



Research Article / Araştırma

İdrar kültürü ve otomatize tam idrar tetkiki cihaz sonuçlarının karşılaştırılması: çok merkezli bir çalışma**Comparison of urine culture and automated complete urinalysis device results: A multicenter study**

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ABSTRACT

Aim: The treatment approach of patients presenting to health centers with urinary tract complaints is closely related to the results of urinalysis. In this study, we aimed to investigate the consistency of complete urinalysis and urine culture results of patients admitted to *** and *** laboratories with similar complaints.

Materials and Methods: Urine tests of 218.022 patients admitted to the biochemistry laboratories of both hospitals were performed with a Beckman iQ@200 automated urine analyzer and urine cultures were performed manually.

Results: When all results were compared, urine culture and leukocyte count discordance was 11.42%, and urine culture and bacterial count discordance was 6.46%. When the diagnostic performance of the automated test was compared with culture results, leukocyte count was superior to bacterial count (leukocyte sensitivity: 91.75%; leukocyte specificity: 87.92%; bacterial sensitivity: 6.45%; bacterial specificity: 98.42%).

Conclusions: When all data are compared, it is thought that test, device, and human factors affecting laboratory performances are important in the approach to patients presenting for urinalysis.

ÖZ

Amaç: İdrar yolu şikayetleri ile sağlık merkezlerine başvuran hastaların tedavi yaklaşımı tetkik sonuçları ile yakından ilişkilidir. Bu çalışmada, *** ve *** laboratuvarlarına benzer şikayetlerle başvuran hastaların tam idrar tetkiki ve idrar kültürü sonuçlarının tutarlılığını incelemeyi amaçladık.

Gereç-Yöntem: Her iki hastanenin biyokimya laboratuvarlarına başvuran 218.022 hastanın idrar testleri Beckman iQ@200 otomatize idrar analizörü ile, idrar kültürleri ise manuel olarak yapılmıştır.

Bulgular: Tüm sonuçlar karşılaştırıldığında, idrar kültürü ve lökosit sayısı uyumsuzluğu %11,42 ve idrar kültürü ve bakteri sayısı uyumsuzluğu %6,46 olarak bulunmuştur. Otomatize testin tanısal performansı kültür sonuçları ile karşılaştırıldığında, lökosit sayımı bakteri sayımından daha üstündü (lökosit duyarlılığı: %91,75; lökosit özgüllüğü: %87,92; bakteri duyarlılığı: %6,45; bakteri özgüllüğü: %98,42).

Sonuç: Tüm veriler karşılaştırıldığında, idrar tahlili için başvuran hastalara yaklaşımda laboratuvar performanslarını etkileyen test, cihaz ve insan faktörlerinin önemli olduğu düşünülmektedir.

ARTICLE INFO/MAKALE BİLGİSİ

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Anahtar Kelimeler: İdrar kültürü, idrar analizi, bakteri sayısı, lökosit sayısı

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Introduction

Urinary tract infections (UTIs) are commonly seen as infections caused mostly by bacteria (1, 2). UTI can be categorized into three groups asymptomatic bacteriuria, lower UTI which affects the bladder and urethra; and upper UTI which affects the ureter, pelvis, and kidneys (1, 3).

The incidence of UTI is higher in women because of the shorter urethra and closeness of the urethra to the anal region anatomically (4). About 1 in every 3 women has UTI attacks at least one time up to 24 years of age which needs antimicrobial treatment. On the other hand, almost half of the young and sexually active women encounter UTI. Catheter-related UTIs are the most common type of infections seen in hospitals and care centers (3, 4).

When the high incidence of UTI is considered, diagnosis treatment, and prevention of disease get quite important. Diagnosis is based on both symptoms like pollakuria, urge incontinence, decrease in urine flow rate, nocturia, pain in the suprapubical or waist, and laboratory findings like pyuria, bacteriuria, leukocyte esterase activity, nitrite positivity, and presence of pathogen bacteria in urine culture. In outpatient admissions, generally, treatment is started without waiting for the urine culture results based on patient symptoms (5, 6).

A complete urinalysis is easily carried out in health centers as it is simple and cheap (7). Complete urinalysis tests include physical, chemical, and microscopical examination of urine specimens. Positive results for both leukocyte esterase and nitrite parameters and also the appearance of both leukocytes and bacteria under the microscope favor positive results while negative tests for these parameters are valuable as exclusion

criteria (8, 9). In this era, the common use of automated urine analyzers has made complete urinalysis simpler and more standardized (10).

Urine culture is accepted as the gold standard in UTI diagnosis. However as the results of culture are obtained in 24-48 hours, treatment is generally started due to clinical symptoms and complete urinalysis results and re-arranged with the results of culture and antibiogram results (10). The present study aims to compare the harmony and correspondence between complete urinalysis and culture results.

Materials and Methods

The study was approved by the Ethics Committee of *** (09.08.2023/179). A complete urinalysis and urine culture data are retrospectively derived from Laboratory Information Systems (LIS) of *** for 5 years (2017-2022) and *** for 12 years (2010-2022). A total of 218.022 patient data (181.783 from *** and 36.239 from ***) were included in the study. Positive/negative leukocyte and bacteria numbers from complete urinalysis were compared with positive/negative urine culture results. Results were also evaluated according to patients' demographical data.

Complete urinalysis was carried out with iQ@200 (Iris Diagnostics, Chatsworth, CA, USA) in both hospitals. Leukocyte counts ≥ 5 and bacteria counts ≥ 1 were accepted as positive.

Midstream urine samples collected in sterile containers were inoculated with calibrated loops into a medium containing 5 % sheep blood agar and eosin-methylene blue and incubated under aerobe conditions at 37 °C for 18-24 hours. Bacterial growth was evaluated quantitatively. For his study, urine samples showing $\geq 5 \times 10^4$ cfu/ml growth at the end of incubation time were accepted as

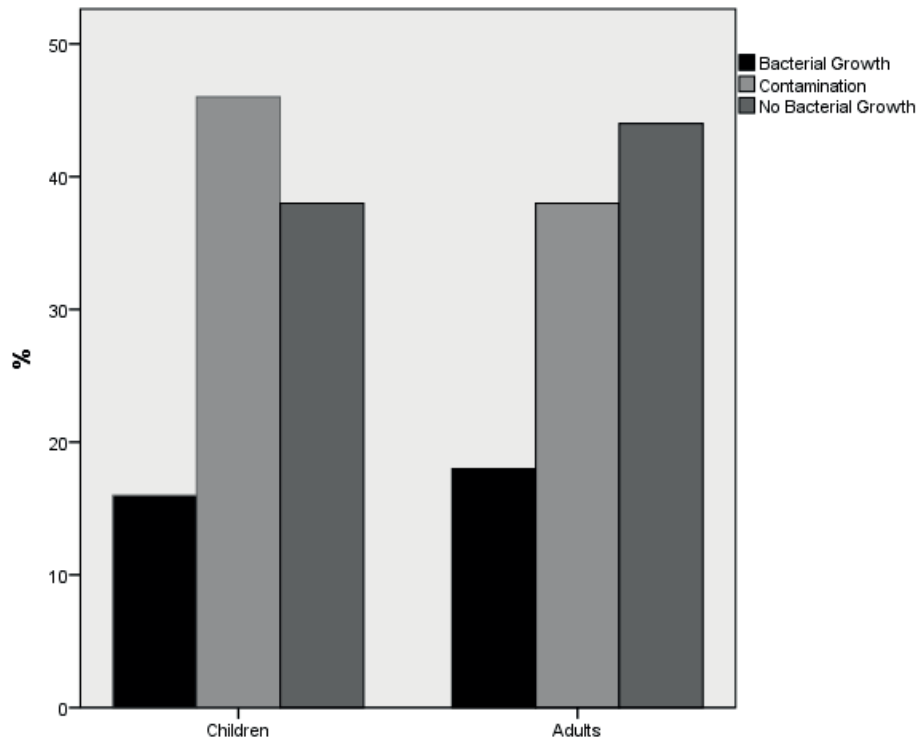


Figure 1: Bacterial growth and contamination percentages in children and adults

positive.

Descriptive statistics were expressed as numbers and percentages. All statistics were carried out with the Statistical Package for Social Sciences (SPSS) 22.0 (SPSS Inc. Chicago, IL, USA) program.

Results

A total of 218.022 urine samples with urine culture test requests were evaluated in this study. 61 % of the samples were from adults (n=132.994) and 39 % were from children

Table 1: Urine culture results in patient groups

URINE CULTURE	ADULT		CHILDREN		TOTAL (n)
	MALE (n-%)	FEMALE (n-%)	MALE (n-%)	FEMALE (n-%)	
POSITIVE	5887 (15.88%)	17422 (47.01%)	5089 (13.73%)	8666 (23.38%)	37.064 (17%)
CONTAMINATION	8843 (9.89%)	41475 (46.4%)	9768 (10.93%)	29303 (32.78%)	89.389 (41%)
NEGATIVE	26088 (28.49%)	33279 (36.34%)	13203 (14.42%)	18999 (20.75%)	91.569 (42%)
TOTAL	40818 (18.72%)	92176 (42.28%)	28059 (12.87%)	56969 (26.13%)	218.022 (100%)

(n=85.028). When the urine culture results were evaluated; 17 % of the samples showed specific uropathogenic growth, 41 % had urethral flora bacteria contamination and 42 % did not show any growth. Results are

children. The discordance between bacteria numbers and culture results was caused by 68.34 % of adults and 31.66 % of children.

Diagnostic performances of tests were evaluated referring to urine culture positivity.

Table 2: Comparison of strip leukocyte and bacteria numbers with urine culture results

LEUKOCYTE AND BACTERIA	ADULT		CHILDREN		TOTAL (n-%)
	MALE (n-%)	FEMALE(n-%)	MALE (n-%)	FEMALE (n-%)	
LEUKOCYTE(-)/CULTURE(+)	29 (0.69%)	76 (0.74%)	33 (0.45%)	36 (0.55%)	174 (0.47%)
LEUKOCYTE(+)/CULTURE(-)	2194 (7.13%)	8659 (10.54%)	4201 (4.27%)	4761 (7.68%)	19815 (10.95%)
BACTERIA(-)/CULTURE(+)	299 (6.53%)	902 (7.11%)	287 (4.23%)	324 (4.85%)	1812 (4.89%)
BACTERIA(+)/CULTURE(-)	698 (1.71%)	1281 (1.53%)	425 (1.19%)	437 (1.67%)	2841 (1.57%)

summarized in Table 1.

Results from the iQ@200 analyzer were compared with culture results. Results of urine culture were classified as specific uropathogenic growth: positive, urethral flora contamination, and negative.

A complete urinalysis results were compared with culture results in terms of leukocytes and bacteria. Leukocyte-negative patients with urine culture positivity were found to be 0.47 %. urine culture-positive patients with leukocyte negativity were found to be 10.95 %. according to these data, 11.42 % of the results were discordant. Bacteria-negative patients with positive urine cultures were 4.89 %. Bacteria-positive patients with negative urine cultures were 1.57 %. In terms of bacteria results; complete urinalysis and culture were discordant at a ratio of 6.46 %. Data is summarized in Table 2.

Bacterial growth was seen in 16.18 % of children and 17.53 % of adults. The contamination ratio was 45.95 % in children and 37.83 % in adults. No growth was detected in 37.87 % of children and 44.64 % of adults (Figure 1). The discordance between leukocyte numbers and culture results was caused by 54.82 % of adults and 45.18 % of

The sensitivity of the leukocyte test was found to be 91.75 % and specificity was found to be 87.92 %. On the other hand, the sensitivity and specificity of the bacteria test were found to be 6.45 % and 98.42 % respectively.

Discussion

UTI is quite common in the community. These infections can be asymptomatic or cause serious patient complaints (2). Apart from this, they cause a high number of outpatient clinics and emergency admission and hospitalization-required disease, therefore, they cause significant labor and economic losses (4). Considering this outcome, their diagnosis, prevention, and treatment are of great importance. Determining the specificity and sensitivity of the methods used for the diagnosis of infection is important in the diagnosis and treatment of these infections (3).

Gulcan et al. found the highest sensitivity level (96 %) for the presence of bacteria in the complete urinalysis, and the highest specificity with 86.4 % in the nitrite test. They stated that the presence of bacteria in patients with suspected UTI and the

leukocyte esterase and nitrite positivity they detected in the IQ 200 IRIS urine autoanalyzer would not be sufficient for diagnosis in single use, these two tests should be evaluated together, but an absolute correlation with culture results should not be expected (3).

Yuksel et al. carried out a retrospective study with 362 patient results, and they found that 50.4 % of 67 urine culture-positive samples were presented with negative leukocyte, nitrite, and bacteria in complete urinalysis. They have found that the sensitivity for leukocyte esterase and leukocyte count in microscopy was high at 86.1 % and 88.0 % respectively. The specificities on the other hand were high for nitrite (95.4 %) and bacteria (86.6 %). They have concluded that fully automated urine analyzers have sufficient diagnostic accuracy but they need to be co-evaluated with urine culture test results for better understanding (9).

In some previous studies, the sensitivity and specificity of complete urinalysis parameters were investigated and different results were reported. The results of Caliskan et al. study have revealed the bacteria counts in complete urinalysis analysis had 78.8 % diagnostic sensitivity and 81.5 % specificity for UTI diagnosis and they declared that culture growth rates are higher in complete urinalysis with higher bacterial counts (10). In our study, bacteria positivity in the complete urinalysis test had 6.45 % sensitivity and 98.42 % specificity in urine culture-positive samples. Tekin et al. studied 183 children and different from our findings, they found these values 91.8 % and 54.9 % respectively and they stated that when the urine is collected with sterile urine bags, the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) are lower; in contrast highest sensitivity is shown by nitrite and highest specificity is shown

by leukocyte esterase. They suggested that none of the complete urinalysis parameters had enough diagnostic power so if possible, the complete urinalysis test needs to be combined with culture results for a better diagnosis of UTI (11).

Nys et al. determined the performance characteristics of diagnostic tests in the study they carried out in 1993 with female patients of 11-70 years of age with acute, uncomplicated by comparing urine culture growth rates and prescribed antibiotics. Overall numbers for PPV for nitrite was 96 % and specificity was 94 %; while positive leukocyte esterase and negative nitrite test had 79 % PPV and 82 % sensitivity. However, in 50 % of the samples with both nitrite and leukocyte esterase negativity, cultural growth was determined. They have concluded that in uncomplicated female UTI patients; leukocyte esterase positivity can confirm UTI whether or not nitrite is positive but nitrite and leukocyte esterase negativity can not exclude infection and urine culture results have to be evaluated for final decision (12).

Amin et al. carried out a study on 1200 children aged between 2.5-7 years (754 male, 446 female). They made culture analysis in both complete urinalysis negative or positive for nitrite and leukocyte. They determined UTI incidence to be 7 %. In 112 children (9.3 %) leukocyte esterase was positive, in 94 (7.8 %) nitrite was positive, in 34 (2.8 %) both leukocyte esterase and nitrite were positive. For complete urinalysis leukocyte esterase; sensitivity was 73.8 %, specificity was 95.5 %, negative predictive value was 98 % and positive predictive value was 55.4 %. On the other hand for nitrite, sensitivity was 66.7 %, specificity was 96.6 %, negative predictive value was 97.5 % and positive predictive value was 59.6 %. When leukocyte esterase and nitrite were co-evaluated; sensitivity was 40.5

%, specificity was 100 %, negative predictive value was 95.7 % and positive predictive value was 100 %. They also concluded that UTI prevalence was statistically different in females (54.8 %) and males (45.2 %) (13).

Spek et al. have commented that UTI is among the most common infections seen in primary health care centers and they paid attention to the difficulties in diagnosing UTI by general practitioners which cause the prescription of irrelevant antibiotics and urine culture requests. They carried out a retrospective study on the night shift with 5657 patients with a mean age of 54, 78.9 % female. It has been detected that urine complete urinalysis has been carried out in 87.5 % of all patients, and urine culture was requested in only 10.3 % of patients in which urine culture was indicated. 74 % of all patients were prescribed antibiotics, and 64.7 % of these were leukocyte esterase negative (14).

Kacmaz et al. detected sensitivity and specificity for leukocyte esterase and nitrite test combination in complete urinalysis as 72.2 % and 97.5 % respectively, bacteriuria and bacteriuria detection with gram staining combination had 95 % sensitivity and 95 % specificity. Sensitivity and specificity were 76.0 % and 84.6 % only in the presence of bacteria. They concluded that microscopical investigation of urine is more guileful than complete urinalysis for diagnosis of UTI (15).

Parlaktas et al. evaluated complete urinalysis and culture results for patients who had possible UTI, and they determined performance characteristics for bacteria, leukocyte esterase, and nitrite. Sensitivity values were 80.5 %, 74.7 %, and 64.4 % respectively; specificities were 88.0 %; 84.8 %; and 98.5 % PPV was 60.4 %; 53.5 %; 92.9 % and NPV was 95 %; 93.7 %; 89.8 % which were all lower than urine culture values (16).

Mohanna et al. evaluated 359 patients aged between 19-65 years and compared complete urinalysis results with culture results and they found sensitivity and specificity for leukocytes as 62.7 % and 100 % for leukocytes and 20.6 % and 93.5 % for nitrite respectively. Sensitivity was higher for leukocytes, while specificity was higher for nitrite (17).

In Martine et al. study, a UriSed urine sediment analyzer was used and they proposed that for leukocyturia and/or bacteriuria 97 % sensitivity, 59 % specificity, 27 % PPV, 99% NPV, and ut-off values for $\geq 12,6$ bacteria/hpf and ≥ 6 leukocyte/hpf, a 64 % accuracy was reached and irrelevant urien cultures were reduced as 52 % (18).

In the pediatric population, urine sample collection for urine analysis is harder. Midstream urine collection to prevent bacterial contamination, and cleansing with soap and salt may provide a more sterile urine specimen and lead to more accurate complete urinalysis and culture results. Kaufman et al. have proposed that leukocyte esterase and nitrite tests within the complete urinalysis are not sufficient in terms of sensitivity and specificity, but when used together; they can be a good scanning tool, in fact still there will be a need for tests with better NPV for excluding UTI. They concluded that complete urinalysis results are better when combined with urine microscopy (19).

Tunga et al. studied the data of 60 children admitted to a pediatric clinic with suspected UTIs. They compared strip leukocyte and nitrite results and microscopic bacterial examination results with cultural growth. They found a good correlation between culture results and strip tests and microscopy and they offered complete urinalysis for quicker diagnosis and treatment of UTI (20).

Sezgin et al. studied the strip leukocyte and nitrite positivity in a group of patients with suspected UTI at the age of 0-16. Sensitivity, specificity, PPV, NPV, and accuracy values were 64.3 %, 95 %, 76.4 %, 91 %, and 88.4 % for leukocytes and 17.1 %, 99 %, 86 %, 83.5 %, 69.8 % for nitrite and concluded that strip test alone is not enough for diagnosis of UTI (21).

Maduemem et al. have included 262 children's strip results in their study, they calculated nitrite and leukocyte esterase sensitivity as 0.54 and 0.86 respectively, and ≥ 100 cell/mm³ pyuria the sensitivity value was 0.92. The lowest sensitivity was found between leukocyte esterase and nitrite co-positivity at 0.49 and a positive leukocyte esterase test had a significant correlation with pyuria. They concluded that complete urinalysis strip urine tests may not be reliable in children to exclude UTI, but both complete urinalysis positivity and pyuria together can be useful in UTI diagnosis (22).

Al-Musawi et al. analyzed data from 143 children and found significant relationships between strip and microscopic evaluation and positive urine culture results. They did not detect any significant difference between sensitivity, specificity, PPV, and NPV between the strip test and pyuria (23).

Conclusion

In the discussion part, it was observed that some studies found the results of complete urinalysis and urine culture compatible, while others found differences between the results. The presence of many variables that will affect the laboratory result in such studies (eg, sample appropriately taken and transferred to the laboratory, the difference in the devices or kits used, the skill of the personnel who planted the culture, etc.) does not make it possible to make an adequate comparison.

At the same time, according to urine culture, false positive and false negative results in complete urinalysis tests were determined to be mostly caused by the pediatric population. Considering this situation, the difficulties of obtaining samples from children, and the supportive aspects of the urine culture of the complete urinalysis results come to the fore even more in children and support its usability.

As a result, it was concluded that complete urinalysis, which clinicians often use for rapid diagnosis, will contribute to a more efficient evaluation of urine culture. The sensitivity and specificity of leukocytes were found to be high in urinary tract infections, and it is thought that negative leucocyte values will help the physician and reduce unnecessary antibiotic use, especially in healthcare institutions where urine culture cannot be performed.

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