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TO STUDY THE EFFECTIVENESS OF INTERNATIONAL CONSENSUS GROUP FOR HEMATOLOGICAL REVIEW (ICGHR) CRITERIA FOR MANUAL PERIPHERAL SMEAR REVIEW

Pathology

Dr. Shweta Kumari PG Resident, Dept. of Pathology, JMC, Jhalawar
Dr. Rishi Diwan Senior Professor & H.O.D., Dept. of Pathology, JMC, Jhalawar

ABSTRACT

Background: The automation of hematology has transformed blood analysis, especially with the integration of analyzers for accurate complete blood count (CBC) assessments. Despite these advancements, manual examination through peripheral blood film (PBF) remains crucial for detecting subtle morphological abnormalities in blood cells. **Objective:** To compare the performance of ICGHR criteria with in-house laboratory criteria for PBF review and assess their impact on the identification of blood abnormalities.**Methods:** A prospective cross-sectional comparative study was conducted at the central laboratory of SRG Hospital, Jhalawar, Rajasthan, involving 800 adult whole blood samples sent for CBC testing. Samples were analyzed using a Sysmex XN-1000 automated hematologyanalyzer and underwent manual smear review and 100-cell differential counts. The analysis followed adapted ICGHR and in-our laboratory criteria, with systematic random sampling and strict quality control. **Results:** Of the 800 samples, 379 (47.38%) were positive according to ICGHR review criteria, while 421 (52.63%) were negative. Among the positive samples, 359 (94.72%) had positive smear findings, whereas 20 (5.28%) were smear-negative. According to laboratory criteria, 557 samples (69.63%) were positive, with 411 (73.79%) confirming positive smear findings. The comparison revealed that all parameters from laboratory criteria were significantly different from ICGHR criteria ($P < 0.001$). **Conclusion:** The study demonstrated that the laboratory criteria facilitated a higher microscopic review rate (69.6%) compared to ICGHR criteria (47.25%), allowing for timely identification of abnormal specimens without significantly increasing workload.

KEYWORDS

Hematology, Complete Blood Count, Peripheral Blood Film, ICGHR criteria.

INTRODUCTION

The advent of automation in hematology has revolutionized blood analysis, integrating various analyzers that offer precise and reliable assessments of blood cell counts, including the complete blood count (CBC), a fundamental diagnostic tool. The CBC evaluates white blood cells (WBCs), red blood cells (RBCs), and platelets, providing insight into the patient's physiological status while aiding in the diagnosis and monitoring of hematological disorders and systemic conditions. The CBC encompasses nine critical parameters: WBC count, RBC count, hemoglobin (Hgb) concentration, hematocrit (Hct) level, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count, and red cell distribution width (RDW). These values help detect abnormalities that often prompt further investigations, including peripheral blood film (PBF) examination.[1]

Despite automation's advances, PBF analysis remains a key diagnostic tool in hematology. This manual examination of blood cell morphology, while simple and cost-effective, provides essential insights that automated analyses might miss. PBF is particularly useful for identifying subtle changes in blood cells' morphology and distribution, contributing to diagnosing various disorders. In some cases, PBF findings alone are sufficient for diagnosis, reducing the need for further invasive or costly tests.[2]

However, the increasing use of automation has sparked debate over the role of routine PBF examination. Some argue that reduced reliance on PBF can save time and resources, given that automation now covers much of the diagnostic ground.[3] Others advocate for PBF's continued use, highlighting discrepancies between automated and manual evaluations, especially in cases where morphology plays a crucial role in diagnosis.[4]

In resource-limited settings, where healthcare systems face unique challenges, PBF examination following CBC often becomes physician-triggered, making it crucial to establish efficient, standardized protocols. In 2005, Dr. Berend Houwen and the international consensus group (ICG) proposed criteria for action after automated CBC and WBC differential analysis. These criteria aim to guide PBF utilization while acknowledging that local factors such as testing volume, instruments, and demographics affect their application. Validation of these criteria is particularly important in developing countries, where diseases like infections significantly influence hematological parameters.[5]

This study aims to evaluate the effectiveness of the ICG criteria alongside laboratory-specific standards to optimize PBF review protocols, enhancing both productivity and cost-effectiveness.

MATERIAL & METHOD

A prospective cross-sectional comparative study was conducted on whole blood samples sent for CBC testing at the central laboratory of SRG Hospital, Jhalawar, Rajasthan. Venous blood (2 ml) was collected from the antecubital vein into K2 EDTA vacutainers under aseptic precautions by nursing staff and analyzed within one hour using the Sysmex XN-1000, a 6-part differential automated hematologyanalyzer. Systematic random sampling was employed, and quality control procedures were followed throughout the study. Thin blood smears were prepared for all samples, stained with Leishman and field stain, and subjected to manual smear review and 100-cell manual differential counts to confirm the analyzer results and identify abnormalities. The samples were reviewed based on adapted ICGHR and in-house laboratory criteria, with flags triggered for results outside specified ranges. Exclusions included samples with errors (e.g., clots, inappropriate proportions) and pediatric samples. The study was hospital-based, analytic, and observational, approved by the institutional review board, and ran until November 2024.

Inclusion Criteria: Adult CBC samples sent to the central lab, SRG Hospital, Jhalawar.

Exclusion Criteria: Pediatric samples, inadequate blood clots.

METHODOLOGY:

After obtaining approval from the institutional ethical committee, patients meeting the inclusion and exclusion criteria were enrolled in the study. Informed consent was obtained from all participants. Patient particulars and RBC parameters were recorded .

STATISTICAL ANALYSIS:

Data were entered in MS Excel and analyzed using IBM SPSS v22. Continuous variables were summarized descriptively and analyzed with regression or ANOVA, while nonparametric methods were applied for non-normal data. Categorical variables were analyzed using logistic regression or exact t-tests for small samples. A significance level of 0.05 with 95% confidence intervals was used. Results were visualized with charts and graphs.

RESULTS AND OBSERVATIONS

In this study of 800 samples, 379 (47.38%) were positive, and 421 (52.63%) were negative based on the ICGHR review criteria. Among the 379 particulars and RBC positive samples, 359 (94.72%) had positive smear findings, while 20 (5.28%) were smear-negative. Of the 421 negative samples, 297 (70.55%) were truly negative on peripheral smear, but 124 (29.45%) had positive smear findings. Based on laboratory criteria, 557 samples (69.63%) were positive, and 243 (30.38%) were negative.

Table 1: Distribution of patients according to our Laboratory Criteria and PBF findings.

		PBF	
		Yes	No
Laboratory Criteria	Yes (N=557)	411 (73.79%)	146 (26.21%)
	No (N=243)	52 (21.4%)	191 (78.6%)

Of the 557 samples positive for the review criteria, 411 (73.79%) had positive smear findings, while 146 (26.21%) were smear-negative. Among the 243 samples that did not trigger any review criteria, 191 (78.6%) were truly negative, but 52 (21.40%) had positive smear findings.

Table 2: Distribution of patients according to RBC Flags.

Paramters	Lab				ICGHR			
	Yes (N=482)		No (N=318)		Yes (N=379)		No (N=421)	
	N	%	N	%	N	%	N	%
RBC Flags	375	77.8	12	3.77	319	84.17	68	83.85

Here, according to Laboratory criteria 22.2% shows flag for RBC and according to ICGHR criteria 15.83% shows flag for RBC.

Table 3:Distribution of patients according to Truth Table.

	LAB	ICGHR	P-value
TP	411 (51.38%)	359 (44.88%)	0.009
FP	146 (18.25%)	19 (2.38%)	<0.0001
FN	52 (6.50%)	125 (15.63%)	<0.0001
TN	190 (23.75%)	297 (37.13%)	<0.0001
SENSITIVITY	88.77	74.17	<0.0001
SPECIFICTY	56.55	93.99	<0.0001
PPV	73.79	94.97	<0.0001
NPV	78.51	70.38	0.0003
EFFECIENCY	75.13	82.00	0.0007
MMR	69.6	47.25	<0.0001

The "Truth Table" comparing the ICGHR and our laboratory criteria is shown in this table. All the parameters obtained from our laboratory criteria were significantly different from the ICGHR criteria with a value of $P < 0.001$.

DISCUSSION

Automated Hematology Analyzers (AHAs) have significantly evolved over the past three decades, driven by advancements in software and new cell analysis principles. They enable rapid and precise blood sample analysis, making them reliable and cost-effective for counting WBCs, RBCs, and platelets, as well as providing differential counts of mature cell forms. Consequently, AHAs are now preferred for complete blood counts (CBC) and WBC differentials, effectively replacing manual smear review (MSR) without compromising result quality. However, results from AHAs need validation, especially in cases of morphological abnormalities, as they are not confirmatory.[6]

Although manual smear examination is labor-intensive, time-consuming, and less precise, leading to higher overall laboratory costs, CAP recommends establishing criteria for performing MSR following automated blood count analysis.[7]

Out of the total samples positive for the review criteria, 411 out of 557 (73.79%) had positive smear findings, while 146 samples (26.21%) were negative. Among the 243 samples that did not trigger any review criteria, 191 (78.6%) were truly negative on peripheral smear examination, with 52 samples (21.40%) showing positive findings.

In manual peripheral smear review, according to laboratory criteria, 22.2% flagged for RBC. In comparison, based on ICGHR criteria, 15.83% flagged for RBC.

A comparison of the ICGHR criteria with our laboratory criteria shows that our criteria have 88.77% sensitivity, 56.55% specificity, 73.79% positive predictive value, 78.51% negative predictive value, and 75.13% efficiency, with a misclassification rate (MMR) of 69.6%. In contrast, the ICGHR criteria exhibit 74.17% sensitivity, 93.99% specificity, 94.97% positive predictive value, 70.38% negative predictive value, and 82.00% efficiency, with a MMR of 47.25%. Significant differences ($P < 0.001$) were noted between the two sets of criteria.

Wang et al.[8] reported that newly established criteria had review, false negative (FN), and false positive (FP) rates of 39.28%, 3.69%, and 17.35%, respectively, with lower review (39.28% vs. 51.25%) and FP rates (17.35% vs. 34.30%) compared to ICGHR. **Katyayani et al.**[6] found MMRs of 47.56% (ICGHR) and 69.30% (laboratory). The College of American Pathologists recommends an MRR of 30%40, while our FN rates were 1.5% (laboratory) and 8.37% (ICGHR), aligning with **Barnes et al.**[9], who suggest a maximum FN rate of 5% for patient safety.

Our FP rates were 26.5% (laboratory) and 9.75% (ICGHR), while **Katyayani et al.**[6] reported 30.12% and 7.91%, respectively. Differences in FP rates may stem from varying cutoff thresholds. **Pratumvinit et al.**[10] found higher efficiency (83.63% vs. 78.86%) for consensus group criteria, with optimized rates yielding efficiency of 87.13%. **Eldanasoury et al.**[11] supported our findings, showing higher FN rates for Consensus Group criteria (9.25% vs. 1.62%) but improved specificity. **Wang et al.**[8] reported a decline in slide review rates from 51.25% to 39.28% with newly established criteria, with improved TP and TN rates.

CONCLUSION

In this study, we compared the performance of the ICGHR criteria with our laboratory criteria, focusing on the impact of different triggering thresholds. Our laboratory criteria demonstrated a microscopic review rate of 69.6% compared to 47.25% for the ICGHR criteria. The newly established criteria allowed for timely identification and verification of doubtful specimens without significantly increasing the workload.

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