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ORIGINAL RESEARCH

Evaluation of Erythrocyte Sedimentation rate by automated analyser VesMATIC cube 80; an observational study to evaluate the sensitivity of automated analyser as compared to the gold standard modified Westergren's manual method for evaluation of ESR

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Abstract

Introduction: ESR is a widely used clinic laboratory indicator of acute phase reactant. The gold standard of measuring ESR is by manual Westergren method according to International committee for standards in hematology. With increasing rise in demand for automation and advantages associated with automated ESR analyzers available in the market, it is mandatory to assess and validate the automated analyzers. Henceforth, present study was commenced to assess the results of ESR performed by automatic analyser VesMATIC cube80 compared to the gold standard Westergren manual method.

Material and Methods: The present study was performed in the pathology laboratory. Sample collected from venepuncture from cubital vein and was collected in EDTA vial. The sample was coded. Double blinding was done. Sample was processed in VesMATIC cube 80 and was manual modified for Westergren method. Test results were analysed. Statistical analysis by Linear regression and Bland Altmann data analysis was carried out.

Results: In the present study the mean difference vary considerably at higher ESR values. We estimated that the one hour ESR readings for 95% of subjects as measured by this automated method was 60mm/hr below the manual method or 20mm/hr above it. The average ESR value by automated method was 20mm less as compared to Westergren method. At lower value by westergren method, the absolute mean difference was less. However at higher values, the ESR by westergren method, absolute difference was higher.

Conclusion: The Westergrens method remains the gold standard for ESR estimation however the use of automated analyzer should be accompanied by a correction factor to rectify the discrepancy while using automated Vesmatic method especially with the higher ESR values.

Keywords: Erythrocyte Sedimentation rate; Inflammation; Manual Westergren method

Introduction

Erythrocyte sedimentation rate (ESR) is a widely used laboratory indicator of acute phase reaction. The gold standard of measuring ESR is by manual Westergren method according to International Committee for Standard in Hematology (ICSH) (1,2) and the National Committee for clinical Laboratory Standards (3).

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Although ESR is not a specific diagnostic test, it is however widely used as an indicator of inflammation, trauma, malignancy etc. It is also used as a monitoring tool in patients with rheumatoid arthritis, temporal arteritis, PR and Hodgkins Disease. (4) It is used as a diagnostic criterion in Multiple Myeloma. ICSH recommends use of modified Westergren as a gold standard where in the undiluted blood sample in K2EDTA as anticoagulant (dilution <1%) is used. (5) Despite being gold standard manual method has significant risk of blood borne infection to health personnel. (6) Several automated methods are now available in the market for use with significant advantages. Thus, with increasing rise in demand for automation and advantages associated with automated ESR analyzers available in the market, it is mandatory to assess and validate the automated analyzers Henceforth, present study was commenced to assess the results of ESR performed by automatic analyser VesMATIC cube80 compared to the gold standard Westergren manual method.

Materials and method

The present study was performed in the pathology laboratoryof Mahatama Gandhi Hospital over a period of 5 months. All coded samples submitted for Erythrocyte sedimentation rate (ESR) during the aforesaid period were taken up for the study.

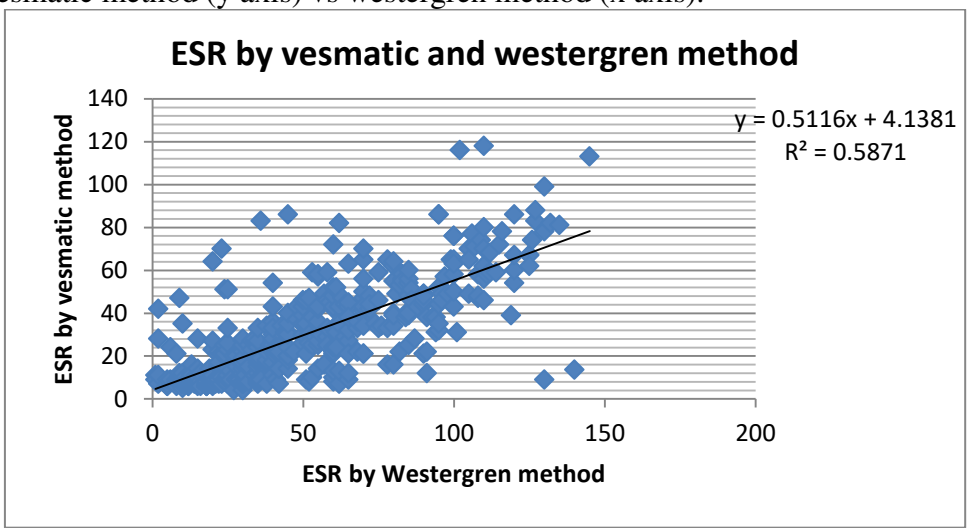
Inclusion criteria comprised of both sexes and all age groups. No controls were used.Exclusion criteria consisted of inadequate sample amount, improper ratio of anticoagulant to sample amount, lipedemic sample, hyperbilirubinemia, hemolysed sample and sample with collection time > 30 seconds/ venous stasis.

Sample collected from venepuncture from cubital vein and was collected in EDTA vial. The sample was coded. Double blinding was done. Sample was processed in VesMATIC cube 80 and was manual modified for Westergren method. Test results were analysed. Statistical analysis by Linear regression and Bland Altmann data analysis was carried out.

Results

ESR was measured in 421 blood samples by both methods i.e. westergren and vesmatc cube 80 methods. The mean ± S.D ESR was 51.53±33.76 mm/hr (range 1-145mm/hr) for the reference (westergren) method and 30.50±22.54mm/hr (range 4-118mm/hr) for vesmatic cube 80 method.

Out of total 421 samples, 121 samples were within reference range used in our hospital (0-25mm/hr), while 300 samples had higher ESR value of more than 25mm/hr. There was a significant correlation between westergren and vesmatic method. The comparison of methods plotted vesmatic method (y axis) vs westergren method (x axis).



Graph I: Total cases are included (sample size421).

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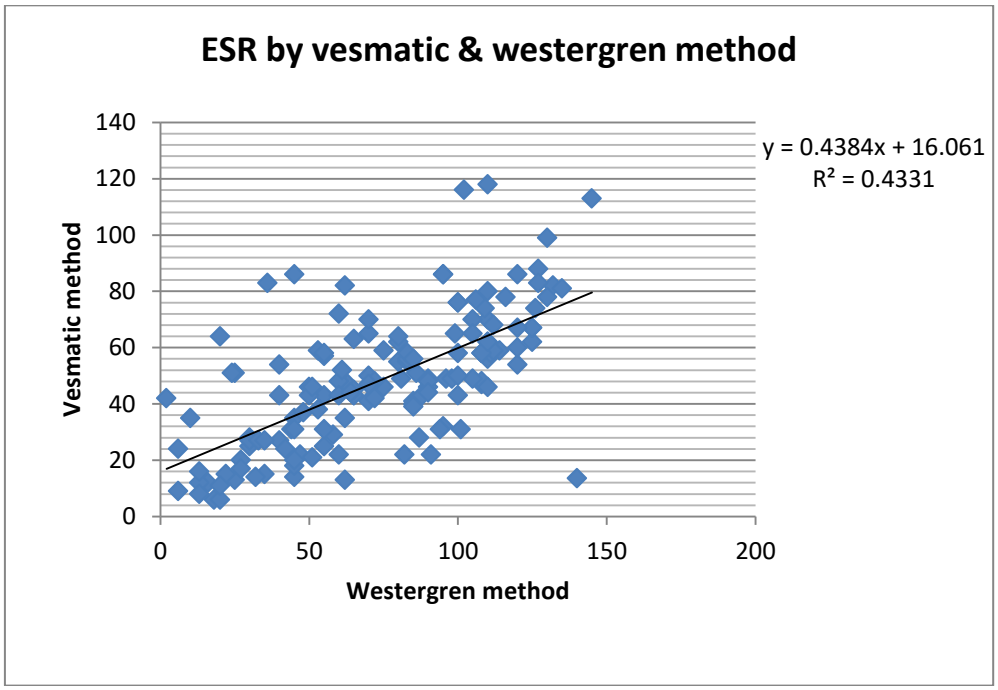
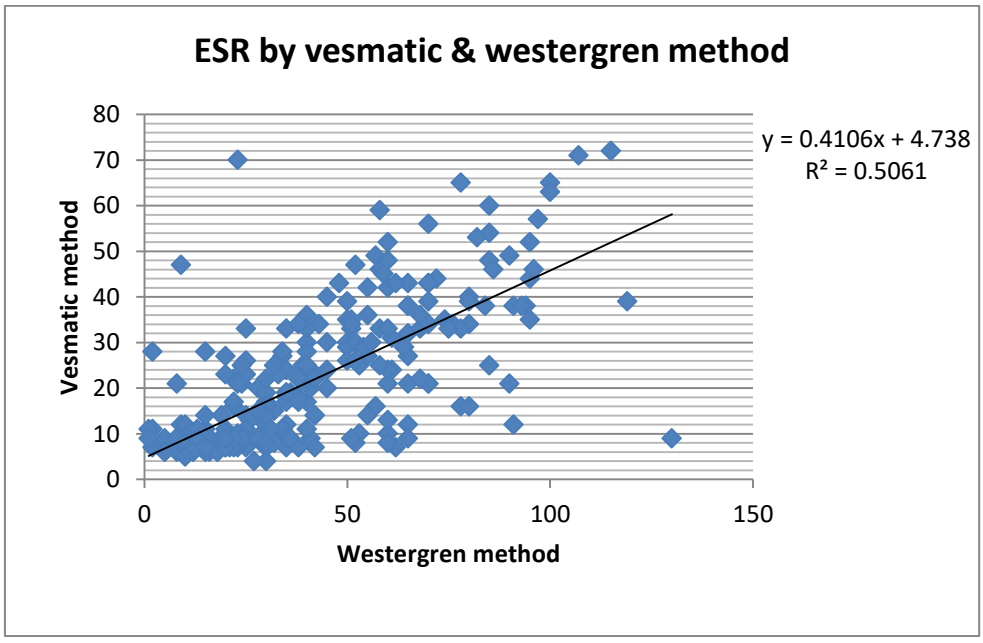
Ordinary linear regression of correlation between two methods i.e., ESR by westergren and vesmatic method. R^2 value was 0.587 so the study was significant for using automated ESR method for the gold standard westergren method (graph I).



Graph II: Anaemic individual cases(sample size145)

R^2 value was 0.433 so the study in anaemic patients was significant for using automated ESR method for the gold standard westergren method (graph II).



Graph III: Normal individual cases (sample size: 276).

R^2 value was 0.506 so the study in normal patients was significant for using automated ESR method for the gold standard Westergren method (graph III).

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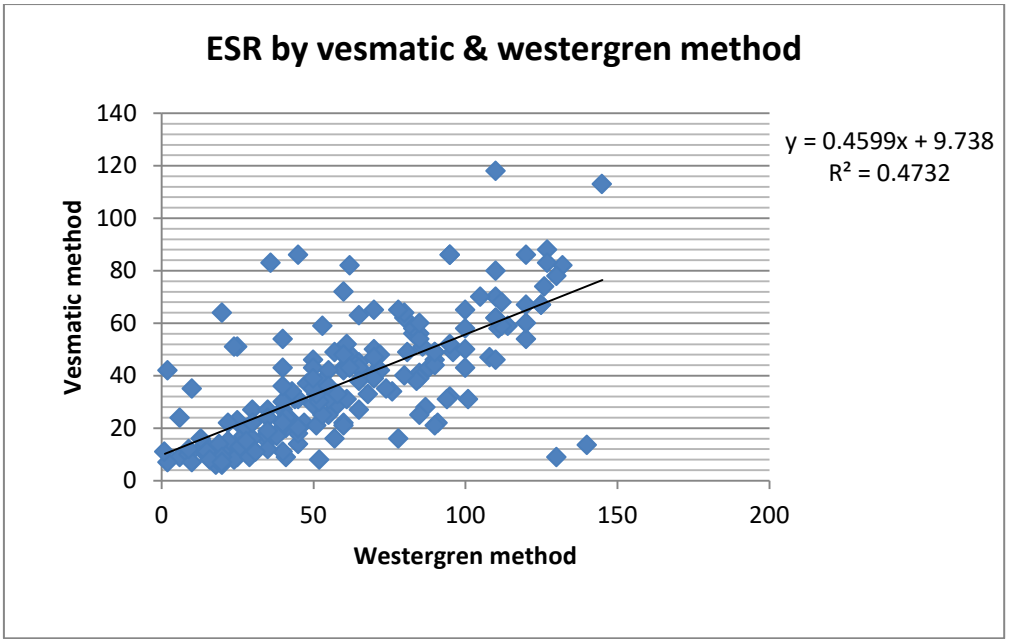
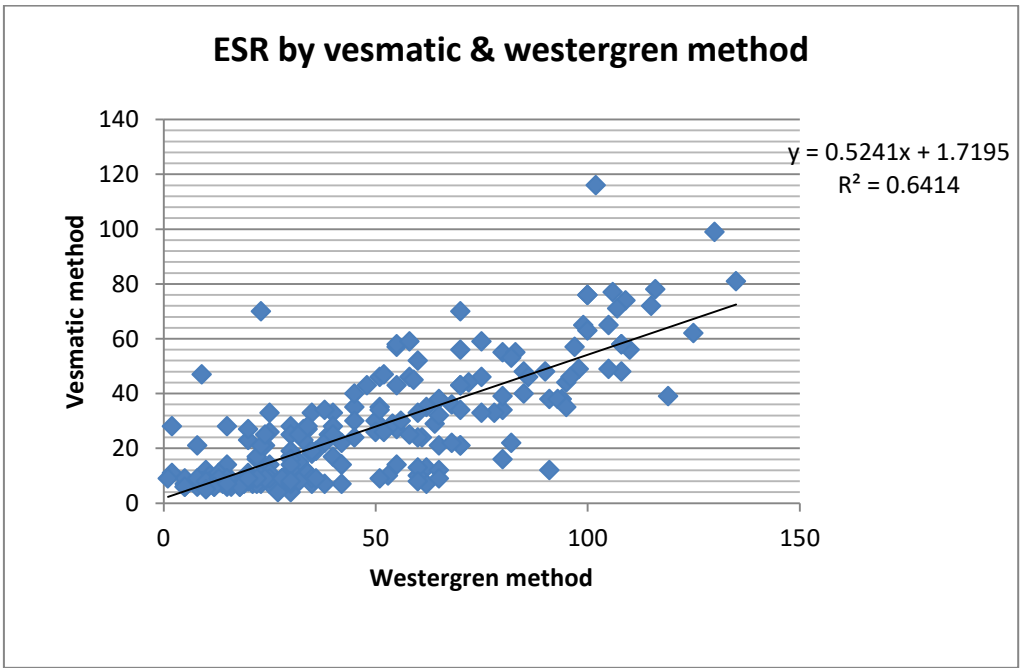


Graph IV: Female individual cases (sample size: 184)

R^2 value was 0.473 so the study in female patients was significant for using automated ESR method for the gold standard westergren method (graph IV).



Graph V: Male individual cases (sample size: 237)

R^2 value was 0.641 so the study in male patients was significant for using automated ESR method for the gold standard Westergren method (graph V).

The agreement between the results obtained by manual westergren and automated vesmatic method for one hour was also demonstrated by Bland- Altman analysis (graph V). The results obtained with the reference method (modified westergren method) were plotted against the difference between the reference and automated method.

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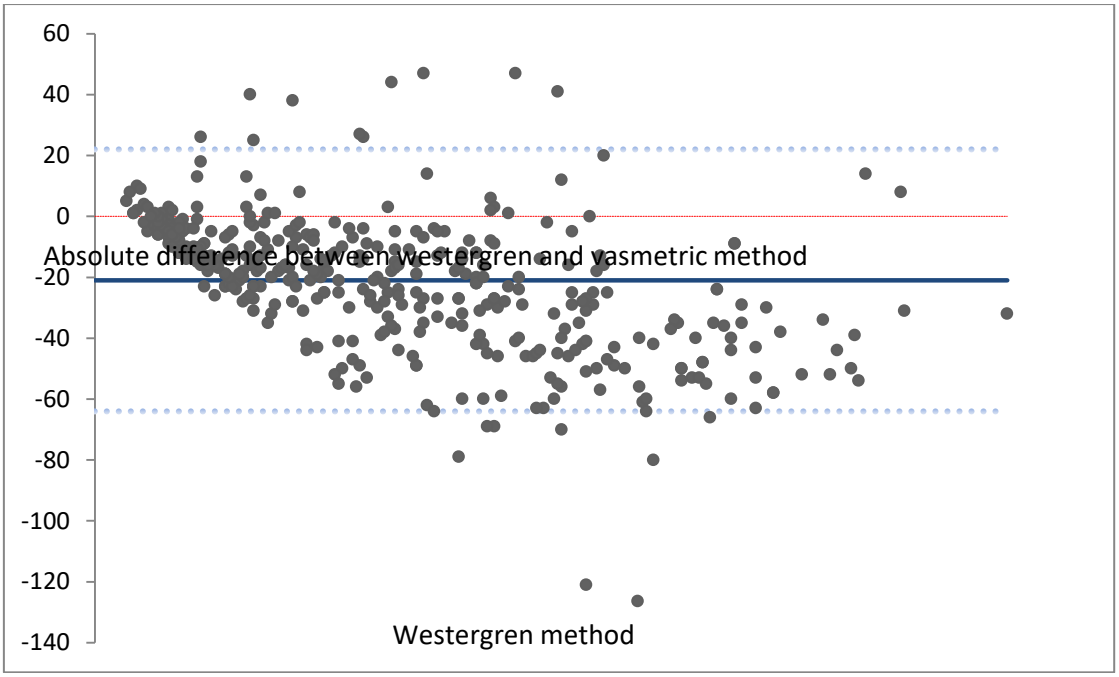

Graph V: Bland and Altman analysis of the comparison between westergren and vesmatic method at 1 hr, mean difference -21.02 (95% limits of agreement are from 20 to -60)

Discussion

ESR estimation is a commonly asked for investigation in clinical practice. Several studies had been performed to study the comparability of automated ESR analysers to manual Westergren method.Sared M etal used SED1 system and performed test on 150 random samples and showed significant comparability.(4) Arulsevi et al used Monitor 100 and tested 200 samples in Trauma care centre (6), Drashti et al used micro SED 10 automated analyser on 500 blood samples (7) and Helena et al (5) and Ash et al(8)used Vesmatic cube 80 on 248 and 162 patients respectively.

Though non-specific it indicates an inflammatory or infectious state of the body. It is also used in a few diagnostic criteria of diseases. Till now the gold standard technique of ESR measurement remains Westergrens method. Still it has many disadvantages especially with the rise of blood borne diseases like HIV and Hepatitis B chances of biohazard exposure is more with the manual method. This disadvantage can be overcome by automated methods of estimation (9).

In the present study, we estimated that the one hour ESR readings for 95% of subjects as measured by this automated method will be 60mm/hr below the manual method or 20mm/hr above it. The average ESR value by automated method was 20mm less as compared to westergren method. At lower value by westergren method, the absolute mean difference was less. However at higher values, the ESR by westergren method, absolute difference was higher.Studies show agreement analysis is a more sensitive method then the correction coefficient for comparison between the two methods (8).

This was unacceptable for clinical interpretation since there was a marked discrepancy between the reference and automated methods. The variation was particularly evident for samples with higher ESR reading >25mm/hr. Hence for samples with higher manual ESR values, the mean difference was estimated to be -28.62. This was also markedly different from the corresponding values for ESR <25mm/hr ie. mean difference was -2.19. Thus our inference was that the samples with high ESR values vary considerably around the mean difference compared with samples which had normal ESR readings. Thus, we recommend a

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correction factor to rectify the discrepancy in the results while using the automated vesmatic method.

Many new automated analyzers have been introduced in the market since 1990 (3). The modifications in the automated systems include use of unopened blood collection tubes, vacuum- controlled aspiration of the sample and automated mixing (10,11). Apart from safety from blood borne diseases the automated method has other advantages also like giving a result in approximately 30 minutes as compared to 1 hour by Westergrens method with all the temperature correction at 18^{o}C (1). Despite the advantages it is important to validate the automated method to enable routine use and also to substitute the standard ESR method. Because ESR is an important investigation in diagnosis and monitoring of treatment, an evaluation and validation of automated method becomes mandatory to avoid errors which may affect patient management. The ESR is affected by packed cell volume and plasma albumin, globulin and fibrinogen (1,12). A lack of visual confirmation of result may lead to erroneous result by automated analyzer. The use of Bland and Altman analysis for comparing the two methods not estimated the mean of difference but also the limits of agreement by calculating the standard deviation of the difference (6).

All these studies showed comparable results though there were limits of agreement. Very low and very high values of ESR showed significant differences between automated and manual analysers.

In the present study the mean difference vary considerably at higher ESR values. This result is comparable to several other studies reviewed.

Conclusion

The Westergrens method remains the gold standard for ESR estimation however the use of automated analyzer should be accompanied by a correction factor to rectify the discrepancy while using automated Vesmatic method especially with the higher ESR values.

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