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INTERNAL QUALITY CONTROL FOR ERYTHROCYTE SEDIMENTATION RATE USING PATIENT BLOOD SAMPLE

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ABSTRACT

The erythrocyte sedimentation rate (ESR) test continues to be used as an important tool in many laboratories; either manually or as automated method. When automation is applied in clinical laboratories, it is imperative that reliable methods for calibration and appropriate control materials are available for monitoring the accuracy and precision of the results generated. But when the commercial control degenerates or is unavailable, alternative sources such as patient blood can be an alternative. **Aims: a**.To assess the usefulness of ESR values of patients' sample in maintaining internal quality control. **b**. To use the patient blood sample in order to ascertain the precision of the ESR test results on two machines: Diesse Ves- MATIC 80™ (machine A and B).**Materials and Methods**: A retrospective cross-sectional study involving 219 blood samples over a period of 8 months was conducted at Kasturba Hospital, Manipal. The patient samples with normal (<10 mm/hr) ESR (Group 1) and the patient samples with abnormal (>60 mm/hr) ESR (Group 2) were run on the 2 Diesse Ves- MATIC 80™ machines (A &B) against two level commercial controls on a daily basis. **Statistics:** Bland and Altman statistical analysis was applied for evaluating comparability of the methodologies. **Results:** Both groups showed a good concordance for all the ESR values and they were within 2SD. The results of higher ESR values were much better than the lower ESR values. **Conclusions:** The fresh patient blood samples as an internal quality control material showed good precision.

INTRODUCTION

Estimation of the erythrocyte sedimentation rate (ESR) has a long-standing history and tradition in clinical laboratories.[1] ESR, the most widely used laboratory measure of disease activity in clinical medicine, is still considered useful for monitoring inflammatory diseases, rheumatoid arthritis in particular.[2] Recent literature reviews and studies indicate that this test is widely used both for the diagnosis and follow-up of patients with many clinical conditions.[3-6]

In recent decades, several new techniques for measuring ESR have been developed and introduced in clinical laboratories in order to guarantee safety to technicians and other operators by using automated and closed systems; to automate the measurement itself and optimize the workflow and the utilization of human resources and to create a unique workstation for measuring ESR and performing other hematologic tests (eg: erythrocyte, leukocyte, and reticulocyte concentrations) in a single specimen. This should be done, as suggested by the International Council for Standardization in Haematology (ICSH) and the National Committee for Clinical Laboratory Standards (NCCLS), by using the recommended specimen, undiluted blood with tri-potassium (K3) EDTA,

which is more reliable than the traditional sodium citrate.[7,8]

In an era where quality assurance and accreditation of medical laboratories is fast gaining precedence, attention to details should be given to the issue of quality control and quality assurance for ESR measurement. Because the human erythrocyte sedimentation reaction is confined to fresh blood and is transient, reference or control materials of the usual type are not available.[9] Stabilized specimens of human or nonhuman origin cannot be considered acceptable in place of fresh human blood or suitable for use in methods which measure the kinetics of RBC sedimentation, not simply the final fall of RBCs after a fixed time.[9]

In order to maintain reliable, accurate and satisfactory results, internal control is imperative. The quality measures can be used to monitor various aspects of test like systemic error or technical error. With regard to ESR, commercial controls are made available by the manufacturers. In case of non-availability or deterioration of commercial controls, patients' whole blood has been used for the daily quality control of ESR in clinical laboratories.[9]

AIMS AND OBJECTIVES

The study was conducted with the following primary objectives:

a. To assess the usefulness of ESR values of patients sample in maintaining internal quality control.
b. Using patient blood sample to ascertain the precision of the ESR test results on two machines -Diesse Ves-MATIC 80™ (machine A and B).

MATERIALS AND METHODS

The study design was a retrospective cross-sectional type, involving 219 blood samples over a period of 8 months conducted at Clinical Laboratory and Haematology division, Kasturba Hospital, Manipal. An approval from the Institutional Ethics Committee, Kasturba Hospital, Manipal was obtained before the study.

Inclusion Criteria

Patients of both sexes and all age groups were included in the study.

Exclusion Criteria

Blood samples which were not in proper proportions to the anticoagulant, strongly lipemic, hyperbilirubinemic and hemolyzed samples were excluded.

The 219 patient samples were assessed for the study on two ESR machines -Diesse Ves-MATIC 80™ (machine A and B)

A total of 219 patient samples were assessed for the study on two ESR machines -Diesse Ves MATIC 80™ (machine A and B) on daily basis along with commercial controls supplied by the machine providers.

The study was divided into 2 groups:

Group 1: Patient samples with normal (<10 mm/hr) ESR

Group 2: Patient samples with abnormal (>60 mm/hr) ESR

Commercial controls were of two levels, normal (range 3-10 mm/hr) and abnormal (range 55-85 mm/hr).

STATISTICAL ANALYSIS

The statistical analysis of data was carried out using MS Excel '98 software (Microsoft, Seattle, WA). Additional statistical analysis was performed using SPSS 16.0 for Windows (SPSS Inc., Chicago, IL, USA). The method comparison and the differences between ESR values from day to day were performed by using Bland-Altman method in order to measure the comparability of the methods. Average ESR results of 219 patients samples with both the ranges on both the machines were plotted against the difference between them. The 95% limits of agreement were calculated as d ± 1.96 SD where d = mean

difference between the two measurements; and SD = standard deviation of differences.

RESULTS

Group 1: Patient samples with Normal ESR on two Diesse VesMATIC 80™ machines. Mean of the ESR results of 219 patients samples with the range [0-10 mm/hr] on both the machines were plotted against the difference between them (Fig.1).

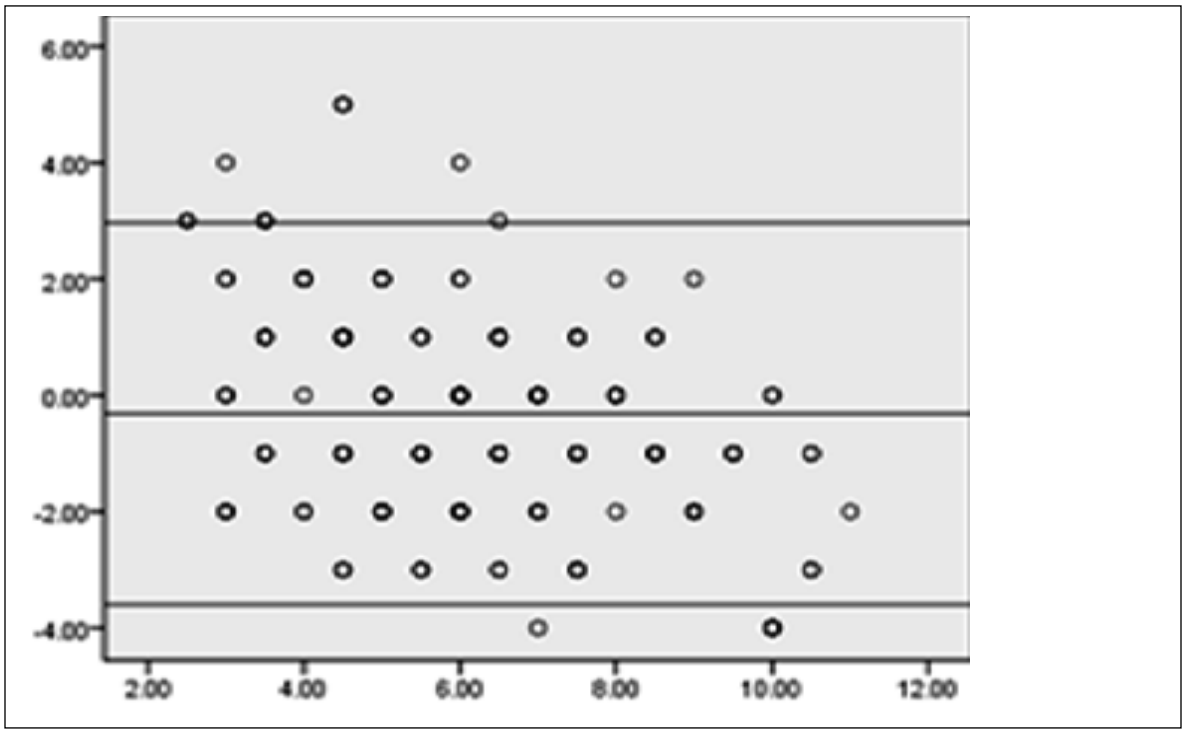

Figure 1: The mean difference between the two machines for lower values was found to be -0.315±1.64 (95% limits of agreement, -3.56 to 2.97)
(95% limits of agreement, -3.56 to 2.97)

The mean difference between the two machines for lower values was found to be -0.315± 1.64 (95% limits of agreement, -3.56 to 2.97). The ESR readings for 95 % of the samples (IQC) on two machines [Diesse Ves-MATIC 80™ (A & B)] were within 2 standard deviation i.e., -3.56 mm/hr below or +2.97 mm/hr above it.

Group 2: Patient samples with Abnormal ESR on two Diesse Ves-MATIC 80™ machines. Mean of the ESR results of 219 patients samples with the range [>60 mm/hr] on both the machines were plotted against the difference between them (Fig.2).

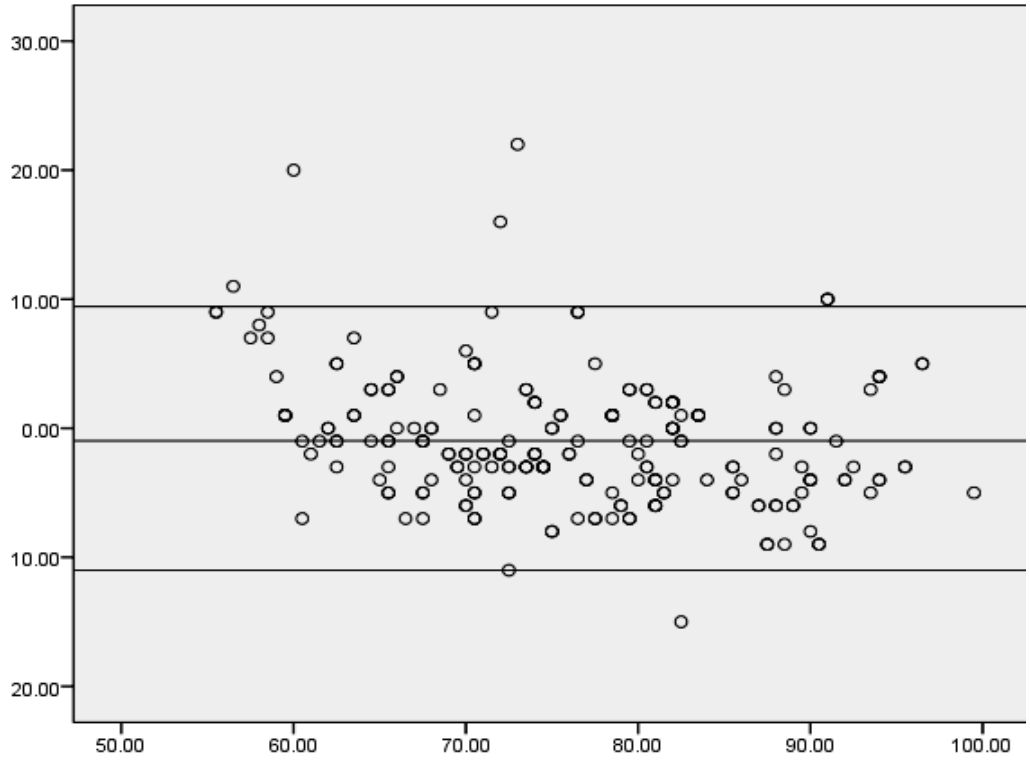

Figure 2: The mean difference between the two machines for higher values was found to be -0.977±5.01 (95% limits of agreement, -10.997 to 9.43)
(95% limits of agreement, -10.997 to 9.43)

The mean difference between the two machines for higher values was found to be -0.977±5.01 (95% limits of agreement, -10.997 to 9.43). The ESR readings for 95 % of the samples (IQC) on two machines [Diesse Ves-MATIC 80™ (A & B)] were within 2 standard deviation i.e.,-10.997 mm/hr below or +9.43 mm/hr above it.

DISCUSSION

Erythrocyte sedimentation rate continues to be used as an indicator of inflammation and infection in all levels of laboratory services; despite being a non-specific test. The gold standard technique for measuring ESR is the Westergren method. However, this method has distinct disadvantages which limit its applications.[10] Over the years, several attempts to introduce automated systems for measuring ESR have evolved. The modifications introduced include the use of unopened blood collection tubes, vacuum-controlled aspiration of the sample (which intends to provide a correct dilution with the anticoagulant) and automated mixing.[11-14] Due to the rise in the prevalence of diseases such as hepatitis B and HIV, transmitted by blood, safety precautions against contamination of laboratory personnel are imperative.

Several automated systems have been introduced since the last two decades and have been evaluated for performance with each other as well

as with the standard Westergren method. These automated techniques offer more benefits in terms of reduced biohazard risks, speedy processing time, and quicker results. Using an automatic analyzer is one such evolutionary step in this regard. Recently, we evaluated and validated a new automated measurement procedure, the Diesse Ves-MATIC 80^{TM} , that allows automated, safe, precise, and accurate measurement of the ESR in clinical practice. The advantages of using this technique include the aforementioned. However, the major advantage conferred by this machine is its use of undiluted K3 EDTA-anticoagulated samples to measure ESR. It is well known that ESR is affected mainly by RBC aggregation or rouleaux formation. The collection of specimens with K3EDTA is known to maintain blood cell stability, thus favoring rouleaux formation, preserving the morphologic features and this is of crucial importance in the ESR reaction.[15]

However, in an era dominated by quality assurance and accreditation of medical laboratories, greater attention should be given to the issue of quality control for ESR measurement. The commercial controls provided by the manufacturers do address this issue. In case of non-availability or deterioration of commercial control however, the alternatives are scarce. Moreover, the nature of the human erythrocyte sedimentation reaction is such that a suitable reference or control material of the usual type is not available in the market. Although several stabilized specimens of human origin have been introduced in clinical laboratories, their kinetic properties, which are different from those of fresh blood erythrocytes, preclude their use for ESR determination.

In the year 2000, NCCLS suggested that the only feasible way of providing a control material is to specify a method for the production of such material in the laboratory where it is to be used.[8] Recently, Plebani and Piva successfully evaluated a quality control procedure that uses fresh whole blood specimens on the machine (TEST1EC).[9] Thus, we decided to use the patient EDTA sample for internal quality control (IQC) of ESR.

In the present study, we found that both the groups (i.e. patients with low and high ESR) showed a good concordance for all the ESR values when they were run alongside two level commercial controls. Also, they were within 2 standard deviation (SD). It was also noticed that the results of higher ESR values concurred better than the lower ESR values.

CONCLUSIONS

In our study, the use of fresh patient blood sample as an internal quality control material showed good precision. While quality control has been neglected and considered irrelevant unimportant for tests such as ESR, efforts are necessary to assure that adequate control materials and procedures are provided. Our results, obtained in patient blood samples, demonstrate that the quality control for the measurement of ESR is feasible, inexpensive and reliable. In case of non-availability or deterioration of commercial control, patient's sample is a useful substitute. This procedure is easily to perform and can be monitored. Many more studies would be necessary to ensure reliability of this method.

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