Original Article

Cukurova Anestezi ve Cerrahi Bilimler Dergisi

The Analytical Performance of an Automated Urine Analyzer - Iriscell IQ200

Didem Akal Tascioglu[*1], *Muge Kanmaz Ozer*[2], *Beyhan Omer*[3], *Ahmet Dirican*[4], *Nilgun Sema Genç*[3], *Haluk Eraksoy*[5]

1 Istinye University, Faculty of Medicine, Department Infectious Disease and Clinical Microbiology, Istanbul, Türkiye
2 Prof. Dr. Cemil Tascioglu City Hospital, Department of Biochemistry, Istanbul, Türkiye
3 Istanbul Health and Technology University, Faculty of Medicine, Department of Biochemistry, Istanbul, Türkiye
4 Istanbul University Cerrahpaşa, Faculty of Medicine, Department of Biostatistics, Istanbul, Türkiye
5 Istanbul University, Faculty of Medicine, Department of Infectious Disease and Clinical Microbiology, Istanbul, Türkiye
***Correspondence:** Didem Akal Tascioglu, MD; didem.tascioglu@istinye.edu.tr
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Abstract

Aim: To evaluate the analytical performance of the analyzer's urine parameter measurements and compare them with urine culture results. **Methods:** The study was undertaken in the clinical laboratory of Istanbul University, Istanbul Faculty of Medicine. Fresh urine samples were collected from 437 consecutive in- and out-patients (263 women and 174 men) and analyzed within an hour using the Iris IQ200. For each sample, automated chemical analysis (dipstick) and sediment analysis were performed. **Results:** During the study period, 437 consecutive urine samples were investigated. The analyzed urine samples were from 263 females and 174 males aged between 1 and 89 years (average age: 47.5 years). Forty-eight contaminated urine samples were excluded from the study. Urine culture was positive in 109 patients. Of the 437 samples analyzed with the IQ200 Elite, 217 (49.6%) met the predefined thresholds (WBCs, leucocyte esterase, bacteria, ASP) for UTI and were redirected for urine culture. Of these samples, only 83 (38.2%) were positive in the urine culture. A total of 172 samples had values below the threshold and were considered negative. However, the false-negative rate was 20%. **Conclusion:** Iris IQ200 is a very effective screening instrument for urine cultures. It provides advantages by improving the reliability of urinalysis, such as standardizing results, increasing the precision of direct examination, and enabling direct data transfer to the LIS.

Keywords: Iris IQ200; urine cultures; automated chemical analysis; urinary tract infection; iChem

1. Introduction

Urinary tract infection (UTI) is the most frequently seen infectious disease in in- and out-patients, and women are about 35 times more likely to be affected. Some 50% of women will have at least one episode of UTI throughout their life[1]. The diagnosis of UTI is performed with a cytologic examination, following a urine culture study, which is accepted as the gold standard. However, 80% of the examined specimens are negative on

culture[2]. Manual microscopy is extremely time-consuming and has low precision because of the different sediment preparation and counting techniques of each technician[3,4]. Urine culture studies also take time and need a minimum of 24-48 hours to give proper results. Antibiotics may be started in symptomatic patients before culture results are available. Moreover, the unnecessary and extensive use of antimicrobial agents has been known to have led to the development of antibiotic resistance. Accordingly, the need to alleviate unnecessary antibiotic administration, obviate redundant urine culture tests, minimize the costs and adverse effects of antibiotics, and address the increasing number of urinalysis requests has led to the development of automated methods to analyze urine samples. To standardize and improve microscopic sediment results, automated urine analyzers were developed, and the number of studies on their accuracy and precision has increased over recent years, but few have gained recognition[4,5].

In this study, an automatized urine analyzer with a combined chemical analyses, iChem velocity strip test and urine sediment analyzer (Iris IQ200 ELITE system, Iris Diagnostics, Chatsworth, CA, USA) was investigated. The primary objective was to evaluate the analytical performance of the Iris IQ200 with respect to specificity, sensitivity, and negative and positive predictive values of the urine parameters, which are recorded on the analyzer, and to compare these with urine culture results.

2. Material and Methods

The study was undertaken in the clinical laboratory of Istanbul University, Istanbul Faculty of Medicine. Fresh urine samples were collected from 437 consecutive in- and outpatients (263 women and 174 men) who attended the Istanbul Faculty of Medicine clinical laboratory and were analyzed within an hour using the Iris IQ200 (Chatsworth, California, USA). For each sample, automated chemical analysis (dipstick) and sediment analysis were performed.

2.1. Chemical Urine Analysis (iChem Velocity, Strip Tests)

iChem velocity is an automated urine chemistry system that determines urine physical and chemical constituents using test strips and wavelength reflectance. The test strip reagent pads react with urine components, producing color changes. The strip-reading module (SRM) measures the color of each pad and transforms the data into analyte semiquantitative concentrations. Ketones, urobilinogen, bilirubin, color, protein, hemoglobin, pH, glucose, leucocyte esterase (LE), and nitrites were determined. LE was calibrated as follows: trace, ≥ 15 leucocytes x 10^6/L; +, ≥ 70 leucocytes x 10^6/L; ++, ≥ 125 leucocytes x 10^6/L; and +++, ≥500 leucocytes.

2.2. Automated Urine Microscopy Analysis

IrisIQ200 Elite consists of an automated urine microscopy analyzer (IQ200), connected to an automated urine chemistry analyzer (Arkray, Kobe, Japan) based on reflectometry, and a computer workstation for reporting results. This automated urine analyzer uses digital imaging and a neural network (Auto Particle Recognition (APR) software). Individual particle images are isolated within each frame, and the APR uses neural network-based techniques to analyze particle size, shape, contrast, and texture. After autoclassification, all abnormal particles are reviewed and interpreted by a trained operator.

The instrument reports red and white blood cells (RBC, WBC), bacteria, squamous and non-squamous epithelial cells (SQEP, NSE), yeast, mucus, hyaline and non-hyaline casts, and all small particles (ASP). The minimum size of the recognized particle is 3 μm, which is the size for bacilli and Gram-positive cocci. Bacteria smaller than 3 μm were defined as "all small particles," which also included bacterial elements. Bacteriuria was classified as follows: 1+, 1-2 bacteria; 2+, 3-4 bacteria; 3+, 5-9 bacteria; and 4+, 10 and over.

The manufacturers' positive control material for high control, diluted high control (1:5), and low control were used to determine the assay imprecision. The two-level controls were studied 20 times each to assess within-run and between-day precision on consecutive days. The IRIS IQ 200 automated urine analyzer had within-run CVs of 2.05% and between-day CVs of 10.5% for the high control, and within-run CVs of 8.3% and between-day CVs of 1.6% for the low control.

2.3. Urine Culture

Culture method: Urine samples were inoculated quantitatively in Columbia agar with 5% sheep blood and eosin-methylene blue (EMB) agar to detect possible urinary pathogens (Gram-negative bacilli, staphylococci, streptococci, enterococci, and yeasts). Plates were interpreted after 24 hours at 35-37ºC. The plates with no growth were incubated for an additional 24 hours and were interpreted after 48 hours. A colony count of 10^8 colony-forming units per mL (CFU/mL) or greater was accepted as the criterion of urinary tract infection[6].

2.4. Statistical Interpretation

Data were presented as median and range. Statistical analysis was performed using SPSS version 15.0 (SPSS Inc., Chicago, IL, USA). Receiver operating characteristic (ROC) curves were used to show the relationship between the sensitivity and 1-specifity (false positive) at various threshold settings in order to determine the predictive value of these markers. Multivariate logistic regression (backward conditional) was performed to examine the relation between the biomarkers. Statistical significance was defined as $p<0.05$.

3. Results

During the study period, 437 consecutive urine samples were investigated. The analyzed urine samples were from 263 females and 174 males aged 1-89 years (average age: 47.5 years) (Table 1). Forty-eight contaminated urine samples were excluded from the study. Urine culture was positive in 109 patients. Of the 437 samples analyzed with IQ200 Elite, 217 (49.6%) met the predefined threshold values (WBCs, leucocyte esterase, bacteria, ASP) for UTI and were redirected for urine culture. Of these samples, only 83 (38.2%) were positive in the urine culture. A total of 172 samples had values below the threshold and were considered negative. However, the false-negative rate was 20%. Microorganisms isolated from the urine cultures are listed in Table 2.

Table 1. Prevalence of UTI by patient's age and gender

	N (Number)	Women (n, %)	Men (n, %)	Required culture with IQ200	Not required culture with IQ200
	437	263 (60.2%)	174 (39.8%)	217 (49.6%)	172 (39.4%)
Negative	286 (65.4)	164 (57.3%)	122 (42.7)	134 (61.7%)	151 (87.8%)
Positive	104 (24.9)	68 (66%)	35 (34%)	83 (38.3%)	21 (12.2%)
Mixed flora	48 (10.9%)	31 (64.5%)	17 (35.4%)		

UTI risk scores, which were determined from dipstick (LE) and urine sediment tests (nitrite, bacteria, ASP), were found to be significant with multivariable logistic regression analysis and further evaluated for their predictive values ($p= 0.002$, $p= 0.0001$, $p= 0.001$, respectively) (Table 3). ROC curves were used to determine the best cut-off point for predicting UTI. The best cut-off point was 5.0 for WBC (area under the curve (AUC) = 0.71), with 68.6% sensitivity and 61.1% specificity; the positive predictive value (PPV) and negative predictive value (NPV) were 38.5% and 84.1%, respectively. For ASP, the cut-off point was 2282 (AUC; 0.67) with 67% sensitivity and 55% specificity. The PPV and NPV

were 35.1% and 82%, respectively. For bacteria, AUC was 0.62 with 29.1% sensitivity and 95.8% specificity. The PPV and NPV were 71.4% and 78.9%, respectively. For LE, the AUC was 0.54 with 12.6% sensitivity and 94.8% specificity. The PPV and NPV were 46.4% and 75%, respectively.

Table 2. Microorganisms isolated from urine culture

Microorganism	N (Number)	% (Percentage)
Escherichia coli	50	46.3
Enterococcus spp	11	10.2
Candida spp	26	24.1
Klebsiella pneumonia	8	7.4
Pseudomonas aeruginosa	5	4.6
Enterobacter spp.	2	1.9
Staphylococcus saprophyticus	1	0.9
Non-hemolytic streptococcus spp.	1	0.9
Acinetobacter spp.	1	0.9
Morganella morganii	1	0.9
Proteus mirabilis	1	0.9
Stenotrophomonas maltophilia	1	0.9

Table 3. Discriminative and predictive values of UTI risk factors (dipstick and urine sediment tests) with IQ200 Urine analyzer

Variable	ROC-AUC	OR	Sensitivity %	Specificity %	Positive predictive value	Negative predictive value
Microscopy						
Leucocyte	0.71	4,852	68.6 (58-77)	61.1 (55-66)	38.5 (31-45.9)	84.1 (78.4-88.8)
ASP	0.67	1,000	67 (56-75.1)	55 (48.8-60.6)	35.1 (28.4-42.2)	82 (75.8-87.1)
Bacteria >3x10⁶/L	0.62	4,852	29.1 (21-38)	95.8 (94-98)	71.4 (56-82)	78.9 (74-82)
Dipstick						
LE > 15x10⁶/L	0.537	—	12.6 (69-85)	94.8 (91-96)	46.4 (29-64)	75 (70-79)
Nitrite	0.585	6,878	18.4	98	82	77
IRIS Results	—	1,001	78.6 (69-85)	52.8 (47-58)	37.5 (31-44)	87.3 (81-91)

4. Discussion

Urinary tract infections (UTIs) are the most common bacterial infections. There are about 150 million urinary tract infections worldwide each year[7]. UTI is also the most common nosocomial infection and accounts for approximately 35% of all hospital-acquired infections. The most common etiologic agent in UTIs is E.coli. In our study, E. coli was also the predominant etiologic agent (46.3%). Urine culture and microscopic examination are the reference standards for diagnosing UTI[8]. Good correlations between IRIS IQ200 results and microscopic examination and urine culture findings have been reported[9].

In the current study, we compared the analytical performance of Iris IQ200 ELITE with culture results. The main purpose was to reduce the number of urine samples sent for culture and to find a fast, cost-effective, and time-effective way to reach a diagnosis. Researchers have revealed that the combination of dipstick testing with automated microscopy increased the sensitivity of screening, and the automated methods might be verified by manual microscopic studies when the number of cells was low[10–12].

In our study, of 437 patients, only 103 (23.6%) urine samples were culture-positive, and 10.9% were excluded due to contamination. Urine culture count ≥ 10^8 CFU/L was accepted as indicating urinary infection[6]. Some recent publications reported that even lower

bacterial counts might be significant for UTI; however, this cut-off value had a good sensitivity[6,13]. In the present study, nitrite, bacteria, and ASP were found significant with multiple logistic regression analysis. When UTI risk scores, LE, leucocyte, bacteria, and ASP were evaluated for their predictive values, the best cut-off point was 5.0 for WBC with 68.6% sensitivity and 61.1% specificity, and the positive predictive value (PPV) and negative predictive value (NPV) were 38.5% and 84.1%, respectively. Akin et al. reported NPV and PPV for WBC by IQ200 of 96% and 90.3%, respectively[11]. For bacteria, AUC was 0.62 with 29.1% sensitivity and 95.8% specificity, and the NPV was 78.9%. Other studies have reported higher sensitivities for WBC and bacteria[10,14]. For ASP, the cut-off point was set at 2282, which was lower than the manufacturer's recommendation of 7000, with 67% sensitivity and 55% specificity; the NPV was 82%. LE and nitrite showed low sensitivity, with NPVs and PPVs of 75% and 77%, respectively. Due to the low sensitivity of LE and nitrite tests, some authors have argued that diagnosing UTI solely on dipstick results may miss urinary infections[15]. However, a meta-analysis and cost-effectiveness study revealed that negative dipstick results of both LE and nitrite might be sufficient to rule out infection[16,17]. The accuracy of automated methods depends on the cut-off value assigned and the cell types. The false-negative rate was estimated at 20% in our study, which was lower than the 36% reported with the IQ200 analyzer in a previous study[9].

In our study, of the 437 samples analyzed using the IQ200 Elite, 217 (49.6%) were reported to have WBC, leucocyte esterase, bacteria, and ASP levels above the predefined values for UTI, and 83 samples were culture-positive (24.9%). This prevalence was higher than reported in previous studies[18,19]; however, it should not be forgotten that the prevalence, sensitivity, and specificity of studies are all affected by the study population. This study was performed retrospectively, using data and clinical information from patients who attended the laboratory; the final diagnoses of the patients were not available. These are all accepted limitations of the study.

5. Conclusion

In the overall evaluation, Iris IQ200 is a highly effective screening instrument for urine cultures. It provides advantages by improving the reliability of urinalysis, such as standardizing results, increasing the precision of direct examination, and transferring data directly to LIS. While it may miss some false negatives, the Iris IQ200 automated urine analyzer could be used as a screening tool before culture studies.

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