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Research Paper

Automated Erythrocyte Sedimentation Rate Analyser V/S The Westergren's Manual Method In Measurement Of Erythrocyte Sedimentation Rate: A Comparative Study

Medical Science

KEYWORDS : Comparison, ESR, MicroSED-10®, Westergren's method.

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ABSTRACT

MicroSED-10® (Electra Lab,Italy) is automated method for measurement of erythrocyte sedimentation rate (ESR). The aim of our study was to compare the ESR values by MicroSED-10® against the standard Westergren's method. Study was conducted in outpatient department of pathology at P.D.U. MEDICAL COLLEGE & HOSPITAL-RAJKOT on 209 patients. The samples taken were as per the recommendations charted out by International Council for Standardization in Haematology (ICSH). Bland and Altman statistical analysis was applied for evaluation. The analysis revealed a low degree of agreement between the manual and automated method especially for higher ESR values[>25mm/hour],mean difference~2.58±9.17(95% limits of agreement,-15.39 to 20.55) as compare to lower ESR value[<25mm/hour],mean difference~1.22±1.90(95% limits of agreement,–2.50 to 4.94) & Over all whole ESR data analysis shows, mean difference~2.37±8.34(95% limits agreement,-13.94 to 18.68) for 1 hour. The fully automated system MicroSED-10® for ESR measurement tends to underestimate the manual ESR readings especially at higher ESR values.

INTRODUCTION

The erythrocyte sedimentation rate (ESR) is very basic and still widely used investigation in clinical practice as an indicator of inflammation, infection, trauma, or malignant disease etc.[1] It can be effective in determining prognosis, as in Hodgkin's disease or prostatic cancer, and for monitoring disease activity as in Rheumatoid arthritis.[2,3,4] The first method recommended by International Council for Standardization in Haematology (ICSH) is based on that of Fahraeus and Westergren was introduced in 1921.[5,6] Despite its advantages, the risk to the medical staff regarding contact with blood specimens leading to blood borne infection is very high.[1] MicroSED-10®(Electra lab, Italy) is an automated technique for measuring ESR. The greatest advantage with this method is that it can give the ESR readings in 30 minutes of 10 patients with all the temperature corrections at 18°C using infrared barriers. However there is no such report regarding the validity of ESR measurement using the MicroSED-10®. Therefore, the aim of the present study was to compare the performance of MicroSED-10®, an automated ESR analyzer with the gold standard manual Westergren's method.

Patients

It was a cross-sectional study done on routine haemogram samples over a period of couple of months October & November 2013 respectively. Patients presenting to the outpatient department were randomly selected and after getting an informed consent from the patient or patient's attendant, total of 500 samples were collected. All ESR tests were carried out within 3 hours from the time of blood collection.

Inclusion Criteria

Patients from both sexes and all age groups with hematocrit ≥30% and ≤36% were included in the study. No controls were included in the study.

Exclusion Criteria

Blood collected by vein puncture taking more than 30 seconds & with excessive venous stasis and Blood samples which were not in proper proportions to the anticoagulant, strongly lipemic, hyperbilirubinemic, haemolysed samples were also excluded. Finally, samples from patients with hematocrit values <30% and >36% were not included.

Samples

Under all aseptic precautions, samples were collected from the antecubital vein using a 10-ml disposable syringe with 24G needle. Four millilitre of blood sample was drawn in the two special 2-ml EDTA vacutainers containing 1.5 mg/ml of EDTA and mixed immediately five times.

Conventional Westergren's Method

In this method, Glass tube with a bore size of 2.55 mm and a length of 230 mm, vertically aligned, open at both ends was used. The pipette was filled with K3 EDTA anticoagulated venous blood to a height of at least 200 mm. The sedimentation occurring at 60 minutes from the beginning of the test was noted in mm/hour equivalent to the Westergren's ESR.

MicroSED-10® (Electra Lab, Italy)

The blood was drawn into special MicroSED-10® vacutainers of MicroSED-10® (1.6 ml, 120 mm long, 6 mm diameter) with 1.28 ml automatic draw containing 0.32 ml of 3.2% sodium citrate. The blood citrate mix filled up to a maximum length of 60 mm or minimum length of 50 mm from the bottom of the tube. MicroSED-10® processes the sample only if the blood level is between these two limits. After mixing, the samples were promptly transferred to the analyzer. The ESR reading was taken through a 45-mm high window 2 mm above the maximum sample level. The MicroSED-10® has the advantage of giving the results of 10 samples in 30 minutes (equivalent to 1 hour Westergren's reading).

Reading Principle of MicroSED-10®

Ten infrared barriers vertically cover 10 test tube positions. At 2.0 mm intervals, all 10 positions on the reading plate are analyzed at the same time. As soon as the reading plate comprising ten pairs of infrared rays begins to rise, the indicating system intercepts any position occupied by samples containing the right level of blood. After approximately 3 minutes, the actual analysis begins. The computer records the zero time of each at regular intervals of 3 minutes for sample a total of 30 minutes. The instrument automatically converts the temperature to 18°C and gives the reading in 30 minutes.

RESULTS

Of the total 500 samples collected, 209 samples were within

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the recommended ICSH hematocrit range (≤36% and ≥30%) and hence included in the present study. The rest of the samples, i.e., 291 samples, were outside the range, and therefore were excluded from the study. Out of these 209 samples, 49 samples were within 0–25 mm/hour. While 160 samples had higher ESR values of more than 25mm/hour. Agreement between the results obtained by manual and automated method is shown in Figures 1, 2 & 3.

Table-1: One-Sample Statistics [for whole samples ESR data values]

	Number of Samples	Mean	Standard Deviation	Standard Error Mean
DIFFERENCE	209	2.37	8.319	0.574

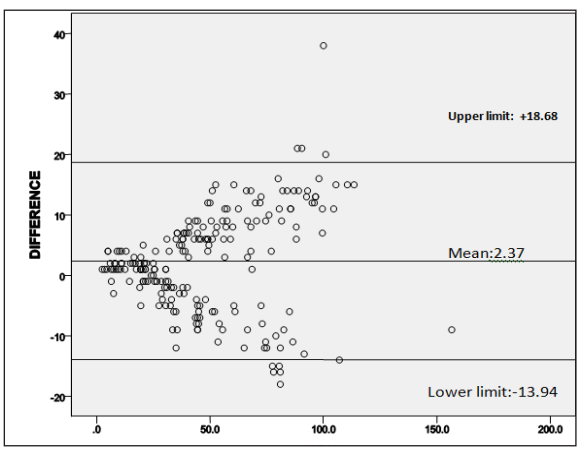

Figure-1:Bland & Altman analysis of whole samples ESR data values {95% limit of agreement [Mean +/-1.96×SD]:(-13.94 to 18.68)}

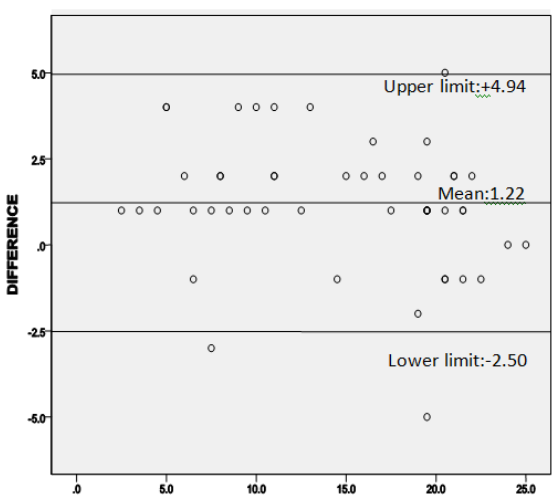

Figure-2: Bland Altman analysis for 0-25mm ESR values

Table-2: One-Sample Statistics[for ESR value<25mm/hr]

	Number of Samples	Mean	Standard Deviation	Standard Error Mean
DIFFERENCE	49	1.22	1.907	0.272

Table-3: One-Sample Statistics[for ESR value>25mm/hr]

	Number of Samples	Mean	Standard Deviation	Standard Error Mean
DIFFERENCE	160	2.58	9.174	0.739

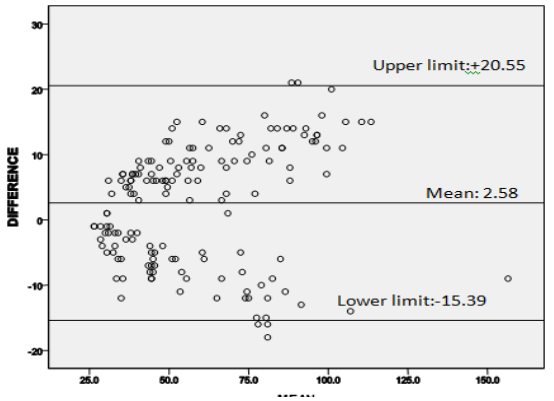

Figure-3: Bland Altman analysis for >25mm ESR values

The results obtained with the reference method were plotted against the difference between the reference and the automated method for 1 hour values. The mean difference between the two methods and 95% limits of agreement at 1 hour for whole data was found to be~2.37±8.34 (95% limits of agreement,–13.94 to 18.68) [Table-1]. Thus we estimate that the 1 hour ESR readings for 95% of subjects as measured by the automated method will be 13.94 mm/hour below the manual method or 18.68 mm/hour above it. This was unacceptable for clinical interpretation since there was a marked discrepancy between the reference and the automated methods. This variation was particularly evident for samples with high ESR readings greater than 25mm/hour. Hence for samples with higher ESR values (>25mm/hour), the mean difference was estimated to be~2.58±9.17 (95%limits of agreement,-15.39 to 20.55) [Table-3] which was markedly different from the corresponding mean difference values ~1.22±1.90 (95%limits of agreement,–2.50 to 4.94) for ESR values less than 25 mm/hour.[Table-2] Thus samples with high ESR values vary considerably around the mean difference compared with samples which had normal ESR readings.

DISCUSSION

The gold standard technique for measuring ESR is the Westergren's method. However, it have many disadvantages like rise in blood borne diseases such as Hepatitis B, HIV etc, which are prevented by using an automated Westergren's such as MicroSED-10®.[7] Many new automated systems have been introduced since 1990s and have been evaluated for performance with each other as well as with the gold standard Westergren's method. Although those automated techniques offer more benefits in terms of reduced biohazard risks, speedy processing time, and quicker results, it is essential to validate these equipments against the standard Westergren's method to enable routine use at any hospital setting. MicroSED-10® is a newly developed automated method which can give the ESR readings in 30 minutes (equivalent to 1 hour Westergren's) of 10 patients with all the temperature corrections at 18°C using infrared barriers. [2] The Westergren's ESR reading at 1 hour correlated with 30 minutes reading of automated analyser. The added advantage of MicroSED-10® is that there is no external influence on the final reading such as temperature, contaminating dust particles, tilting of tube, and ratio of diluents. The number of samples that can be processed with this method is higher (maximum of 10 samples can be processed at a time) than the manual method with the additional benefit that samples can be added in between. In the present study, the results obtained with the automated technique were compared with the gold standard Westergren's method using the agreement analysis of Bland and Altman.[10] Agreement analysis is a more sensitive method than the correlation coefficient for comparison between the two methods. Bland and Altman analysis revealed marked discrepancy between the two methods especially for higher ESR values. This discrepancy was not evident for ≤25mm/hour ESR values(mean difference~1.22±1.90;limits of agreement,–2.50 to 4.94) & marked discrepancy was noted for ESR values >25mm/hour (mean difference ~2.58±9.17; 95%limits of agreement,-15.39

to 20.55). Such discrepancies with the ESR automated analyzers have also been shown previously by various authors. We also obtained similar result. Newer automated systems for measuring ESR have shown comparably good agreement results enabling their use in clinical laboratories with a high workload as well as for emergency laboratories.[8,9] The use of Bland and Altman analysis for evaluating the agreement between the two methods not only assesses the mean of the difference (d) between the two methods (i.e., bias) but also the limits of agreement by calculating the standard deviation of the differences (d ± 1.96SD). It should be kept in mind that these device evaluation and method agreement studies are basically done with the desire to know how much hope we should place on these equipments for making important decisions in patient management.

CONCLUSIONS

Though automation helped a lot in measurement of ESR values. On comparing the manual and automated methods, marked discrepancy in the ESR results was noted for high ESR values. However, this was not evident for normal ESR values. Thus the automated system tended to underestimate the manual readings for ESR values on the higher range which is clinically unacceptable. Hence it is recommended that a correction factor be applied for the range of ESR values while using this equipment.

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