

# The Sensitivity and Specificity of a Urine Leukocyte Esterase Dipstick Test for the Diagnosis of Urinary Tract Infection in the Outpatient Clinic of Rajavithi Hospital

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**Background:** Urinary tract infection (UTI) is frequently found in family physician clinics. The present study was designed to assess the reliability of a leukocyte esterase urine dipstick test in detecting UTI.

**Objective:** Compare the performance and reliability of leukocyte esterase dipstick urinalysis with microscopic examination for detection of clinically suspected UTI.

**Material and Method:** A retrospective descriptive study was conducted on 109 patients who visited the outpatient clinic with a clinical suspicion of UTI between November 2010 and July 2011. The subjects consisted of patients from the age of 15 years and over regardless of gender. A dipstick test (Combur-Test® M strip, Roche) was used. All dipstick-positive samples were processed to microscopic examination and urine culture was used as gold standard. Sensitivity, specificity, and predictive values were analyzed for the dipstick test (leukocyte esterase) as compared to microscopic examination. Statistical analysis was performed by using the t-test.

**Results:** The sensitivity of leukocyte esterase test and the combined leukocyte esterase and nitrite test were 63.6% and 66.7%, respectively. The presence of pyuria demonstrated the highest sensitivity (95.6%) and specificity (60.9%) for positive urine culture compared to the dipstick test. Statistical analysis revealed a significant correlation between the dipstick test (leukocyte esterase) and microscopic examination ( $p < 0.001$ ).

**Conclusion:** Pyuria can be used to detect UTI instead of urine culture due to its significant incidence. In the present study, the presence of pyuria had a higher specificity (60.9%) compared to the dipstick test (44.2%). However, the significantly positive dipstick and pyuria results make the combined test more useful than the single test, and there is a statistically significant correlation between the dipstick test (leukocyte esterase) and the microscopic examination ( $p < 0.001$ ). Therefore, the dipstick test (leukocyte esterase) can be used as a diagnostic tool in detecting UTI cases.

**Keywords:** Leukocyte esterase dipstick test, Pyuria, Urinary tract infection

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Urinary tract infection (UTI) is defined as the presence of bacteria in urine along with symptoms of infection. Urinary tract infection is frequently encountered in general practitioner clinics, and it is a common clinical problem requiring treatment. Diagnosis of UTI usually involves the appearance of symptoms such as pyuria, fever, or abdominal pain, and it is confirmed by positive culture of possible urinary pathogens<sup>(1,2)</sup>. Several rapid tests for early detection of UTI have been studied for their reliability. Among these, the dipstick test based on leukocyte esterase, and urinary nitrite production an indicator of pyuria, is commonly used to detect bacteriuria.

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Leukocyte esterase (LE) is an enzyme produced in neutrophils and is not normally found in urine<sup>(3,4)</sup>. Its presence in urine indicates pyuria, which is an indirect indicator for UTI. Early diagnosis and treatment of UTI is important to prevent permanent renal damage. The present study is designed to assess the reliability of a dipstick test in detecting UTI.

The objective of the present study was to compare the performance and correlation of a leukocyte esterase dipstick test with microscopic examination for detection of clinically suspected UTI.

#### Material and Method

A retrospective descriptive study was conducted on 109 patients who visited Rajavithi Hospital outpatient clinic with a clinical suspicion of UTI between November 2010 and July 2011. The inclusion criteria were the patients from the age of

15 years and older with no history of antibiotics taken within one week, and with formal consent signed. The exclusion criteria were the patients with pregnancy or menstruation and patients with no urine. The dipstick test was conducted using the Combur-Test® M strip (Roche) and read by an urisyn 1800 and an urisyn 2400. The presence of leukocyte (pyuria) ( $\geq 5$  WBC/HPF) in the urine predicts a positive urine culture, which indicated UTI. A cultured urine specimen with  $>10^5$  CFU/ml of one or more pathogens was defined as a positive culture. All the urine samples were submitted for routine urinalysis (dipstick test and microscopy) and urine culture as a gold standard for diagnosis of UTI<sup>(5,6)</sup>. Data were analyzed using diagnostic tests of sensitivity, specificity, and positive and negative predictive values (PPV, NPV)<sup>(7,8)</sup>. Statistical analysis was performed by using the t-test at 95% confidence level. The present study was approved by Rajavithi hospital Ethics Committee.

## Results

### Leukocyte esterase

Samples were analyzed by urine dipstick. The results of leukocyte esterase in urine samples are shown in Table 1. The sensitivity of leukocyte esterase alone and combined leukocyte esterase and nitrite for positive culture were 63.6% and 66.7% respectively. The specificity of leukocyte esterase in UTI cases was 44.2%. The positive and negative predictive values of leukocyte esterase alone were 63.6% and 44.2%. The positive and negative predictive values of combined leukocyte esterase and nitrite were 64.7% and 46.3%.

### Microscopic examination

Samples were analyzed for pyuria by microscopy, and the results of leukocytes (WBC) in

urine samples are shown in Table 2 and 3. The sensitivity of leukocyte esterase test was 39% in detecting WBC 0-2/HPF in urine, and 85% to 100% in detecting WBC 3-5/HPF to WBC  $>20$ /HPF. The positive predictive value was 36.4% and 100% in WBC 0-2/HPF and WBC  $>20$ /HPF respectively. Statistically significant correlations were revealed between the dipstick test (leukocyte esterase) and microscopic examinations ( $p = 0.000$ ), and the dipstick test (nitrite) and microscopic examinations ( $p < 0.014$ ).

Urine samples were obtained from 109 patients with the symptoms of UTI. Only 66 (60.6%) of urine cultures demonstrated a pure growth of one or more potential uropathogens, while 43 (39.4%) urine samples showed no growth. The sensitivity of leukocyte esterase alone and combined leukocyte esterase and nitrite for positive culture were 63.6% and 66.7%, respectively (Table 1). The presence of pyuria has the highest sensitivity (95.6%) and specificity (60.9%) for positive urine culture compared to the dipstick test (Table 4). Statistical analysis revealed a significant correlation between the dipstick test (leukocyte esterase) and microscopic examination ( $p < 0.001$ ) (Table 5).

## Discussion

The most common tests used for detecting pyuria in patients who are suspected to be suffering from UTI are dipstick urinalysis and direct microscopy. The combined leukocyte esterase and nitrite test on the single dipstick had much better sensitivity (66.7%) than nitrite alone (15.2%) but comparable with leukocyte esterase alone (63.6%). This finding was common since determining leukocyte esterase alone or nitrite alone for microscopic urinalysis has been found to be a poor predictor of positive urine

**Table 1.** Sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of leukocyte esterase urine dipstick in (UTI) cases (age  $>15$  and over)

Urine dipstick n = 109, male = 15; female = 94	Positive culture n = 66	Negative culture n = 43	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Leukocyte						
Positive	42	24	63.6	44.2	63.6	44.2
Negative	24	19				
Nitrite						
Positive	10	2	15.2	95.3	83.3	42.3
Negative	56	41				
Leukocyte and nitrite						
Positive	44	24	66.7	44.2	64.7	46.3
Negative	22	19				

**Table 2.** Sensitivity of leukocyte esterase on urine dipstick detecting pyuria UTI cases

Leukocyte esterase	Microscopic analysis				
	WBC 0-2 (n)	WBC 3-5 (n)	WBC 5-9 (n)	WBC 10-20 (n)	WBC >20 (n)
True positive	25	11	13	5	14
False negative	39	2	0	0	0
Sensitivity	39%	85%	100%	100%	100%

**Table 3.** Positive predictive value of leukocyte esterase urine dipstick test versus microscopic examination

Clinical microscope	Urine culture		
	True positive (n)	False negative (n)	Positive predictive value (%)
WBC 0-2	24	37	36.4
WBC 3-5	10	4	71.4
WBC 5-9	10	2	83.3
WBC 10-20	6	0	100.0
WBC >20	16	0	100.0

**Table 4.** Accuracy of screening test (dipstick and microscopic) in UTI cases

Test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Leukocyte esterase	63.6	44.2	63.6	44.2
Pyuria (WBC/HPF)	95.6	60.9	87.5	60.6

**Table 5.** Group statistic t-test correlation between leukocyte esterase and nitrite

Urine test	Nitrite	n	Mean	Sig. (2-tailed)
WBC	Positive	11	3.45	0.014
	Negative	92	1.78	
Urine test	Leukocyte	n	Mean	Sig. (2-tailed)
WBC	Positive	64	2.38	0.001
	Negative	41	1.29	

cultures<sup>(9,10)</sup>. Therefore, the combination of positive leukocyte esterase and nitrite tests provided better overall performance than the single test for detecting pyuria and bacteriuria in UTI.

The direct correlation between the sensitivity of leukocyte esterase and positive predictive value of leukocyte and the number of white blood cells on chemical microscopy was due to the fact that the leukocyte esterase test uses derivatized pyrrole amino acid ester to detect leukocyte esterase in white blood cells<sup>(11)</sup>. The presence of pyuria has a high specificity (60.9%) for identifying positive urine culture as compared to the dipstick test, and the presence of leukocytes (pyuria) ( $\geq 5$  WBC/HPF) in the urine predicts a positive urine culture, which indicates UTI. However, false positive and false negative results from microscopic examination can occur due to a

variety of factors including specimen contamination, certain organisms, and the timing of a specimen collection<sup>(12,13)</sup>. High sensitivity and high positive predictive value has been proved to increase the accuracy in diagnosing UTI.

The present data have revealed a statistically significant correlation between dipstick testing (leukocyte esterase) and microscopic examination ( $p < 0.001$ ), and dipstick testing (nitrite) and microscopic examination ( $p = 0.014$ ). Importantly, a combination of dipstick testing and microscopy has been found in this study to be reliable in detecting pyuria. Many studies have investigated the reliability of dipstick testing in detecting pyuria, and have suggested that the dipstick test including leukocyte esterase and nitrite was as accurate as microscopic examination in predicting pyuria and bacteriuria<sup>(14)</sup>. The advantage of urine leukocyte esterase dipstick testing in detecting UTI cases for general practitioners is that decision on antibiotic prescription or patient reassurance can be made immediately<sup>(15,16)</sup>.

For further study, the performance of leukocyte esterase dipstick testing in detecting UTI should be investigated in different hospitals and with a higher number of samples. Not only should differences between pyuria in males and females be investigated in diagnosis of UTI cases, but also specific

inclusion criteria of either male or female should be taken into consideration.

### Conclusion

Determination of significant pyuria can be used to detect UTI without the need for urine culture. In the present study, the presence of pyuria had higher specificity (60.9%) than the dipstick test (44.2%). The significant positive results from combined dipstick and pyuria were more useful than the single test. A statistically significant correlation between dipstick testing (leukocyte esterase) and microscopic examinations was obtained ( $p < 0.001$ ), therefore, the dipstick test (leukocyte esterase) can be used as a reliable diagnostic tool in detecting UTI cases.

### Potential conflicts of interest

None.

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## ความไวและความจำเพาะของแถบจุ่มตรวจปัสสาวะเอนไซม์เอสเตอเรสของเม็ดเลือดขาวเพื่อวินิจฉัยผู้ติดเชื้อทางเดินปัสสาวะ ห้องตรวจโรคผู้ป่วยนอกโรงพยาบาลราชวิถี

สิริรัตน์ เล่าสู่อังกูร

**ภูมิหลัง:** การติดเชื้อทางเดินปัสสาวะเป็นโรคที่พบบ่อยในเวชปฏิบัติ การวินิจฉัยโรคได้เร็วจะสามารถทำให้ผู้ป่วยได้รับการรักษาที่เหมาะสม การศึกษานี้จึงใช้แถบจุ่มตรวจปัสสาวะเพื่อศึกษาการทำงานและความน่าเชื่อถือของการตรวจการติดเชื้อ โดยการตรวจค่าเอนไซม์เอสเตอเรสของเม็ดเลือดขาวในการวินิจฉัยผู้ป่วยติดเชื้อทางเดินปัสสาวะเปรียบเทียบกับการตรวจปัสสาวะโดยใช้กล้องจุลทรรศน์

**วัตถุประสงค์:** เพื่อศึกษาการประเมินการทำงานและความเชื่อถือของการใช้แถบจุ่มตรวจปัสสาวะกับการตรวจปัสสาวะโดยใช้กล้องจุลทรรศน์เพื่อค้นหาผู้ป่วยที่สงสัยว่ามีการติดเชื้อทางเดินปัสสาวะ

**วัสดุและวิธีการ:** เป็นการศึกษาย้อนหลังในผู้ป่วย 109 ราย ที่มารับการตรวจที่แผนกผู้ป่วยนอกด้วยอาการที่สงสัยว่ามีการติดเชื้อทางเดินปัสสาวะ ระหว่างเดือนพฤศจิกายน พ.ศ. 2553 ถึง เดือนกรกฎาคม พ.ศ. 2554 โดยไม่จำกัดเพศ อายุตั้งแต่ 15 ปีขึ้นไป โดยใช้การตรวจแถบจุ่มตรวจปัสสาวะของบริษัทโรช เพื่อตรวจค่าเอนไซม์เอสเตอเรสและไนไตรต์ ปัสสาวะที่ให้ผลบวกทั้งหมดจะถูกส่งไปตรวจจำนวนเม็ดเลือดขาวในปัสสาวะด้วยกล้องจุลทรรศน์ จากนั้นก็ส่งตรวจปัสสาวะเพาะเชื้อเพื่อเป็นการยืนยัน ข้อมูลทั้งหมดจะถูกนำไปวิเคราะห์ทางสถิติ

**ผลการศึกษา:** ผลการตรวจปัสสาวะผู้ป่วย 109 ราย ที่มีอาการพบว่าผลปัสสาวะเพาะเชื้อเป็นผลบวกมี 66 ราย และผลลบ 43 ราย ค่าเอนไซม์เอสเตอเรสของเม็ดเลือดขาวในแถบจุ่มตรวจปัสสาวะที่มีปัสสาวะเพาะเชื้อเป็นบวก มี sensitivity 63.6% และเม็ดเลือดขาวจากการตรวจทางกล้องจุลทรรศน์ที่มีปัสสาวะเพาะเชื้อเป็นบวกมีค่า sensitivity สูงถึง 95.6% ค่าเอนไซม์เอสเตอเรสของเม็ดเลือดขาวในแถบจุ่มปัสสาวะมีค่า sensitivity และ positive predictive value เพิ่มขึ้นเมื่อจำนวนเม็ดเลือดขาวในปัสสาวะที่ตรวจด้วยกล้องจุลทรรศน์เพิ่มขึ้น ความสัมพันธ์ของเอนไซม์เอสเตอเรสของเม็ดเลือดขาวในแถบจุ่มปัสสาวะ และการตรวจทางกล้องจุลทรรศน์มีนัยสำคัญทางสถิติ ( $p < 0.001$ )

**สรุป:** การวิเคราะห์จากการศึกษานี้พบว่าค่าความจำเพาะของเม็ดเลือดขาวในปัสสาวะติดเชื้อมีค่าสูงถึง 60.9% เมื่อเปรียบเทียบกับค่าเอนไซม์เอสเตอเรสของเม็ดเลือดขาวในแถบจุ่มตรวจปัสสาวะที่มีเพียง 44.2% อย่างไรก็ตามความสัมพันธ์ของเอนไซม์เอสเตอเรสของเม็ดเลือดขาวในแถบจุ่มปัสสาวะ และการตรวจทางกล้องจุลทรรศน์มีนัยสำคัญทางสถิติ ดังนั้นการใช้ค่าเอนไซม์เอสเตอเรสของเม็ดเลือดขาวของแถบจุ่มปัสสาวะมีความถูกต้อง และใช้ได้ดีเมื่อเทียบกับการตรวจเม็ดเลือดขาวด้วยกล้องจุลทรรศน์ในการวิเคราะห์ผู้ติดเชื้อทางเดินปัสสาวะ โดยเฉพาะในรายที่มีปริมาณเม็ดเลือดขาวมาก

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