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ORIGINAL RESEARCH

A Prospective Study on the Predictive Validity of Urine Dipstick Tests for Diagnosing Urinary Tract Infections in Children

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ABSTRACT

Background: Urinary tract infections (UTIs) are common in children and can lead to significant morbidity. Rapid and accurate diagnosis is essential for timely treatment and reducing complications. This study evaluates the predictive validity of urine dipstick tests for nitrites and leukocyte esterase (LE) in diagnosing UTIs compared to urine culture.**Methods:**A prospective study was conducted at the Department of Pediatrics, Southern Railway Headquarters Hospital, Chennai. A total of 186 children aged 3 to 12 years with suspected UTI were included. Urine samples were analyzed using dipstick tests for nitrites and LE, with urine culture as the reference standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated.**Result:**Nitrite test sensitivity was 82.19%, specificity 92.92%, PPV 88.24%, and NPV 88.98% ($P < 0.001$). LE test sensitivity was 87.67%, specificity 82.30%, PPV 76.19%, and NPV 91.18% ($P < 0.001$). Diagnostic accuracy for nitrites was 88.71% and for LE was 84.41%.**Conclusion:**Urine dipstick tests for nitrites and LE are reliable screening tools for UTIs in children, providing high specificity and reasonable sensitivity. They facilitate prompt treatment decisions, improving clinical outcomes.

Key words: Urinary Tract Infections, Pediatric, Urine Dipstick, Nitrites, Leukocyte Esterase, Diagnostic Accuracy.

INTRODUCTION

Urinary tract infections (UTIs) represent a significant and common health issue among children, with an overall prevalence ranging from 2% to 8% during childhood[1]. These infections can lead to severe long-term complications such as renal scarring, which may cause hypertension, proteinuria, and in severe cases, progressive renal failure. The risk of recurrent UTI in children during the first 6-12 months after an initial infection range from 12% to 30%[2]. The pathogenesis of UTIs in older children often involves the ascent of periurethral organisms, where bacterial virulence and host defense mechanisms play crucial roles.

UTIs are among the most common bacterial infections during childhood. In pediatric practice, when an infant presents with fever or an older child with urinary symptoms, 6%–8% of these cases will be UTIs[3]. The prevalence of UTIs varies with age, peaking in young infants, toddlers, and again in older adolescents. Females and uncircumcised male infants are more prone to UTIs due to anatomical factors, such as the shorter urethral length in females and the increased surface area of the foreskin in uncircumcised males. During the toddler years, toilet training can lead to bladder stasis and subsequent UTIs, while in adolescent females, sexual activity can introduce bacteria near the urethral orifice[4].

The risk of recurrent UTIs is significant, with over 30% of children experiencing recurrence. Factors contributing to recurrent UTIs include vesicoureteric reflux (VUR) and bladder-bowel dysfunction. By the age of seven, approximately 7.8% of girls and 1.7% of boys will have experienced a UTI. By the age of 16, these figures rise to 11.3% for girls and 3.6% for boys[5].

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The definitive diagnosis of UTI relies on urine culture, which involves identifying a significant number of bacteria or fungi in the urine. Early detection is crucial to prevent complications like renal scarring. However, urine culture is time-consuming, costly, and requires specialized microbiology laboratory facilities. The method and timing of urine sample collection are also critical for accurate diagnosis[6].

Upon the initial presentation of a suspected UTI, a urine dipstick test and microscopy are commonly performed for rapid diagnosis. The urine dipstick test is readily available, inexpensive, and is considered positive with the presence of leukocyte esterase (LE) and/or nitrite. These indicators are more reliable than the presence of blood and protein in diagnosing UTIs. Rapid urine tests, including dipstick and microscopy, can guide immediate therapy, especially in settings where urine culture facilities are not readily accessible[7].

The urine dipstick test is a rapid bedside method used to detect UTIs. Leukocyte esterase is a semi-quantitative test that detects esterase released from degraded white blood cells in the urine, indicating an immune response to infection. The nitrite test identifies nitrite produced by bacterial reduction of nitrate, which is not normally present in urine. A positive nitrite test suggests significant bacteriuria (>100,000/ml)[8].

Various factors can predispose children to recurrent UTIs, including vesicoureteral reflux and dysfunctional elimination. Escherichia coli (E. coli) is the most common causative organism, accounting for 60%–92% of pediatric UTI cases. Other common pathogens include Klebsiella, Proteus, Enterococcus, and Enterobacter species. Less common pathogens, such as Pseudomonas, Group B Streptococcus, and Staphylococcus aureus, are more frequently seen in children with anatomical abnormalities, kidney stones, or those who have undergone genitourinary surgery or bladder catheterization[9].

Given the high prevalence and potential severity of UTIs in children, early and accurate diagnosis is imperative. Untreated UTIs can lead to serious complications such as renal insufficiency or end-stage renal disease. The difficulty in diagnosing UTIs in very young children, who may be unable to articulate their symptoms, underscores the need for vigilant parental and physician observation to avoid missed infections and ensure early intervention. While urine culture remains the gold standard for diagnosing UTIs, its limitations necessitate the use of rapid and reliable screening tools like the urine dipstick test. This study aims to determine the predictive validity of the urine dipstick test, specifically the nitrite and leukocyte esterase tests, in diagnosing UTIs in children compared to urine culture and sensitivity, thereby potentially streamlining the diagnostic process and improving early treatment outcomes.

MATERIALS AND METHODS

Study Setting: This study was a hospital-based prospective observational study aimed at evaluating the predictive validity of the urine dipstick test as a rapid screening tool for diagnosing urinary tract infections (UTIs) among children. The study was conducted in the year 2022.

Study Place: The research was carried out at the Department of Pediatrics, Southern Railway Headquarters Hospital, Chennai. The study population consisted of pediatric patients with suspected UTI attending the outpatient department (OPD) or those admitted to the hospital.

Study Participants: Inclusion criteria included children aged between 2 and 12 years with signs and symptoms suggestive of UTI, and febrile children with no apparent focus of infection. Exclusion criteria were children under 2 years of age, due to decreased likelihood of urinary retention for the necessary four hours required for the nitrite test, and children with difficulty in urine collection, particularly those not yet toilet trained.

Sample Size: The sample size was calculated based on the expected prevalence of UTI, which was assumed to be 36.5%, according to the range reported by Deepthi Joella Fernandes et al [10]. The sensitivity and specificity of the urine dipstick test were considered 31.58% and 96.97%, respectively. Using a 95% confidence level and a precision of 12% for both sensitivity and specificity, the sample size was calculated. Based on this calculation, the required sample size was 158 subjects. To account for a non-participation rate of approximately 12%, an additional 20 subjects were included, bringing the final sample size to 180.

Sampling Technique: A consecutive sampling method was employed, where all eligible children presenting with symptoms suggestive of UTI or febrile illness without a clear source of infection were considered for inclusion until the desired sample size was achieved.

Study Methodology:

- **Data Collection**: Following informed parental consent, a detailed clinical history was taken, and a physical examination was performed. Comorbidities were noted, and a panel of investigations, including basic investigations like complete blood count, urine analysis, and renal function tests, was conducted. Ultrasonography of the abdomen and pelvis was performed for all children. As per the Indian Academy of Pediatrics (IAP) guidelines, a micturating cystourethrogram was done for eligible children.
- **Urine Sample Collection**: A clean-catch midstream or catheterized urine specimen was collected to minimize contamination by periurethral flora. Genitalia were washed with soap and water before sample collection. The samples were collected in sterile containers and sent to the clinical pathology and microbiology

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laboratories within two hours of collection. Urine culture specimens were plated within one hour of collection. If contamination was suspected (e.g., mixed growth of multiple pathogens), the urine culture was repeated.

- **Microscopic Analysis**: Urine samples were centrifuged, and the sediment was examined under a microscope. The microscopic analysis involved identifying and quantifying bacteria, cells, and other materials in the sediment. The presence of red blood cells (RBCs), white blood cells (WBCs), and bacteria was assessed.
- **Urine Dipstick Test**: The urine dipstick was dipped in the urine sample for 60 seconds to detect the presence of nitrites and leukocyte esterase (LE). A positive nitrite test was indicated by a color change to pink. Results were graded based on the intensity of the color change. Any color change other than colorless was considered positive.

Study Tools: The primary tools used in the study included urine dipstick tests for nitrite and leukocyte esterase, urine culture plates for microbial growth assessment, and microscopes for detailed urine sediment analysis. The urine dipstick tests were evaluated for their predictive validity in diagnosing UTIs compared to the gold standard urine culture.

Statistical Analysis: Descriptive statistics, including frequency and proportion for categorical variables were used. The Chi-square test was employed to test statistical significance. Urine culture was considered the gold standard, and the combined dipstick test was treated as a screening tool. Sensitivity, specificity, predictive values, and diagnostic accuracy of the dipstick test were calculated along with their 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS version 22.

Ethical Issues: The study protocol was reviewed and approved by the Institutional Human Ethics Committee. Informed written consent was obtained from the parents or guardians of all participants. The nature of the study, including potential risks and benefits, was explained thoroughly to the parents before obtaining consent. Participation was voluntary, and parents were assured that they could withdraw their child from the study at any time without affecting their medical care. All data were handled confidentially, and the identity of the participants was protected throughout the study.

RESULT

The study included 186 participants, with a majority (56.99%) aged between 6 and 10 years, followed by 36.02% in the 3 to 5 years age group, and only 6.99% older than 10 years. The gender distribution was nearly even, with 52.15% males and 47.85% females. Notably, 74.73% of participants experienced increased micturition, while 25.27% had normal micturition. Additionally, 52.69% of the participants had normal body temperatures, whereas 47.31% presented with increased temperatures (Table 1).

Table 1: Characteristics of the study participants (N = 186)

Variables		Number	Percentage
Age group	3 to 5	67	36.02%
	6 to 10	106	56.99%
	>10yrs	13	6.99%
Gender	Male	97	52.15%
	Female	89	47.85%
Micturition	Increased	139	74.73%
	Normal	47	25.27%
Temperature	Normal	98	52.69%
	Increased	88	47.31%

The comparison between urine culture results and the presence of nitrites and leukocyte esterase (LE) showed significant associations. Among the 73 participants with a positive urine culture, 82.19% had positive nitrites, while only 7.08% of those with a negative urine culture had positive nitrites. Similarly, 87.67% of participants with a positive urine culture had positive LE, compared to 17.7% with a negative culture. Both associations were statistically significant with p-values less than 0.001 (Table 2).

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Table 2: Comparison of nitrites and leucocyte esterase between urine culture (N=186)

Variables		Urine Culture		Chi square	P value
		Positive (N=73)	Negative (N=113)		
Nitrites	Positive	60 (82.19%)	8 (7.08%)	107.881	<0.001
	Negative	13 (17.81%)	105 (92.92%)		
Leucocyte esterase	Positive	64 (87.67%)	20 (17.7%)	87.677	<0.001
	Negative	9 (12.33%)	93 (82.3%)		

The predictive validity of nitrites for urine culture showed a sensitivity of 82.19% and a specificity of 92.92%. The false positive rate was 7.08%, and the false negative rate was 17.81%. The positive predictive value was 88.24%, and the negative predictive value was 88.98%, resulting in an overall diagnostic accuracy of 88.71%. The positive likelihood ratio was 11.61, while the negative likelihood ratio was 0.19 (Table 3).

Table 3: Predictive validity of nitrites in predicting urine culture (N=186)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	82.19%	71.47%	90.16%
Specificity	92.92%	86.53%	96.89%
False positive rate	7.08%	3.11%	13.47%
False negative rate	17.81%	9.84%	28.53%
Positive predictive value	88.24%	78.13%	94.78%
Negative predictive value	88.98%	81.90%	94.00%
Diagnostic accuracy	88.71%	83.26%	92.87%
Positive likelihood ratio	11.61	4.61	19.054
Negative likelihood ratio	0.19	0.05	0.315

For leukocyte esterase, the sensitivity was higher at 87.67%, with a specificity of 82.30%. The false positive rate was 17.70%, and the false negative rate was 12.33%. The positive predictive value stood at 76.19%, and the negative predictive value at 91.18%. The diagnostic accuracy was calculated at 84.41%, with a positive likelihood ratio of 4.95 and a negative likelihood ratio of 0.15 (Table 4).

Table 4: Predictive validity of leukocytes esterase (LE) in predicting urine culture (N=186)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	87.67%	77.88%	94.20%
Specificity	82.30%	74.00%	88.84%
False positive rate	17.70%	11.16%	26.00%
False negative rate	12.33%	5.80%	22.12%
Positive predictive value	76.19%	65.65%	84.81%
Negative predictive value	91.18%	83.91%	95.89%
Diagnostic accuracy	84.41%	78.38%	89.30%
Positive likelihood ratio	4.95	2.9	9.187
Negative likelihood ratio	0.15	0.01	0.278

DISCUSSION

Urinary tract infections (UTIs) are among the most common bacterial infections in children, leading to significant morbidity if not promptly diagnosed and treated. Our study aimed to evaluate the predictive validity of urine dipstick tests for nitrites and leukocyte esterase (LE) in diagnosing UTIs in children, compared to the gold standard of urine culture. The findings underscore the utility of these rapid screening tools in a clinical setting.

The study included 186 children, predominantly aged between 6 to 10 years (56.99%), followed by those aged 3 to 5 years (36.02%), and a smaller group older than 10 years (6.99%). This age distribution aligns with the known epidemiology of UTIs, which are more frequent in younger children due to anatomical and behavioral factors. The gender distribution was nearly even, with 52.15% males and 47.85% females, reflecting the increased susceptibility of females due to their shorter urethra.

The comparison of urine culture results with dipstick findings for nitrites and LE revealed significant associations. For nitrites, the sensitivity was 82.19%, specificity was 92.92%, with a positive predictive value (PPV) of 88.24% and a negative predictive value (NPV) of 88.98%. This high specificity indicates that a positive nitrite test strongly suggests a UTI, corroborating findings from other studies such as

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those by Huicho et al. (2002)[11] and Shaikh et al. (2008)[12], who reported similar specificity and sensitivity values.

Leukocyte esterase showed a sensitivity of 87.67% and specificity of 82.30%, with a PPV of 76.19% and an NPV of 91.18%. These results are consistent with those reported by Gorelick and Shaw (1999)[13], who found LE to be a reliable marker for pyuria and thus indicative of UTI. Our findings confirm that LE is a valuable indicator, although slightly less specific than nitrites.

Our study's sensitivity and specificity for nitrites (82.19% and 92.92%, respectively) are comparable to those reported by Gorelick and Shaw (1999)[13], who found a sensitivity of 82% and specificity of 98% for nitrites. Similarly, a study by Hay AD et al. (2010)[14] reported sensitivity of 81% and specificity of 98% for nitrites. These consistent findings across different studies reinforce the robustness of nitrite testing as a rapid screening tool for UTIs.

For LE, our sensitivity (87.67%) and specificity (82.30%) are in line with the meta-analysis by White SL et al.[15], which reported sensitivity and specificity of 83% and 78%, respectively. These variations might be attributed to differences in study populations, sample handling, and interpretation criteria. However, the overall agreement on LE's utility supports its inclusion in routine screening protocols.

The rapid and non-invasive nature of urine dipstick tests makes them ideal for initial screening in both outpatient and emergency settings. Given their high specificity, especially for nitrites, positive dipstick results can prompt immediate empirical antibiotic therapy while awaiting culture results, thus reducing the risk of complications such as renal scarring.

Moreover, the high NPV of both nitrites (88.98%) and LE (91.18%) suggests that negative dipstick results can reliably exclude UTIs in many cases, potentially reducing unnecessary antibiotic prescriptions and associated resistance issues. This is particularly important in pediatric practice, where overuse of antibiotics is a significant concern.

While our study provides valuable insights, several limitations should be acknowledged. First, the study was conducted in a single tertiary care hospital, which may limit the generalizability of the findings. Multicenter studies involving diverse populations are needed to validate these results further. Additionally, urine dipstick tests have inherent limitations, such as false positives due to contamination and false negatives in cases of low bacterial counts or non-nitrite producing organisms.

CONCLUSION

Our study confirms that urine dipstick tests for nitrites and leukocyte esterase are effective screening tools for diagnosing urinary tract infections in children. The high specificity of nitrites and the robust sensitivity of LE highlight their clinical utility in rapid and initial diagnosis. These tests can guide early treatment decisions, improving patient outcomes and potentially reducing the burden of UTIs in the pediatric population. By integrating these rapid tests into routine practice, healthcare providers can enhance the timely management of UTIs, ultimately improving the quality of care for children.

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