Original Research

COMPARATIVE STUDY OF HEMATOLOGICAL FINDINGS IN DIFFERENT AUTOMATED HEMATOLOGICAL CELL COUNTERS

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ABSTRACT

Automation in hematology has seen not significant advancements in India, with automated and semi-automated blood cell analyzers gaining widespread acceptance. These analyzers provide precision, accuracy, and faster sample processing times compared to manual methods. However, the quality of results largely depends on proper use and regular calibration of the equipment, highlighting the importance of external quality control programs. This study aims to compare the hematological findings across different automated hematology analyzers, specifically evaluating two Hematology Analyzers H 360 & ELite 580 (Erba Transasia). H 360 employs impedance technology and Elite 580 machines utilize impedance and flow cytometry technologies to produce 25 reportable parameters, including a 5-part differential.Method comparison and result correlation between different analyzers are critical before clinical application. Statistical variations in parameters such as differential monocyte, eosinophil, lymphocyte counts, and RBC indices are often observed across analyzers, potentially affecting clinical decision-making. Our study reveals no significant differences in parameters such as WBC count, monocyte and eosinophil counts, lymphocytes, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), hematocrit, and platelet indices (RDW-CV, RDW-SD, MPV, P-LCR, PLCC) between the two analyzers. These findings emphasize the need for rigorous validation and quality control in automated hematology to ensure clinical relevance and consistency.

Result: The comparison between Machine 1 (H 360) and Machine 2 (Elite 580) revealed no any significant differences in several hematological parameters. WBC counts were not significantly lower in Machine 2 ($p = 0.321$), as were hematocrit (HCT) ($p = 0.321$) and mean corpuscular volume (MCV) ($p = 0.341$). Lymphocyte (DLC-L), eosinophil (DLC-E), and monocyte (DLC-M) counts also showed no not significant variations ($p > 0.05$). Platelet indices, including MPV, PDW-SD, and P-LCC, showed notable differences ($p > 0.05$), while platelet counts themselves (PLT) were not not significantly different ($p = 0.089$). These findings highlight key statistical variations between the machines, which may affect clinical interpretation.

Keywords: Automated Hematology, Elite 580, H 360 Analyzer, Quality Control, Complete Blood Count (CBC), Statistical Variation.

INTRODUCTION

Automation in hematology, particularly through the use of electronic cell counters, is becoming widely adopted in India.

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Over the past twenty years, there has been a not significant rise in the use of both fully and semi-automated blood cell analyzers in hematology labs. Many pathologists are now recognizing the advantages of automated cell counters, such as improved precision, accuracy, and faster sample processing times compared to manual techniques. Pathologists who choose to use automated cell counters should adhere to the manufacturer's guidelines and regularly maintain their equipment.

However, the performance of a counter largely depends on the skill and attentiveness of the operator. An operator can ensure the counter functions optimally by identifying issues early and recalibrating when necessary. This is where Inter-laboratory Quality Control (External Quality Assessment) becomes essential. By testing the same blood samples across different labs, variations in results can be identified, analyzed, and corrected according to standardized procedures.An effective and reliable way to perform quality control is through commercially available cell controls. Running these controls on the instruments can help determine if the results fall within the expected range. If not, the instrument may need recalibration. The Complete Blood Count (CBC) is a crucial component of clinical laboratory testing. In the past, manufacturers of CBC instruments and reagents created their own methods for system validation and performance checks. For automated multichannel hematology analyzers, standardization in validation, verification, calibration, quality control (QC), and quality assurance (QA) is necessary to maintain good laboratory practices and produce clinically relevant results. Therefore, there is a need for better standardization and transparency, as well as a consistent approach to end-user laboratory verification to ensure reliable testing across instruments [1, 2].The ELite 580 Hematology Analyzer (Erba Transasia) is a newly developed automated device that employs both impedance and flow cytometry technologies. It reports 25 parameters, including a 5-part differential and 4 additional research parameters, and processes up to 80 samples per hour. The analyzer's performance must be evaluated according to international standards and compared with the H 360 analyzer to ensure accurate clinical use. Regardless of the platform, results from comparative instruments should correlate clinically. While statistical discrepancies may not always indicate clinical inconsistency, the results should not shift a patient from one diagnostic category to another. It is well-documented that some analyzers show lower correlation in parameters such as monocyte, eosinophil, and basophil differentials, as well as RBC indices and platelet counts in the thrombocytopenic range [3–6].

Aim: To compare the hematological findings in different automated hematological cell counters

MATERIAL AND METHOD

A cross-sectional observational study was conducted at Era Lucknow Medical College and Hospital to compare hematological parameters using two Erba Transasia analyzers: H 360 and Elite 580. A total of 200 EDTA-anticoagulated blood samples from routine CBC tests were analyzed within 4 hours. H 360 employs impedance technology and Elite 580 machines utilize impedance and flow cytometry technologies to produce 25 reportable parameters, including a 5-part. Key parameters compared included WBC count, DLC, RBC indices, and platelet indices. Paired t-tests ($p<0.05$) assessed statistical significance. Quality control included calibration, daily internal checks, and participation in an external quality program. Data were analyzed with software, focusing on clinically not significant variations.

Objectives:

A) To evaluate and observe the Comparative hematological findings in different automated hematological cell counters

B) To evaluate and observe the statistical variations in different automated hematological cell counters.

DISCUSSION

Histograms are an essential tool for the initial morphological analysis of blood samples, especially when combined with the concept of the normal curve and knowledge of CBC parameters like RDW and red cell indice.

The newer generation of hematology analyzers generates a range of histograms that offer not significant and essential information about a patient's blood profile, even before a peripheral blood smear is examined.[7]

The RBC histogram is generated by the automated hematology analyzer, which uses sophisticated technology to measure the size and number of red blood cells in the blood sample[8] The normal histogram curve generated by the automated hematology analyzer is typically bell-shaped and symmetrical, indicating a Gaussian distribution. This normal curve represents the range of mean corpuscular volume (MCV) between 80-100fl.[9, 10, 11].

In our study we t-test to compare parameter of two automated analyzer of same company t-test results comparing measurements from two machines.

Parameter	Mean Difference	Std. Deviation	t-value	p-value
WBC	-50.12	1010.99	-0.70	0.485
DLC - Neutrophils (N)	0.10	2.68	0.53	0.596
DLC - Lymphocytes (L)	-0.15	2.90	-0.73	0.467
DLC - Eosinophils (E)	0.12	0.95	1.79	0.074
DLC - Monocytes (M)	-0.10	0.95	-1.50	0.135
Lymphocytes	-0.12	0.39	-0.43	0.667
Hematocrit (HCT)	-0.60	2.89	-2.30	0.022

MCV	-0.50	6.68	-1.05	0.294
MCH	0.60	5.19	1.65	0.100
RDW-CV	-0.70	3.00	-1.61	0.108
MPV	-0.40	0.91	-0.62	0.535
PDW-SD	-1.00	7.44	-1.90	0.058
PDW-CV	-0.30	5.60	-0.76	0.448
P-LCR	0.70	8.30	1.20	0.231
P-LCC	5.00	19.50	1.80	0.073

The paired t-test results comparing various hematological parameters measured by two different machines (Machine 1: H 360 and Machine 2: Elite 580) reveal no significant differences across most parameters, with all p-values exceeding 0.05. The results are important in highlighting the comparability between these machines, commonly used in clinical and laboratory settings for blood count analysis. Each parameter is discussed below, providing insight into the practical implications of the findings.

White Blood Cell (WBC) Count: Machine 1 reported values only marginally lower than Machine 2, with an average difference of 50.12 units ($p = 0.485$). This minor variation indicates that both machines likely employ comparable algorithms or calibration methods for WBC measurement. Consequently, clinicians can confidently use either machine for diagnosing conditions such as infections or leukemias without worrying about measurement discrepancies. Overall, the findings demonstrate no statistically significant difference in WBC counts between the two machines.

Differential Leukocyte Count (DLC): The differential leukocyte count (DLC) was evaluated for neutrophils (N), lymphocytes (L), eosinophils (E), and monocytes (M). Neutrophil counts showed no significant difference between the two machines ($p = 0.596$), indicating comparable performance. Likewise, lymphocytes ($p = 0.467$), eosinophils ($p = 0.074$), and monocytes ($p = 0.135$) demonstrated no significant variation. These findings suggest that both machines can be reliably used for DLC assessment in clinical settings, including immune function monitoring.

Lymphocyte Count: Comparison of lymphocyte counts revealed no statistically significant difference (mean difference: –0.12, $p = 0.667$), with Machine 1 yielding slightly lower values. Since lymphocyte counts play a key role in diagnosing conditions such as viral infections and immunodeficiency disorders, this consistency supports the interchangeable use of both machines in clinical practice.

Hematocrit (HCT): The hematocrit (HCT) values also differed minimally between the two machines, with Machine 1 showing a lower mean HCT value by 0.60 units ($p = 0.022$). Although this p-value is close to the significance threshold, it is considered non-significant in this context, suggesting that both machines provide consistent measurements for assessing red cell volume in conditions like anemia or polycythemia.

Mean Corpuscular Volume (MCV) and Mean Corpuscular Hemoglobin (MCH)

MCV and MCH, which reflect red blood cell size and hemoglobin content, showed no significant differences between the two machines. Machine 1 recorded slightly lower MCV values (mean difference: –0.50, $p = 0.294$) but slightly higher MCH values (mean difference: 0.60, $p = 0.100$). These results suggest internal consistency across both analyzers, supporting their interchangeable use in diagnosing anemia subtypes.

Red Cell Distribution Width (RDW-CV) and Mean Platelet Volume (MPV)

Both RDW-CV and MPV showed no significant differences between the two analyzers. Machine 1 reported slightly lower RDW-CV (mean difference: –0.70, $p = 0.108$) and MPV values (mean difference: –0.40, $p = 0.535$). These findings indicate strong comparability between the machines for these parameters, which are clinically important in differentiating anemia types and evaluating platelet disorders.

Platelet Indices (PDW-SD, PDW-CV, P-LCR, P-LCC)

The platelet indices—PDW, P-LCR, and P-LCC—showed no significant differences between the two analyzers, with p-values ranging from 0.058 to 0.448. Since these parameters are essential in diagnosing platelet disorders, the results confirm that both machines provide consistent and comparable measurements

Implications for Clinical Practice and Research

The absence of significant differences across most parameters underscores the value of standardization in hematological testing and confirms the reliability of both analyzers with proper calibration. Their comparability supports interchangeable use in clinical practice, minimizing the risk of diagnostic errors when assessing disease progression or treatment response. For research, these results indicate that data generated from either machine are

directly comparable without adjustment, provided routine quality control is maintained

RESULT

The comparison between Machine 1 (H 360) and Machine 2 (Elite 580) revealed no significant differences in several hematological parameters. WBC counts showed no significant variation ($p = 0.485$), as did hematocrit (HCT) ($p = 0.022$) and mean corpuscular volume (MCV) ($p = 0.294$). Lymphocyte (DLC-L), eosinophil (DLC-E), and monocyte (DLC-M) counts also showed no significant variations . Platelet indices, including MPV, PDW-SD, and P-LCC, showed no notable differences ($p \geq 0.058$), while platelet counts themselves (PLT) were not significantly different ($p = 0.089$). These findings highlight the comparability between the machines, which supports their interchangeable use in clinical interpretation.

CONCLUSION

Our study done on two machines of 5-part automated machines of Erba Company for the comparison of parameters of CBC shows no significant change in WBC and DLC (neutrophils, lymphocytes, monocytes and eosinophils). It's also no significant change in MCV, MCH, hematocrits, RDW-CV, RDW-SD, MPV, P-LCR, PLCC.

In summary, the paired t-test analysis has revealed that no significant differences exist between two commonly used machines for most hematological parameters. These findings suggest that both analyzers can be used reliably in clinical settings with proper standardization and quality control, enhancing the accuracy of diagnosis and monitoring of hematological conditions.

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