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Validity Of Urine Dipstick Parameters In Identifying Urinary Tract Infections

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Abstract

Objective: To evaluate the diagnostic accuracy of urine dipstick parameters using semi-quantitative urine culture as the reference standard in the assessment of UTI.

Methods: A cross-sectional validation study was conducted over 12 months in the Department of General Medicine in a public sector tertiary care hospital in Islamabad. A total of 303 cases suspected of having UTIs were included. Combur10 Roche dipstick was used as a diagnostic test dipstick for the detection of urine leucocyte esterase and Urine nitrite. Cystine-lactose electrolyte deficient agar (CLED) media was used for quantitative culture of urinary microorganisms, the results of which were considered the gold standard.

Results: 149 were females with a mean age of 50±20 years, while 154 participants were males with a mean age of 49±24 years. A total of 42.6% (N=129) of the population studied had a positive result for urine culture, with the most commonly isolated organism being the Klebsiella species (8.3%). The most specific parameter was the combination of nitrite positive and leucocyte esterase positive with a specificity of 98.9% (95% CI= 96.5-99.8%). The least specific results were those that were either nitrite positive or leucocyte esterase positive, with a specificity of 75.9% (95% CI 69.2-81.8). The overall sensitivity of the dipstick analysis was relatively poor.

Conclusion: The combination of both the dipstick parameters, nitrite and leucocyte esterase, showed better accuracy in terms of specificity and, therefore, ruled in the presence of UTI. The sensitivity, however, was generally poor, and it can be inferred that the dipstick is not a useful investigation in successfully ruling out the presence of UTI; urine culture must, therefore, be performed in highly suspicious cases.

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Introduction

Urinary tract infections (UTIs) are significant health concerns due to their frequency and potential complications if left untreated. Due to variability in the immune responses and susceptibilities to infections, immunocompromised and immunocompetent people can react differently to urinary tract infections.[1] A urinary tract infection is diagnosed upon detecting a significant bacterial proliferation in the urinary tract (≥105 counts/mL of urine) regardless of whether clinical symptoms are evident or not.[2] The most typical symptoms of urinary tract infection (UTI) are suprapubic discomfort, increased frequency and urgency of urination, and dysuria. Patients may also experience hematuria in some situations. Severe infections such as pyelonephritis might manifest atypically, exhibiting symptoms such as fever, nausea, and flank pain. [3 Approximately] a total of seven million cases of UTIs have been reported in emergency settings, while healthcare facilities record about 100,000 cases of nosocomial infections annually.[4] It is estimated that UTIs affect 150 million people worldwide annually. The prevalence of UTIs in Pakistan is 62%.[5] Uncomplicated UTIs are relatively common in the United States, with an overall prevalence of 8% to 11% and 20% among women 65 years of age and older.[1]

Recurrent urinary tract infections (UTIs) are defined as three or more symptomatic UTIs that have been medically diagnosed within the previous year, provided that each infection has been confirmed to have cleared up before the next episode is identified.[6] Although both genders are capable of getting UTIs, historically, women have been more likely to get them—half of all females will get one at some point in their lives. Furthermore, approximately one in four women who get their first bout of bacterial cystitis go on to get another one within six months. Among them, some endure six or more infections in the year following the initial episode.(6). Healthy males are largely protected by their anatomy across various ages. However, males at both extremes of the age range exhibit a higher incidence of UTI. Notably, in infants younger than six months, boys experiencing UTI outnumber girls, which may be related to the presence of androgens in the blood. On the other hand, prostatic hypertrophy-related urodynamic dysfunction is frequently the cause of urinary tract infections in older men.[7]

The term "UTI" refers to a variety of illnesses from mild kidney infections like asymptomatic bacteriuria (ASB) and cystitis to more serious illnesses like pyelonephritis. According to estimates, ASB occur in 2% to 10% of cases. Research carried out in the 1960s and 1970s revealed that patients with untreated ASB had a 20% to 30% risk of developing pyelonephritis. On the other hand, this risk was 80% lower with an early diagnosis and suitable antibiotic therapy.[2]

Seventy-five to ninety-five per cent of UTI cases are caused by Escherichia coli, while Enterococcus faecalis, Proteus mirabilis and Klebsiella pneumoniae are also commonly implicated.[8] The gold standard test for the diagnosis of urinary tract infections is urine culture. However, dipstick tests like Leucocyte esterase, urinary nitrites and pyuria by microscopy are different diagnostic tests which can be used to diagnose urinary tract infections.[9]

Several expedient diagnostic techniques are available, including wet mount microscopy, Gram staining, dipstick assays, and automated tests. Nevertheless, the gold standard for diagnosing UTIs remains quantitative urine culture. Standard laboratory procedures typically require up to 18 hours for bacterial growth on culture media, resulting in a diagnostic uncertainty period of 24 to 48 hours following presentation, which delays the onset of treatment. Additionally, urine culture is a costly procedure that necessitates a well-equipped microbiology laboratory staffed by proficient technicians.[10]

Microorganisms detection via urine culture is considered the most significant in diagnosing UTI.[3] A delay in the diagnosis might occur due to atypical clinical presentation, lack of quick diagnostic facility and relying solely upon the growth of urine culture, which may lead to multiple complications. To initiate antimicrobial therapy on time, early diagnosis of UTI is crucial, which would be possible through the use of rapid diagnostic methods.[10]

In clinical settings, dipstick analysis is a quick and reliable initial diagnostic test for urinary tract infections.[11,12] It looks for markers of potential bacterial infection and inflammation in urine, such as nitrites, leukocyte esterase, and pH levels. However, false positive results of these tests may also lead to the inappropriate administration of antibiotics, playing a role in the development of antibiotic resistance. Healthcare professionals can quickly diagnose UTIs with the use of these easy-to-use, non-invasive techniques, which help them make the best treatment choices. In contrast, nitrites in urine need particular circumstances to convert bacteria.[13] In terms of cost-effectiveness, time efficiency, and accessibility, rapid diagnostic tests are useful for ruling out urinary tract infections (UTIs).[10]

The clinical significance of prompt diagnosis has led to the widespread use of fast urine diagnostics, like dipstick analysis. Our study aimed to evaluate the accuracy of dipstick tests for leukocyte esterase and nitrite in quickly screening urine samples, with a semi-quantitative culture serving as the reference standard for diagnosing UTIs.

Materials And Methods

A cross-sectional validation study was conducted over 12 months in the Department of General Medicine in a public sector tertiary care hospital in Islamabad. From the results of a similar study, a total of 303 participants were recruited according to the World Health Organization (WHO) sample size calculator.[5] Regardless of the gender or age group, those who presented with symptoms of urinary tract infection were included in the study. However, those who had a history of antibiotic use in the last 48 hours were excluded. Clean-catch mid-stream urine samples were collected for both dipstick analysis and microbiological assessment. The results of these tests were retrospectively reviewed.

Combur 10 Roche dipstick was used as a diagnostic test dipstick for the detection of urine leucocyte esterase and Urine nitrite. A greater than trace amount detected was considered to be positive.

Filter paper strips were used to inoculate a standard amount of urine on Cystine-lactose electrolyte deficient agar (CLED) media for quantitative culture of urinary microorganisms using standard microbiological protocols. The results of urine culture were considered to be the gold standard in analyzing the diagnostic performance of urinary nitrite and leucocyte esterase tested on a dipstick.

The data was entered and analyzed in SPSS version 22.0. The quantitative data, like age, was measured in terms of mean and standard deviation. The qualitative variables like gender, urine culture, leucocyte esterase and urine nitrite were recorded as frequency and percentages. Keeping the urine culture a gold standard investigation, the sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio and negative likelihood ratio were calculated, with 95% CI, for urine

nitrite and leucocyte esterase, both individually and combined. The level of agreement between the dipstick analysis and urine culture was also tested using Cohen's kappa statistic.

The study was conducted with consent from the hospital ethics committee and administrative authority from the department head for the use of patient records.

Results

From a total of 303 cases recruited in the study, 149 were females with a mean age of 50±20 years, while 154 participants were males with a mean age of 49±24 years. A total of 42.6% (N=129) of the population studied had a positive result for urine culture, whereas the remaining 57.4% (N=174) did not reveal growth of any organism on urine culture. Urine culture was more likely to show bacterial growth in advanced age. Applying an independent t-test, this difference was found to be statistically significant with p=0.003. There was no significant gender-based difference in culture positivity with the results of urine culture being positive in 47% (N=70) of the female population and 38.3% (N=59) of the male population. Amongst the organisms isolated, Klebsiella was found to be the most frequent one, overall, with a frequency of 8.3% (N=25). However, in the female population, Escherichia Coli was most commonly isolated, i.e. in about 10% (N=15) of the female participants of the study. The results of the urine culture are summarized in Figure 1.

Considering the urine culture results as a gold standard in the diagnosis of UTI, the combination of nitrite positive and leucocyte esterase positive was the most specific parameter with a specificity of 98.9% (95% CI= 96.5-99.8%). The combination of nitrite-positive or leucocyte esterase-positive results was the least specific with the specificity being 75.9% (95% CI= 69.2-81.8. Overall, a very low level of sensitivity was recorded for all the parameters, ranging from 12.4% to 61.2%. No gender-based differences in the diagnostic accuracies of these parameters were observed. These results are summarized in Table 1.

Table 1: Diagnostic Performance of nitrite and leucocyte esterase results relative to quantitative urine culture. (NIT=Nitrite, LE=Leucocyte esterase)

	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	+LR (95% CI)	-LR (95% CI)
NIT+	33.3 (25.6-41.7)	96 (92.4-98.3)	86 (74.7-93.7)	66 (60.0-71.7)	8.29 (3.9-17.8)	0.69 (0.6-0.8)
LE+	40.3 (32.1-48.9)	78.7 (72.3-84.4)	58.4 (48.1-68.3)	64 (57.4-70.3)	1.9 (1.3-2.7)	0.76 (0.6-0.9)
NIT+ or LE+	61.2 (52.7-69.4)	75.9 (69.2-81.8)	65.3 (56.6-73.4)	72.5 (65.8-78.7)	2.54 (1.9-3.4)	0.51 (0.4-0.6)
NIT+ and LE+	12.4 (7.5-18.8)	98.9 (96.5-99.8)	88.9 (69.5-98.1)	60.4 (54.6-65.9)	10.79 (2.5-46.1)	0.89 (0.8-0.9)

Table 2: Level of concordance between dipstick analysis and urine culture results

	Culture					
	Positive	Negative	Agreement	Kappa	95% CI	P Value
Leucocyte esterase						
Positive	52(17.2%)	37(12.2%)	62.4%	0.198	0.09 - 0.31	P<0.001
Negative	77(25.4%)	137(45.2%)				
Nitrite						
Positive	43(14.2%)	7(2.3%)	69.3%	0.318	0.23 - 0.41	P<0.001
Negative	86(28.4%)	167(55.1%)				
Nitrite or Leucocyte esterase						
Positive	79(26.1%)	42(13.9%)	69.6%	0.374	0.27 - 0.48	P<0.001
Negative	50(16.5%)	132(43.6%)				
Nitrite and Leucocyte esterase						
Positive	16(5.3%)	2(0.7%)	62.0%	0.127	0.06 - 0.19	P<0.001
Negative	113(37.3%)	172(56.8%)				

The highest level of agreement, calculated up to 69.6% with a kappa value of 0.374, with urine culture results was observed with the combination of Nitrite or leucocyte esterase with a proportion of 79 cases being true positives and 42 false positive cases, keeping urine culture as a gold standard. The lowest level of concordance with urine culture results was observed with the

combination of nitrite-positive and leucocyte esterase-positive results, which yielded 16 true positive cases and 2 false positives, having an agreement of 62% and a kappa value of 0.127. These results are summarized in Table 2.

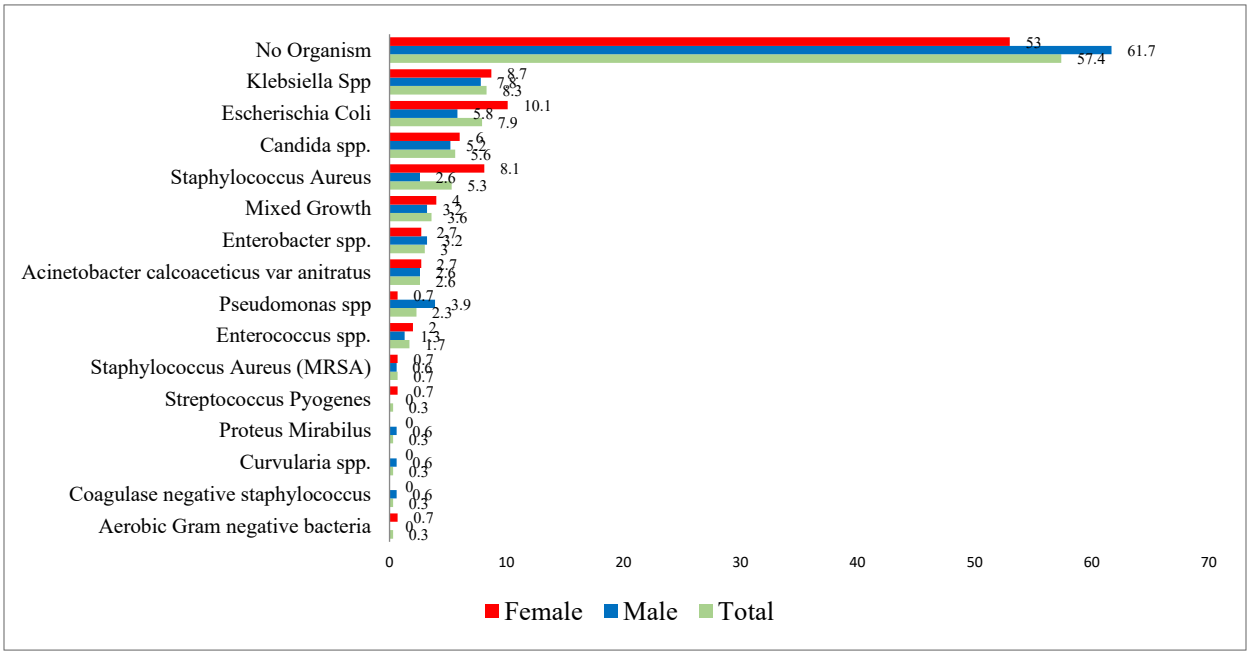

Figure 1: Results of Urine culture depicted as frequencies of organisms detected in the study population as a whole and gender-based frequencies

Discussion

Our study was carried out at a public sector, tertiary care hospital in Islamabad for 1 year. We included 303 patients in our study fulfilling our inclusion criteria Findings from this study showed that nitrite-positive and leucocyte esterase-positive combined urine samples relatively produce higher yields of urine culture-positive results than nitrite-negative and leucocyte esterase-negative urine samples respectively.

The results demonstrated an overall higher specificity of dipstick analysis, making it more effective at identifying true negatives than true positives. Our study showed that the sensitivity of Nitrite was 33.3%, specificity of 96%, positive predictive value (PPV) of 86 % and negative predictive value (NPV) of 66%, these results were quite comparable with the study carried out by Anastasiya et al. which showed sensitivity of nitrite was 46.5% with specificity of 90%, PPV of 85.9% and NPV of 66.8%, showing that the nitrite was quite specific marker for detecting Urinary Tract Infections. A study carried out by Almuhanna et al showed PPV and specificity of nitrites were high which was synonymous with our study that also showed high PPV and specificity values of nitrite while the sensitivity and specificity of leucocyte esterase carried out by Almuhanna et al were 68% and 81% respectively and in our study there were 40.3% and 78.7% respectively.[10] Another study by Abilash J. Bhansali et al. showed LE is more sensitive than nitrite (65% vs 40%), and nitrite is more specific (95% with PPV of 84%) in comparison to LE (73 % with PPV of 51%), quite similar to our research.[14] A study carried out by Nasreen et al. showed similar results that nitrite was more specific than sensitive.[15] In contrast to our study, which showed leucocyte esterase (LE) was 40.3 % sensitive, specificity was 78.7%, PPV was 58.4% and NPV was 64%, a study by Anastasiya et al. showed sensitivity for LE is 80.9%, specificity 58%, PPV of 54.5% and NPV 75.9%.[16] So our study showed that LE has more specificity than sensitivity, while a study by Anastasiya et al. showed the opposite result that the specificity of LE is less than sensitivity. A study carried out by John Maina et al. showed that nitrite had a low sensitivity value as compared to LE (50.7% vs 62.6%) so the results are quite comparable to our study which also showed that LE have more sensitivity as compared to nitrite but when combined sensitivity and specificity of nitrite and LE was compared the sensitivity of 87%, specificity of 40.1% was mentioned but in our study nitrite and LE combined have more specificity than sensitivity (sensitivity of 12.4%, specificity of 98.9% respectively) in detecting Urinary Tract Infections.[17]

Gram-positive bacteria do not produce nitrite reductase enzymes, making the nitrite test unreliable in detecting UTIs caused by these bacteria. Furthermore, the decreased excretion of nitrites in urine lowers pH, which can also cause a low sensitivity for the nitrite test, which explains the present study's findings.[18] Additionally, the timing of sample collection may affect the nitrite test's sensitivity. A midstream sample taken during the first void of the morning is likely to produce a superior sensitivity because nitrification, the process of converting nitrate to nitrite, takes time -at least 4 hours.[17] Most infections elicit an immune response and production of WBCs, which could explain why leucocyte esterase was a better UTI predictor. Nonetheless, nitrite and L.E. tests combined were a better UTI predictor, with the highest specificity of 98.9% and PPV of 88.9% than either of the separate

tests. The relatively low sensitivity of the L.E. test may be attributed to factors such as low bacterial counts in urine, elevated specific gravity and glycosuria.[19]

In our study, we found out that urine culture was more likely to show bacteriuria in advanced age. Similarly, a study carried out by Domingo et al. showed a strong association between UTIs and advanced age, leading to a higher risk of mortalities. It can be explained by age-related immunological senescence, which impairs both innate and adaptive immune responses and makes older people more prone to UTIs. Additionally, reduced immunoglobulin production and impaired urine acidification lead to adverse complications of UTIs.[20,21] A systemic review carried out by Dutta et al. also showed that UTIs are common in the elderly, primarily due to age-related vulnerabilities like malnourishment, poorly controlled diabetes mellitus, problems with bladder control leading to incontinence or urine retention, constipation, extended hospital stays, enlargement of the prostate, vaginal atrophy, inadequate hygiene practices, and disruptions in mental processes and our study also proved that UTIs are more common in old age group.[22] Another study by Guohua et al. also proved that UTI is a significant and common problem of old age, which our study also proved.[23] Research carried out by Chih-Yen et al. also mentioned that elderly patients are more likely to get uroseptic shock compared to their younger counterparts. Longer hospital admissions, greater rates of AKI, and higher in-hospital mortality are common outcomes for those who experience uroseptic shock. Urinary incontinence, incomplete bladder emptying, catheter use, obstructive uropathy in men, and changes in vaginal flora in women due to decreased estrogen levels, which promote uropathogen colonization, are some of the variables that increase vulnerability to UTIs as people age.[24]

According to our study, there was no gender-based difference, i.e. the culture positivity in males and females, as well as no significant difference in sensitivity, specificity, PPV and NPV of dipstick parameters. In another study carried out by Anastasya et al., there was no gender-based difference similar to our study.[16] In contrast to our study, a study carried out by John et al. showed that the sensitivity and PPV of dipstick test analysis were higher in females than males.[17] Another study by Sadam et al. showed that culture positivity was found more in females than males.[25]

In our study, we found Klebsiella pneumonia to be the most common cause of UTI overall, with E.coli being most common in women. A study carried out by Sofia et al. showed that UTIs are frequently caused by Klebsiella pneumoniae (UTIs). Its increasing resistance to a wide variety of antibiotics limits the efficacy of existing treatments for these illnesses. The virulence characteristics possessed by these bacteria allow them to colonize and cling to the mucosa of the urinary system, avoid immunological responses from the host, and form biofilms on medical devices such as urinary catheters.[26] In a study carried out by Mays et al., the results showed that E.coli was the most common organism causing UTI, followed by Klebsiella, while in our study, Klebsiella was found to be the most common organism causing UTI overall.[27] In a study carried out by Zuhair et al., it was shown that E.coli was the most common organism in females causing UTI, which was similar to our study.[28] In another study conducted by Mahabubu et al. Escherichia coli and Klebsiella species were the most common gram-negative bacteria found in urine samples from UTI patients.[29,30] Candida species causing UTI are also significantly increasing after E.coli and Klebsiella as shown in the study, and our study also found similar results that Candida species are causing UTI significantly after E.coli and Klebsiella overall. Possible reasons include using corticosteroids, immunosuppressive medications, broad-spectrum antibiotics excessively, old age, diabetes mellitus and anatomical or functional problems of the urinary system necessitating nephrostomy tubes or urine catheters.[31]

The sample size taken in our study was 303 patients, which may not be adequate to represent a population due to diversity in clinical features, age factor, ethnicity and immunity. A study may be conducted on a larger scale population to get more generalizability. Comorbidities and inflammatory markers such as WBC count, procalcitonin, and CRP may be investigated further to help guide the diagnosis and treatment of UTIs. These indicators may enhance care, especially in high-risk groups, when combined with patient characteristics. Variability in sample collection techniques, storage circumstances, and user methods can all have an impact on dipstick analysis results. The study is cross-sectional, and results cannot be applied to the whole population. Selection bias may be introduced by the study's dependence on participants who underwent dipstick testing when presenting for care. The study's patient population might not accurately represent those who did not seek medical care or received alternative treatment, which could bias the results in favour of particular patient demographics or disease severity levels.

Conclusion

A high specificity of dipstick analysis hints towards a greater accuracy to rule in the presence of UTI. As per the results of our study, both the dipstick parameters, leucocyte esterase and urinary nitrite, when considered in combination, had the greatest value of specificity. While urine culture remains the gold standard for UTI diagnosis, urine dipstick analysis is a convenient, rapid, and cost-effective alternative for initial screening, especially in settings where immediate culture results are not available. This can, therefore, aid clinicians in early detection and timely management with early initiation of appropriate antibiotics, particularly in cases where a quick diagnosis is crucial, such as in complicated UTIs or urosepsis.

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A.J, M.B, A.S, A.M.J, - Conception of study
- Experimentation/Study Conduction
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