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Comparison of urine sediment microscopy from two automated urine analyzers versus manual analysis

Urine sediment microscopy

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Abstract

Aim: Urine is considered a liquid biopsy sample, and its analysis consists of three main stages: physical, chemical, and microscopic sediment examination. These analyses can be performed manually or using automated urine analyzers. In this study, two different models of the same brand, DIRUI FUS-200 and DIRUI FUS-3000Plus, were evaluated by comparing their microscopic analysis results with manual examination findings, which were accepted as the reference method.

Methods: Parameters assessed included red blood cells (RBC), white blood cells (WBC), epithelial cells, hyaline casts, granular casts, and calcium oxalate crystals, which are among the most clinically relevant urine sediment elements. When statistical significance was detected, pairwise comparisons were conducted using the Mann–Whitney U test with Bonferroni correction. Binary parameters were evaluated using the McNemar test, and agreement between methods was assessed using Cohen's kappa coefficient.

Results: No statistically significant differences were found among the three methods for WBC, RBC, and epithelial cell distributions ($P > .05$), consistent with previous reports on automated urine analyzers. In contrast, significant differences were observed among the methods for hyaline casts, granular casts, and calcium oxalate crystals ($P < .05$), indicating variability in the detection of rare or pathological sediment components.

Conclusion: The DIRUI FUS-200 and DIRUI FUS-3000Plus automated urine analyzers demonstrated comparable performance to manual microscopic examination for common urine sediment parameters such as WBC, RBC, and epithelial cells. Therefore, while automated urine analyzers provide reliable support for routine clinical urinalysis, manual microscopic examination remains essential for the confirmation of specific sediment components.

Keywords

urine sediment, microscopy analysis, automated urine analyzer, DIRUI FUS-200, DIRUI FUS-3000plus

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Introduction

Urine analysis is among the most commonly requested laboratory tests in clinical practice and has an important role in diagnosing and monitoring renal, metabolic, and systemic diseases.[1] Because it is non-invasive and diagnostically informative, urine has been referred to as a "liquid biopsy," offering valuable insights through the evaluation of physical, chemical, and microscopic parameters.[2] Among these methods, microscopic examination of urine sediment remains essential, enabling the detection of cells, casts, crystals, and microorganisms that indicate underlying pathological processes.[3]

Despite being regarded as the reference method, manual urine sediment microscopy is labor-intensive, time-consuming, and subject to inter- and intra-observer variability.[4,5] These limitations have led to the widespread use of automated urine analyzers, which are intended to improve standardization, shorten turnaround time, and increase reproducibility in routine laboratory workflows.[6] Modern automated systems use digital imaging, flow cell technology, and artificial intelligence–based algorithms to classify and quantify urine sediment elements.[7]

However, previous studies have demonstrated that although automated analyzers show high concordance with manual microscopy for common parameters such as red blood cells (RBC) and white blood cells (WBC), their performance may vary considerably for rare or morphologically complex particles, including casts and crystals. Therefore, ongoing validation of automated urine analyzers against manual microscopy is necessary to ensure analytical reliability and clinical safety.[8-11] In this context, the present study aimed to evaluate and compare the performance of two automated urine sediment analyzers from the same manufacturer, DIRUI FUS-200 and DIRUI FUS-3000Plus, with manual microscopic examination. The analysis focused on both numerical parameters (RBC, WBC, epithelial cells) and binary parameters (hyaline casts, granular casts, calcium oxalate crystals), which are critical for clinical interpretation. A comprehensive graphical summary is presented in Supplementary Figure 1.

Materials and Methods

Study Design and Sample Collection

This analytical comparison study was conducted at the Atlas University Hospital Medical Laboratory. A total of 100 midstream urine samples obtained from both inpatient and outpatient individuals were included. Samples were collected in sterile containers and analyzed within two hours of collection in accordance with European Urinalysis Guidelines.[11]

Manual Microscopic Examination (Reference Method)

Manual urine sediment analysis was accepted as the reference method. Each sample was centrifuged at 1500 rpm (≈400 g) for 5 minutes. After decanting the supernatant, approximately 0.5 mL of sediment was resuspended and examined under a light microscope at 10× and 40× magnifications. At least 10 microscopic fields were evaluated per sample, and results were reported as averages per low-power field (LPF) and high-power field (HPF).

Automated Urine Analysis

The remaining non-centrifuged aliquots were analyzed using DIRUI FUS-200 and DIRUI FUS-3000Plus analyzers according to the manufacturers' instructions. The FUS-3000Plus uses AI-supported image analysis combining bright-field and phase-contrast microscopy, whereas the FUS-200 employs flow cell digital imaging technology for particle classification.

Evaluated Parameters

RBC, WBC, and epithelial cells were evaluated as ordinal variables (0–5, 6–10, 11–20, >20 per field). Hyaline casts, granular casts, and calcium oxalate crystals were recorded as binary variables (absent/present).

Ethical Approval

Ethical approval was not required because the study used anonymized routine laboratory data without direct patient intervention.

Statistical Analysis

Statistical analyses were performed using SPSS Statistics 20.0 (IBM Corp., Armonk, NY, USA). Ordinal variables were compared using the Kruskal–Wallis test, followed by Mann–Whitney U tests with Bonferroni correction. Binary variables were analyzed using McNemar's test. Agreement between methods was assessed using Cohen's kappa coefficient. A *P* value <0.05 was considered statistically significant.

Reporting Guidelines

This study is reported in accordance with the STROBE guidelines.

Results

Numerical Parameters

No statistically significant differences were observed among manual microscopy, DIRUI FUS-200, and DIRUI FUS-3000Plus for WBC, RBC, and epithelial cell distributions (*P* > .05). The detailed data are provided in Table 1.

Table 1. WBC, RBC, Epithelial Cells Comparisons Between Devices

Parameters	x^2	*P* value
WBC	.612	.736
RBC	2.736	.255
Epitelial cells	3.735	.154

(Pairwise comparisons Mann–Whitney U Test with Bonferroni Correction) Also Revealed no Significant Differences (all Adjusted P > 0.05). These Findings Suggest That all Three Methods Yielded Comparable Results for the Quantitative Parameters

Table 2. Comparison Of Binary Parameters Between Devices

Parameters	Comparisons	McNemar *P* value	Kappa
Hyaline Cast	Manuel vs 3000Plus	.00087	≈0.00 (Poor)
Hyaline Cast	Manuel vs FUS200	*N*/A	Unidentified
Granular Cast	Manuel vs 3000Plus	.023	≈0.21 (low)
Granular Cast	Manuel vs FUS200	1.00	.00 (very low)
Calcium Oxalate	Manuel vs 3000Plus	.00051	≈0.19 (low)
Calcium Oxalate	Manuel vs FUS200	.00018	.00 (very poor)

Comparison of Hyaline Casts, Granular Casts, and Calcium Oxalate Crystals Detected by Manual Microscopy, DIRUI FUS-200 and DIRUI FUS-3000Plus

casts, while both devices showed lower sensitivity for calcium oxalate crystals compared to manual microscopy. A comprehensive summary is presented in Table 2.

Discussion

The findings of this study indicate that automated urine analyzers provide reliable results for common urine sediment elements such as RBC and WBC, consistent with previous studies.[8] However, variability in the detection of rare particles such as casts and crystals highlights the limitations of automated classification algorithms.

Over-reporting of casts by automated systems may be related to image misclassification or threshold sensitivity, whereas under-detection of crystals may result from particle size, morphology, or low prevalence effects. These findings emphasize the importance of confirmatory manual microscopy in cases with suspected pathological findings.

Future Perspective

Advances in artificial intelligence, deep learning–based image recognition, and adaptive classification algorithms are expected to enhance the accuracy of automated urine analysis, particularly for rare and pathological elements. Future studies incorporating large, well-annotated image datasets and multicenter validation are needed to further refine analyzer performance and reduce inter-device variability. Ultimately, the integration of intelligent automation with expert laboratory oversight may lead to more precise, efficient, and clinically impactful urinalysis.

Limitations

This study has several limitations that should be considered when interpreting the results. First, the study was conducted in a single center with a relatively limited sample size, which may restrict the generalizability of the findings to other laboratory settings or patient populations. Manual microscopic examination was accepted as the reference method; however, it is inherently subject to observer-dependent variability despite being performed by experienced personnel. The study focused on a selected group of urine sediment parameters, and other clinically relevant elements, such as bacteria, yeast, or dysmorphic erythrocytes, were not evaluated. Future multicenter studies with larger sample sizes and a broader range of sediment components are warranted to further validate the performance of automated urine analyzers.

Conclusion

A high level of agreement was observed between automated urine analyzers and manual microscopic examination for routine parameters such as WBC, RBC, and epithelial cells. These findings support the use of automated systems as reliable tools in routine clinical laboratory workflows, particularly for high-throughput settings where standardization and rapid turnaround time are essential.

However, significant discrepancies were identified in the detection of rare or pathological sediment components, including hyaline casts, granular casts, and calcium oxalate crystals. This variability highlights the current limitations of automated image recognition algorithms when interpreting morphologically complex or infrequent particles and underscores the continued importance of manual microscopic examination for confirmatory purposes.

Overall, while automated urine analyzers offer substantial advantages in efficiency and reproducibility, manual microscopy remains indispensable for ensuring diagnostic accuracy in selected cases. An integrated approach combining automated analysis with targeted manual review appears to be the most appropriate strategy for optimal clinical decision-making.

Declarations

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was waived due to the retrospective nature of the study and the use of fully anonymized data.

Data Availability

The datasets used and/or analyzed during the current study are not publicly available due to patient privacy reasons, but are available from the corresponding author on reasonable request.

Conflict of Interest

The authors declare no conflict of interest.

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Author Contributions (CRediT Taxonomy)

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Methodology: B.D.
Software: B.D.
Validation: B.D., H.N.H.T.
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AI Usage Disclosure

The authors declare that no AI-assisted technologies were used.

Abbreviations

AI: Artificial intelligence
HPF: High-power field
LPF: Low-power field
RBC: Red blood cell
STROBE: Strengthening the reporting of observational studies in epidemiology
WBC: White blood cell

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