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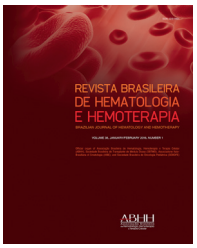

Original article

Evaluation of criteria of manual blood smear review following automated complete blood counts in a large university hospital

Q1 *Samuel Ricardo Comar*, Mariester Malvezzi, Ricardo Pasquini*

Universidade Federal do Paraná (UFPR), Curitiba, PR, Brazil

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ABSTRACT

Background: There is great interest in reducing the number of automated complete blood counts requiring manual blood smear reviews without sacrificing the quality of patient care. This study was aimed at evaluating and establishing appropriate screening criteria for manual blood smear reviews to improve the performance in a hematology laboratory.
Method: A total of 1977 consecutive samples from the daily workload were used to evaluate four sets of screening criteria for manual blood smear reviews to identify samples with positive smear findings. Three sets of screening criteria were arbitrarily proposed in this study: Group 1 (narrow ranges), Group 2 (intermediate ranges), and Group 3 (wide limits) and one set (Group 4) was adapted from the International Society for Laboratory Hematology. All samples were run on Sysmex hematology analyzers and were investigated using manual blood smear reviews. Diagnostic accuracy and agreement were performed for each set of screening criteria, including an investigation of microscopic review rate and efficiency.
Results: The microscopic review rates for Groups 1, 2, 3 and 4 were 73.85%, 54.52%, 46.33% and 46.38%, respectively; the false-negative rates were 0.50%, 1.97%, 2.73% and 3.95%, respectively. The efficiency and negative predictive values of Group 3 were 73.04% and 4.91%, respectively.
Conclusions: Group 3 was the best relationship between safety (false-negative rate: ≤3%) and efficiency to estimate the limits of automation in performing complete blood counts. This study strengthens the importance of establishing screening criteria for manual blood smear reviews, which account for the different contexts in which hematological determinations are performed. Each laboratory should optimize the screening criteria for manual blood smear reviews in order to maximize their efficiency and safety.

Q2 * *Corresponding author at:* Laboratório de Hematologia, Unidade de Laboratório de Análises Clínicas, Hospital de Clínicas, Universidade Federal do Paraná (UFPR), Rua Padre Camargo, 280 – Alto da Glória, 80060-240 Curitiba, PR, Brazil.
E-mail address: srcomar@ufpr.br (S.R. Comar).
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Introduction

A manual blood smear review (MBSR) is defined as the thorough and careful microscopic analysis of a well-prepared and stained smear of peripheral blood, with the objective of seeking morphological changes relevant to the diagnosis and monitoring of patients. It is also considered a tool of internal quality control for the evaluation of parameters provided by hematology analyzers. The process of MBSR is among the most time-consuming in hematology laboratories, and requires high technical competence to minimize errors inherent to the subjectivity of MBSR, including manual differential leukocyte counts (MDLC).[1–6]

Over the last few years, the performance and abilities of automatic hematology analyzers have improved considerably. Although they still cannot identify all morphological abnormalities that may occur in peripheral blood, they can reliably decrease the MBSR without sacrificing quality.[7–12] The establishment of screening criteria (SC) for MBSR is critical and is based on the determination of screening limits for the major hematological parameters and occurrence of suspect flags. The morphological changes and cell percentages relevant for the diagnosis and monitoring of patients are defined as positive smear findings (PSF). The SC are formulated such that MBSR occurs only when needed for confirming the parameter values, or to provide relevant clinical information represented by the PSF in addition to that generated by hematology analyzers.[13–18]

The main factors influencing the establishment of SC for MBSR can vary between institutions and include features such as, the type of population served, type of hematology analyzer employed, training and experience of the medical team, volume of work, number of professionals in the laboratory, medical specialties involved, complexity of the services offered, financial considerations, and regulatory policies of institutions.[1,4,19] Although many SC for MBSR have been proposed, they are not completely applicable to all laboratories. Our previous work demonstrated that SC for MBSR adapted from the International Society for Laboratory Hematology (ISLH)[16] were not adequate or safe for use in the Clinical hematology laboratory of Hospital de Clínicas at the Federal University of Paraná (HC-UFPR).[20] Thus, as an improvement in searching for the ideal SC for MBSR with broader application in hematology laboratories, the objective of this study was to propose and evaluate new SC for MBSR, which serve as a model for adjustments and consider peculiarities in the profile of the populations served, maintaining safety and efficacy.

Methods

Study site

The investigation was conducted in the hematology laboratory of HC-UFPR, a general Class IV hospital and the largest provider of government healthcare services in the State of Paraná, southern Brazil, with 627 beds (574 in operation). Moderately to highly complex procedures are carried out in 59 departments including a hematologic malignancy unit, bone marrow transplant unit, emergency department and intensive care units. Approximately 30,000 outpatients are seen each month.

Samples, patients and hematology analyzers

The study design was approved by the local Ethics Review Board recognized by the National Research Ethics Committee (CONEP). Whole blood samples were collected in ethylenediaminetetraacetic acid (EDTA)-K_2 (1.8 mg/mL) and results were obtained from the laboratory routinely, on seven consecutive days in the months of November and December (spring in the southern hemisphere) after their release into the hospital information system. Altogether 1977 (1100 females and 867 males) consecutive samples meeting the local specimen acceptance criteria were obtained from 1615 patients (946 females and 669 males), with an average age of 39.7 ± 22.7 years (range: 1 day to 96 years). Within these samples, 1320 (66.76%) were outpatients and 657 (33.24%) were being admitted or were hospitalized. Four hundred and ten samples were from the hematology unit, 232 from the emergency department, 154 from the intensive care unit (ICU), 94 from the adult ICU, 45 from the neurology unit, 37 from the bone marrow transplant unit, 27 from the pediatric and neonatal ICU, 27 from the infectious diseases unit, 21 from the liver transplantation unit, and two from the renal transplantation unit, among others. Three hundred and twenty-nine samples were from children aged ≤12 years and 36 were newborn babies. Furthermore, 1573 samples were analyzed in a Sysmex XE-2100D and 404 in a Sysmex XT-2000i hematology analyzer (both from Sysmex Corporation, Kobe, Japan), within 3 h after collection. The results of all 1977 samples provided by the hematology analyzers and MBSR were recorded in a spreadsheet. Of the 1615 patients, 1412 performed a single complete blood count (CBC) during the sample collection period while 203 underwent more than one CBC (117 patients underwent two, 30 patients underwent three; 40 patients underwent four; 15 patients underwent five and one patient underwent six). Both internal and external quality control procedures were followed to monitor performance of the hematology analyzers as well as reliability of the results. The adjustments and settings on the analyzers were performed by the manufacturer's scientific and technical support staff.

Manual blood smear review

For each sample, a blood smear was prepared and stained using the Sysmex SP-1000i automatic slide maker-stainer (Sysmex Corporation, Kobe, Japan). Samples that contained a low volume of whole blood were prepared manually by the wedge-spread film technique, using the May-Grünwald & Giemsa stains. MBSR and MDLC were performed in all samples in accordance with the recommendations of Barnes et al.[16] regarding the step by step validation of criteria for MBSRs. In most cases, 100 leukocytes were counted in each smear by one of six independent observers with extensive experience (10–30 years) in MBSR. A count of 100 or 200 cells per sample on a single slide for only one of each observer was considered a suitable reference method to compare the findings.[16,21] All observers followed the same guidelines on classification

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