greater was set as the positive urine dipstick, we derived the result of 90.9% sensitivity, 87.2% specificity, and 81.5% PPV. If we set the cutoff value for the dipstick result as 1+ or greater, the sensitivity decreased to 80.7%, the specificity increased to 95.9%, and the PPV increased to 92.5% (Table 2).

When PCR ≥ 0.5 g/g was set as the reference standard, the AUC of the ROC curve was 0.968 (95% CI, 0.964–0.971), and the 1+ cutoff was closest to the ideal test point (Fig. 1). When trace or more was set as a positive dipstick result, we obtained 98.6% sensitivity, 75.6% specificity, and 56.8% PPV. If we set the cutoff value for the dipstick result to 1+ or greater, the results are as follows: sensitivity, 95.6%; specificity, 86.9%; PPV, 70.4% (Table 2).

ACR group

The ACR was calculated for a total of 3,873 urine dipstick tests (3,685 patients). Of the patients, 94.1% were males. Their mean age was 67.7 ± 6.2 years, and 95.3% were older than 60

Table 1. Demographic data and clinical characteristics by urine dipstick result

	(–)	Trace	1+	2+	3+	Total	P
PCR group (N=10,348)	(n=5,935)	(n=962)	(n=1,094)	(n=1,373)	(n=984)		
Age (y)	68.2 ± 8.0	69.3 ± 8.7	68.2 ± 9.6	67.9 ± 9.9	67.3 ± 8.6	68.2 ± 8.6	
Total	57.4	9.3	10.6	13.3	9.5	100.0	NS*
Men	89.8	90.5	90.5	89.1	92.3	90.1	< 0.001*
PCR ≥ 0.2	6.0	41.9	78.2	98.4	100	38.2	< 0.001*
PCR ≥ 0.5	0.6	8.0	30.0	81.4	100	24.6	
ACR group (N=3,873)	(n=2,917)	(n=354)	(n=276)	(n=214)	(n=112)		
Age (y)	67.6 ± 6.0	68.0 ± 6.5	68.3 ± 6.9	68.5 ± 7.4	68.0 ± 5.9	67.7 ± 6.2	
Total	75.3	9.1	7.1	5.5	2.9	100.0	
Men	93.6	95.8	96.4	93.5	95.5	94.1	NS*
ACR ≥ 300	0.03	4.0	18.8	77.1	99.1	8.9	< 0.001*
ACR ≥ 30	15.4	61.0	89.1	98.6	99.1	31.7	< 0.001*

* Chi-square test.

Data are presented as % or mean \pm SD.

ACR, spot urine albumin/creatinine ratio (mg/g); NS, not significant; PCR, spot urine total protein/creatinine ratio (g/g); SD, standard deviation.

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