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Evaluation of BT uricell1280 automated urine sediment analyzer performance

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Abstract
Fully automated urine analyzers are generally preferred in laboratories with high throughput. When these systems are used; especially the sediment analysis should be made by a well-skilled technician before reporting to discriminate well the interferences (like yeast or crystals) from erythrocytes and leukocytes. The purpose of the present study is to detect the correlation of erythrocyte and leukocyte numbers without any corrections in sediment field images of BT Uricell 1280 (BT products, İzmir, Turkey) fully automated urine analyzer with manual microscopy reports. A total of 528 first morning urine samples were studied by both BT Uricell 1280 and manual microscopy concurrently. The degree of concordance (Kappa coefficient) were evaluated. The sensitivity, specificity and positive and negative predictive value for the BT Uricell 1280 compared to manual microscopic examination were assessed. Precision and carry over studies were also performed. The degree of concordance of erythrocyte and leukocyte counts in microscopy of 528 urine specimens with manual microscopy was found to be 0.42 and 0.52 respectively (kappa coefficient). The sensitivity and specificity values of RBC and WBC were calculated for BT Uricell 1280 as 62.6%, 91.1%, 77.6%, 88.8%, respectively. The results of carry over analysis for both RBC and WBC were 0 %. The sediment microscopy analysis of erythrocytes and leukocytes with BT Uricell 1280 without any corrections presented moderate correlation with manual microscopy. A better correlation can be achieved by a more detailed examination of field images of the analyzer.

Keywords: Urine microscopy, erythrocytes, leukocytes

Introduction

Urine analysis is one of the most frequently studied tests in clinical laboratories. In routine analyses, urine specimen is a preferred test by physicians as the sample can be collected easily at any given time and pre-informing of the patient is not necessary [1,2]. An accurate urine analysis report gives information about renal and genitourinary systems of patients. Although the conventional urine sediment microscopy has been standardized by the recommendations of NCCLS (National Committee for Clinical Laboratory) and the European Urinalysis Guidelines, it is labor-intensive, time consuming, uncertain and also has high interobserver variation [3]. Recently, attention has been given to lower the variations between manual microscopy and the automated urine analyzers have been developed to save time and labor. Automated urine analysis is usually preferred for laboratories with intensive workload [4,5].

Two systems using different Technologies have been developed to automate manual urine microscopy. One of them uses flow cytometry technique [6]. While the other one uses a video camera to capture the images of the urine particles [7]. Increased precision and labor productivity are the common advantages of both systems [8,9].

The BT Uricell 1280 (BT products, İzmir, Turkey) is a new, digital image-based automatic particle recognition system and uses a video camera to capture the digital images of the samples from planar flowcell technique. The current study includes the comparison of manual microscopy and device based microscopy results of BT Uricell 1280.

Material and methods

Urine specimens

A total of 528 fresh urine samples were obtained from patients who admitted Bozok Training and Research Hospital for one-week period. The study was approved by the Ethics Committee of Bozok Training and Research Hospital and conducted according to the revised Declaration of Helsinki (1998). The urine samples were collected in sterile disposable containers by midstream urine collection technique. The samples were collected and portioned into two different containers. All urine samples were analyzed with BT Uricell 1280 (BT products, İzmir, Turkey) automated systems and all urine sediment of the samples were confirmed by an educated technician in manual microscopy who was blinded to

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the test results. All samples were completely processed within 2 hours after acceptance to the laboratory.

BT Uricell 1280

Urine samples were placed in racks and introduced to the BT Uricell 1280. The BT Uricell 1280 aspirated 1 ml of urine sample into microscope by flow cell technique. The digital images of the elements in urine samples were taken by CCD (charged coupling device) digital camera that captures 600 frames per sample. The images formed on the screen are transmitted to a processor. The clustered images are combined with particle recognition technology and classified as erythrocytes, leukocytes, leukocyte clusters, squamous epithelial cells, pathological cylinders, bacteria, yeast, crystals, mucus and sperm. The speed of the instrument is 100 urine samples/hour.

Manual microscopy

Total of 528 fresh urine samples were examined by microscopy. The 10 ml urine specimens were centrifuged at 2000 rpm for 5 minutes and 9.5mL of the supernatant was discarded. After homogenization of 0.5 mL remaining portion, it was applied on slides in order to be evaluated by an experienced technician on light microscope (x400). 5 fields were evaluated on the microscope and results were presented after taking an average of the number of cells in 5 fields. Sample results for erythrocyte and leukocyte cells were classified semi-quantitatively as shown in Table 1.

Table 1. Semi-quantitative range classification of urine particles

Parameters	Negative	Few	Moderate	High	Many
Erythrocyte (cells/HPF)	0-4	5-10	11-20	21-50	>51
Leukocyte (cells/HPF)	0-4	5-10	11-20	21-50	>51

Precision tests

Low, medium and high urine pools were prepared and analyzed 20 times consecutively during one day for within-run imprecision. For between-run imprecision, level 1(Lot Number:1722105), level 2 (Lot Number:1722106), and level 3 (Lot Number:1722107), urine sediment analyzer control (ref: QC22-40) samples of the manufacturer's recommendation were analyzed for 20 days. The precision was assessed by the percentage coefficient of variation (CV%).

Carryover

Carryover which is known as the contamination across samples was detected by analyzing two highly concentrated samples with RBC and WBC for three times (H1,H2,H3), followed by the normal urine for three consecutive times on the BT URICELL1280 analyzer (D1,D2,D3). The carryover was calculated using the formula of (D1-D3)/(H3-D3) x100. D1 is the first and D3 is the third measurement of the normal urine. H1 is the first and H3 is the third measurement of the highly concentrated urine.

Statistical analysis

Statistical analysis was performed with SPSS for Windows 18(SPSS Inc., Chicago, IL). Gamma statistics analysis was applied to WBC and RBC in calculating correlation depending on matching and non-matching pairs of observation in the cross tables. Cohen's kappa coefficient was calculated for concordance between methods. Values for Cohen's kappa coefficient of 0-0.21, 0.21-0.40, 0.40-0.60, 0.61-0.80 and 0.81-1.00 are characterized as poor, fair, moderate, good, and very good agreement, respectively. The sensitivity, specificity and positive and negative predictive value for the BT Uricell 1280 according to manual microscopic examination was assessed. A value of $P < 0.05$ was considered as statistically significant.

Results

Gamma statistic comparisons of leukocyte and erythrocytes counts between manual method and automated BT Uricell 1280 urine analyzer are shown in Table 2 and 3. From this table (Table 2 and 3), cut off value > 4 HPF of BT Uricell 1280 concordance rate(%) with manual microscopy are %86.54 and 85.61 respectively. Cohen's kappa coefficients for erythrocyte and leukocyte counts in microscopy of BT Uricell 1280 and manual microscopy were found to be 0.42 and 0.52 respectively (Table 4). The sensitivity, specificity, and positive and negative predictive values of the BT Uricell1280 were assessed according to manual microscopic results (Table 5).

Within-run imprecision and between-run imprecision of the BT Uricell 1280 were evaluated by analyzing urine samples for RBCs and WBCs. And the results are presented in Table 6.

Two patient samples were assessed to establish the carryover of the BT Uricell 1280 analyzer for RBCs and WBCs, the results are shown in Table 7.

Table 2. Comparison of BT Uricell 1280 and manual for leukocytes

	Leukocyte by BT URICELL 1280, cells/HPF					
Leukocyte by manual microscopy, cells/HPF	0-4	5-10	11-20	21-50	>50	Total
0-4	334	27	11	3	1	376
5-10	28	24	11	3	1	67
11-20	6	4	12	9	2	33
21-50	0	0	2	8	3	13
>50	0	0	2	7	30	39
Total	368	55	38	30	37	528

Cut-off point for leukocyte in microscopy is >4cells/HPF

Table 3. Comparison of BT Uricell 1280 and manual for leukocytes

	Erythrocyte by BT URICELL 1280, cells/HPF					
Erythrocyte by manual microscopy, cells/HPF	0-4	5-10	11-20	21-50	>50	Total
0-4	398	25	10	3	1	437
5-10	27	8	4	2	1	42
11-20	4	2	1	5	0	12
21-50	2	0	2	0	1	5
>50	1	0	0	6	25	32
Total	432	35	17	16	28	528

Cut-off point for Erythrocytes in microscopy is >4cells/HPF

Table 4. Degree of concordance between BT Uricell 1280 and manual methods for clinical results

	BT Uricell 1280 vs Manual	
	Kappa (95% CI)	P value
Erythrocytes	0.420a	<0.001
Leukocytes	0.526a	<0.001

aModerate agreement

Table 5. Degree of concordance between BT Uricell 1280 and manual methods for clinical results

Parameters	Sensitivity (%)	Specificity(%)	PPV(%)	NPV(%)
Erythrocyte (cells/HPF)	62.63	91.07	40.62	92.12
Leukocyte (cells/HPF)	77.63	88.82	73.75	90.76

Cut-off point for eryhrocyte and leukocyte in microscopy is >4 cells/HPF

Table 6. Within-run imprecision and Between-run imprecision of the BT Uricell 1280 automated urine microscopy analyzer

Cell type	Within-run imprecision Meancell (cells/HPF)±SD	CV(%)	Between-run imprecision Meancell (cells/HPF)±SD	CV(%)
RBC	4.91±1.78	36.28	192.9±23.62d	12.24
	10.4±12.70	25.97	456.21±61.52e	13.48
	286.2±8.13c	2.84		
WBC	2.27±1.65 a	72.88	85.92±9.44 d	10.99
	31.8±3.63 b	11.42	391.78±61.88 e	15.79
	117.2±9.03 c	7.71		

CV: coefficient of variation, RBC: red blood cell, WBC: white blood cell, HPF: high power field, a: low urine pool, b: medium urine pool, c: high urine pool, d: Level 2 (QC22-40), e: Level 3(QC22-40)F

Table 7. Carry over analysis of the BT Uricell 1280 analyzer

	H1	H2	H3	D1	D2	D3	Carryover %
RBC(cells/HPF)	181	158	117	0	0	0	0
WBC(cells/HPF)	617	614	741	0	0	0	0

Discussion

Manual microscopic examination of centrifuged urine has different sources of variation associated with sample preparation, centrifugation and counting (by a technician) [10]. The automation of microscopic urinalysis could be a solution for these standardization problems [11].

In our study the BT Uricell 1280 automated urinalysis system demonstrated acceptable precision. Within-run imprecision of the BT Uricell 1280 for RBC were 36.28%, 25.97%, 2.84 % and 72.78%, 11.42%, 7.71% for WBC values from low, medium and high pool respectively. Between-run imprecision of RBC and WBC for level 2 and level 3 were 12.24%, 10.99%,13.48% and 15.79% respectively. Between-run imprecision for Level 1 control could not be calculated as the mean cell results were zero for RBC and WBC. Within-run and between-run precision of the UriSed for red blood cells (RBC) and white blood cells (WBC) were acceptable at all levels (CV < 20%) [12]. Lamchiagdhase et al. reported that between-run CV of iQ200 (Iris Diagnostics, Chatsworth, CA), of RBC for negative and positive control were 61.6% and 6.4% respectively [10]. Yüksel et al. reported that within-run CVs of FUS-100 (Dirui, Changchun, China) for RBC were 19.3% and 5.1% and for WBC were 21.2% and 10.1% for 2 levels of quality control material, respectively [13]. Between-run CVs of RBC, WBC for level 2 were 4.7% and 18.6% respectively [13].

Bakan et al. found carry over results for erythrocytes, leukocytes, as 0% by the Cobas 6500 the (Roche, Mannheim, Germany) [14]. In concordance with this study, carryover values were found to be zero for RBCs and WBCs in our study.

The first study to compare BT Uricell 1280 and manual microscopy, for clinical results, the concordance between BT Uricell 1280 and manual method was moderate for erythrocytes and leukocytes. (Table 4). In clinical decision making, non-concordances lower than 13.46% and 14,39 % in WBCs and RBCs parameter were observed for manual microscopy (cut-off value of < 4 WBCs and RBCs /HPF).

In the study of Shayanfar et al. [15], the detection sensitivities of the Iris iQ200 for erythrocytes and leukocytes were found to be 70% and 76%, respectively. Another study determined the sensitivities of the Iris iQ200 for erythrocytes and leukocytes as 75.8% and 85.5%, respectively [16]. Yüksel et al. found the sensitivity of the Dirui FUS-100 for erythrocytes and leukocytes [13]. In our study, the BT Uricell 1280 demonstrated sensitivity for erythrocytes and leukocytes calculated as 62,63% and 77,63%, respectively. Yüksel et al's [13] calculated the negative predictive and positive predictive values for erythrocytes and leukocytes (95%, 92%, 47% and 60%, respectively) were also similar to our study (Table 5). In contrast to our study, Dewulf et al. found sensitivities of the Iris iQ200 for erythrocyte and leukocyte to be 95% and 100%, respectively; and the negative predictive values were 93% and 100%, respectively[17]. Bakan et al. found the sensitivity of the Cobas 6500 for erythrocytes and leukocytes [14].

Nousin et al. reported that UF 100 (Sysmex UF-100; Sysmex, Kobe, Japan) is more sensitive than iQ200 (Iris Diagnostics, Chatsworth, CA, USA) in terms of leukocyte analysis. UF 100 (Sysmex UF-100; Sysmex, Kobe, Japan) uses the flow cytometer technique and iQ200 (Iris Diagnostics, Chatsworth, CA, USA) uses image-based technique. UF 100 (Sysmex UF-100; Sysmex, Kobe, Japan) can detect the cytoplasmic DNA when the leukocytes are damaged morphologically but iQ200 (Iris Diagnostics, Chatsworth, CA, USA) cannot count damaged leukocytes. Also, it was shown that UF 100 reports false positive results in the presence of epithelial cells [15]. In our study the BT Uricell 1280 uses the combination of flow cell and image-based technique.

Linko et al compared RBC and WBC counts made by iQ200 (Iris Diagnostics, Chatsworth, CA, USA) with manual microscopy and they found concordant results [18]. Wah et al found better correlation between the iQ200 (Iris Diagnostics, Chatsworth, CA) and manual cell counting by Fuchs-Rosenthal counting chambers for RBCs, WBCs and epithelial cells [19]. Also they reported that iQ200 (Iris Diagnostics, Chatsworth, CA) determined fewer number of cells when compared to manual microscopy counts [19].

Conclusion

As a result, the microscopic sediment analysis of erythrocytes and leukocytes with BT URICELL 1280 without any corrections demonstrated moderate correlation with manual microscopy. Images should be reviewed for every sample when automated systems are used for urine analysis. A better correlation can be achieved by a more detailed examination of field images of the analyzer.

Competing interests
The authors declare that they have no competing interest.

Financial Disclosure
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