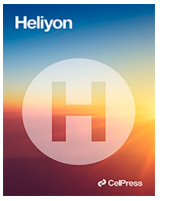
Heliyon 9 (2023) e19649

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon



Simultaneous uroflowmetry and urinalysis with single specimen – A prospective evaluation of automatic urine strip analyzer of ORUBA INALYS: Uroflowmetry-urinalysis combined device

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ARTICLE INFO

Keywords:
Uroflowmetry
Urinalysis
Urine strip
Screening
Biochemistry

ABSTRACT

Objective: To evaluate the consistency of the urinalysis results performed with the ORUBA INALYS device, (Oruba, Ankara, Turkey) which can perform urinalysis and uroflowmetry simultaneously, with the analysis results performed with the SYSMEX UC3500 automated urine chemistry analyzer (Sysmex, Kobe, Japan).

Material and methods: In this prospective study, urinalysis of 50 male patients with lower urinary tract symptoms were evaluated. The parameters of glucose, pH, urobilinogen, bilirubin and ketone, leukocyte, protein, and blood were measured with ORUBA INALYS, and the same urine specimens collected from ORUBA INALYS by a special setup were sent to the laboratory for urinalysis with Sysmex UC-3500 to assess the concordance of the results between two devices.

Results: Urinalysis results in ORUBA INALYS device in terms of glucose, pH, urobilinogen, bilirubin, and ketone parameters were shown to achieve 100% agreement within ±1 category with SYSMEX UC3500 whereas these values were slightly decreased to 88%, 96%, and 98% for leukocyte, protein, and blood, respectively. Among the calculable weighted kappa values for the test parameters, the highest value was found for glucose and followed by blood, pH, leukocyte, and specific gravity respectively.

Conclusion: Significant consistency of the urinalysis results obtained from ORUBA INALYS with those obtained from device SYSMEX UC3500 shows the reliability of the urinalysis performed with ORUBA INALYS. ORUBA INALYS could minimize costs and workload, provide time save and reduce plastic waste.

1. Introduction

Uroflowmetry is a non-invasive, low cost and easy-to-perform urodynamic investigation that has an important role in the objective assessment and follow-up of lower urinary tract symptoms (LUTS) including intravesical obstruction [1,2]. While urine flow rate has

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https://doi.org/10.1016/j.heliyon.2023.e19649
Received 11 March 2023; Received in revised form 28 August 2023; Accepted 29 August 2023
Available online 6 September 2023

been clinically evaluated since 1950s, uroflowmetry is currently the most widespread urodynamic test for this purpose [3]. UK National Institute for Health and Care Excellence (NICE), European Association of Urology (EAU), International Consultation on Incontinence (ICI) and American Urological Association (AUA) recommend the uroflowmetry test to be performed as an initial screening for the males suffering from LUTS [4–7]. In the assessment of LUTS, the most ordered test by clinicians along with uroflowmetry is urinalysis which constitutes an important part of the routine health screening and helps the diagnosis of urinary tract infections, renal diseases, diabetes mellitus, and malignancy. Although microscopic urine sediment analysis had been the gold standard in the 1900s; some drawbacks of this method including high labor intensity and wide interobserver variability led to higer use of urine chemical analysis by test strips [8]. Visual reading of the test strip results, which was a popular approach until the beginning of the 2000s, is replaced by automated reading with increased number of urine chemical analyzers of improved reliability [9,10]. Despite being two of the most important and common tests in urology, uroflowmetry and urinalysis require providing two different urine specimens at separate times by the patient, which causes a significant waste of time, increased workload and increased cost. Accordingly, a technology that allows simultaneous uroflowmetry and urinalysis by single urine specimen is clearly helpful in increasing patient comfort and reducing workload and cost in hospitals.

In this prospective randomized study, urine strip analyzer performance of ORUBA INALYS device (Oruba, Ankara, Turkey) capable of performing simultaneous uroflowmetry and urinalysis is evaluated. For this purpose, a method comparison study is conducted to compare test strip results on ORUBA INALYS with those of SYSMEX UC3500 automated urine chemistry analyzer (Sysmex, Kobe, Japan), which is a commonly found device in hospital laboratories.

2. Materials & methods

In this prospective study, urine specimens from 50 male patients with lower urinary tract symptoms who visited our clinic between April 2021 and September 2021 are evaluated. In this comparison, the power analysis was done and Effect size (Cohen's d), Alpha (significance level) and desired power calculated as 0.5, 0.1 and 0.8, respectively. Total number of groups was planned as 2 (two groups being compared). The calculated required sample size per group would be approximately 50 participants. High significance level (the chance of a Type I error = %10) are direct result of using dipstick method to determine that parameters. Method has high error rates. Also prevalence of urobilinogen and ketone detection with dipstick method is rarely low. It's important to show Type I Error does not occurs.

After the urinalysis performed on ORUBA INALYS-Uroflowmetry and Urinalysis Combined Device, the same urine specimens collected from INALYS by a special setup are sent to the laboratory for analysis on Sysmex UC-3500 to assess the concordance of the results between two devices.

2.1. Working principle of Oruba INALYS: uroflowmetry-urinalysis combined device

ORUBA INALYS is a urinal-shaped medical device capable of performing uroflowmetry and urinalysis simultaneously. With direct voiding into the urinal during the test and automated cleaning after each test, the procedure of INALYS does not require any physical contact of the device with the patient and assistance from operators. In addition to a regular uroflowmeter, INALYS incorporates a two-chamber cassette containing urine test strips, a dripping module, and an image-processing module for urinalysis. The test procedure includes transfer of a certain amount of urine from the collecting cup to the dripping module, dripping of the urine into the reagent pads on the strips that move from one chamber towards the other with the help of reels within the cassette, correct positioning of the strip of interest in front of the camera, acquisition of the strip images from the camera and comparison of the obtained colors on the reagent pads with the colors of the reference chart by analyzing them in a color space. SYSMEX UC3500 is a fully automated urine chemistry analyzer that offers semi-quantitative and qualitative results by using Meditape UC-9A test strips whereas ORUBA INALYS semi-quantitatively measures all parameters by using URS-10T test strips. Both devices use a color CMOS sensor to scan each test strip and both devices can automatically detect the position of the test strip pads [11–15]. With all these steps, the whole urinalysis process is completed in a fully automated and human error-free way.

2.2. Specimen collection

During a uroflowmetry test on ORUBA INALYS, urine needs to be collected in a cup coupled with a load cell to measure volume and flow rate. For this study, a special setup that collects the required volume of the urine from collecting cup of the uroflowmeter is added to INALYS device in order to use the same specimen during urinalysis on SYSMEX-UC3500. This setup is designed to be free of contaminants to ensure identicalness of the specimens used in urinalysis on both devices.

2.3. Comparison of SYSMEX UC-3500 and ORUBA INALYS results

SYSMEX UC3500 is a fully automated urine chemistry analyzer that offers semi-quantitative and qualitative measurement of leukocyte, nitrite, bilirubin, ketone, protein, glucose, pH, urobilinogen, and blood in urine by using Meditape UC-9A test strips. The measurement technology used for these parameters is reflectance photometry, whereas specific gravity measurements are based on refractometry and reported as quantitative results. Refraction measures the curvature of light as it passes through a urine sample. Specific gravity is determined by measuring the refractive index of urine. A few drops of urine are deposited on the surface of the refractometer prism. Light passing through the urine is refracted and the angle of refraction is used to calculate the density value.

Refractometers are considered to be a very accurate method for measuring the specific gravity of urine, providing accurate numerical results. It offers high accuracy and can detect small changes in specific gravity, making it useful for monitoring small changes in hydration status. The urine strip method, also known as the dipstick method, uses chemical reagents impregnated on the strip to react with components of urine and change color based on specific gravity. A urine strip is dipped into the urine sample and the color change on the strip is compared with the color chart provided on the strip container to estimate the specific gravity value. Although urine dipstick methods can give a rough estimate of specific gravity, they are often less accurate than refractometry. Urine strips are more economical than refractometers. On the other hand, ORUBA INALYS semi-quantitatively measures all the 10 parameters by using URS-10T test strips.

For this method comparison study, 50 urine specimens are tested for leukocyte, nitrite, bilirubin, ketone, protein, glucose, pH, urobilinogen, blood, and specific gravity on both devices. Since the number and the concentration ranges of the categorical results for 8 strip parameters are different in Meditape UC-9A and URS-10T, new categories are assigned to these results to develop a uniform evaluation system between two devices (Fig. 1). The assignment of common categories to the discordant test strip semi-quantitative fields is a previously applied approach [16]. For specific gravity, quantitative results from SYSMEX UC3500 are categorized into ranks that have the same order as URS-10T color blocks (Fig. 1). Since nitrite results are qualitatively reported in both devices (negative and positive), an additional categorization is not implemented for this parameter.

2.4. Statistical analysis

Number of test results are entered in each cell of 10 matrix tables constructed for 10 parameters. Percent agreement within the same category is calculated for each of the 10 parameters tested, whereas percent agreement within ±1 categories is calculated for each of the 9 parameters except nitrite. Since refractometric results of specific gravity are reported to be theoretically within ±0.005 of the semi-quantitative strip test results; results found in adjacent categories that includes ±0.005 values of the URS 10T specific gravity results are considered as results agreed within the same category. For some of the parameters, kappa coefficients with squared weights are also calculated in addition to the percent agreement. A kappa coefficient can have a value between −1 and 1; where it indicates a maximum interrater agreement at the value of 1, a complete interrater disagreement at the value of −1, and an interrater agreement

a.

Ketone (mg/dL)						
URS-10T	<5.1	5.1-15.3	15.3-40.8	40.8-81.6	81.6-163.2	>163.2
Category	1	1	2	3	4	4
Meditape UC-9A	<10	10-30	30-80	>80		
Category	1	2	3	4		

b.

Protein (mg/dL)						
URS-10T	< trace	trace-30	30-100	100-300	300-2000	>2000
Category	1	2	3	4	5	6
Meditape UC-9A	< 15	15-30	30-100	100-300	300-1000	>1000
Category	1	2	3	4	5	6

c.

Glucose (mg/dL)						
URS-10T	<90	90-270	270-540	540-1080	1080-1980	>1980
Category	1	2	3	4	4	5
Meditape UC-9A	<50	50-100	100-250	250-500	500-2000	>2000
Category	1	1	2	3	4	5

d.

Blood (mg/dL)					
URS-10T	<0.03	0.03-0.075	0.075-0.24	0.24-0.6	>0.6
Category	1	2	3	4	5
Meditape UC-9A	<0.03	0.03-0.06	0.06-0.15	0.15-0.75	>0.75
Category	1	2	3	4	5

e.

Bilirubin (mg/dL)				
URS-10T	<1	1- 2.92	2.92- 5.84	>5.84
Category	1	2	3	3
Meditape UC-9A	<0.5	0.5 -1	1- 2	>2
Category	1	1	2	3

f.

pH							
URS-10T	5-6	6-6.5	6.5-7	7-7.5	7.5-8	8-8.5	>8.5
Category	1	2	2	3	3	4	4
Meditape UC-9A	5-6	6-7	7-8	8-9	>9		
Category	1	2	3	4	4		

g.

Urobilinogen (umol/L)					
URS-10T	3.2-16	16-32	32-64	64-128	>128
Category	1	1	2	3	4
Meditape UC-9A	<34	34-68	68-135	135-202	>202
Category	1	2	3	4	4

h.

	Leukocyte (cells/ uL)				
URS-1OT	<15	15-70	70-125	125-500	>500
Category	1	2	3	3	4
Meditape UC-9A	<25	25-75	75-500	>500	
Category	1	2	3	4	

i.

Specific gravity							
URS-10T	1-1.005	1.005-1.010	1.010-1.015	1.015-1.020	1.020-1.025	1.025-1.030	> 1.030
Category	1	2	3	4	5	6	7
Refractometer	1-1.005	1.005-1.010	1.010-1.015	1.015-1.020	1.020-1.025	1.025-1.030	> 1.030
Category	1	2	3	4	5	6	7

Figure-1. Assigned categories for comparison of URS-10T and Meditape UC-9A test strip results of ketone, glucose, blood, bilirubin, pH, urobilinogen, and leukocyte. For specific gravity, refractometry results from Sysmex UC3500 are categorized into ranks that have the same order as URS-10T color blocks.

based on only chance at the value of 0 [17,18].

3. Results

Concordance tables for the results on ORUBA INALYS and SYSMEX UC-3500 are shown in Fig. 2, while calculated percent agreement values and kappa coefficients are given in Table 1. Considering all the parameters; the percent agreement values within the same category and within ±1 category range from 60% to 100% and from 80% to 100%, respectively. These ranges change to 74%–100% and 88%–100% if the calculated parameters for specific gravity are excluded from analysis. In particular, performance of glucose, pH, urobilinogen, bilirubin and ketone tests is shown to achieve 100% agreement within ±1 category with SYSMEX UC3500,

a.

Leukocyte					
	ORUBA	1	2	3	4
SYSMEX					
1		39	0	5	0
2		2	0	0	0
3		1	0	2	0
4		0	0	0	1

b.

Ketone					
	ORUBA	1	2	3	4
SYSMEX					
1		50	0	0	0
2		0	0	0	0
3		0	0	0	0
4		0	0	0	0

c.

Nitrite			
	ORUBA	Negatif	Pozitif
SYSMEX			
Negatif		45	5
Pozitif		0	0

d.

Glucose						
	ORUBA	1	2	3	4	5
SYSMEX						
1		46	2	0	0	0
2		0	0	0	0	0
3		0	0	0	0	0
4		0	0	0	0	0
5		0	0	0	2	0

e.

Protein							
	ORUBA	1	2	3	4	5	6
SYSMEX							
1		40	1	0	0	0	0
2		3	1	0	0	0	0
3		0	0	0	0	0	0
4		1	1	2	1	0	0
5		0	0	0	0	0	0
6		0	0	0	0	0	0

f.

Blood						
	ORUBA	1	2	3	4	5
SYSMEX						
1		40	1	0	0	0
2		6	1	0	0	0
3		1	0	0	0	0
4		0	0	0	0	0
5		0	0	0	0	1

g.

pH					
	ORUBA	1	2	3	4
SYSMEX					
1		0	6	0	0
2		0	41	0	0
3		0	1	0	0
4		0	0	2	0

h.

Urobilinogen					
	ORUBA	1	2	3	4
SYSMEX					
1		50	0	0	0
2		0	0	0	0
3		0	0	0	0
4		0	0	0	0

i.

Bilirubin				
	ORUBA	1	2	3
SYSMEX				
1		37	13	0
2		0	0	0
3		0	0	0

j.

Specific gravity								
	ORUBA	1	2	3	4	5	6	7
SYSMEX								
1		0	0	1	0	0	0	0
2		0	4	5	5	4	4	0
3		0	2	5	0	0	2	0
4		0	1	4	4	1	3	0
5		0	0	0	1	2	0	0
6		0	0	0	0	0	1	0
7		0	0	0	0	0	0	1

Figure-2. Tables showing concordance between ORUBA INALYS and SYSMEX UC-3500 results for 50 clinical urine samples. Cells with dark- and light blue shades indicate concordant results within the same category and within ±1 categories, respectively.

whereas these values are slightly decreased to 88%, 96%, and 98% for leukocyte, protein, and blood, respectively. Among the calculable weighted kappa values for the test parameters, the highest value is found for glucose (k = 0.92); while kappa values for blood, pH, leukocyte and specific gravity results are reported to be 0.73, 0.7, 0.5, 0.47, and 0.4, respectively (Fig. 2, Table 1). Although agreement percentages for nitrite, bilirubin, ketone and urobilinogen results are high; calculation of kappa values for these parameters is not possible due to the inadequate number of results for some of the categories.

4. Discussion

Uroflowmetry's diagnostic accuracy for diagnosing bladder outlet obstruction (BOO) varies greatly and is heavily impacted by threshold levels. A threshold Qmax (maximum flow rate) of 10 mL/s provides a 70% specificity, a 70% PPV, and a 47% sensitivity for BOO. The specificity was 38% at a threshold Qmax of 15 mL/s, the PPV was 67%, and the sensitivity was 82%. Qmax values below 15 mL/s in uroflowmetry should be examined for underlying pathologies. These values are considered as abnormal urine flow rate. If Qmax is more than 15 mL/s, physiological compensating processes rule out BOO. Low Qmax can be caused by BOO, detrusor underactivity, or an under-filled bladder. As a result, it is restricted as a diagnostic test since it cannot distinguish between the underlying processes. Repeated flow rate testing can increase specificity. For these reasons, it is recommended by the guidelines as an initial test for men with LUTS symptoms [5]. The basic tests recommended by EAU and AUA guidelines for assessment of LUTS in men include uroflowmetry, urinalysis, symptom score questionnaire, and bladder diary records [19,20] The first step in differential diagnosis of LUTS is to try to eliminate genitourinary tract infections, tumor, kidney stone disease, or morphological defects of urinary tract as underlying reasons. These diseases can be diagnosed by the help of patient history, physical examination, laboratory tests and radiological techniques; among which urinalysis is one of the most performed investigations [8,17]. Urinalysis is the third most frequently used in-vitro diagnostic screening test after serum biochemistry and complete blood count in laboratory studies [8,17]. Updated recommendations of AUA guideline include utilizing urinalysis results for the initial evaluation of patients with LUTS and subsequently performing uroflowmetry for the selected patient groups [21]. The most used urinalysis method is the chemical analysis, which can be performed manually or automatically using urine strips, in which the chemical properties are determined. Some urinalysis results are considered to be indicative of urinary tract infection, kidney stone, and other renal diseases; therefore, urinalysis has an important part in urological practice to differentiate glomerular, renal and urological causes of a condition [22]. At this point, it is not currently possible with any device to simultaneously perform urinalysis and uroflowmetry, which are two required tests for evaluation of many diseases. Since the patient must wait for his/her bladder to refill after a test for the next one, this situation increases the time spent in hospital by patients and workload of clinicians.

SYSMEX UC3500 Fully Automated Urine Chemistry Analyzer is capable of processing 276 samples per hour which is faster than ORUBA INALYS in terms of number of tests per hour however, ORUBA INALYS shortens the time required for one patient to get the results after giving sample. The way SYSMEX UC3500 is used in the laboratories is that many samples from many patients are first collected in disposable urine cups and after a required number of samples is obtained, the evaluation of these samples are performed using the analyzer. The device is capable of processing 276 samples per hour however, a patient must wait for a long time after urinating in a cup since there are many more samples to come. ORUBA INALYS is more patient-friendly since it allows the patients to get their results in approximately 5 min after urinating. In addition, it saves the patient from urinating in a cup and makes the process more patient-friendly by allowing the patient to urinate directly in a urinal-shaped medical device. This property of ORUBA INALYS also helps reducing the usage of disposable urine cups which is both cost effective and environment friendly.

ORUBA INALYS combined device designed to perform simultaneous uroflowmetry and urinalysis allows the patient to give the urine specimen for urinalysis at the same time he is tested for uroflowmetry without additional effort and increases patient comfort. Also, test procedure of INALYS does not require additional help from personnel for neither uroflowmetry nor urinalysis, eliminates sampling processes performed in laboratory, and decreases workload and cost. Another advantage of ORUBA INALYS device is that the absolute reduction in workload. Without the requirement for any human assistance, the urinalysis results automatically transferred to the system and presented to the clinician for evaluation simultaneously with the uroflowmetry result. [İmportant issues to be considered are that the reduction within the total cost and contribution to environmental health. According to the data of a Spanish study, 11 million urinalysis were performed per year [23]. The absence of the cost of plastic urine containers in combined device brings a significant advantage by being protected from plastic waste, as well as reducing the total cost.

Table 1
Summary of the comparison of ORUBA INALYS and SYSMEX UC3500 results.

	Percent agreement within the same category (%)	Percent agreement within ±1 category (%)	Weighted kappa
Leukocyte	84%	88%	0.5
Nitrite	90%	–	–
Bilirubin	74%	100%	–
Ketone	100%	100%	–
Protein	84%	96%	0.7
Glucose	92%	100%	0.92
pH	82%	100%	0.47
Urobilinogen	100%	100%	–
Blood	84%	98%	0.73
Specific gravity	60%	80%	0.4

In addition to the operational advantages offered by ORUBA INALYS, the reliability of the urinalysis results of this device is also an important criterion. Based on the fact that the urine is an unstable fluid whose content is continuously changing with time; it is crucial to properly collect, transport, and maintain the specimen in the current laboratory procedures in order to reduce the risk of artefactual test results. In this context, elimination of all these collection, transport and maintenance processes in ORUBA INALYS is a huge benefit for accuracy of the results. Based on reliability, the concordance of the results obtained from the new device with those obtained from an established and widespread device is also an important concept that applies to clinical studies in the literature [17]. The two most common parameters calculated for concordance are agreement percentages and kappa coefficients, while European urinalysis guidelines recommend reporting of weighted kappa coefficients for the comparison of test parameters with 4 or more categories between two urine strips [24]. Accordingly, we used agreement percentages and weighted kappa coefficients as parameters that represent concordance of the results between two devices. Based on the available classification of kappa values into different levels of agreement [25], the correlation between ORUBA INALYS and SYSMEX UC 3500 results was found to be ‘‘very good’’ for glucose, ‘‘good’’ for protein and blood, and ‘‘moderate’’ for pH, specific gravity and leukocyte. Overall, glucose was shown to be the parameter with the best performance, whereas specific gravity was identified as the parameter with the weakest performance. This relatively poor performance of the specific gravity can be attributed to the previously reported low correlation between refractometric and dipstick results [26].

There are also limitations in this study: The number urine specimens used for the method comparison ($n = 50$) is relatively low. Increasing the number of specimens would provide a better statistical significance of the results observed. The isolation midstream urine, which is considered as the ideal catch of urine for reliability of urinalysis results, is technically not feasible in ORUBA INALYS device, although individual separation of the initial or final-stream parts of the urine is notified to be possible. Although agreement percentages for ketone and urobilinogen results are high, there were no positive results for these tests. It was another limitation of this study.

5. Conclusion

The good agreement of the urinalysis results obtained from ORUBA INALYS with those obtained from a widespread comparative device SYSMEX UC3500 shows the reliability of the urinalysis performed on ORUBA INALYS. As a common screening test in urology, the simultaneous test procedure of urinalysis with uroflowmetry on a single device by using a single specimen provides increased patient comfort, reduced workload in hospitals, reduced cost, and a time-saving process for both patients and clinicians.

Ethical approval

This study was conducted according to the ethical standards laid down by the 1964 Declaration of Helsinki and its later amendments and approved by the local ethics committee of Ankara University School of Medicine (No. 08-334-21, Date: 21.04.2021) This study is also approved by the Republic of Türkiye Ministry of Health.

If requested, relevant documents will be sent to editorial office.

Author contribution statement

Murat Topcuoğlu: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Murat Can Karaburun: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Adem Sancı: Analyzed and interpreted the data.

Ozden Kokurcan: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Erdinç Devrim: Contributed reagents, materials, analysis tools or data.

Ömer Gülpınar: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data, manuscript editing.

Role of funding source

Oruba Technology & Innovation’ has supported this study by lending Oruba INALYS: Uroflowmetry-Urinalysis Combined Device. ‘Oruba Technology & Innovation’ has no extra contribution to the authors or the study.

Informed Consent

Oral and written consent was obtained from all patients.

Data availability statement

Data associated with this study has been deposited at Ankara University, Avicenna Patient Database

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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