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Original Article

Validity of Leukocyte Esterase Dipstick Test Compared to Gold Standard Urine Culture in Hospitalized Children Suspected of Urinary Tract Infections

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Abstract

Background : Urinary tract infection (UTI) is an illness that affects specifically the bladder and other structures in the urinary tract. The leukocyte esterase dipstick examination is recognized for its high sensitivity but limited specificity. Additional diseases, like glomerulonephritis, can yield positive outcomes in this test. This research was conducted to determine the validity of leukocyte esterase examination in urine culture in children suspected of urinary tract infection.
Aims : To assess the accuracy of leukocyte esterase testing on urine culture in children suspected of having a .
Methods : This study employed a diagnostic test method with a cross-sectional design. Research data were obtained from medical record of pediatric patients admitted to RSUP dr. Hasan Sadikin from 2022 to 2023 with suspected urinary tract infection.
Results : The values for the diagnostic test results are follows true positive 80%, false positive 51%, true negative 25%, and false negative 40% respectively. The calculations reveal that the leukocyte esterase dip stick has a sensitivity of 67%, specificity of 33%, positive predictive value (PPV) of 61%, negative predictive value (NPV) of 38%, a positive likelihood ratio of 1.56, and a negative likelihood ratio of 0.625.
Conclusion: This study indicates that the leukocyte esterase dipstick examination has a sensitivity rate of 67%, specificity rate of 33%, PPV of 61%, and NPV value of 38%. The leukocyte esterase dipstick has a high sensitivity level and a low specificity level.

Keywords: Leukocyte Esterase; Urine Culture; Validity Test; Urinary Tract Infections; Pediatric Urinary Tract Infections.

INTRODUCTION

Urinary tract infection (UTI) is an illness that affects explicitly bladder and other structures in the urinary tract. Urinary tract infection can arise from the presence of bacteria, viruses, or other pathogens.[1] According to the 2019 Global Burden of Disease, Injury, and Risk Factor Study (GDB), there were over 404.6 million individuals worldwide who experienced urinary tract infection, resulting in the deaths of more than 236.786 individuals.[2] According to data from the Indonesian Ministry of Health in 2014, it is evident that the incidence of urinary tract infection in Indonesia is as high as 90–100 cases per 100.000 population annually. Failure to appropriately treat a urinary tract infection can lead to significant complications.[3] Urinary tract infection is not limited to adults but is also a common infection in children.[4] The majority of urinary tract infection cases (70–95%) are caused by *Escherichia coli*.[5]

Multiple diagnostic procedures can identify urinary tract infection. Urinary tract infection can be diagnosed by analyzing urine samples using urinalysis. Urinalysis is a method performed by examining and analyzing urine. Urinalysis comprises three components, among others macroscopic, microscopic, and chemical examination. Chemical examination can be conducted by determining pH levels and the presence of red blood cells, protein, nitrites, and leukocyte esterase. The urine can be chemically examined using a dipstick. Dipstick values utilized are pH, nitrite, and leukocyte esterase.[6] Leukocyte esterase can be utilized to detect white blood cells in urine. White blood cells release leukocyte esterase in reaction to present germs in urine.[7]

Leukocyte esterase dipstick examination is recognized for its high sensitivity but limited specificity. Additional diseases, like glomerulonephritis, can make the positive outcomes in this test.[7] Presently, urine culture is the established benchmark utilized for diagnosing suspected urinary tract infection.[8] A urine culture is performed by obtaining a urine specimen from an individual suspected of having an urinary tract infection.[9] The urine culture examination must be performed at a laboratory facility. Nevertheless, this unit is exclusively accessible at select health centers or primary care hospitals. Urinary tract infection can be quickly assessed using a leukocyte esterase dipstick test, which is simple and cost-effective. This inspection could decrease the quantity of negative urine samples delivered to the laboratory, thereby expediting the examination process.[10] Early detection of urinary tract infection can effectively hinder the transmission of the disease, hence decreasing the chances of developing more severe urinary tract infection. Efficient and suitable administration can alleviate the strain on healthcare resources.[7]

Leukocyte esterase dipstick examination is a cheap and fast examination. In developing countries, rapid tests such as urine dipstick tests are used for patients suspected of having urinary tract infection due to the lack of specialized laboratories with complete equipment to perform various diagnostic tests, including urine culture. The examination method using urine dipsticks has been widely used throughout the world. Many countries use it as an initial test to identify urinary tract infection in health facilities because using leukocyte esterase dipsticks is straightforward, and the examination is inexpensive, including in Indonesia, an archipelagic country with diverse geographical conditions.[25,26]

Urinary tract infections are among the most common bacterial infections in the pediatric population and may lead to significant morbidity if not diagnosed promptly. Accurate and timely identification is critical for initiating appropriate antimicrobial therapy and reducing the risk of complications. While urine culture is considered the gold standard for diagnosis, it is often inaccessible or impractical in many Indonesian healthcare facilities due to geographic and infrastructural limitations. Consequently, clinicians frequently use urine dipstick tests for leukocyte esterase as an initial screening method. The leukocyte esterase dipstick is valued for its simplicity, rapid results, cost-effectiveness, and suitability in resource-limited settings. Nevertheless, uncertainty persists regarding the sensitivity and specificity of this test for diagnosing urinary tract infections in children, especially in cases with atypical clinical presentations. This study aims to further evaluate the sensitivity and specificity of the leukocyte esterase dipstick test in diagnosing urinary tract infections in pediatric patients.

This study evaluates the diagnostic accuracy of the leukocyte esterase urine dipstick test in children with suspected urinary tract infections. By examining its sensitivity and specificity, the research aims to provide evidence-based recommendations for the use of this test as a supportive diagnostic tool in Indonesia. The results are expected to enhance the diagnosis of pediatric urinary tract infections, inform clinical practice, and support optimal resource allocation and management.

This study aimed to assess the accuracy of leukocyte esterase testing on urine culture in children suspected of having a urinary tract infection. The validity of a test is determined by calculating its sensitivity, specificity, negative predictive value, positive predictive value, positive probability, and negative likelihood using the chi-square test method. This research aims to provide a reliable reference for conducting urine exams, enabling prompt and accurate diagnosis of urinary tract infections in children suspected of having such diseases.

METHODS

This study employed a diagnostic test method with a cross-sectional design at the Central General Hospital

(RSUP) Dr. Hasan Sadikin Bandung. Secondary data from patient medical records and laboratory results were utilized as a reference. Research data were obtained from medical record of pediatric patients admitted to RSUP dr. Hasan Sadikin from 2022 to 2023 with suspected urinary tract infection. The samples used adhered to the specified inclusion requirements. Specifically, pediatric patients who presented themselves for examinations and had their urine culture findings included from RSUP Dr. Hasan Sadikin Bandung. The patient data excluded from the study were those of children suspected of urinary tract infection who did not undergo a leukocyte esterase dipstick examination and had incomplete data. The research was conducted with explicit authorization in compliance with the ethical exemption granted by the Padjadjaran University Research Ethics Committee under the reference number 331/UN6.KEP/EC/2024.

The collected data comprises results from urine culture examinations, leukocyte esterase levels from standard urine tests, and characteristics of pediatric patients suspected of having urinary tract infections. The data were analyzed using IBM's SPSS Statistics version 27 software. The chi-square test method was used to process the characteristic data. The chi-square test table compares the leukocyte esterase diagnostic test to the urine culture. Calculations are performed to ascertain the sensitivity, specificity, negative predictive value, positive predictive value, positive likelihood ratio, and negative likelihood ratio.

RESULTS

The study utilized medical data of children admitted to Dr. Hasan Sadikin Bandung Hospital suspected of having urinary tract infections. 196 samples met the inclusion criteria, whereas the exclusion criteria were not applicable. The attributes of the subject are displayed in Table 1.

The accuracy assessment of the leukocyte esterase dipstick test was conducted on 196 samples that satisfied the specified requirements and were not excluded. The test results were compared to the urine culture, considered the most reliable method (gold standard). The findings are summarized in Table 2.

The sample characteristics revealed that a significant proportion of children tested positive for urinary tract infection based on the findings from urine culture (41.3%) and leukocyte esterase dip strips (+1=5.6%; +2=8.7%; +3=28.1%; +4=1%). The majority of the children with urinary tract infection were female. The age group that had the highest number of urinary tract infection based on urine culture testing findings was the age group over 2 years, with 92 patients (14.3%). This was followed by the age group of 1–2 years, with 33 patients (16.8%), and the age group under 1 year, with 6 patients (3.1%). The leukocyte esterase dipstick examination yielded results consistent with the age groups over 2 years, with the highest incidence of urinary tract infection (1+=7.1%; +2=5.6%; +3=32.1%; +4=1.5%). This was followed by the 1-2 year age group (1+=0%; +2=2.6%; +3=9.7%; +4=0.5%) and the age group below 1 year (1+=0%; +2=2%; +3=11.2%; +4=0.5%).

The majority of the samples in the study did not exhibit any comorbidities, such as diabetes and malignancies (63.3%), followed by malignancies (2.6%) and diabetes (1%). Meanwhile, the leukocyte esterase results indicated that most research samples had no comorbidities (1+=6.6%; +2=7.7%; +3=40.8%; +4=2%). This was followed by cases of malignancy (1+=0%; +2=0.5%; +3=2.6%; +4=0%) and diabetes (1+=0.5%; +2=0%; +3=0.5%; +4=0%). Based on urine culture analysis, the percentage of samples without a history of catheter use (50.5%) was higher than that of samples with a history of catheter use (16.3%). The leukocyte esterase dipstick examination yielded results consistent with samples that did not have a prior history of catheter usage (1+=6.1%; +2=7.7%; +3=35.2%; +4=0%), compared to samples with a history of catheter use (1+=1%; +2=0.5%; +3=3.6%; +4=2%).

The analysis of the samples revealed that the predominant microorganisms were Gram-negative bacteria, as shown by both urine culture investigation (33.7%) and leukocyte esterase dipsticks (1+=1.5%; +2=1.5%; +3=19.9%; +4=0%). *Escherichia coli*, a gram-negative bacterium, was the most commonly discovered, with 51 samples. In this study, 7 samples (3.6%) had a concentration of bacteria ≥ 105 CFU/mL, whereas 2 samples (1%) had a concentration of microorganisms $<10^5$ CFU/mL. However, most medical record data, specifically 122 data points (62.2%), needed information regarding the number of bacteria in the urine culture.

According to the table, the values are true positive 80%, false positive 51%, true negative 25%, and false negative 40% respectively. The calculations reveal that the leukocyte esterase dip strip has a sensitivity of 67%, specificity of 33%, a positive predictive value (PPV) of 61%, negative predictive value (NPV) of 38%, a positive likelihood ratio of 1.56, a negative likelihood ratio of 0.625.

DISCUSSION

This study found that urinary tract infections were more common in women than in men. Female are more prone to urinary tract infection than males due to the shorter length of their urethra compared to men. This syndrome facilitates the entry of pathogenic microorganisms into the bladder. Furthermore, the anatomical positioning of the urinary system in women is in excellent proximity to the rectal region, facilitating the movement and infiltration of bacteria into the urinary tract. On the other hand, males possess a longer urethral structure, which

TABLE 1
Characteristics of Research Subjects

Patient Characteristics	Category	Total Sampel (n=196)						
		Urine Culture (1.63 ± 1.421)		Leukocyte Esterase Dipstick (1.33 ± 0.472)				
		Positive	Negative	Negative	+1	+2	+3	+4
Gender	Male	50 (25.5%)	29 (14.8%)	34 (17.3%)	3 (1.5%)	9 (4.6%)	31 (15.8%)	2 (1%)
	Female	81 (41.3%)	36 (18.4%)	42 (21.4%)	11 (5.6%)	7 (8.7%)	55 (28.1%)	2 (1%)
Age	<1 years old	6 (3.1%)	0 (0%)	2 (1%)	0 (0%)	0 (0%)	4 (2%)	0 (0%)
	1-2years old	33 (16.8%)	8 (4.1%)	16 (8.2%)	0 (0%)	5 (2.6%)	19 (9.7%)	1 (0.5%)
	>2 years old	92 (46.9%)	57 (29.1%)	58 (29.6%)	14 (7.1%)	11 (5.6%)	63 (32.1%)	3 (1.5%)
Comorbidities	Without comorbidities	124 (63.3%)	63 (32.1%)	75 (38.3%)	13 (6.6%)	15 (7.7%)	80 (40.8%)	4 (2%)
	Diabetes	2 (1%)	1 (0.5%)	1 (0.5%)	1 (0.5%)	0 (0%)	1 (0.5%)	0 (0%)
	Malignancy	5 (2.6%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5)	5 (2.6%)	0 (0%)
Catheter	Without catheter	99 (50.5%)	55 (28.1%)	58 (29.6%)	12 (6.1%)	15 (7.7%)	69 (35.2%)	0 (0%)
	With catheter	32 (16.3%)	10 (5.1%)	18 (9.2%)	2 (1%)	1 (0.5%)	17 (3.6%)	4 (2%)
Type of Microorganism	Without Microorganism	0 (0%)	65 (33.2%)	25 (12.8%)	10 (5.1%)	8 (4.1%)	21 (10.7%)	1 (0.5%)
	Gram-negative bacteria	66 (33.7%)	0 (0%)	21 (10.7%)	3 (1.5%)	3 (1.5%)	39 (19.9%)	0 (0%)
	Gram-positive bacteria	16 (8.2%)	0 (0%)	6 (3.1%)	0 (0%)	3 (1.5%)	7 (3.6%)	0 (0%)
	Fungi	14 (7.1%)	0 (0%)	0 (0%)	1 (0.5%)	1 (0.5%)	4 (2%)	0 (0%)
	Others	6 (3.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (1.5%)	0 (0%)
	Polymicrobial	29 (14.8%)	0 (0%)	12 (6.1%)	1 (0.5%)	1 (0.5%)	12 (6.1%)	3 (1.5%)
Number of Mikroorganism	Not mentioned	122 (62.2%)	0 (0%)	46 (23.5%)	4 (2%)	8 (4.1%)	61 (31.1%)	3 (1.5%)
	$< 10^5$ CFU/mL	2 (1%)	63 (32.1%)	25 (12.8%)	10 (5.1%)	8 (4.1%)	21 (10.7%)	1 (0.5%)
	$\geq 10^5$ CFU/mL	7 (3.6%)	2 (1%)	5 (2.6%)	0 (0%)	0 (0%)	4 (2%)	0 (0%)

TABLE 2
Diagnostic Test of Leukocyte Esterase Dipstick

Leukocyte Esterase Dipstick	Urine Culture		Total (n=196)
	Positive	Negative	
Positive	80	51	131
Negative	40	25	65
Total	120	76	196
Leukocyte Esterase			
Sensitivity (%)			67
Specificity (%)			33
Positive Predictive Value (%)			23.08
Negative Predictive Value (%)			23.08
Likelihood Ratio Positive			15.38
Likelihood Ratio Negative			23.08

serves as a barrier against bacterial contamination, making it more difficult for bacteria to infiltrate the bladder than females.[10]

Urinary tract infection can occur at any age, from adults to children. Our research examined data from children suspected of having a urinary tract infection. The data was divided into three age groups, under 1 year, 1 to 2 years, and over 2 years. Our analysis revealed that children under 1 year of age were the most likely group to experience urinary tract infections. This is because the number of children under 1 year of age was higher than in the other two groups. A study revealed a higher incidence of urinary tract infection among children who utilized specific categories of diapers. Various types of diapers can lead to inadequate ventilation in the genital area, resulting in reduced airflow.[11] Infants under the age of 1 are also more vulnerable to infection.[12] According to this survey's findings, the age group above 2 years old constitutes the greatest demographic. This is because the sample size used to obtain research data for children over 2 years is larger, resulting in a higher incidence of urinary tract infection in this age group.

The study did not find a significant association between comorbidities such as diabetes mellitus (DM) and malignancies, including leukemia and preleukemia. This is evident from the findings of the urine culture analysis. The study found that only a small proportion of children with suspected urinary tract infections were also diagnosed with significant comorbid conditions, including diabetes mellitus or malignancies. Most children in this group did not exhibit evidence of these additional pathologies, underscoring the infrequency of such comorbid presentations within this clinical population. This study demonstrates that there is no substantial prevalence of diabetes and cancer among children who are suspected of having a urinary tract infection. The findings of this study contradict the previous research conducted by Regina (2023), which indicated a correlation between DM and bacteriuria, serving as a potential predictor of urinary tract infection. Patients with diabetes mellitus who have high blood sugar levels can encounter issues such as compromised immune function and urinary tract dysfunction. Elevated blood glucose levels result in glucosuria and impaired neutrophil function, heightening susceptibility to urinary tract infection.[13]

Based on urine culture analysis, the percentage of samples from individuals without a history of catheter use was higher than that of samples from individuals with a history of catheter use. Leukocyte esterase dipstick examination showed consistent results in samples without a history of catheter use, compared to samples with a history of catheter use. This study suggests that the use of catheters does not increase the likelihood of urinary tract infections in children. The prevalence of samples with a history of catheter use was quite substantial in this study. Meanwhile, based on research conducted at Medan Regional Hospital, the use of catheters increases the likelihood of urinary tract infections.[14] The majority of urinary tract infections are caused by the use of catheters. This contradicts the author's study findings.

The analysis of the samples revealed that the predominant microorganisms were Gram-negative bacteria, as shown by both urine culture investigation and leukocyte esterase dipsticks. *Escherichia coli*, a gram-negative bacterium, was the most commonly discovered. It was identified among additional microorganisms

(polymicroorganisms) or as the sole type present. *Escherichia coli* is a bacteria typically present in the normal intestinal flora. However, it can potentially cause infections in other body sections, including the digestive system and beyond, such as the urinary tract, leading to urinary tract infection. Extraintestinal *Escherichia coli* infections typically occur when *Escherichia coli* bacteria move from the intestine to other body parts. Extraintestinal *Escherichia coli* infections frequently occur in the urinary tract.[15] *Escherichia coli* has fast growth in both aerobic and anaerobic conditions. Urinary tract infection mainly result from bacterial infection when bacteria enter the urinary tract via the urethra. Subsequently, the bacteria undergo replication and adhere to the bladder. Moreover, microorganisms can infiltrate the kidneys. *Escherichia coli* possesses uropathogenic strains that can initiate urinary tract infection.[16] In the urine culture examination conducted on children suspected of urinary tract infection, other gram-negative bacterial microorganisms were found, such as *Klebsiella pneumonia, Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter cloacae,* and *Morganella morganii*. Previous research found that Klebsiella pneumoniae (33.4%) is a gram-negative bacteria that is also often found in urinary tract infection patients.[27] Several other types of anaerobic bacteria were found, namely *Enterococcus faecalis, Acinetobacter baumannii, Candida albicans,* and *Candida tropicalis*.

An analysis of the data obtained from urine culture examinations indicates that, in the majority of cases, the corresponding medical records lack detailed documentation regarding the quantitative enumeration of bacterial colonies present in the samples. Specifically, most of the medical record entries related to urine cultures merely note the presence or absence of bacterial growth, without providing precise counts or concentrations. Only a limited subset of urine culture reports explicitly enumerate the number of bacteria detected. Analysis of samples with known bacterial counts revealed that most positive samples had counts of $\geq 10^5$ CFU/mL. According to Sulistiani's (2021) research, a urine culture investigation is considered positive for urinary tract infection if the number of bacteria is equal to or $\geq 10^5$ CFU/mL. This aligns with a study demonstrating that most samples containing microorganisms have findings $\geq 10^5$ CFU/mL.[17]

Millner and Becknell's earlier study established that the leukocyte esterase examination is very sensitive but lacks specificity when it comes to identifying urinary tract infection. A positive leukocyte esterase test does not always mean that there is a urinary tract infection. Several diseases, such as glomerulonephritis and appendicitis, can cause positive leukocyte esterase examination results.[8,18] These findings align with the author's research at RSUP Dr. Hasan Sadikin, demonstrating a high sensitivity (67%) and low specificity (33%) of leukocyte esterase. A high sensitivity score suggests that the leukocyte esterase dipstick can reliably identify children with a urinary tract infection. At the same time, a low specificity value shows that the leukocyte esterase dipstick cannot accurately identify patients without a urinary tract infection. Thus, leukocyte esterase is recognized as a susceptible but less specific diagnostic test for suspected urinary tract infections in children.

These findings align with the author's research at RSUP Dr. Hasan Sadikin, demonstrating a high sensitivity (67%) and low specificity (33%) of leukocyte esterase. A high sensitivity score suggests that the leukocyte esterase dipstick can reliably identify children with a urinary tract infection. At the same time, a low specificity value shows that the leukocyte esterase dipstick cannot accurately identify patients without a urinary tract infection. Thus, leukocyte esterase is recognized as a susceptible but less specific diagnostic test for suspected urinary tract infections in children.[19,20]

This study determined the NPV and PPV values to be 38% and 61%, respectively. Previous studies have established that the PPV is 44% and the NPV is 92%.[21] The PPV score of 44% suggests that the leukocyte esterase dipstick is less accurate in detecting an illness, as it is further from 100%. PPV represents the likelihood that an individual who tests positive for a disease has the ailment. PPV and NPV are utilized to assess the likelihood of an individual's illness, considering positive or negative outcomes from diagnostic tests.[22] The PPV and the NPV for both are approximately 100%. The study determined that the PPV was 61%. The study revealed that 61% of pediatric patients suspected of having a urinary tract infection were diagnosed with a urinary tract infection. The author's research has a net present value of 38%, significantly lower than 100%. The NPV indicates that 38% of children suspected of having a urinary tract infection and test negative do not indeed have a urinary tract infection. The research findings suggest that leukocyte esterase dip strips with poor NPV are unsuitable for investigating children's urinary tract infection. The outcomes of dip strip examination may differ among various study populations. The dip strip examination is not regarded as accurate for identifying urinary tract infections in children due to the potential for sample contamination. This may explain why the NPV of leukocyte esterase dip strips in children is comparatively lower.[23] The author's examination results are consistent, revealing a comparatively low NPV value.

Previous research shows that the likelihood ratio has a positive likelihood ratio (LR+) value of 2.6 and a negative likelihood ratio (LR-) value of 0.6. This value is recognized to have a negligible impact on the probability of disease.[24] This is also consistent with the research conducted by the author, which has an LR+ value of 1.56 and an LR- value of 0.625, indicating a minor influence. The LR+ value from this study only slightly increases the

likelihood that someone with a positive test result truly has a urinary tract infection. The LR-value from this study only slightly reduces the likelihood that someone with a negative test result does not have a urinary tract infection. The diagnostic test for leukocyte esterase dipstick has shown low validity. Mistakes in urinary tract infection diagnosis might also arise from faults in collecting the sample.[23] Menstrual spots and other similar situations can potentially introduce technical errors during urine collection, impacting examination results' accuracy. This can have an impact on the outcomes of the conducted research. This study was conducted with a relatively large sample size, providing sufficient statistical power. However, there was a limitation due to incomplete medical records, which reduced the number of samples available for analysis.

CONCLUSION

This study indicates that leukocyte esterase has high sensitivity (67%) and low specificity (33%), meaning it can accurately detect urinary tract infections in children, but it is not reliable for identifying children without such infection. A value of 61% PPV indicates that leukocyte esterase dipstick examination is quite good, shows that 61% of children suspected of having urinary tract infection do indeed have the condition. NPV value based on the diagnostic test is far from 100%, indicating that the leukocyte esterase dipstick is less accurate for examining urinary tract infection in children. Based on the results, it can be seen that the leukocyte esterase dipstick is less suitable for use in examining urinary tract infection in children because it has a low validity value. Therefore, leukocyte esterase dipstick examination results need to be supported by examinations using other methods to obtain more accurate urinary tract infection diagnosis results, such as nitrite examination or urine culture. In conducting similar studies in the future, it is hoped that the prevalence in the population to be used can be known with certainty to obtain more optimal results.

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CONFLICT OF INTEREST

No potential conflicts of interest that might be perceived as influencing the impartiality of the reported research.

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