Practical Laboratory Medicine 5 (2016) 14–20

Contents lists available at ScienceDirect

Practical Laboratory Medicine

journal homepage: www.elsevier.com/locate/plabm

The comparison of automated urine analyzers with manual microscopic examination for urinalysis automated urine analyzers and manual urinalysis

Fatma Demet İnce [a,*], Hamit Yaşar Ellidağ [b], Mehmet Koseoğlu [b], Neşe Şimşek [a], Hülya Yalçın [a], Mustafa Osman Zengin [a]

[a] Department of Medical Biochemistry, Tepecik Education and Research Hospital, Izmir, Turkey
[b] Medical Biochemistry, Atatürk Education and Research Hospital, Izmir, Turkey

ARTICLE INFO

Article history:
Received 17 December 2015
Received in revised form
3 March 2016
Accepted 9 March 2016
Available online 11 March 2016

Keywords:
Urinalysis
Autoanalysis
Microscopy

ABSTRACT

Objectives: Urinalysis is one of the most commonly performed tests in the clinical laboratory. However, manual microscopic sediment examination is labor-intensive, time-consuming, and lacks standardization in high-volume laboratories. In this study, the concordance of analyses between manual microscopic examination and two different automatic urine sediment analyzers has been evaluated.

Design and methods: 209 urine samples were analyzed by the Iris iQ200 ELITE (İris Diagnostics, USA), Dirui FUS-200 (DIRUI Industrial Co., China) automatic urine sediment analyzers and by manual microscopic examination. The degree of concordance (Kappa coefficient) and the rates within the same grading were evaluated.

Results: For erythrocytes, leukocytes, epithelial cells, bacteria, crystals and yeasts, the degree of concordance between the two instruments was better than the degree of concordance between the manual microscopic method and the individual devices. There was no concordance between all methods for casts.

Conclusion: The results from the automated analyzers for erythrocytes, leukocytes and epithelial cells were similar to the result of microscopic examination. However, in order to avoid any error or uncertainty, some images (particularly: dysmorphic cells, bacteria, yeasts, casts and crystals) have to be analyzed by manual microscopic examination by trained staff. Therefore, the software programs which are used in automatic urine sediment analysers need further development to recognize urinary shaped elements more accurately. Automated systems are important in terms of time saving and standardization.

1. Introduction

An accurate urine sediment analysis is a good indicator of the status of the renal and genitourinary system. General indications for urinalysis are: the possibility of urinary tract infection or urinary stone formation; non-infectious renal disease secondary to systemic diseases such as rheumatic diseases, hypertension, toxaemia of pregnancy, or to the adverse effects of drugs; non-infectious post-renal disease; in pregnant women and patients with diabetes mellitus or metabolic

* Correspondence to: The Department of Biochemistry, Tepecik Education and Research Hospital, Gaziler Street, 35170, Yenişehir, Izmir, Turkey.
E-mail address: fatmademet.arslan@gmail.com (F.D. İnce).

http://dx.doi.org/10.1016/j.plabm.2016.03.002
2352-5517/

states who may have proteinuria, glycosuria, ketosis or acidosis/alkalosis [1]. The traditional strategy recommended by the European Urinalysis Guidelines consists of two steps [1]. In the first step, there is a visual inspection and dipstick test. Semi-quantitative dipstick tests are used in this step to exclude the urine samples from further analysis if hemoglobin, leukocyte esterase activity, nitrite and protein are negative. In the second step, if there is erythrocyturia, leukocyturia, bacteriuria or proteinuria, urine samples are subjected to further analysis by microscopy. Because the first step has poor sensitivity and negative predictive value, screening by dipstick alone carries the risk of missing infections and other urinary diseases [2–5].

There are different manual methods for urine sediment examination such as counting in a standardized or non-standardized way under a coverslip or counting of centrifuged or uncentrifuged urine specimens in a chamber. Traditional (non-standardized) urine sediment analysis has been used in many laboratories. However, because of wide uncertainty of results and reduced sensitivity in detecting essential formed elements, the non-standardized sediment procedure was not recommended. Standardized urine sediment examination under a coverslip instead of non-standardized sediment procedure is recommended as a routine visual procedure for kidney-related urine formed elements. A reference method for urine microscopy should provide both correct identification of the different formed elements and quantify them accurately. Currently, no such method exists. In particle counting, bright-field microscopy of unstained preparations is inadequate for detection of bacteria, erythrocytes and hyaline casts. For this reason, either supravital staining or phase-contrast microscopy, or both, is recommended for better examination [1]. However, phase-contrast microscopy is not available in every laboratory.

The potential variables in the microscopic examination of the urine are as follows: the speed and time of centrifugation, the amount of urine remaining in the tube for resuspension, and whether urine is stained. Manual microscopic examination requires well trained and experienced staff and consumes a considerable amount of time. Therefore, automatic urine sediment analyzers for high-volume laboratories were developed in order to provide better standardization, improve the certainty of measurement and save staff time.

The methodology of urine particle analysis started with the introduction of automated microscopes and flow cytometry devices inspired by blood cell counting [1]. These analyzers use two analytical principles for urine sediment analysis, one based on electrical impedance, and the other dependent on image-based analysis systems that sort particles according to preset particle dimensions. It is not currently clear which principle is superior.

The image-based analysis systems automatically scan the formed elements of flowing urine and display the images of formed elements on a screen. Before reporting the results of analysis, the shaped elements must be examined visually by well trained staff who can decide to approve, delete or reclassify them. However, laboratories who have made the transition from manual microscopic method to automatic systems still have some concerns about the concordance of results.

The use of the automated analyzers (Iris iQ200 ELITE and Dirui FUS-200) has gradually increased in medical laboratories. These analyzers are both image-based analysis systems and there has not been any published study comparing the two instruments. We evaluated the concordance between manual microscopy and the two automatic urine sediment analyzers.

2. Materials and methods

209 randomly selected patients who attended the laboratory of our hospital were studied. All patients provided signed written consent prior to enrollment into the study, and the study was performed in compliance with the Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects).

The collection, transport, preparation of specimens and urinalysis was performed according to European Urinalysis Guidelines [1]. Mid-stream samples (30 mL) were collected into primary containers which had no risk of spillage, transported in the primary containers and transferred to secondary containers (three different conical tubes) in the laboratory. The secondary tubes were translucent to allow a clear view of the sample. 10 mL urine sample was added to each tube. Each sample was examined within one hour by the three methods. The first tube was centrifuged for 5 min at 1500 rpm (400 g) for manual microscopic examination. The supernatant was decanted until 0.5 mL urine remained at the bottom of the tube. The sediment was resuspended, and then one drop of sediment was placed on a microscope slide, covered with a cover slip and examined by light microscope. Evaluation of urine formed elements was performed by one biochemistry specialist and one biologist, independently using the same microscope slide. During the examination, at least 10 different microscopic fields were scanned at magnifications of $\times 100$ and $\times 400$ (per low power field; LPF and per high-power field; HPF). The results were calculated by averaging the formed elements and reported as cells or particles in a field. If there was an inconsistency between the results of the two evaluators, the analysis was repeated with another sample in order resolve the discrepancy.

The evaluation of urine formed elements in the other two (uncentrifuged) tubes was performed on the Iris iQ200 ELITE (İris Diagnostics, Chatsworth, CA, USA) and Dirui FUS-200 (DIRUI Industrial Co., Changchun, China) automatic urine sediment analyzers. The results from the instruments were obtained as average of formed elements per LPF and HPF. The analytical principle of the Dirui FUS-200 analyzer is flow cell digital imaging and identification using an artificial intelligence technique. The analytical principle of the Iris iQ200 ELITE analyzer is Digital Flow Morphology technology using the Auto-Particle Recognition (APR) software. As the urine passes through the flow cell, urine is illuminated by a special light source, and the images are recorded by a digital camera placed into the eyepiece of the microscope and transmitted to the computer. The software classifies these images and displays them on the screen for the operator. The operator accepts, changes