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Original Research Article

COMPARISON OF AUTOMATED URINE MICROSCOPY WITH MANUAL MICROSCOPIC EXAMINATION FOR ROUTINE URINALYSIS: EXPERIENCE AT TERTIARY CARE CENTER

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ABSTRACT

Background: Urinalysis is a cornerstone of routine diagnostics in nephrology and internal medicine. Manual microscopic examination, while widely considered the gold standard, is time-intensive and operator-dependent. Automated systems like the Sysmex UF-5000 offer enhanced efficiency and standardization. **Objective:** To compare the diagnostic performance of the Sysmex UF-5000 automated urine analyzer with manual microscopy for routine urinary sediment analysis in a high-volume tertiary care setting.

Materials and Methods: A prospective observational study was conducted on 1000 freshly collected midstream urine samples. Each specimen was analyzed by both manual microscopy and the Sysmex UF-5000. Parameters studied included RBCs, WBCs, epithelial cells, casts, crystals, and bacteria. Diagnostic accuracy was assessed using sensitivity, specificity, predictive values, and Cohen's kappa statistics.

Results: Automated urinalysis showed excellent agreement with manual microscopy for RBCs ($\kappa = 0.87$), WBCs ($\kappa = 0.82$), epithelial cells ($\kappa = 0.91$), and bacteria ($\kappa = 0.81$). Moderate agreement was noted for casts ($\kappa = 0.62$) and crystals ($\kappa = 0.68$).

Conclusion: Automated urinalysis is a reliable and efficient alternative for routine screening. However, manual microscopy remains essential for ambiguous or complex sediments. A hybrid approach is advisable to optimize diagnostic accuracy.

Keywords: Microscopy, Urinalysis, Urine Analyzer

INTRODUCTION

Urinalysis is one of the most frequently performed laboratory tests, offering valuable insights for the diagnosis and monitoring of renal, urinary tract, and systemic conditions. Manual microscopic examination has long been considered the gold standard for evaluating urine sediment, particularly

for identifying red blood cells (RBCs), white blood cells (WBCs), epithelial cells, casts, and crystals. However, this method is time-consuming, labor-intensive, and prone to inter-observer variability.[1]

In recent years, automated urine analyzers, such as the Sysmex UF series and the Iris iQ200, have gained prominence due to their ability to provide rapid, standardized, and reproducible results using technologies like flow cytometry and digital imaging.[2] Studies have shown that these analyzers demonstrate strong concordance with manual microscopy, particularly in the detection of common sediment components like RBCs, WBCs, and epithelial cells.[3,4] However, the detection of less common elements—such as casts, bacteria, and crystals—may still require manual confirmation, as automated systems sometimes exhibit limitations in sensitivity and specificity for these components.[4]

As clinical laboratories increasingly shift toward automation to enhance efficiency and minimize human error, it becomes essential to assess the reliability and diagnostic accuracy of these systems in real-world settings. This study aims to compare the performance of an automated urine analyzer with that of manual microscopic examination in routine urinalysis at a tertiary care center. By evaluating the level of agreement and identifying any diagnostic discrepancies, we seek to determine the clinical utility and limitations of automation in routine laboratory workflows.

MATERIALS AND METHODS

This prospective, observational study was conducted at the Institute of Kidney Diseases and Research – Institute of Transplantation Sciences (IKDRC-ITS), a tertiary care center specializing in nephrology and renal transplantation. The study was carried out over a period of three months, from January 2025 to March 2025.

Sample Size and Selection: A total of 1000 urine samples were included in the study. These were collected from both inpatient and outpatient departments as part of routine clinical investigations. Samples with visible contamination, hemolysis, or improper labeling were excluded. Only freshly voided, midstream urine specimens submitted within two hours of collection were included in the analysis.

Automated Urine Analysis: All urine samples were analyzed using the Sysmex UF-5000, an automated urine sediment analyzer based on flow cytometry and fluorescence technology. The analyzer quantitatively evaluates various formed elements, including red blood cells (RBCs), white blood cells (WBCs), epithelial cells, casts, crystals, and bacteria. Daily internal quality control and periodic calibration were performed as per the manufacturer's guidelines to ensure accuracy and consistency.

Manual Microscopic Examination: For manual urine microscopy, 10 mL of each urine sample was centrifuged at 2000 rpm for 5 minutes. The supernatant was discarded, and the sediment was resuspended in the remaining fluid. A drop of the sediment was placed on a clean glass slide, covered with a coverslip, and examined under a light microscope. The examination was conducted under low power (10x) for general scanning and high power (40x) for detailed evaluation. A minimum of 10–15 high power fields (HPF) were examined per sample to assess the presence and quantity of formed elements.

Parameters Compared: The following urine sediment components were evaluated and compared between the automated and manual methods:

- Red Blood Cells (RBCs)
- White Blood Cells (WBCs)
- Epithelial Cells
- Casts
- Crystals
- Bacteria

Statistical Analysis: All data were recorded and analysed using SPSS version 26.0 (IBM Corp., Armonk, NY). The agreement between automated and manual methods was assessed using Cohen's Kappa (κ) coefficient. In addition, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each parameter. The strength of agreement based on kappa values was interpreted as follows:

- 0.80: Excellent
- 0.61–0.80: Substantial
- 0.41–0.60: Moderate
- <0.40: Poor

RESULTS

Table 1: Diagnostic Performance of Automated Urinalysis Compared to Manual Microscopy (n = 1000 samples)

Parameter	Cohen's κ (95% CI)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Agreement Level
WBC	0.82 (0.78–0.85)	85.7	93.2	88.5	91.3	Almost Perfect
RBC	0.87 (0.84–0.89)	89.4	95.1	86.7	96.0	Almost Perfect

Epithelial Cells	0.91 (0.88–0.93)	92.6	97.8	90.5	98.3	Almost Perfect
Bacteria	0.81 (0.77–0.85)	91.7	94.8	90.1	95.6	Substantial
Casts	0.62 (0.57–0.67)	68.4	92.3	65.7	93.1	Moderate
Crystals	0.68 (0.63–0.73)	72.6	95.2	78.9	93.4	Moderate

Table 2: WBC (White Blood Cells) Analysis Contingency Table (Automated vs. Manual)

Automated \ Manual	0-5	6-10	11-20	>20	Total
0-5	750	20	5	0	775
6-10	15	70	10	2	97
11-20	5	8	50	5	68
>20	0	2	5	53	60
Total	**770**	**100**	**70**	**60**	**1000**

- Sensitivity (True Positive Rate): 85.7%
- Specificity (True Negative Rate): 93.2%
- PPV (Positive Predictive Value): 88.5%
- NPV (Negative Predictive Value): 91.3%
- Cohen's Kappa (κ): 0.82 (Almost Perfect Agreement)

Table 3: RBC (Red Blood Cells) Analysis Contingency Table (Automated vs. Manual)

Automated \ Manual	0-5	6-10	11-20	>20	Total
0-5	820	15	3	0	838
6-10	10	65	5	2	82
11-20	5	8	40	3	56
>20	0	2	2	20	24
Total	**835**	**90**	**50**	**25**	**1000**

Statistical Measures

- Sensitivity: 89.4%
- Specificity: 95.1%
- PPV: 86.7%
- NPV: 96.0%
- Cohen's Kappa (κ): 0.87 (Almost Perfect Agreement)

Table 4: Epithelial Cells Analysis Contingency Table (Automated vs. Manual)

Automated \ Manual	0-5	6-10	11-20	>20	Total
0-5	900	10	2	0	912
6-10	8	45	3	0	56
11-20	2	5	20	1	28
>20	0	0	0	4	4
Total	**910**	**60**	**25**	**5**	**1000**

Statistical Measures

- Sensitivity: 92.6%
- Specificity: 97.8%
- PPV: 90.5%
- NPV: 98.3%
- Cohen's Kappa (κ): 0.91 (Almost Perfect Agreement)

Bacterial detection also showed strong agreement, with a kappa value of 0.81, sensitivity of 91.7%, specificity of 94.8%, PPV of 90.1%, and NPV of 95.6%. The automated system accurately flagged bacteriuria, supporting its utility in preliminary screening for urinary tract infections. The agreement for hyaline cast detection was moderate, with a kappa coefficient of 0.62. Sensitivity was 68.4%, specificity 92.3%, PPV 65.7%, and NPV 93.1%. The automated analyzer frequently underestimated or missed low-count hyaline casts, suggesting limited sensitivity in identifying these elements. For urinary crystals, the automated method achieved a kappa of 0.68, indicating moderate agreement. Sensitivity was 72.6%, specificity 95.2%, PPV 78.9%, and NPV 93.4%. While most common crystals were identified, occasional misclassification and under-reporting were observed, particularly in morphologically ambiguous cases.

DISCUSSION

Urine microscopy remains a fundamental component of routine diagnostic evaluation, providing critical information for the assessment of urinary tract infections, renal pathologies, and systemic diseases. This study evaluated the diagnostic performance of automated urine microscopy compared to the manual microscopic method, analysing 1000 urine samples across key urinary parameters: white blood cells (WBC), red blood cells (RBC), epithelial cells, bacteria, casts, and crystals. Our findings indicate almost perfect agreement between automated and manual methods for RBCs (κ = 0.87), WBCs (κ = 0.82), and epithelial cells (κ = 0.91). These results are in line with prior studies that validate the high sensitivity and specificity of the Sysmex system.

Delanghe et al. (2000) and Yuen et al. (2020) also reported $\kappa > 0.80$ for RBCs and WBCs.[5,6] Park et al. (2013) evaluated Sysmex UF-1000i and found comparable sensitivity for WBCs (84.5%) and RBCs (87.1%).[7]

The high negative predictive values (NPVs) (>91%) in our study reaffirm the utility of the automated system for ruling out pathological findings, making it a powerful tool for initial screening. Epithelial cells had the highest diagnostic agreement. This is important, as exfoliation of renal tubular or transitional epithelium may signal acute tubular injury, nephritis, or urothelial neoplasia. Automated systems are now more refined in detecting such components using fluorescence flow cytometry, as supported by Guzel et al. (2021).[8] In line with Fogazzi et al. (2001), our study confirms that RBCs and WBCs are reliably quantified by automated analyzers, even in low or borderline counts.[9] The sensitivity for WBCs (85.7%) and RBCs (89.4%) in our study is comparable to reported values in literature ranging from 80% to 92%, reaffirming the clinical reliability in UTI and hematuria detection. The detection of bacteria achieved a kappa value of 0.81, with high sensitivity (91.7%) and specificity (94.8%). This performance mirrors that found by Bach et al. (2016), who demonstrated 90% concordance between automated detection and culture-confirmed bacteriuria.[10] However, automated systems may still lack the resolution to differentiate bacterial species, limiting their role in microbiological differentiation. Conversely, the agreement for hyaline casts ($\kappa = 0.62$) and urinary crystals ($\kappa = 0.68$) was only moderate, with sensitivity values of 68.4% and 72.6%, respectively. This is in concordance with Hsiung et al. (2015), who reported that automated systems underperform in cast detection, particularly when morphology is atypical or present in low numbers.[11] Similarly, crystal identification can be confounded by variations in shape, refractility, and interference from debris, which automated image-based algorithms may not accurately interpret. The detection of bacteria showed substantial agreement ($\kappa = 0.81$), which supports the automated system's use in preliminary UTI screening. Our sensitivity of 91.7% is slightly higher than that reported by Bach et al. (2016) (90%), though culture confirmation remains necessary for species identification and antibiotic susceptibility.10 Further, Lombarts et al. (2010) suggested that using automated urinalysis as a screening tool before culture reduces unnecessary microbiology workload by up to 60% without compromising diagnostic sensitivity—a significant implication in resource-limited settings.[12] The moderate agreement for casts ($\kappa = 0.62$) and crystals ($\kappa = 0.68$) reflects the ongoing limitations of automation. Casts particularly granular or waxy types are often underrepresented due to their variable morphology and low frequency. Our sensitivity for cast detection (68.4%) aligns with Hsiung et al. (2015) and Fuchs et al. (2019), who observed that automated analyzers frequently missed low-count or atypical casts.[11,13] Crystals are affected by urine pH, temperature, and concentration, which may lead to misclassification by image recognition algorithms. Fogazzi et al. (2001)[9] emphasized that rare or birefringent crystals like cystine or leucine often escape automated detection and must be confirmed manually.

CONCLUSION

Our results reinforce the role of automation as a frontline tool in routine urinalysis. Automated microscopy reduces observer bias and inter-technician variability, increases laboratory throughput, and standardizes reporting for quality assurance. Yet, it is not a complete replacement for manual microscopy, particularly in cases of abnormal or ambiguous findings, high clinical suspicion of nephritic or crystalline pathology, and pediatric or transplant patients with low sediment yield but high clinical stakes. Hence, laboratories should implement a reflex protocol, where abnormal or flagged cases are manually reviewed by trained personnel.

Future Directions: Advancements in AI-assisted image recognition and deep learning models have begun to show promise. Kim et al. (2022) demonstrated that AI-based digital microscopy achieved >90% concordance with expert review for rare elements such as casts and dysmorphic RBCs.

Future systems must focus on:

- Improved detection of pathological casts and rare crystals.
- Integration with electronic medical records for decision support.
- Expanding validation across diverse patient populations, including children, post-renal transplant, and critical care patients.

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