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Innovative Approach to Bedside Urinary Diagnostics: Prospective Study of Diaper-Embedded Test Strips

Ashra Barengodi[1], Prabha Adhikari1, Vinitha R Pai[2]

[1]Department of Geriatric Medicine, Yenepoya Medical College Hospital, Yenepoya Deemed to be University, Mangalore, Karnataka, India;
[2]Department of Biochemistry, Yenepoya Medical College Hospital, Yenepoya Deemed to be University, Mangalore, Karnataka, India

Correspondence:
Prabha Adhikari, Department of Geriatric Medicine, Yenepoya Medical College Hospital, Yenepoya Deemed to be University, University Road, Deralakatte, Mangalore, Karnataka, 575018, India Email prabha.raghuveer@gmail.com

ABSTRACT

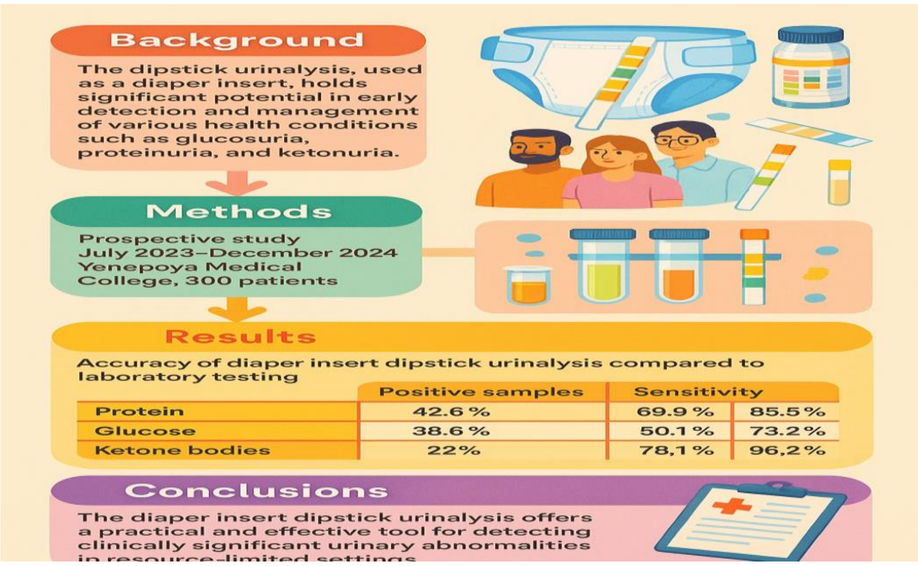
Background: The most often requested test in many developing nations, particularly in lower-level medical facilities, is the dipstick urinalysis. The dipstick test, when used as a diaper insert, holds significant potential in early detection and management of various health conditions such as glucosuria, proteinuria, and ketonuria. By providing a convenient, non-invasive method of monitoring urine composition, it can help identify abnormalities in the urinary system. This could lead to earlier interventions, potentially reducing the number of patients requiring more invasive or complex treatments for these conditions. The integration of this technology into daily life allows for continuous monitoring, improving disease management and preventing complications associated with untreated urinary tract or metabolic disorders.

Methods: A prospective study was conducted between July 2023 and Deember 2024. The study involved 300 patients attending Yenepoya Medical College, Deralakatte. The samples were subjected to dipstick urinalysis as diaper insert (Protien, ,Glucose, and Ketone bodies) and quantitative laboratory urine analysis method.

Results : In this study, we evaluated the accuracy of diaper insert dipstick urinalysis compared to laboratory spot testing for detecting urinary protein, glucose, and ketone bodies. Laboratory testing identified 133 (44.3%) positive samples for protein, 123 (41%) for glucose, and 66 (22%) for ketone bodies, while diaper insert dipstick testing identified 128 (42.6%), 116 (38.6%), and 73 (24.2%) positive samples for the same parameters, respectively. The sensitivity, specificity, and accuracy of urine dipstick tests in this study were high for glucose (96.2%, 100%, and 98.3%, respectively) and ketone bodies (90.4%, 100%, and 97.7%), indicating excellent diagnostic performance, while protein testing showed good sensitivity (87%), specificity (94.9%), and accuracy (91.7%), making all three reliable tools for screening metabolic and renal abnormalities with slight variation in their false positive and false negative rates.

Conclusions: Urine dipstick tests for glucose, protein, and ketone bodies provide rapid and practical screening tools exhibiting generally high sensitivity, specificity, and accuracy, making them effective for early detection and monitoring of metabolic and renal conditions, though confirmatory testing remains essential to address limitations related to false positives and negatives.

KEYWORDS: Urine Dipstick Test, Diagnostic Sensitivity, Specificity and Accuracy, Glucose Monitoring, Proteinuria Screening, Ketone Body Detection.



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BACKGROUND

Urinary tract infections (UTIs) are among the most common bacterial infections worldwide, presenting a significant burden on healthcare systems, especially in populations such as the elderly, infants, and individuals with cognitive or physical impairments who may have difficulty articulating their symptoms (1,2). Early and accurate detection of UTIs is crucial to prevent complications such as pyelonephritis, sepsis, and chronic kidney disease, particularly in these vulnerable groups (3). Dipstick urine analysis has emerged as a widely used, affordable, and rapid method for UTI screening, demonstrating notable effectiveness in elderly populations (4). This method relies on the detection of surrogate markers such as leukocyte esterase and nitrites, which are indicative of infection, and its simplicity and immediacy make it particularly valuable in settings where laboratory infrastructure is limited or where rapid clinical decisions are needed (5).

Despite the utility of dipstick testing, the gold standard for UTI diagnosis remains urine culture, which is time-consuming and resource-intensive (5). Automated urine analyzers have been developed to improve screening performance and throughput, providing reliable results in clinical laboratories; however, these analyzers are not designed for point-of-care testing (POCT), limiting their use in bedside or remote environments where immediate screening is essential (6). The need for accessible, rapid, and user-friendly diagnostic tools has spurred innovation in POCT technologies, including the development of diaper-embedded test devices that integrate urine collection and analysis into a single, non-invasive platform (7,8). Such devices have the potential to revolutionize UTI screening by enabling continuous monitoring, particularly in populations where traditional urine sampling is challenging or impractical (9).

The diagnostic effectiveness of diaper-embedded test devices for detecting UTIs, especially in critically ill patients, remains an area of active investigation. While these devices offer the promise of immediate, on-site screening, studies assessing their sensitivity, specificity, and overall clinical utility are limited (7,8). This gap in evidence is particularly pertinent given the unique challenges associated with UTI diagnosis in the elderly. A substantial proportion of older adults, especially those residing in nursing homes, exhibit asymptomatic bacteriuria—a condition characterized by the presence of bacteria in the urine without clinical symptoms of infection (10,11). A Belgian study highlighted the high prevalence of asymptomatic bacteriuria in female nursing home residents with urinary incontinence or significant dependency and disorientation, reporting rates as high as 80–90% (12). This phenomenon complicates the interpretation of positive urine tests and underscores the need for diagnostic tools that can reliably distinguish between colonization and true infection (13).

The clinical implications of asymptomatic bacteriuria are significant. Overdiagnosis and overtreatment can lead to unnecessary antibiotic use, contributing to the growing problem of antimicrobial resistance (14). Conversely, underdiagnosis may result in missed opportunities for intervention in those who are truly infected (15). Therefore, a nuanced approach to UTI screening is required, one that balances the risks and benefits of treatment while accounting for the unique characteristics of at-risk populations (16). In this context, rapid and simple urinary screening methods are urgently needed for individuals who may not present with specific symptoms or who are unable to communicate their discomfort, such as infants, children, and the elderly with cognitive impairment (13,17). POCT technologies, including urine dipsticks, have facilitated faster diagnosis and more timely treatment decisions, improving patient outcomes in both hospital and community settings (18).

For a practical and effective UTI screening solution, it is essential to integrate urine sampling, testing, and analysis into a streamlined process that minimizes patient discomfort and maximizes diagnostic yield (19). This is particularly important for populations who face barriers to conventional sample collection, such as those with mobility limitations, incontinence, or severe illness (20). Diaper-embedded dipstick tests represent a promising step forward, offering a convenient, non-invasive means of continuous urine monitoring (21). Beyond UTI detection, these devices can also screen for metabolic abnormalities such as glucosuria, proteinuria, and ketonuria, providing early warning signs of systemic diseases like diabetes and renal dysfunction (22). By enabling early identification of urinary and metabolic abnormalities, such technologies may facilitate prompt intervention, reduce the need for invasive diagnostics, and ultimately decrease the incidence of complications associated with untreated conditions (23).

The integration of POCT devices into daily life, particularly in institutional and home care settings, has the potential to transform disease management and preventive care (24). Continuous, real-time monitoring can alert caregivers and healthcare providers to emerging health issues before they progress to more severe stages, supporting proactive rather than reactive medical interventions (25). Moreover, the widespread adoption of such technologies aligns with broader trends in digital health and personalized medicine, empowering patients and caregivers with actionable health information. As research continues to evaluate and refine the diagnostic performance of diaper-embedded urine tests, these innovations are poised to play a central role in the early detection and management of UTIs and related disorders, especially among those most at risk.

METHODS

Study design and population

This prospective study focused on elderly patients admitted to Yenepoya Medical College Hospital, Mangalore, with participants recruited between June 2023 and December 2024. The study was approved by the Ethics Committee of Yenepoya Medical College Hospital (decision number YEC-1/2021/058), and only those patients who provided informed consent were enrolled in the study. The study was in compliance with the ethical principles in accordance with the Declaration of Helsinki for medical research of human samples. The demographic details, including age and gender, were collected from patient records. The researchers systematically recorded the results from two different methods of urine analysis: the diaper-embedded test strips and the automated urine dipstick test. Automated urine analysis results were obtained from the hospital's central laboratory to provide comparative data. This multi-method approach allowed for a thorough evaluation of urine testing techniques in the elderly population.

Urine sample collection

For each patient, mid-stream urine (MSU) samples were collected in two sterile containers to ensure proper testing. One of the containers was promptly transported to the testing laboratory within two hours of collection, where it was processed according to standard laboratory procedures for urine analysis. The second container was used by the researcher for an alternative analysis method. In this case, the researcher poured the urine sample directly into the patient's diaper. This approach allowed the researcher to assess the urine using the diaper-embedded test strips, which functioned as a point-of-care diagnostic tool to detect various urinary parameters. This dual collection method ensured both conventional laboratory analysis and an innovative testing approach using the diaper insert for comparison.

Standardized procedure

In the present research, two methods to urine sampling were compared: sterile containers and the diaper-based approach to ensure accurate and consistent results. The test strip was inserted into the pad, ensuring it rests on the outermost layer of the pad, avoiding contact with the cotton padding to prevent contamination Then placed the sanitary pad with the urine analysis strip on the diaper, ensuring direct contact between the strip and the urine sample. Pre-marked the test area on the diaper for repeatable placement. Next, poured a fixed volume of urine to the designated area using a measuring tool, ensuring even distribution without over- or under-saturating the diaper. Allow the strip to incubate for the time recommended by the manufacturer, 60 seconds, using a timer for accuracy. After incubation, carefully remove the strip without scraping its surface and blot excess urine using a consistent technique on a clean tissue. Finally, observed and recorded the test results at the manufacturer's recommended time, using a standardized light source to prevent colour interpretation errors. Consistency in every step was maintained, from placement to observation, is key to obtaining reliable results.

Laboratory urine analysis method for Glucose, Protein and Ketone bodies

Urine analysis using strips with an automated machine was conducted in the laboratory following standard procedures. A fresh urine sample was collected in a clean, labeled container, ensuring it was free from contaminants. The urine analyzer was powered on, calibrated with control solutions, and checked for cleanliness and functionality. Compatible reagent strips were loaded into the designated slot, ensuring proper handling to maintain their sensitivity. The urine sample was transferred using a pipette, ensuring no cross-contamination. The machine analyzed the sample by applying it to the strip and detecting color changes using photometric or reflectance technology. Results for parameters such as glucose, protein and ketonr bodies were displayed and saved electronically. The results were validated using control samples and clinical standards, documented, and reported appropriately. After the analysis, the machine was cleaned as per the manufacturer's guidelines, and used strips were disposed of in biohazard waste bins.

Statistical analysis

We compared the diagnostic accuracy of the two different urine tests in the urine analysis based on 2-way comparisons. For each urine test, the sensitivity (probability that a test result will be positive in both the methods i.e as a spot test and as diaper inserts), specificity (probability that a test result will be negative as a spot test when tested in the diaper embedded test) and accuracy were calculated with a 95% confidence interval. All the comparisons were made for detection of protein, glucose,ketone bodies level separately. The sample size was determined based on the assumption that 30% of geriatric patients require a diaper change, using the following formula. Data from test strips were compared with results from standard laboratory urinalysis.

Data collected from test strips were compared with those obtained through the standard laboratory urinalysis method. To compare test strip performance as diaper insert regarding protein, glucose, and ketone bodies with the laboratory reference standard, we used contingency (2 × 2) tables

RESULTS

In this study 300 geriatric patients were recruited for the estimation of Glucose, Protein and Ketone Bodies as spot and diaper samples. Unclear or partially wet urine analysis strips were excluded

In the present study, routine urine analysis strips (Combur M test strips) were used to compare the accuracy of urine parameters detection via spot testing and diaper inserts. Results were categorized as true positive (degree of concentrations), true negative, or trace based on strip readings.

Analysis of glucose, protein and ketone bodies in urine

The urinary glucose, protein, and ketone bodies were analysed as follows: Urine samples positive for these three parameters showed concentration depended change in colour which was reported as 1+/2+/3+ (semi-quantitative) based on the intensity of the colour obtained which was compared with the colour index given by the manufacturer of the strip. The samples negative for these parameters did not show any colour change.

Detection of glucose protein and ketone body in urine

Table 1 shows majority of the samples were negative for all three parameters by both spot test and diaper embedded strip method. However, analysis for glucose and protein, showed higher positive results in spot method as compared to the diaper embedded strip method, while ketone bodies showed more positive cases in diaper embedded strip method than in the spot method. Comparison of the analysis by the two methods was found to be non-significant for all the three parameters: glucose (p=0.6805), protein (p=0.5594), and ketone bodies (p=4982).

These findings indicate that detection of glucose, protein and ketone bodies by diaper embedded strip method yields results comparable to that obtained by spot urine samples by laboratory method, demonstrating their suitability as an alternative method for routine biochemical screening in clinical and geriatric research settings.

Table 1 Comparison of urine glucose, protein and ketone bodies between spot test and diaper embedded strip method N= 300

The data is expressed in frequency (f) and percentage (%) in parenthesis. Urine glucose, protein and ketone bodies detection was compared using spot test and diaper

Sl. No	Parameters	Results (%)				p value
		Negative		Positive		
1.	Glucose	Spot	167 (55.7)	Spot	133 (44.3)	0.6805
		Diaper	172 (57.3)	Diaper	128 (42.6)	
2.	Protein	Spot	177 (59.0)	Spot	123 (41.0)	0.5594
		Diaper	184 (61.3)	Diaper	116 (38.6)	
3.	Ketone Bodies	Spot	234 (75.7)	Spot	66 (22.0)	0.4982
		Diaper	227 (78.0)	Diaper	73 (24.3)	

embedded strip methods. Statistical test used: Chi-square. Level of significance: *$p<0.05$ was considered significant, $p>0.05$ was considered non-significant.

Semi quantitative estimation of urinary glucose, protein and ketone bodies

The semi quantitative analysis was done for those urine samples positive for glucose
(i) spot test (n= 133) (ii) diaper embedded strip method (n=128), protein (i) spot test (n=123) (ii) diaper embedded strip method (n=116), and for ketone bodies (i) spot test (n=66) (ii) diaper embedded strip method (n=73).

Table 2 shows the distribution of intensity levels (1+, 2+, and 3+) for glucose, protein, and ketone bodies analysed by both the spot urine method and the diaper embedded strip method. Overall, higher intensity grades (2+) were more frequent by spot test for glucose and protein, and the diaper embedded strip method also demonstrated relatively higher distribution of moderate positivity (2+) for these parameters. In contrast, for ketone bodies, majority of the samples displayed highest intensity (3+) compared to the spot method.

These observations suggest that both methods show a similar grading pattern of biochemical positivity, with minor variations in intensity distribution across parameters. The diaper embedded strip method therefore appears to provide a reliable semi-quantitative assessment of glucose, protein, and ketone bodies comparable to conventional spot urine testing.

Table 2 Semi quantitative estimation of urinary glucose, protein and ketone bodies between spot test in the laboratory and diaper embedded strip method

Sl. No	Parameter	n=positive samples	Test method used	Results (%)		
				3+	2+	1+
1.	Glucose	133	Spot	44 (33.0)	51 (38.3)	38 (28.5)
		128	Diaper	42 (32.8)	64 (50.0)	25 (19.5)
2.	Protein	123	Spot	38 (30.8)	62 (50.4)	23 (18.6)
		116	Diaper	66 (56.8)	30 (25.8)	20(17.2)
3.	Ketone Bodies	66	Spot	28 (42.4)	14 (21.2)	24 (36.3)
		73	Diaper	38 (52.0)	13 (17.8)	21(28.7)

The data is expressed in frequency (f) and percentage (%) in parenthesis. Analysis of urine protein, glucose, ketone body using (i) spot test and (ii) diaper insert methods are compared. Analysis was done semi-quantitatively as follows: 3+is the highest concentration, 2+is moderate and 1+ indicates the lowest concentration in urine sample based on the colour obtained in the strip and compared with the index given by the manufacturer.

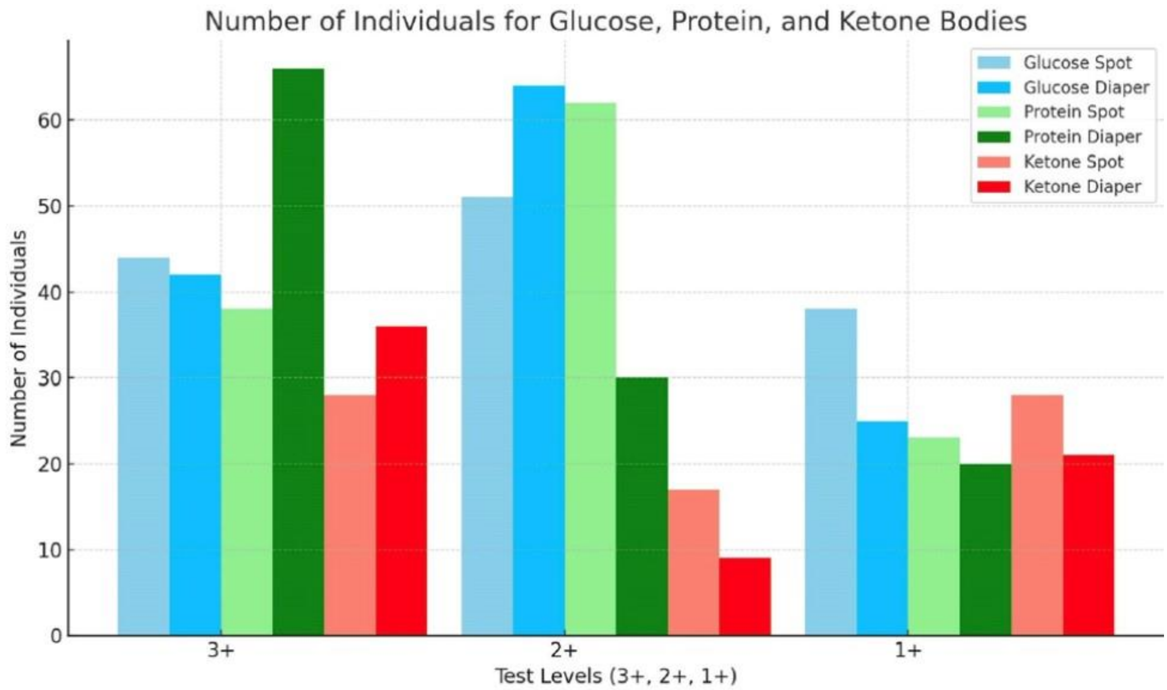

Fig 1 : This bar

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The levels are categorized into three test ranges: 3+, 2+, and 1+, which likely indicate increasing concentrations of these substances.Glucose: Diaper samples seem to dominate at middle concentrations (2+). Protein: Diaper samples generally have higher concentrations (3+ and 2+). Ketones: Spot samples show a higher prevalence at high concentrations (3+ and 2+), with less difference at 1+.

Table 3 Sensitivity, specificity and accuracy of Urine analysis as diaper insert for the detection of Glucose, Protein and ketonebodies

Test	Sensitivity		Specificity		Accuracy (%)
	Estimate	95% CI	Estimate	95% CI	
Glucose	96.2	(91.5, 98.4)	100	(97.8, 100.0)	98.3
Ketone	90.4	(81.5, 95.3)	100	(98.3, 100.0)	97.7
Protein	87	(79.9, 91.8)	94.9	(90.6, 97.3)	91.7

The table 3 presents the diagnostic performance of three tests—Glucose, Ketone, and Protein—based on sensitivity, specificity, and accuracy. Sensitivity measures the test's ability to correctly identify those with the condition, with Glucose showing the highest sensitivity at 96.2%, followed by Ketone at 90.4%, and Protein at 87%. This means that the Glucose test has the lowest chance of missing true positive cases among the three tests. The 95% confidence intervals indicate the statistical range in which the true sensitivity values lie, showing high precision for all tests.

Specificity, which reflects the ability of the test to correctly identify those without the condition (true negatives), is perfect (100%) for both Glucose and Ketone tests, meaning they accurately classify all healthy individuals as negative. The Protein test shows slightly lower specificity at 94.9%, indicating some false positives might occur. High specificity is critical to avoid unnecessary further testing or treatments for individuals who do not have the condition.

Accuracy represents the overall correctness of the test in classifying individuals as either positive or negative. Here, the Glucose test has the highest accuracy at 98.3%, closely followed by Ketone at 97.7%, and Protein at 91.7%. These results suggest that all three tests are generally reliable, with Glucose performing best, combining strong sensitivity and perfect specificity, while Protein is somewhat less accurate but still acceptable for clinical use. The confidence intervals for sensitivity and specificity reinforce the reliability of these estimates within the given ranges.

DISCUSSION

Glucose Testing

The glucose dipstick test in this study demonstrated a high sensitivity of 96.2%, perfect specificity of 100%, and an overall accuracy of 98.3%. These values indicate that the test is highly effective at correctly identifying individuals with elevated glucose levels while minimizing false positives(29-32). The excellent sensitivity makes it a valuable screening tool for diabetes mellitus and related hyperglycemic conditions. However, factors such as renal glucose threshold variability, acute stress, and interfering substances can affect results(33-37). Therefore, positive glucose dipstick results require confirmation using more specific methods such as fasting plasma glucose or glycated hemoglobin (HbA1c) assays, aligning with recommendations from diabetes guidelines(38-40).

Protein Testing

Protein dipstick testing showed strong diagnostic performance with a sensitivity of 87%, specificity of 94.9%, and accuracy of 91.7%. The high sensitivity supports its utility as an initial screening tool for proteinuria, a critical marker for renal impairment especially in diabetic nephropathy(41-46). However, the moderate specificity suggests some false positives that may arise due to conditions like urinary tract infections, contamination, or physiological variances(47,48). The dipstick's semi-quantitative nature and influence of urine concentration and pH may cause variability, underscoring the need for confirmatory quantitative tests like urine protein-to-creatinine ratio or 24-hour collections in clinical practice(49-52).

Despite these limitations, the high sensitivity of the dipstick protein test makes it an excellent initial screening tool, especially in resource-limited settings or for large-scale population screening (53). However, positive results should be interpreted with caution and confirmed with quantitative methods, particularly when clinical suspicion for kidney disease is high (54).

Ketone Body Testing

The ketone dipstick demonstrated a sensitivity of 90.4%, perfect specificity of 100%, and accuracy of 97.7%, indicating strong overall diagnostic reliability. This suggests the test is excellent at detecting elevated ketone bodies commonly seen in diabetic ketoacidosis and other metabolic conditions while effectively ruling out false positives(55-59). The slightly lower sensitivity compared to specificity suggests some mild ketosis cases might be missed. Limitations include detection primarily of acetoacetate rather than beta-hydroxybutyrate, the latter being predominant in severe ketoacidosis(610,61). Recent advancements in enzymatic assays may enhance detection accuracy. Regular ketone monitoring is essential in diabetic patients for timely detection and management of ketoacidosis(62,63).

Future Directions

To improve the diagnostic accuracy of these tests, further research should focus on:

1. Developing more specific biomarkers: For instance, integrating advanced proteomic or metabolomic techniques may improve test specificity (McMahon et al., 2020)[10].
2. Exploring the impact of clinical variables: Studies investigating the influence of co-morbidities, medications, and demographic factors on test performance would provide valuable insights into optimizing their use in diverse populations.
3. Combining tests: Using these tests in conjunction with other diagnostic tools may enhance overall accuracy and reduce false positives or negatives.
4. Adopting newer technologies: The use of enzymatic assays, fluorescence-based methods, or point-of-care testing devices with higher precision could further enhance diagnostic outcomes.

While glucose, protein, and ketone body tests provide essential information for clinical decision-making, their limitations in specificity—especially for glucose and protein—highlight the need for supplementary testing and innovative approaches to improve their diagnostic utility.

CONCLUSION

This study evaluated urine dipstick testing for glucose, protein, and ketone bodies, assessing their diagnostic performance and comparative results between spot and diaper samples. The data revealed similar positivity rates across sample types for each parameter, with no statistically significant differences ($p > 0.05$). For glucose, positive results were observed in 44.3% of spot samples and 42.6% of diaper samples. Protein positivity was found in approximately 41.0% (spot) and 38.6% (diaper), while ketone bodies were detected in 22.0% (spot) and 24.3% (diaper) of samples. These comparable results support the reliability of both sampling methods in clinical or geriatric settings.

The glucose dipstick demonstrated excellent sensitivity (96.2%) and perfect specificity (100%), with an overall accuracy of 98.3%, affirming its value as a highly sensitive screen for hyperglycemia and diabetes mellitus. Protein testing showed high sensitivity (87%) and good specificity (94.9%), alongside 91.7% accuracy, making it a useful initial screen for proteinuria related to renal impairment, despite potential false positives. Ketone body detection exhibited both high sensitivity (90.4%) and perfect specificity (100%), with accuracy of 97.7%, underscoring its importance for timely identification of ketosis and diabetic ketoacidosis. Together, these findings emphasize the clinical utility of urine dipstick testing as rapid, cost-effective tools for diagnosing key metabolic and renal abnormalities.

Despite strong diagnostic performance, dipstick tests have inherent limitations. Factors such as urine concentration, pH variability, physiological conditions, or contamination can influence results, leading to occasional false positives or negatives. The semi-quantitative nature of dipstick assays necessitates that positive findings be confirmed using more specific, quantitative laboratory methods for accurate diagnosis and management, particularly in high-risk or symptomatic patients. Clinical correlation with patient history and symptoms remains essential to guide appropriate interpretation and follow-up testing.

In conclusion, urine dipstick tests for glucose, protein, and ketones maintain a critical role in routine screening and early detection of metabolic and renal disorders. The comparable performance of spot and diaper samples further broadens their applicability in various patient populations. Careful application of these tests, combined with confirmatory assays and clinical evaluation, can optimize diagnostic accuracy and patient outcomes. Future advances in dipstick technology hold promise to enhance sensitivity and specificity further, strengthening the impact of point-of-care urine analysis in healthcare.

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Disclosure
The authors report no conflicts of interest in this work.

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