Original Article

Performance of Automatic Urine Analyzer Compared with Manual Microscopy in Urinary Tract Infection Cases in a Tertiary Care Hospital

Shaista Bakhat, Yasmeen Taj, Maria Ali, Sana Barkat Ali Bhayani, Luqman Satti, Hina Wasti

ABSTRACT

Objectives: This study aimed to assess and compare the results of automated urine analyzers and manual urine analysis in the evaluation of urinary tract infections (UTIs) at Pakistan Navy Shifa Hospital Karachi.

Study Design and Setting: A cross-sectional study was conducted from March 2022 to December 2022 in the Microbiology Department of Pakistan Navy Shifa Hospital Karachi.

Methodology: Urine samples were randomly selected, and both automated urine analyzers (Urised, 77 Electronika, Hungary) and manual analysis methods were used for evaluation. Key urine parameters, including red blood cells, epithelial cells, leukocytes and crystals, were analyzed. Statistical analysis was performed using the Chi-square test with p-value less than .05. Sensitivity, specificity, PPV. And NPV were also determined.

Results: A total of 169 urine samples were analyzed. Significant differences were observed between the automated and manual methods for leukocytes (P-value < 0.000). Crystals were determined by both methods, automatic analyzer was unable to describe structure and morphology as compare to manual method.

Conclusions: Automated urine analyzers are essential for efficient and large-scale sample processing and standardization. However, further development is needed to improve the accuracy of identifying certain urinary elements. Manual microscopic examination remains crucial for confirming pathological cases. In high-volume settings like Pakistan, automated systems offer significant time-saving benefits but should be complemented with manual analysis for comprehensive diagnosis.

Key words: cross-sectional study, pH, red blood cells, specific gravity.

How to cite this Article:
Bakhat S, Taj Y, Ali M, Bhayani BA, Satti L, Wasti H. Performance of Automatic Urine Analyzer Compared with Manual Microscopy in Urinary Tract Infection Cases in a Tertiary Care Hospital. J Bahria Uni Med Dental Coll. 2025;15(2):109-114 DOI: https://doi.org/10.51985/JBUMDC2025499

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Received: 06-01-25
Accepted: 28-03-25
1st Revision: 16-01-25
2nd Revision: 27-02-25
3rd Revision: 14-03-25

INTRODUCTION

Urinalysis is an essential tool in clinical diagnostics, widely used for screening and monitoring a range of health conditions, particularly those affecting the kidneys and urinary tract. It ranks third in diagnostic tests, following serum chemistry and complete blood count, due to its non-invasive, cost-effective nature and its ability to provide early indications of renal and genitourinary diseases.[1,2] Urinalysis plays a critical role not only in detecting conditions such as urinary tract infections (UTIs), kidney stones, and glomerulonephritis, but also in identifying signs of systemic diseases such as diabetes mellitus, hypertension, and toxemia of pregnancy. This makes it a vital component of both routine health check-ups and targeted diagnostic investigations for individuals with suspected genitourinary issues.[3]

Urinalysis is particularly valuable for detecting renal and genitourinary diseases in their early stages. Through microscopic examination of urine sediment, it allows the detection of abnormalities like proteinuria, hematuria, bacteriuria, and leukocyturia, which are indicative of underlying pathologies.[4] Despite its utility, traditional manual urinalysis procedures face significant limitations. These include labor-intensive processes, susceptibility to human error, and challenges associated with large sample volumes, which can lead to inconsistencies and delays in results.[5] Manual urinalysis typically involves a series of steps, including a dipstick test, visual inspection, and microscopic analysis of urinary sediment.[6] While these methods are standardized, they are time-consuming and highly dependent on the skill and experience of the technician performing the analysis. Furthermore, manual procedures are prone to inter-observer variability, as well as potential issues such as cell lysis and the loss of cellular elements during analysis.[7] The centrifugation speed, urine staining quality, and volume of urine available for re-suspension can also affect the accuracy of results. These challenges make manual analysis particularly difficult for large-scale or high-volume clinical testing.[8]

To address these challenges, automated urine analyzers have been introduced to improve the efficiency and consistency of urinalysis. These devices utilize advanced technologies, including image recognition and sensors, to detect urinary elements more accurately and with minimal human intervention.[9] Automated systems offer several advantages, including the ability to process large numbers of samples more quickly and efficiently than manual methods. However, concerns regarding the diagnostic accuracy of automated analyzers persist, particularly when it comes to their ability to match or surpass the results obtained through manual microscopic analysis. In laboratories that have transitioned from manual to automated systems, discrepancies between the two methods have been reported. These discrepancies often raise questions about the reliability of automated systems and whether they can identify urinary abnormalities with the same level of precision as manual methods.[10] As such, further research is needed to compare the diagnostic performance of manual urinalysis with fully automated urine analyzers, particularly in terms of sensitivity and specificity for detecting key markers of genitourinary conditions.

The lack of sufficient research in our region comparing the diagnostic capabilities of manual urinalysis with automated urine analyzers represents a significant gap in literature. This study aims to fill this gap by evaluating the sensitivity of automated urine analyzers in diagnosing genitourinary pathologies, such as proteinuria, hematuria, and leukocyturia, in comparison to manual microscopy. By investigating whether automated systems can reliably detect these urinary abnormalities, the study seeks to determine if they can match or even surpass the diagnostic accuracy of manual methods, particularly in high-volume clinical settings where speed and efficiency are crucial. The results of this study will provide valuable insights into the practical applications and limitations of automated urine analyzers in clinical practice, particularly in regions where manual methods are still commonly used.

By comparing the performance of both manual and automated techniques, this study will contribute to the refinement of urinalysis practices, ensuring that healthcare providers can make more accurate and timely diagnoses of genitourinary diseases. The findings will be particularly relevant in settings where clinical demand is high, and where automation can help streamline the diagnostic process without compromising the quality of care. Ultimately, this research will contribute to better patient outcomes through the adoption of more reliable and efficient diagnostic methods.

METHODOLOGY

This cross-sectional study was conducted in the Microbiology Department of Pakistan Navy Shifa Hospital, Karachi, from March 2022 to December 2022, with approval from the Institutional Review Board of the Bahria University Health Sciences (BUHS) (ERC# 67/2022). The study adhered to ethical standards, and informed consent was obtained from all participants before their inclusion in the study.

To determine the appropriate sample size, the open-source online EPI software (https://www.openepi.com/Menu/OE_Menu.htm) was utilized, ensuring that the sample size was sufficient to obtain statistically significant results. A total of 169 urine samples were analyzed, which were selected using a simple random sampling technique, ensuring an unbiased and representative sample for the study.

The inclusion criteria for the study were specifically defined to ensure that only valid and reliable samples were analyzed. The selected samples included freshly voided midstream urine, with a minimum volume of 30 mL, collected within 30 minutes of urination. These samples were obtained from both outpatients and inpatients, allowing the study to encompass a diverse population. The exclusion criteria were also carefully defined to eliminate any samples that could interfere with the analysis. Excluded were urine samples with a volume of less than 15 mL, contaminated samples, or samples that had spilled out of the collection containers. Additionally, samples that contained preservatives, such as those obtained from 24-hour urine collections, were also excluded. Patients were already on use of antibiotics were excluded from study.

For the analysis, each urine sample was divided into two aliquots, one for manual analysis and the other for automated analysis. The preservative-free midstream urine samples were carefully collected in wide-mouth, spill-resistant containers to ensure that the sample remained uncontaminated during transport to the laboratory. Once the samples arrived at the microbiology department, they were processed by centrifuging at 1500 rpm for five minutes to obtain sediment for microscopic evaluation. This step allowed for the separation of the solid components of the urine, including cells and particles, which could then be analyzed under the microscope.

For the manual analysis, a small drop of the sediment was placed on a glass slide, covered with a cover slip, and examined using an Olympus microscope. The samples were scanned under both low power (100x) and high power (400x) magnifications. The analysis included the enumeration of red blood cells (RBCs), white blood cells (WBCs), epithelial cells, and yeast cells, with results reported as the number of cells or particles per Low Power Field (LPF) and High Power Field (HPF).

In parallel, the second aliquot was processed using the Urised 77 Electronika automated analyzer, which provided results for RBC count, WBCs, epithelial cells, and yeast cells. This automated method was used to assess the consistency and comparability of the results with the manual microscopy method.

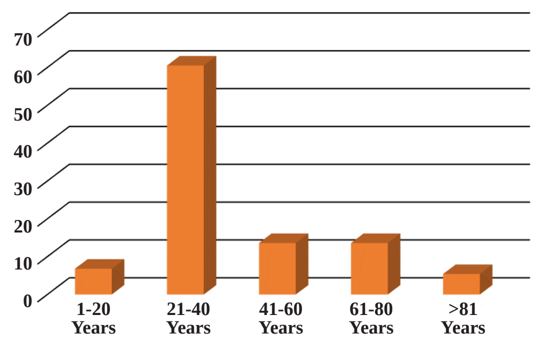
The collected data were analyzed using IBM SPSS version 23, which allowed for the calculation of descriptive statistics. To assess the statistical significance of differences between the two methods, the Chi-square test was applied, with p-value less than .05. Sensitivity, specificity, PPV, NPV was determined.

RESULTS:

A total of 169 cases were analyzed, focusing on demographic and clinical data. The results from the urine automated analyzer were compared with those obtained through manual microscopy. In accordance with the protocol, relevant demographic details, clinical information, and both microscopic and automated findings were recorded and analyzed.

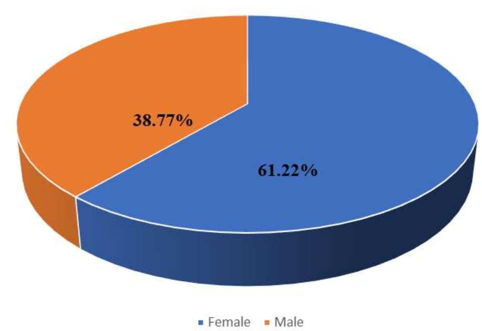
The patients' ages varied widely, ranging from 1 to 90 years. The majority of patients fell within the 21-40 years age group, comprising 60.50% of cases, followed by the 41-80 years age range, which accounted for 13.60% of the cases. The comparison between the WBC counts obtained from the automated analyser and manual microscopy revealed a statistically significant difference, as indicated by a p-value below the significance threshold. The comparison between the RBC counts obtained from the automated analyser and manual microscopy revealed a statistically insignificant difference, as indicated by a p-value. For the RBC count of >100/hpf, automated analyser, reported exact number of cells per high power field, while current study reported “RBC Full field” on manual microscopic examination in same number of cases. These results imply high sensitivity of automated analyser. The comparison between epithelial cells obtained from the automated analyser and manual microscopy revealed a statistically insignificant difference, as indicated by a p-value. For the epithelial cell count of >100/hpf, automated analyser, reported exact number of cells per high power field, while current study reported “epithelial cells Full field” on manual microscopic examination in same number of cases. These results imply high sensitivity of automated analyser. The crystal count result for the 0-10/hpf category was nearly identical between the automatic analyser and manual microscopic examination. However, a difference was observed in the counts for the >10/hpf range. This suggested that the automatic analyser was highly specific in counting crystals per hpf. However, it was unable to identify the type and morphology of the crystals, making manual microscopy necessary for accurate reporting.

Figure 1: Distribution of patients as per age



Majority of patients were females (61.22%) with Male: female ratio of 1:1.57.

Figure 2: Distribution of patients as per gender



Majority of cases presented with burning micturition (40.80%)

Figure 3: Distribution of patients according to clinical features

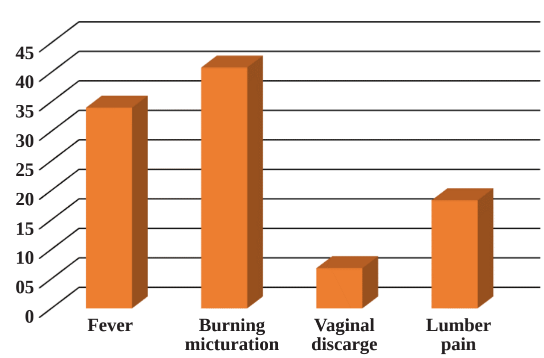


Table 1: Comparison of frequency of WBC per HPF observed in automated analyser as compare to manual microscopy

WBC	Automated analyser	Manual	*p*-value
>5-10/hpf	70	60	0.000
>10-20/hpf	30	20	
>20/hpf	47	40	

Table 2: comparison the frequency of RBC per HPF observed in automated microscopy compare to routine microscopy

RBCs	Automated Analyser	Manual	p-Value
>3-5/hpf	60	50	0.556
>5-10/hpf	20	30	
>10-20/hpf	30	20	
>20/hpf	5	9	
>100/hpf (Automated analyzer)	5	-	
Full field (manual)	-	5	

Table 3: comparison the frequency of epithelial cells per HPF observed in automated microscopy compare to routine microscopy

Epithelial cells	**Automated analyser**	**Manual**	**p-Value**
>15-20/hpf	75	55	0.761
>20/hpf	67	90	
>100/hpf (Automated analyzer)	1	-	
numerous (manual)	-	1	

Table 4: Displaying the frequency of crystals observed in automated microscopy compared to routine microscopy

Crystals	Automatic analyser	Manual	p-value
0-10/hpf	10	12	.032
>10/hpf	3	10	
Absent	134	98	

Table 5: Displaying sensitivity, specificity, PPV, NPV in case of WBC in both methods

WBCs Ranges	Sensitivity	Specificity	PPV	NPV
>5-10/hpf	100%	88.5%	85.7%	100%
>10-20/hpf	100%	92.1%	66.7%	100%
>20/hpf	100%	93.5%	85.1%	100%

PPV (Positive predictive value), NPV (Negative predictive value)

DISCUSSION

Urinary tract infections (UTIs) are one of the most prevalent bacterial infections worldwide, ranking just behind respiratory tract infections. They are frequently encountered in clinical practice, with many cases being asymptomatic, posing a risk of complications like kidney scarring and pregnancy-related issues if left undiagnosed and untreated. Urine, unlike other bodily fluids, lacks lysozyme, immunoglobulins, and complement proteins, making it a favorable medium for bacterial growth. As such, accurate and reliable urinalysis plays a vital role in diagnosing and preventing UTIs and other urinary tract disorders.[12] Early diagnosis of UTIs is essential, as untreated infections can lead to severe renal complications. This study aimed to evaluate the accuracy of an automated urine analyzer (Urised, 77 Electronika, Hungary) in comparison to the gold standard of manual urine microscopy, focusing on physical, chemical, and microscopic parameters.

Our study demonstrated a significant level of agreement between manual and automated urine analysis, these findings align with previous studies, such as the work by Ince et al., who reported strong correlations between manual and automatic urine analyzers, especially for components like red blood cells (RBCs), white blood cells (WBCs), and epithelial cells.[13] Bakan et al. also found that the manual and automated approaches were compatible and reliable for detecting these components.[14] These studies confirm the validity and reliability of automated urine analyzers in providing consistent results similar to manual microscopy, particularly for routine urinary parameters.

However, our study also found some differences between the manual and automated methods. The automated analyzer detected a higher percentage of RBCs (71%) compared to manual microscopy (67%). This discrepancy suggests that automated systems may have increased sensitivity in detecting RBCs, which is consistent with findings from Ahmed et al., who noted that automated analyzers performed better than manual microscopy for RBC detection.[15] This suggests that automated analyzers can identify certain elements that may be overlooked during manual examination, potentially improving diagnostic accuracy in specific cases. Similarly, Tantisaranon et al. observed a strong correlation for epithelial cells between both methods, although differences were noted for RBCs and leukocytes.[16] These findings highlight the strengths of automated analyzers in detecting certain elements while acknowledging that manual techniques may still have advantages for others.

Damaged leukocytes are not counted by the automated instrument, but distorted and disrupted cells again may be counted as an artifact. A study by Shayanfar, et al. demonstrates abnormal erythrocytes, such as ghost and dysmorphic cells, are found in some cases with potentially falsely high erythrocyte count due to misclassification of yeast.[17] The blood count needs to be adjusted and Iris iQ200 counts fewer erythrocytes. Wah, et al. reported similar false-positive results. and manual microscopy is therefore the only way of determining urine samples from patients suffering from kidney disorders.[18]

Another significant parameter analyzed in our study was urine color and appearance. Our results showed that the automated analyzer identified straw-colored urine in 63.9% of samples, while manual observation recorded this color in only 46.7%. Similarly, the automated system detected cloudy urine in 64.5% of samples compared to 47.3% in manual observation. These differences, which were statistically significant (p=0.002), suggest that automated systems may be more effective in consistently detecting color and appearance, which could be subject to subjective interpretation in manual analysis. These findings are consistent with those of Gyamfi et al., who also observed good agreement between manual and automated methods for urine color and appearance.[19]

While automated systems excel at handling large volumes of samples efficiently and reducing laboratory staff burden, they may not always detect certain crucial elements. For example, dysmorphic RBCs, casts, and crystals may be missed by automated analyzers, which are essential for diagnosing complex conditions like glomerulonephritis and nephrolithiasis.[20] We sara chkitti et al. also emphasized the importance of manual microscopy for detecting these elements, which automated systems may fail to identify accurately. Therefore, while automated analyzers are valuable for routine screening, manual examination remains critical for confirming pathological findings and detecting subtle abnormalities that may have clinical significance.[21]

The complementary use of both manual and automated methods is essential for ensuring diagnostic accuracy and reliability. While automated systems can streamline the urinalysis process, especially in high-volume settings, the manual approach provides an added layer of scrutiny that is necessary for detecting rare or complex conditions. This study's findings align with the broader consensus in literature, which suggests that combining both methods offers the most comprehensive and reliable diagnostic approach. This is particularly true in high-demand environments like PNS Shifa Hospital, where the use of automated analyzers can expedite the diagnostic process while still allowing for manual examination in cases where further investigation is warranted.[24] Overall, this study underscores the importance of incorporating both manual and automated urine analysis techniques in clinical practice. The combination of both methods helps overcome the limitations inherent in each and ensures more accurate and reliable diagnoses, particularly in the context of UTIs and other urinary tract disorders. The findings also support the continued use of manual microscopy as a complementary tool in diagnosing more complex or subtle urinary tract conditions, especially in high-volume clinical settings where automated systems are invaluable.

CONCLUSION:

The concordance between the automatic analyzer and manual microscopic examination demonstrated high sensitivity, specificity, positive predictive value, negative predictive value. One notable advantage of the automatic analyser was its "red flag" functionality. It provided specific counts for parameters such as RBCs, WBCs, and epithelial cells, unlike manual microscopy, which often reported a "full field" for large numbers. However, while the automatic analyser could detect and count crystals, it was unable to identify their type or morphology, which still required manual microscopy. Additionally, the automatic analyzer was faster and less labor-intensive than manual microscopy when analyzing urine samples.

Authors Contribution:
Shaista Bakhat: The article was initially written by her, and provided the original statistics
Yasmeen Taj: Made overall modifications to the manuscript
Maria Ali: Contributed to the discussion section and assisted with referencing
Sana Barkat Ali Bhayani: Helped with data collection
Luqman Satti: Supported the gathering of data from PNS Shifa.
Hina Wasti: Helped with the data collection

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