Chron Precis Med Res 2022; 3(2): 52-56
DOI: 10.5281/zenodo.6965805

ORIGINAL ARTICLE
ORİJİNAL ARAŞTIRMA

Diagnostic Performance Evaluation of Complete Urinalysis in the Diagnosis of Urinary Tract Infection

İdrar Yolu Enfeksiyonu Tanısında Tam İdrar Tetkikinin Tanısal Performansının Değerlendirilmesi

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ABSTRACT

Aim: The aim was to evaluate the adequacy of the diagnostic performance of urinalysis parameters in the diagnosis of urinary tract infection.

Material and Method: In this retrospective study, the results of 13,315 individuals who had urine culture and complete urinalysis were analyzed. Midstream urine culture results were taken as a reference in the diagnosis of urinary tract infections. The diagnostic performance of urinalysis' chemical parameters [appearance, leukocyte esterase(LE), nitrite] and microscopic parameters (bacteria and squamous epithelium) individually and in combination were evaluated. Two different cut-off values (trace and 1+) were used while performing the analysis. Sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios were calculated. The area under the curve (AUC) was evaluated with receiver operating curve (ROC) analysis.

Results: Of the samples, 10.1% were evaluated as culture positive. The highest sensitivity rate was observed in the combination of the presence of any of the LE (trace), nitrite (trace), and bacteria parameters (86%). When evaluated as a single parameter, the highest sensitivity was observed in the LE(trace) parameter (81.6%). The negative predictive value was >90% in both single-parameter and combination evaluations. The AUC of the LE and nitrite tests was calculated as 0.758 and 0.718, respectively.

Conclusion: The parameters evaluated in this study, singly or in combination, showed sufficient performance in predicting negative urine cultures. Although complete urinalysis analyses cannot replace culture examinations, we believe that they can reduce unnecessary culture examinations.

Keywords: complete urinalysis, urine culture, diagnostic performance

ÖZ

Amaç: İdrar yolu enfeksiyonu (İYE) tanısında idrar tetkiki parametrelerinin tanısal performans yeterliliğinin değerlendirilmesi amaçlandı.

Gereç ve Yöntem: Retrospektif dizayn edilen bu çalışmada 13,315 bireye ait idrar kültürü ve tam idrar tetkiki analizi çalışmaya dahil edildi. İYE tanısında orta akım idrar kültürü sonuçları referans alındı. İdrar tetkiki kimyasal parametreleri [görünüm, lökosit esteraz (LE), nitrit] ve mikroskopik parametrelerin (bakteri,skuamöz epitel) tanısal performansları tekil ve kombinasyon halinde değerlendirildi. Değerlendirme yapılırken iki farklı cut-off değeri (Eser ve1+) kullanıldı. Sensitivite,spesifite, pozitif ve negative prediktif değer ve olabilirlik oranları hesaplandı. Receiver operating curve (ROC) analizi ile eğri altındaki alan (AUC) değerlendirildi.

Bulgular: Sonuçların %10.1'i kültür pozitif olarak değerlendirildi. En yüksek sensitivite oranı LE (eser), nitrite (eser), bakteri testlerinin herhangi birinin pozitifliği kombinasyonunda izlendi (%86.6). Tek bir parametre olarak değerlendirildiğinde ise en yüksek sensitivite oranı LE (eser) testinde izlendi (%81.6). Negatif prediktif değer; tek veya kombinasyon halindeki incelemelerin tümünde >%90 oranındaydı. LE ve nitrit testeri için AUC sırasıyla 0.758 ve 0.718 olarak hesaplandı.

Sonuç: Çalışmada değerlendirmeye alınan herbir parametre tekil olarak veya kombinasyon halinde negatif idrar kültürünü öngörmede yeterli performans gösterdi. Kültür incelemelerinin yerini alamayacak olsa da tam idrar tetkikinin gereksiz kültür incelemelerini azaltabileceği kanaatindeyiz.

Anahtar Kelimeler: tam idrar tetkiki, idrar kültürü, tanısal performans

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Başvuru Tarihi/Received: 30.03.2022
Kabul Tarihi/Accepted: 22.04.2022

INTRODUCTION

Urinary tract infections (UTIs), which are among the most common infections, cover a wide range of clinical conditions, ranging from asymptomatic bacterial colonization to sepsis. Various types of pathogens, such as Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterococcus faecalis, and Staphylococcus saprophyticus, can cause UTI (1, 2). Pollakiuria, polyuria, dysuria, suprapubic pain, hematuria, and fever can be seen with UTI (3). Laboratory findings include leukocytosis, increased CRP and erythrocyte sedimentation rate, leukocyte esterase and nitrite positivity in urine chemical analysis, and the presence of leukocytes and bacteria in urine microscopy. To diagnose UTI by microbiological culture, some threshold values indicating significant growth have been determined. When a uropathogen is detected in the culture examination of midstream urine specimens, this value is 104 cfu/ml; when two uropathogens are detected, it is 105 cfu/ml for each isolate (4). Urine is sterile in healthy individuals. If bacteria are seen in the urine, UTI or contamination should be suspected. Bacteria in the form of bacilli are the most common bacteria in urine. If bacteria without pyuria are identified, contamination should be considered by reviewing the preanalytical phase (5,6).

Many studies have examined the performance of urinalysis (UA) parameters in the diagnosis of UTI. However, the results of the studies vary widely (12-19). This study aimed to evaluate the adequacy of the diagnostic performance of the chemical and microscopy parameters of complete UA by taking culture examinations as a reference in the diagnosis of urinary tract infections.

MATERIAL AND METHOD

80,055 urinalysis and 19,529 midstream urine culture tests analyzed in xxx Central Laboratory between January and December 2016, were retrospectively scanned. Individuals whose ages ranged from 0–65 years were included in the study. Among them, the results of a total of 13,315 individuals whose urine culture and UA samples were taken simultaneously were evaluated.

Midstream urine specimens sent in a sterile urine container were planted in 5% sheep blood agar and eosin-methylene blue agar with 0.01 µl essence without waiting. The media were incubated for 18–24 hours in a 37°C aerobic environment. 104 cfu/ml in the presence of one uropathogen and 105 cfu/ml for each isolate in the presence of two uropathogens; was used as a positive cut-off value in culture analysis (4). Growths containing three uropathogens and more bacterial species were considered contaminated (4). Candida growth, which is seen in urine culture, can be an indication of not only urinary tract infection but also contamination, colonization, or disseminated candida infection (9). Therefore, specimens evaluated as contaminated or showing Candida growth were excluded from the study. The identification and antibiotic susceptibility of the grown bacteria were determined with the BD PhoenixTM automated system. Complete urinalysis and chemical and microscopic analyses were performed on the AX-4280 (Arkray, Kyoto, Japan), and iQ200 (Iris Diagnostics, Chatsworth, CA, ABD) devices.

Urine culture examinations were taken as the reference in the diagnosis of UTI. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio [LHR(+)] and negative likelihood ratio [LHR(-)] were calculated for some strip chemical parameters (appearance, leukocyte esterase, nitrite) and some microscopic analysis parameters (bacteria and squamous epithelial cells). The AUC was calculated by ROC analysis. These values were also calculated for the combination parameters. The combinations were as follows:

1. The positivity of all three tests of LE, nitrite, and bacteria (LE + nitrite + bacteria)
2. The positivity of any of the LE, nitrite, or bacteria tests (LE / nitrite / bacteria)

LE, nitrite, which were analyzed semi-quantitatively, were evaluated by taking two limit values at the trace and 1 (+) levels. A cloudy or very cloudy appearance, bacteria 1 (+) and above, and squamous epithelium > 5/hpf were evaluated as positive (8).

The data were analyzed using the Microsoft Excel and SPSS Statistics 22 programs. A $p < 0.05$ level was considered statistically significant.

RESULTS

Of the total individuals, 60.0% were female (7,989). Of the samples, 10.1% (1,351) were evaluated as culture positive, while 65.9% (890) of the positive samples showed E. coli growth.

Indications regarding the diagnostic performance of the tests are summarized in **Table 1** and **Figure 1**. When each parameter was evaluated singly, for LE (trace) and 1 (+) levels, the sensitivity was 81.6% and 74.9% and the specificity was 70.1% and 76.7%, respectively. For the nitrite (trace) and 1 (+) levels, the sensitivity was 46.0%; 46.0%, and the specificity was 97.2%; 97.7%, respectively.

The highest sensitivity was calculated in LE (trace)/ nitrite(trace)/bacteria combinations (86%). The lowest sensitivity was calculated in LE(1+)+nitrite(1+)+bacteria combinations (8.1%). When evaluated with a single parameter, the highest sensitivity was calculated in LE (trace), (81.6%) and the lowest sensitivity in the squamous epithelium test (5.7%).

Table 1. Data on diagnostic accuracy performance of complete urinalysis parameters.

Parameter/ Combination	Sensitivity (±%95 CI)	Spesifity (±%95 CI)	PPV (±%95 CI)	NPV (±%95 CI)	LHR(+) (±%95 CI)	LHR(-) (±%95 CI)	AUC
LE (1+) + Nitrite (1+) + Bct	8.1 (6.7-9.7)	99.9 (99.8-99.9)	89.3 (82.5-93.7)	90.6 (90.5-90.8)	74.3 (41.9-131.6)	0.9 (0.91-0.93)	0.540
LE (t) + Nitrite (t) + Bct	8.6 (7.2-10.2)	99.9 (99.8-99.9)	89.2 (82.7-93.5)	90.6 (90.5-90.8)	73.4 (42.3-127.5)	0.9 (0.9-0.93)	
LE (1+) / Nitrite (1+) / Bct	82.3 (80.2-84.3)	74.9 (74.1-75.7)	27.0 (26.2-27.7)	97.4 (97.1-97.7)	3.3 (3.1-3.4)	0.2 (0.21-0.26)	0.786
LE (t) / Nitrite (t) / Bct*	86.0 (84.0-87.8)	68.4 (67.6-69.3)	23.5 (22.9-24.1)	97.7 (97.4-98.0)	2.7 (2.6-2.8)	0.2 (0.18-0.23)	
LE (1+)	74.9 (72.5-77.2)	76.7 (75.9-77.5)	26.6 (25.8-27.5)	96.4 (96.1-96.7)	3.2 (3.1-3.4)	0.3 (0.3-0.4)	0.758
LE (t)	81.6 (79.4-83.6)	70.1 (69.3-70.9)	23.5 (22.9-24.2)	97.1 (96.8-97.4)	2.7 (2.6-2.8)	0.26 (0.23-0.29)	
Nitrite (1+)	46.0 (43.4-48.7)	97.7 (97.4-97.9)	68.9 (66.0-71.6)	94.1 (93.8-94.4)	19.6 (17.2-22.3)	0.5 (0.53-0.58)	0.718
Nitrite (t)	46.0 (43.3-48.7)	97.2 (96.8-97.4)	64.6 (61.8-67.3)	94.1 (93.8-94.4)	16.1 (14.3-18.2)	0.56 (0.53-0.58)	
Bct	16.1 (14.1-18.1)	98.9 (98.7-99.0)	61.5 (56.5-66.2)	91.3 (91.1-91.4)	14.1 (11.5-17.4)	0.8 (0.83-0.87	0.574
Appearance	66.1 (63.5-68.6)	75.2 (74.5-76.0)	23.2 (22.3-24.1)	95.2 (94.8-95.5)	2.7 (2.5-2.8)	0.4 (0.4-0.5	0.707
Epithelium	5.7 (4.5-7.1)	93.8 (93.4-94.2)	9.4 (7.7-11.6)	90.0 (89.9-90.1)	0.9 (0.7-1.2)	1.0 (0.99-1.01)	0.498

LE: leukocyte esterase, Bct: bacteria, t*: trace, PPV: ositive predictive value, NPV: negative predictive value, LHR:likelihood ratio, (AUC: area under the curve, CI:confidence interval. LE + nitrite + bacteria: The positivity of all three tests of LE, nitrite, and bacteria, LE / nitrite / bacteria: The positivity of any of the LE, nitrite, or bacteria tests

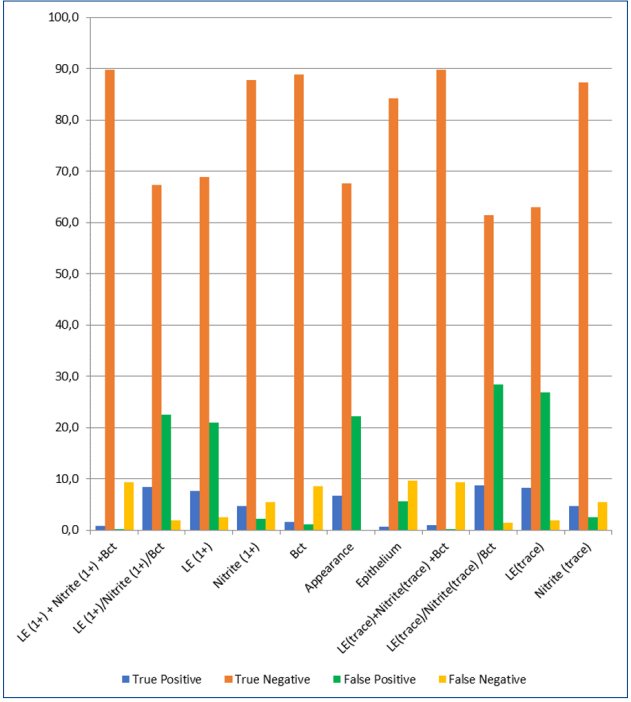

Figure 1. Percentage rates regarding the diagnostic performance of tests.

LE: leukocyte esterase, Bct: bacteria.

- LE + nitrite + bacteria: The positivity of all three tests of LE, nitrite, and bacteria.
- LE / nitrite / bacteria: The positivity of any of the LE, nitrite, or bacteria tests

The highest specificity rate was calculated in the combination LE(1+) + nitrite(1+) + bacteria (99.9%). When considered as the single parameter, the highest specificity was calculated for the positivity of bacteria (98.9%).

The highest PPV was calculated in LE(1+) + nitrite(1+) + bacteria (89.3%), When evaluated with a single parameter, the highest PPV was calculated in the nitrite test (68.9%). The highest NPV was calculated in the LE(trace) / nitrite(trace) / bacteria combination (97.7%). When evaluated with a single parameter, the highest NPV was calculated in the LE (trace) (97.1%).

DISCUSSION

Urine evaluations have an important place in the diagnosis of urinary tract infections. Complete urinalysis with fast results can be used in preliminary diagnosis (9). Costly and time-consuming culture examinations are accepted as the gold standard test in diagnosis (10,11). Many studies have examined the accuracy of UA parameters in the diagnosis of UTI. However, the results are different at a level that can be considered inconsistent (12-19). In present study, the diagnostic performance of UA parameters was evaluated with reference to urine culture in the diagnosis of UTI. All the parameters singly or in combination included in present study performed well in predicting negative urine culture, with an NPV of ≥ 90%.

Memişoğulları et al., in their study with 250 samples, reported the culture positive rate as 35.6% and the E. coli rate as 24.4%. Şahin et al. reported a 12% positive culture analysis in their study with 550 samples. Yüksel et al. reported 33% positive culture analysis in their study with 362 samples, and Yusuf et al. reported 14 % positive culture analysis in their study with 2,351 samples (12-15).

In present study, 10.1% of the samples were evaluated as having a positive culture examination. Of positive samples, 66% were from E. coli growth. In present study, an evaluation was made on a larger sample, and although the literature results differ considerably, the results that we obtained were evaluated as comparable.

While the NPV was calculated as 96%–100% in studies examining the exclusion of UTI by clear-looking urine (16), a similar rate of 95.2% was obtained in present study. Examining the appearance of urine alone performs well in predicting a negative urine culture.

When we look at the results of different studies, it can be seen that the sensitivity values calculated for the LE test cover a very wide range (14.1%–89.3%),(12-15,17-20). In our study, the sensitivity for LE (trace) was calculated as 81.6%. When various studies are examined, similarly, it is possible to talk about a ratio between 93.6% and 18.2% for the specificity of the LE test (12-14,17,19-21) In present study, the specificity for the LE1 (+) level was calculated as 76.7%. The PPV was reported to be between 33.6% and 97.8% in previous studies; it was calculated as 26.6% in present study. The NPV was reported between 58% and 99.3% (12,15,17,19,20,28) in the studies performed; this value was calculated as 97.1% in present study. In the case of LE positivity in patients with negative cultures, it would be beneficial to consider organisms such as Chlamydia and Ureaplasma urealyticum. In addition, in the case of sterile pyuria, it will be useful to review the presence of balanitis, urethritis, tuberculosis, bladder tumors, viral infections, nephrolithiasis, foreign bodies, exercise, and glomerulonephritis, and to question the use of medical treatment.

For the nitrite test in different studies, the sensitivity was calculated as 10.8%–51.5%, specificity was calculated as 86.3%–99.7%, PPV was calculated as 78%–89%, and NPV was calculated at different rates between 69.6%–91.4% (13-15,17,19,21). For nitrit1 (+) in present study, the sensitivity was calculated as 46%, specificity was calculated as 97.7%, PPV was calculated as 68.9%, and NPV was evaluated with a rate of 94.1%. Nitrite positivity can predict significant bacteriuria, and its specificity is high. However, its sensitivity is limited, as determined in present study. It should be kept in mind that false-negative results can be encountered in cases such as high specific gravity and urobilinogen levels, the presence of nitrate reductase negative bacteria, a pH < 6.0, the presence of ascorbic acid, and poor nutrition from nitrate (6).

In various studies on the combination of LE and nitrite, the sensitivity was evaluated as between 66.7%–96.9% and the specificity as between 68.9%–93.8%; the PPV was reported as between 53%–66.9% and the NPV as between 77.4%–98.7% (17-19,22-26). For the combination of LE and bacteria, the sensitivity was calculated as 37.9%, specificity as 92%, PPV as 69.4%, and NPV as 76.6% by Yüksel et al (14). For the LE, nitrite, and blood combination, the sensitivity was calculated as 80%, specificity as 60%, PPV as 52%, and NPV as 84% by Memişoğulları et al (12). In present study, sensitivity of the LE/nitrite/bacteria combination was calculated as >80% and the NPV as >97%. For the LE + nitrite + bacteria combination, the specificity was calculated as 99.9%, and the PPV was >89%. The sensitivity was found to be quite low (8.6%).

In the study by De Boer et al., the sensitivity was calculated as 94.7%, and the specificity was 88.2% for the bacteria parameter using the flow cytometry method (27). For Patrick et al., in a study (using the flow cytometry method) adopting a threshold value of ≥105 cfu/ml, the sensitivity for the bacteria test was 98%, the specificity was 93.7%, and the NPV was 99.3% (28). In a study performed by Yusuf et al., taking ≥105 cfu/ml as a reference, they calculated the sensitivity, specificity, PPV, and NPV values as 91.7%, 87.5%, 53.9%, and 98.5%, respectively (15). In another study conducted by Conker et al., they calculated the sensitivity as 100%, specificity as 43.5%, PPV as 17%, and the NPV as 100% for the threshold of 10 bacteria/µL (in microscobic analysis) taking ≥10 3 cfu/ml as a reference (in urine culture) (29). In present study, the sensitivity of the bacteria test, which was examined by the digital flow microscopy method, was very low at 16.1%. The specificity was very good at 98.9%; the PPV and NPV (61.5%; 91.3%) were similar to those of previous studies. Excessive pyuria can mask the diagnosis of bacteria. Although it is analyzed with automated systems, the examination and reporting of microscopy parameters can depend on the user, and the evaluation of the images of the examinations of the same sample can be interpreted in a different way. Manual microscopy is accepted as the gold standard, although automated urine sediment analyzers provide time and labor benefits compared to manual microscopy.

In the studies, the AUC was calculated between 0.61 and 0.84 for single LE, single nitrite, LE or nitrite combination tests. It was calculated in the range of 0.61–0.96 for single bacterial positivity (19,27,30). The results obtained for LE and nitrite in present study were at a similar level (**Table 1**).

CONCLUSION

The parameters evaluated in present study, alone or in combination, showed sufficient performance to predict a negative urine culture. We are of the opinion that the use of complete urinalysis tests in combination, rather than based on only a single parameter, can increase sensitivity and be more useful in the decision-making processes of clinicians. Urinalysis can predict a negative urine culture. Although complete urinalysis cannot replace culture examinations, it can reduce unnecessary empirical antibiotic therapy and guide the clinician in excluding the diagnosis of UTI in appropriate patient groups.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Van Yüzüncü Yıl University Ethics Committee (Date: 2021, Decision No: 06-16).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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