Research Square

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Utility of the urine dipstick test compared with the urine protein-creatinine ratio in screening for proteinuria among women with hypertensive disorders in pregnancy at Bugando Medical Centre, Mwanza-Tanzania.

Inuka Byabusha
Catholic University of Health and Allied Sciences
Richard Kiritta
kiritta2002@yahoo.com

Catholic University of Health and Allied Sciences
Fridolin Mujuni
Catholic University of Health and Allied Sciences
Edgar Ndaboine
Bugando Medical Centre
Benson R. Kidenya
Catholic University of Health and Allied Sciences
Dismas Matovelo
Catholic University of Health and Allied Sciences

Research Article

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Abstract

Introduction: Hypertensive disorders in pregnancy (HDP) are among the leading causes of maternal and perinatal morbidity and mortality worldwide. In low-income countries, urinary protein excretion is an important diagnostic component of preeclampsia and has prognostic significance. In such settings, urine dipstick testing is still widely used due to its low cost, ease of performance, and rapid point-of-care results. However, concerns remain regarding its diagnostic accuracy compared with quantitative laboratory methods.

Methods: We conducted a hospital-based cross-sectional study that involved 301 pregnant women diagnosed with HDP. Spot urine samples were collected for visual and automated dipstick testing, followed by urine protein-creatinine ratio (UPCR) analysis as the reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the receiver operating characteristic curve (AUC) were calculated. Agreement between dipstick tests and UPCR was evaluated using Cohen's kappa statistic.

Results: The prevalence of significant proteinuria (UPCR ≥ 30 mg/mmol) was 79.7% (240/301). The sensitivity and specificity of visual urine dipsticks were 55.8% (95% CI: 49.3–62.2%) and 75.4% (95% CI: 62.7–85.5%), respectively, while those of automated urine dipsticks were 62.1% (95% CI: 55.6–68.2%) and 75.4% (95% CI: 62.7–85.5%), respectively. AUC was 0.66 for visual and 0.69 for automated methods. Agreement with UPCR was fair for both methods ($\kappa = 0.20$ and $\kappa = 0.26$, respectively). Comparison of ROC curves demonstrated no statistically significant difference in diagnostic performance between the two methods ($p = 0.224$).

Conclusion: Visual and automated urine dipstick tests demonstrate moderate diagnostic accuracy. Although useful for confirming proteinuria, negative results cannot reliably exclude proteinuria. UPCR remains the preferred diagnostic method, particularly in resource-rich settings.

Introduction

Hypertensive disorders of pregnancy (HDP) represent a spectrum of diseases that share common pathophysiological features but vary in severity. Globally, approximately 10% of pregnancies are complicated by HDP. Sub-Saharan Africa (SSA) is disproportionately affected by HDP-related morbidity and mortality (1–3). In Tanzania, HDP affects approximately 6.9% of pregnancies (4), with significant maternal and perinatal consequences (5, 6).

Within this spectrum, preeclampsia is often associated with adverse pregnancy outcomes. It is characterized by new-onset hypertension after 20 weeks of gestation with proteinuria or end-organ dysfunction (6, 7). Proteinuria reflects glomerular endothelial injury and altered filtration barrier integrity (8–12). Although the clinical importance of the degree of proteinuria is debatable (13–15), significant proteinuria has been associated with adverse maternal and fetal outcomes (16–18).

The traditional gold standard for quantifying proteinuria has been 24-hour urine collection; however, this method is cumbersome, while urine protein-creatinine ratio (UPCR) has demonstrated strong correlation with 24-hour protein excretion and is widely recommended as a reliable quantitative alternative (19–21). Several studies have reported that UPCR demonstrates high diagnostic accuracy for significant proteinuria (≥ 300 mg/24 hours), with pooled sensitivity ranging from approximately 83–95% and specificity from 76–99%, depending on the cutoff value used and study population (22, 23). Despite this, urine dipstick testing remains the most commonly used screening tool in low-resource settings due to cost and availability (24–26).

Previous studies have reported wide variability in dipstick diagnostic performance (26–29). Some studies report acceptable accuracy (30–32), whereas others highlight substantial false-negative and false-positive rates (25, 26). Few diagnostic accuracy studies have simultaneously compared visual and automated dipstick testing against UPCR among women with HDP in SSA, and no such study has been conducted in northwestern Tanzania.

Methods

We conducted a hospital-based cross-sectional diagnostic accuracy study between February and August 2025 at Bugando Medical Centre (BMC), a tertiary referral and teaching hospital affiliated with the Catholic University of Health and Allied Sciences (CUHAS) in Mwanza, Tanzania. The study aimed to evaluate the diagnostic accuracy of visual and automated urine dipstick testing for detecting significant proteinuria among pregnant women with HDP, using the UPCR as the reference standard.

Pregnant women with HDP at a gestational age of 28 weeks or more were eligible for enrolment. HDP included gestational hypertension, preeclampsia, eclampsia, chronic hypertension, and chronic hypertension with superimposed preeclampsia, diagnosed according to the American College of Obstetricians and Gynecologists (ACOG) criteria.

The minimum sample size was calculated using Buderer's formula (33), with a urine dipstick test sensitivity of 68% and specificity of 85%, respectively (27). A 95% confidence level and a precision of 0.09 were used, with a 75% prevalence of proteinuria among women with HDP in Uganda (34). A total of 301 eligible participants were recruited.

Consecutive recruitment was used to minimize selection bias by enrolling all eligible women presenting to the inpatient antenatal and labor wards during the study period.

Approximately 30 mL of clean-catch midstream spot urine was collected into a sterile 50-mL universal container. A 10-mL aliquot was transferred into a clean test tube for immediate visual urine dipstick testing using CYBOW™ urine reagent strips manufactured by DFI Co., Ltd., Gimhae-si, Gyeongsangnam-do, South Korea with lot number 230616. The reagent strip was immersed completely in the urine specimen for approximately two seconds and removed. Protein results were interpreted after 60 seconds under standardized ambient lighting conditions according to the manufacturer's instructions.

Following visual interpretation, the same reagent strip was inserted into the CYBOW™ Reader 300 urine chemistry analyzer for automated interpretation according to the manufacturer's operating instructions. Both visual and automated dipstick results were recorded as negative, trace, 1+, 2+, 3+, or 4 + for proteinuria.

Although 24-hour urine protein measurement has traditionally been regarded as the reference standard for quantifying proteinuria, it is time-consuming, inconvenient for patients, and prone to incomplete urine collection. Consequently, the UPCR has been recommended by major international professional bodies, including the American College of Obstetricians and Gynecologists (ACOG) and the International Society for the Study of Hypertension in Pregnancy (ISSHP), as an acceptable quantitative alternative because of its comparable diagnostic accuracy and greater clinical practicality.

Quantitative proteinuria assessment was subsequently performed using the Roche Cobas Integra 400 Plus Chemistry Analyzer. Urinary protein and creatinine concentrations were measured using validated photometric methods, and the urine protein-creatinine ratio was calculated by dividing the urine protein concentration by the urine creatinine concentration and expressed as mg/mmol. A UPCR value of ≥ 30 mg/mmol was considered indicative of significant proteinuria. Personnel performing visual urine dipstick interpretation were blinded to the automated dipstick analysis and UPCR results, while laboratory personnel performing automated dipstick analysis and UPCR measurements were blinded to the visual dipstick findings. Routine internal quality-control procedures and analyzer calibration were performed in accordance with the manufacturer's recommendations and institutional standard operating procedures throughout the study period.

To minimize observer-related variability, all visual urine dipstick interpretations throughout the study were performed by the same trained healthcare professional. Before commencement of the study, the observer underwent color vision assessment using the Ishihara Color Vision Test and was confirmed by an ophthalmologist to have normal color discrimination.

Data were analyzed using STATA version 18. Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratios (LRs), area under the receiver operating characteristic curve (AUC), and Cohen’s kappa statistic for agreement.

Ethical considerations

The Joint BMC/CUHAS Ethics Review Committee approved this study under certificate number CREC/896/2025. Furthermore, the BMC administration also authorized us to conduct this study. We explained the details of the study to all potential participants and assessed for comprehension. Written informed consent or assent was obtained from all participants. Copies are available for review when needed.

Results

Social demographic characteristics of participants

Among the 301 pregnant women with hypertension who were recruited, the majority (59.1%) were aged 25–35 years. Most participants resided in urban areas (82.1%), and nearly half (45.9%) had attained secondary education. Other sociodemographic characteristics are presented in Table 1.

Table 1
Social demographic characteristics of participants (n = 301)

Variable	n (%) or median (IQR)
Age (median, IQR)	30, 26–35
Age category (in years)	
18–24	56 (18.6)
25–35	178 (59.1)
Above 35 years	67(22.3)
Marital status	
Not married	13 (4.3)
Married	288 (95.7)
Education background	
Primary education	83(27.6)
Secondary education	138 (45.9)
University education	80(26.6)
Occupation	
Unemployed	62 (20.6)
Employed	63 (20.9)
Entrepreneurship	176 (58.5)
Residence	
Rural	54(17.9)
Urban	247(82.1)

Clinical characteristics of participants

Multigravida women constituted the majority of participants (82.4%), with a median gravidity of 3. Similarly, multiparous women accounted for the largest proportion (55.2%), with a median parity of 2. Most pregnancies were at term (60.8%). The majority of participants (74.8%) had no history of hypertension before the index pregnancy, and most (81.4%) reported no family history of hypertension. More than half of the participants (59.1%) had no prior use of antihypertensive medication, while 40.9% reported previous antihypertensive use. Notably, most participants (94.4%, n = 284) had no history of other medical illnesses. The mean systolic and diastolic blood pressures were 153.0 mmHg and 99.0 mmHg, respectively. These clinical and obstetric characteristics are summarized in Table 2.

Table 2
Clinical characteristics of participants (n = 301)

Variable	n (%)/median (IQR)/mean
Referral status	
No	210 (69.8)
Yes	91 (30.2)
Gravidity (median, IQR)	3, 2–4
Gravidity category	
Primigravida	53 (17.6)
Multigravida	248 (82.4)
Parity (median, IQR)	2, 1–3
Parity category	
Nullipara	68 (22.6)
Primipara	67 (22.3)
Multipara	166 (55.2)
Gestational age (median, IQR)	38, 35–39
Gestational age category	
Early preterm (28 to < 34 weeks)	60 (16.9)
Late preterm (34 to < 37 weeks)	55 (18.3)
Term (37 to < 42 weeks)	183 (60.8)
Post-term (≥ 42 weeks)	3 (1.0)
History of antihypertensive use	
No	178 (59.1)
Yes	123 (40.9)
History of hypertension before pregnancy	
No	225 (74.8)
Yes	76 (25.3)
Family history of hypertension	
No	245 (81.4)
Yes	56 (18.6)

Variable	n (%)/median (IQR)/mean
History of medical illness	
No illness	284 (94.4)
Illness (diabetes, renal disease, and autoimmune disease)	17 (5.7)
Systolic blood pressure (mean ± SD)	153.4, 13.7
Diastolic blood pressure (mean ± SD)	99.1, 11.2

Note: IQR = interquartile range

Diagnostic Performance of Dipstick Tests

Both tests showed moderate accuracy. The automated analyzer had slightly higher sensitivity (62.1% vs. 55.8%) and AUC (0.68 vs. 0.66), with identical specificity (75.4%). PPV was high (90.9% vs. 89.9%), but NPV was low (33.6% vs. 30.3%), indicating limited ability to rule out significant proteinuria. Tables 3 and 4 and Fig. 1 present the results.

Table 3: Diagnostic Performance of Visual Urine Dipstick Testing

Visual dipstick	UPCR ≥30 mg/mmol	UPCR <30 mg/mmol
Positive (≥2+)	134	15
Negative (<2+)	106	46

Diagnostic performance

- Sensitivity = 55.8% (95% CI: 49.3–62.2%)
- Specificity = 75.4% (95% CI: 62.7–85.5%)
- PPV = 89.9% (95% CI: 83.9–94.3%)
- NPV = 30.3% (95% CI: 23.1–38.2%)
- LR+ = 2.27 (95% CI: 1.44–3.57)
- LR− = 0.59 (95% CI: 0.48–0.72)
- Diagnostic odds ratio = 3.88 (95% CI: 2.07–7.27)
- AUC = 0.66 (95% CI: 0.59–0.72)
- Cohen's κ = 0.20 (95% CI: 0.11–0.29)

Table 4. Diagnostic Performance of Automated Urine Dipstick Testing (threshold ≥2+)

Automated dipstick	UPCR ≥30 mg/mmol	UPCR <30 mg/mmol
Positive (≥2+)	149	15
Negative (<2+)	91	46

Diagnostic performance

- Sensitivity = 62.1% (95% CI: 55.6–68.2%)
- Specificity = 75.4% (95% CI: 62.7–85.5%)
- PPV = 90.9% (95% CI: 85.4–94.8%)
- NPV = 33.6% (95% CI: 25.7–42.1%)
- LR+ = 2.52 (95% CI: 1.61–3.96)
- LR− = 0.50 (95% CI: 0.41–0.62)
- Diagnostic odds ratio = 5.02 (95% CI: 2.67–9.44)
- AUC = 0.69 (95% CI: 0.63–0.75)
- Cohen's κ = 0.26 (95% CI: 0.16–0.35)

Statistical comparison between ROC curves

Comparison of ROC curves using the DeLong test demonstrated that the automated urine dipstick analyzer had a slightly higher AUC (0.6875; 95% CI: 0.6249–0.7500) than the visual urine dipstick test (0.6562; 95% CI: 0.5933–0.7191). However, the difference was not statistically significant ($\chi^2 = 1.48$, df = 1, p = 0.224), indicating comparable overall diagnostic performance between the two methods.

Urine dipstick threshold trade-off

Table 5 demonstrates the diagnostic trade-off across increasing proteinuria thresholds. Lower thresholds improve sensitivity at the expense of specificity, while higher thresholds markedly improve specificity but substantially reduce sensitivity. The ≥2+ threshold provides the most balanced performance for both visual and automated methods in this study population.

Table 5. Visual Dipstick Performance across Thresholds

Threshold	Visual Sensitivity (%)	Visual Specificity (%)	Automated Sensitivity (%)	Automated Specificity (%)
Trace	74.2	47.5	78.3	44.3
1+	67.5	60.7	71.2	58.2
2+	55.8	75.4	62.1	75.4
3+	37.9	91.8	43.3	90.2
4+	13.3	95.1	18.7	94.3

Discussion

The prevalence of significant proteinuria was high (79.7%) among women with hypertensive disorders of pregnancy, reflecting the clinical profile of the population in which preeclampsia predominated. Screening for proteinuria in women with HDP remains clinically important because it helps to identify women with renal dysfunction, supports the diagnosis of preeclampsia, and guides clinical management.

Overall, both visual and automated urine dipstick tests demonstrated moderate diagnostic performance. The automated method showed slightly higher sensitivity (62.1% vs. 55.8%) and AUC (0.69 vs. 0.66) than the visual method, while both methods had identical specificity (75.4%). In addition, both methods demonstrated high PPV (90.9% and 89.9%) but low NPV (33.6% and 30.3%). These findings indicate that positive urine dipstick results substantially increase the probability of significant proteinuria; however, confirmation using a quantitative method such as the UPCR remains desirable whenever available. Conversely, negative dipstick results do not reliably exclude significant proteinuria, particularly in high-risk populations such as women with hypertensive disorders of pregnancy.

The high prevalence of significant proteinuria in our study population likely contributed to the low negative predictive values observed for both methods, since predictive values are influenced by disease prevalence whereas sensitivity and specificity remain relatively stable (35). Despite these limitations, urine dipstick testing remains widely used in resource-limited settings because it is inexpensive, rapid, easy to perform, and often the only available point-of-care screening test.

These findings are consistent with previous systematic reviews reporting variable diagnostic performance of dipstick testing (27–29). Although the automated urine dipstick demonstrated slightly higher sensitivity and AUC than the visual method, the difference was not statistically significant. This suggests that automation alone is not superior to visual interpretation when testing is performed under standardized conditions by observers with normal color vision and adequate lighting, as was done in the present study. Because both methods rely on the same reagent strip technology, similar overall diagnostic performance is expected. Similar findings have been reported in previous studies, where automated readers improved consistency of interpretation but provided only limited improvement in diagnostic accuracy compared with visual interpretation (36).

False-negative results are clinically concerning, as delayed diagnosis of preeclampsia may worsen maternal and fetal outcomes (16, 17). Quantitative methods such as UPCR demonstrate higher diagnostic reliability (20, 21).

The dipstick test showed a fair agreement with the UPCR test, with kappa coefficients of 0.20 for visual interpretation and 0.26 for automated analysis. The observed fair agreement indicates that urine dipstick results should not be considered interchangeable with quantitative UPCR measurements.

Importantly, analysis across thresholds demonstrated the classical diagnostic trade-off. Lower thresholds increased sensitivity but resulted in higher false-positive rates. Conversely, higher thresholds substantially improved specificity but reduced sensitivity, limiting their value as screening cut-offs.

Our data suggest that the ≥ 2 + threshold provides the best balance between sensitivity and specificity and should be considered the preferred threshold when quantitative testing is unavailable, in line with international recommendations (37, 38).

Clinical implications

The findings of this study have important implications for clinical practice in resource-limited settings. The high positive predictive values observed for both visual and automated urine dipstick tests suggest that positive results are strongly associated with significant proteinuria. However, the low negative predictive values indicate that negative dipstick results cannot reliably exclude disease. Therefore, women with persistent hypertension and clinical suspicion of preeclampsia should undergo quantitative proteinuria assessment whenever available. Where UPCR testing is unavailable, urine dipstick testing remains a useful screening tool but should be interpreted alongside clinical findings and blood pressure measurements.

Strengths and limitations

A major strength of this study is the direct comparison of visual and automated urine dipstick methods against the urine protein-creatinine ratio (UPCR) among women with hypertensive disorders in pregnancy. In addition, the study enrolled more participants than the minimum calculated sample size, increasing the precision of diagnostic accuracy estimates. The use of ROC analysis, LR, and agreement statistics provided a comprehensive evaluation of test performance.

Nevertheless, several limitations should be considered. First, the study was conducted at a single tertiary referral hospital, which may limit generalizability to lower-level facilities. Second, the high prevalence of significant proteinuria in the study population may have influenced predictive values. Finally, 24-hour urine protein estimation was not performed; however, UPCR is currently recognized as an acceptable quantitative alternative for assessing significant proteinuria in pregnancy.

Conclusion

Urine dipstick testing demonstrates moderate diagnostic accuracy for detecting significant proteinuria among women with hypertensive disorders in pregnancy. Both visual and automated urine dipstick methods showed comparable diagnostic performance, with no statistically significant difference observed between them. While positive dipstick results were strongly associated with significant proteinuria, the low negative predictive values indicate that neither method reliably rules out significant proteinuria. Therefore, urine dipstick testing should be considered a screening tool rather than a definitive diagnostic method. Quantitative assessment using urine protein-creatinine ratio remains the preferred approach whenever available.

Declarations

Data availability

The data used to support the findings of this study are available from the corresponding author upon request. Consent for publication**:** Not applicable.

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Authors' Contributions

IB is the principal researcher in this work with RK and BK as co-researchers. RK is the guarantor of this manuscript. RK, BK, FM, DM, and ED collaborated in the preparation of this manuscript All the authors approved the final manuscript.

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Ethical approval, consent to participate, and publication

Ethical approval to conduct this study and permission to publish the research findings were obtained from the Joint CUHAS/BMC Research Ethics and Review Committee with a certificate number CREC/896/2025.

Written informed consent to participate in this study and permission to publish the findings were also obtained from all participants prior to enrollment. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Conflict of interest:

The authors declare that there are no financial or non-financial conflicts of interest regarding the publication of this manuscript.

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Figures

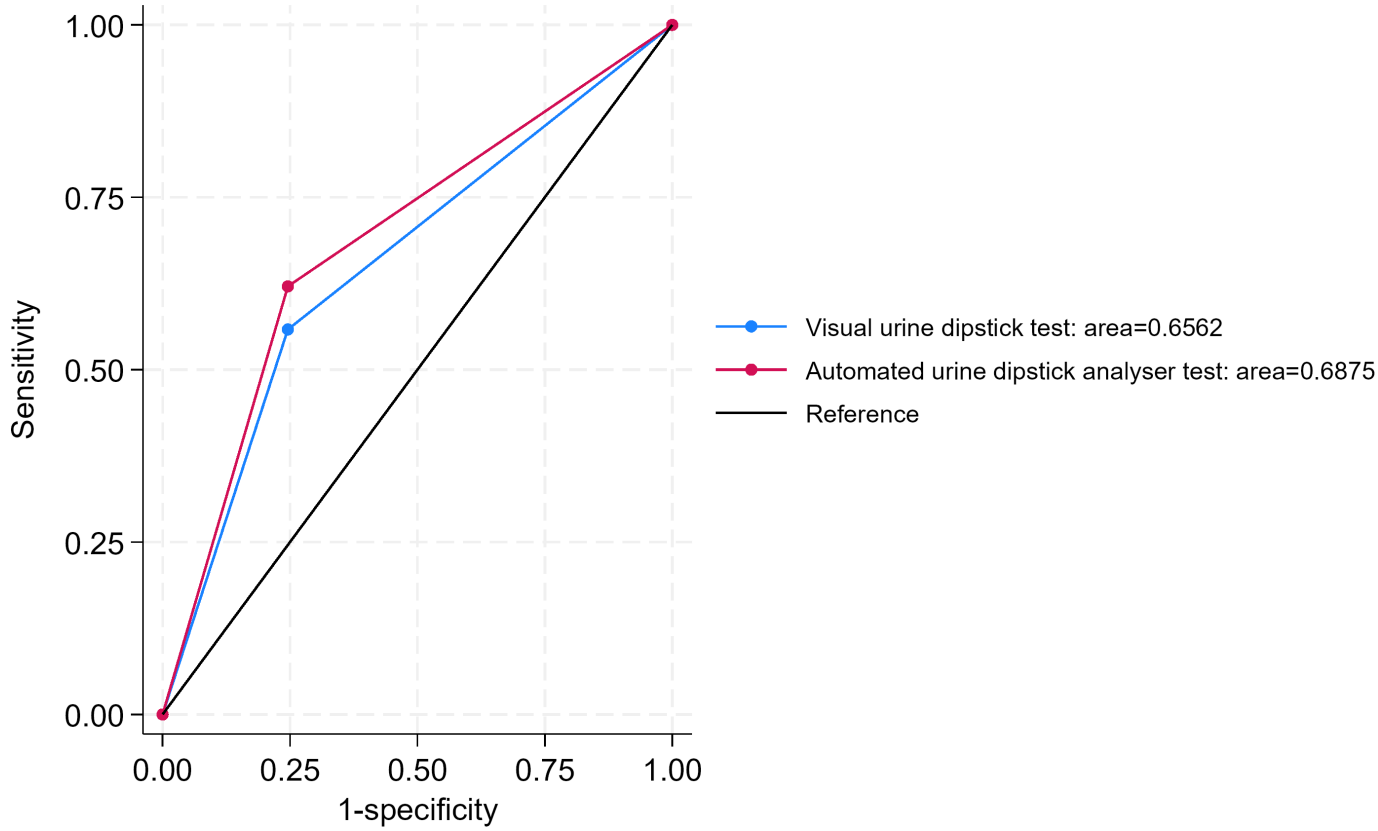


Figure 1

ROC Curve Comparison of Visual and Automated Urine Dipstick Tests