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Original Article

Pathology Section

Evaluation of Artificial Intelligence Driven Digital Morphology for Estimation of Platelet Count: A Cross-sectional Study

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ABSTRACT

Introduction: Nowadays different technologies are employed in the field of automated haematology analyser that provides rapid and reliable estimations and is regularly used for determining the platelet counts. In some cases, it gives erroneous results, especially with Red Blood Cells (RBC)-platelet interference and giant platelets, which need to be verified by manual methods. The traditionally used manual method microscopic estimation of platelet on smear is labour-intensive, produces variable results and is subject to observer bias.

Aim: The present study aimed to compare platelet count estimation by SigTuple-AI100 Shonit™ (AI100)- a digital morphology analyser with manual platelet counts and automated haematology analyser (HORIBA Yumizen H2500).

Materials and Methods: The present cross-sectional comparative study done in Department of Haematology, Suburban Diagnostics Referral laboratory, Mumbai, India for a period of eight months from June 2023 to February 2024. One hundred Ethylenediaminetetraacetic Acid (EDTA) whole blood samples were analysed for platelet count by an automated haematology analyser (HORIBA Yumizen H2500), manual microscopic method, and digital morphology platform (SigTuple-AI100). Results were analysed using IBM Statistical Package for Social Sciences (SPSS) Statistical Software version 26. Estimated platelet counts of AI100 were compared with manual platelet count and Yumizen H2500, using Pearson's correlation coefficient and Bland-Altman plot analysis. Manual platelet count was used as a reference method.

Results: Platelet counts from the AI100 system showed an R^2 of 0.91 when compared to manual platelet estimates and an R^2 of 0.92 when compared to the automated haematology analyser results. Conversion factor was derived and validated on 100 consecutive thrombocytopenic samples. Coefficient of Variance (CV%) of AI100 was 4.95.

Conclusion: The study suggested that the platelet count obtained via the AI100 compared well with both automated haematology analyser and manual method. Though similar platforms are available worldwide, the cost of AI100 is cheaper than other platforms. There is also ease of operations and it being cloud based allows skilled Pathologists and lab technologists to report remotely.

Keywords: Digital morphology analyser, Microscopy, Morphology, Manual platelet count

INTRODUCTION

Platelets are small, anucleate cytoplasmic fragments present in blood, which play a key role in haemostasis and thrombosis [1]. Platelet count is an essential examination in patient management and an important diagnostic tool in haemorrhagic disorders. The normal range of platelet count in a healthy individual is 150-450 $x10^3/\mu L$ [2,3].

Accurately determining the platelet number is of prime importance. Platelet count can be estimated by various methods including manual methods {e.g., haemocytometer counting and Peripheral Blood Smear (PBS) analysis} and automated methods [4,5]. However, among these, immunological platelet counting method is considered as the gold standard for platelet counting [6]. Morphological analysis of the blood smear has traditionally been performed using manual microscopy. Although this method is widely used, it has the disadvantages of being time consuming, labour-intensive, requiring continuous training of personnel, and being subject to relatively large interobserver variability [7]. Nowadays, the automated haematology analyser capable of providing quick and accurate complete blood counts has replaced the traditional manual methods. Impedance is the most common technique used in haematology analysers for platelet counts from within the same chamber as RBCs. Newer technologies, such as optical and fluorescence methods, available in high-end haematology analysers and immunofluorescence techniques using monoclonal antibodies directed against glycoproteins of the surface membrane of platelet are the methods of platelet estimation [8]. Automated haematology analysers sometimes produce erroneous results which may not align with the clinical condition of the patient. In such cases, manual microscopic estimation is warranted.

Hence, the objectives of the study are:

1. To evaluate the correlation between average platelet-per-field (aPPF) values obtained using the AI100 Shonit™ digital morphology analyser and platelet counts provided by the HORIBA Yumizen H2500 automated haematology analyser and manual microscopic aPPF estimates from the same slides.
2. To determine a Conversion Factor (CF) to calculate platelet count from aPPF in normal and thromobocytopenic patients.

MATERIALS AND METHODS

The present cross-sectional comparative study conducted at Suburban Diagnostics Referral Laboratory, Mumbai, India for a period of eight months (June 2023-February 2024). A total of 100 samples consisting of 50 consecutive normal and 50 abnormal haemogram (thrombocytopenic) samples based on automated haematology analyser results were included in this study.

Inclusion criteria: Adult patients both male and female of age greater than 18 years were included in this study.

Exclusion criteria: The samples that were inadequate, clotted, lysed, and smears showing platelet clumps or satellitism were excluded from the study.

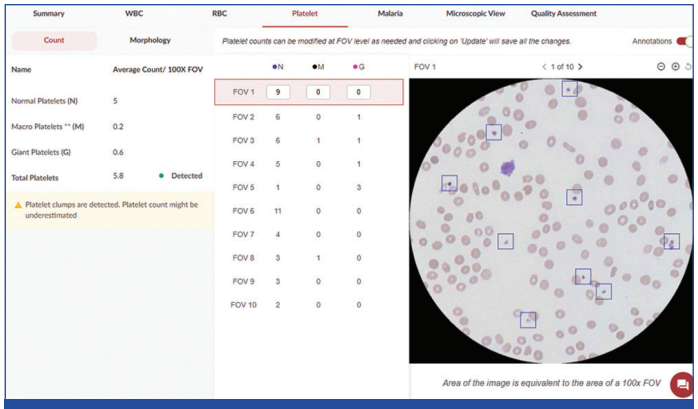
Study Procedure

The 200 samples were collected and analysed within four hours of collection. The study was done on retained leftover samples. The anonymity of all samples included in the study was strictly maintained. The 2 mL of blood was received in a tube containing K2 EDTA as an anticoagulant for complete haemogram and were analysed using three platelet counting techniques:

Automated analyser platelet counts: Automated platelet counts (as part of complete blood counts) were performed utilising the automated haematology analyser HORIBA Yumizen H2500. This analyser uses both impedance and optical extinction technology wherever warranted, according to the laboratory defined reflex testing rules, used to determine the platelet counts [9]. The present laboratory follows the International Society for Laboratory Haematology (ISLH) consensus guidelines for slide review criteria [10]. K2 EDTA anticoagulated blood samples were fed to the automated haematology analyser. The HORIBA automated Yumizen Slide Preparation System (SPS) was used to prepare PBS stained with Romanowsky stain (Leishman stain/Giemsa stain) for analysis using manual microscopy and the AI100 digital morphology analyser.

Manual platelet counts: The PBS slides were examined independently by two experienced Pathologists for platelet estimation and morphology assessment. Platelet estimation was made according to established laboratory procedures. The PBS was examined under 100x oil immersion lens with 21mm eye piece diameter. The aPPF was determined after examining 10 representative fields. The total platelet count was calculated by taking the average of the aPPF determined by both Pathologists and multiplying it by 15,000 [11,12].

Platelet counts by digital morphology analyser: The same PBS slides were analysed on the digital morphology analyser AI100. The 100x Field of Vision (FOV) of AI100 corresponds with that of the manual microscope (100x oil immersion lens) [13]. The aPPF value obtained by AI100 was multiplied by a conversion factor of 15,000 to get estimated platelet count. However, a conversion factor was derived from an initial 100 samples of same set that was 14500. For universal applicability and to overcome study bias, a commonly accepted conversion factor of 15000 was used for the study. One normal sample and one thrombocytopenic sample were analysed five times each for precision study on AI100. The precision study demonstrated an acceptable Coefficient of Variation (CV%) of 4.95 [Table/Fig-1].



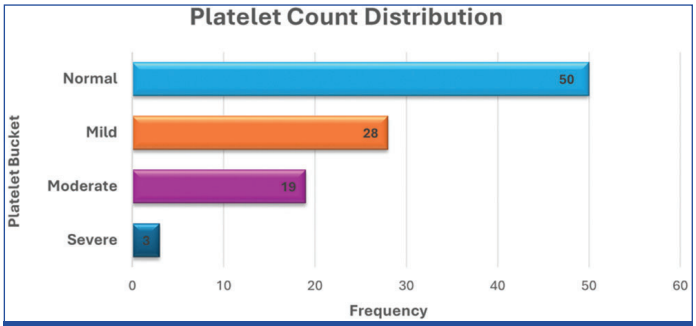
[Table/Fig-1]: Screenshot from Mandara software of SigTuple- AI100 ShonitTM showing one Field of Vision (FOV) with counting of platelets.

STATISTICAL ANALYSIS

Data entry was done on Microsoft Excel 365. Pearson's correlation analysis between platelet counts estimated by the manual microscopy method and AI100was done on IBM SPSS Statistical Software version 26. Correlation and Bland-Altman plots were used to compare AI100 results.

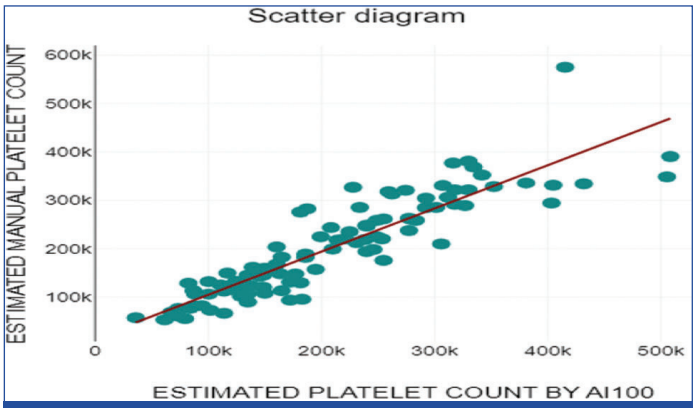
RESULTS

A total of 100 samples were used in the present study to calculate the platelet count using three different techniques: Automated haematology analyser, digital morphology analyser, traditional manual platelet count. To better understand the sample profile, samples were stratified in four categories based on platelet count: normal (>150,000 platelets per microliter), mild thrombocytopenia (100,000 to 150,000 platelets per microliter), moderate thrombocytopenia (50,000 to 100,000 platelets per microliter), and severe thrombocytopenia (<50,000 platelets per microliter) [Table/Fig-2] [6].



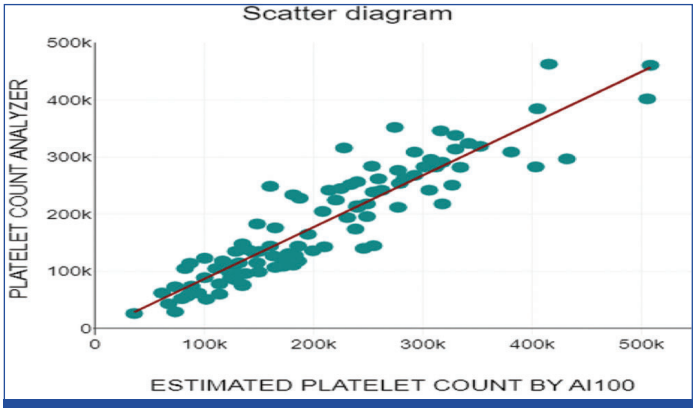
[Table/Fig-2]: Frequency distribution of cases as per platelet count: Normal (>150,000/µL), mild (100,000-150,000/µL), moderate (50,000-100,000/µL), and severe (<50,000/µL).

To compare between the platelet counts obtained from AI100 with manual platelet counts and Yumizen H2500 platelet counts, Pearson's correlation coefficient was calculated. The correlation coefficient showed a positive correlation between the two methods. Comparison of the AI100 platelet counts with manual platelet counts showed R^2 value of 0.91 [Table/Fig-3].



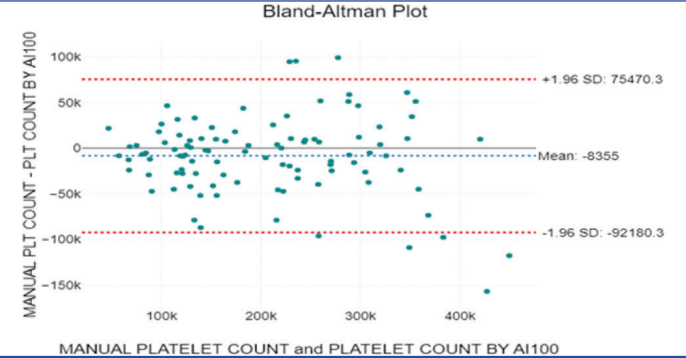
[Table/Fig-3]: Correlation of estimated Manual platelet counts with AI100 platelet counts.

Comparison of the AI100 platelet counts with an automated haematology analyser platelet counts showed R^2 value of 0.92 [Table/Fig-4]. On depicting the Bland-Altman difference plot, it illustrates that the majority of platelet counts from AI100 and manual method fall within 95% agreement (±1.96 SD), with only a few



[Table/Fig-4]: Correlation of automated haematology analyser results with AI100 platelet counts.

outliers at higher levels. One outlier was found to be beyond 3SD value (-134948) in the Bland-Altman plot analysis [Table/Fig-5].



[Table/Fig-5]: Difference versus mean plots for Sigtuple AI100 and manual platelet counts according to the Bland-Altman design. The middle solid line is the mean of the difference; the outer solid lines are the upper and lower limits of agreements (mean±1.96 SD).

DISCUSSION

The comparison of the AI100 system with manual microscopic method and the automated haematology analyser yields R^2 values of 0.91 and 0.92, respectively suggesting a good correlation between them.

Hence, AI100 platform can address the limitations of the manual microscopic method, namely time-consuming, labour-intensive, requirement of continuous training of personnel. The digital morphology platform, AI100, can reduce interobserver bias by enabling remote reporting and providing visual, evidence-based classifications for normal/macro platelets, giant platelets, and platelet clumps. AI100 allows for the review of platelet counts and morphology under microscopic view for verification of platelet count. Additionally, it leads to standardisation of platelet count estimation.

The statistical analysis using Bland-Altman plot analysis showed one outlier beyond 3SD value (-134948) as illustrated in [Table/Fig-5] above, this can be explained by the variation between the two observers exceeding the acceptable limit (>18%). This finding prompted us to investigate the interobserver bias between the two Pathologists for the manual microscopy method. The average interobserver variability between the two Pathologists for manual microscopy method was 11.8%. The precision study done on AI100 showed a good CV% of 4.95.

The authors compared the findings of the present study study with studies on multiple digital morphology analyser platforms like CellaVision DM96, Sysmex DI-60, and Scopio Labs X100 [Table/Fig-6]. As elaborated in [Table/Fig-1] CellaVision DM96, Scopio Labs X100 shows R^2 of 0.94 in correlation with manual microscopy method [14,15], which is comparable to the present study findings (R^2=0.91). On correlation of CellaVision DM96, Sysmex DI-60, Mindray MC-80, and Scopio Labs X100 with automated haematology analyser R^2 value ranges between 0.90 to 0.98 [14-17], whereas in the present study R^2 is 0.92 showing a good correlation. Hence this validates the reliability and efficiency of digital morphology analysis in hematological assessments.

S. No.	Author name	Digital morphology analyser used	Company	Correlation with manual microscopic method	Correlation with automated haematology analyser
1	Present study	AI100	SigTuple	R^2=0.91	R^2=0.92
2.	Gao Y et al., [14]	DM96	CellaVision	R^2=0.94	R^2=0.92
3.	Tantanate C [16]	DI-60	Sysmex	-	R^2=0.98
4.	Katz BZ et al., [15]	X100	Scopio Labs	R^2=0.94	-
5.	Üstündağ Y et al., [17]	MC-80	Mindray	-	R^2=0.90

[Table/Fig-6]: Comparison of different digital morphology analysers regarding their correlation with manual platelet counts and automated platelet counts [14-17].

Limitation(s)

In the present study, authors did not confirm the platelet count using the immunological platelet counting method which is gold standard method for platelet counting. Secondly, the sample size was limited.

CONCLUSION(S)

AI backed digital morphology platforms have been gaining lot of interest in recent years. These platforms minimise interobserver bias, are useful for reporting in emergency situations and facilitate expert opinion virtually. The present study demonstrated that platelet counts obtained through AI100 system compared well with both traditional manual microscopy and automated haematology analyser highlighting its reliability and clinical applicability. Though similar platforms are available worldwide, the cost of AI100 is cheaper than other platforms. There is also ease of operations and it being cloud based allows skilled Pathologists and lab technologists to report remotely. Hence, this platform can be used in resource poor settings and remote areas to enhance the outreach of quality diagnostic to the last mile where it is needed the most.

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Statement of Ethics: This study was done on leftover samples and the anonymity of samples included was maintained.

Conflict of Interest: PA is employee of HORIBA Medical, India.

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