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Research Article

CONVENTIONAL ESR V/S AUTOMATED TEST 1(ALIFAX) ESR: A COMPARATIVE STUDY AT TERTIARY CARE CENTER

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ABSTRACT

Objective: The erythrocyte sedimentation rate (ESR) is a key test for detecting inflammation, typically measured using the manual Westergren method. Implementing automated systems like Test 1 (ALIFAX) offers advantages like quicker results and improved precision. This study compares the accuracy of the conventional Westergren method with the automated Test 1 (ALIFAX) system.

Methods: A cross-sectional study was conducted at RNT Medical College, Udaipur, using 100 blood samples. ESR was measured by both the manual Westergren method and the automated Test 1 analyzer, which utilizes capillary photometry. The correlation between the two methods was evaluated using Pearson's correlation coefficient.

Results: The mean ESR values for females were 41.88 mm/h (automated) versus 44.31 mm/h (manual), and for males, 32.16 mm/h (automated) versus 35.18 mm/h (manual). The Pearson's correlation coefficient was 0.94, indicating a strong positive correlation. Differences between the methods were minimal for ESR values <60 mm/h but larger for values >60 mm/h.

Conclusion: The automated Test 1 analyzer showed strong agreement with the Westergren method, suggesting it is a reliable and efficient alternative for ESR measurement in clinical practice.

Keyword: Erythrocyte Sedimentation Rate, Automation, Westergren Method

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INTRODUCTION

The concept of erythrocyte sedimentation rate (ESR) emerged in medical practice back in 1897, initially referred to as the Biernacki or Fahraeus–Westergren method. It measures the distance red blood cells settle in a vertical tube over a specific timeframe [1]. This test serves as a valuable screening tool, with the conventional manual method being simple, cost-effective, and not reliant on a power source, making it suitable for point-of-care testing [2].

ESR is utilized to assess the prognosis and diagnosis of various diseases, indicating chronic inflammation present in numerous conditions [3]. While not specific to any particular ailment, this economical test is commonly employed in diagnosing and monitoring conditions such as multiple myeloma, tuberculosis, giant cell arteritis, and rheumatoid arthritis. In addition, it holds clinical significance in predicting relapse in Hodgkin's disease and offers prognostic insights in stroke and coronary artery disease [4].

The approach endorsed by both the International Council for Standardization in Hematology (ICSH) and several national authorities follows the method established by Westergren. Westergren's method for ESR estimation is the gold standard method according to ICSH. Westergren devised this test in 1921 primarily for investigating patients with pulmonary tuberculosis. It involves measuring the sedimentation of red blood cells in diluted blood after allowing it to stand for 1 h in an open-ended glass tube, typically 30 cm in length, positioned vertically on a stand [5].

In the past three decades, numerous new automated or semi-automated methods have emerged. These advancements have brought continuous technical innovations to existing procedures, resulting in enhanced performance. The primary focus of these innovations has been on automation, allowing for operator independence and ensuring results are traceable to the reference method. In addition, the adoption of automated and closed systems has heightened operator safety. Some analyzers now permit the use of specimens collected in ethylenediamine tetraacetic acid (EDTA) tubes alongside complete blood count (CBC) samples, streamlining workflow and reducing test turnaround time. EDTA samples maintain red blood cell morphology, enhance stability, and do not interfere with erythrocyte sedimentation mechanisms. Furthermore, EDTA-anticoagulated blood samples are suitable for additional hematological tests using the same specimen [6].

In our hematology laboratory, automated ESR estimation began in the year of 2016 using the ALIFAX ESR ANALYSER T1 3627.

Test 1 conducted by Alifax s.r.l. in Polverara, PD, Italy, utilizes an alternative technology centered around capillary photometry. This innovative approach enables the measurement of ESR within a short span of minutes [7].

The present study is a generous attempt to compare the results of automated and manual ESR methods and to establish a correlation between them.

METHODS

A cross-sectional study was carried out in the hematology section of the Pathology Department at RNT Medical College, Udaipur. The study involved analyzing 100 blood samples for ESR using both the manual Westergren method and the automated method.

Test 1, developed by Alifax s.r.l. in Polverara, PD, Italy, is an automated device designed for ESR assessment, employing the modified Westergren

method. It employs an EDTA tube and a rack specifically designed for CBC instruments, utilizing quantitative capillary photometry. In one rack 15 samples can be run at a time which takes 20 min to estimate ESR. The required sample volume (175 uL) is drawn into a capillary tube via a fixed needle, where it flows through a transparent capillary within the instrument, maintained at 37°C. Fig. 1 shows the TEST 1 machine in our laboratory.

Inter-run precision was assessed by regularly conducting quality control (QC) samples on the Test 1 (ALIFAX) automated analyzer for ESR. Fig. 2 is showing Westergren method for ESR estimation.

For the Westergren method, venous blood was drawn into a solution of 3.8% tri-sodium citrate in a 4:1 ratio of blood to citrate. The anticoagulated blood sample was thoroughly mixed and then poured into a Westergren tube up to the "0" mark. This tube was then placed vertically in an ESR stand and left undisturbed for 1 h. After precisely 1 h, the height of the plasma column above the red cell column was measured in millimeters.

The readings from both methods were compared across all samples, and the correlation coefficient was determined. Pearson's correlation coefficient analysis was employed to evaluate the relationship between the automated analyzer and the Westergren method.

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Fig. 1: Automated TEST 1 (ALIFAX) for ESR estimation

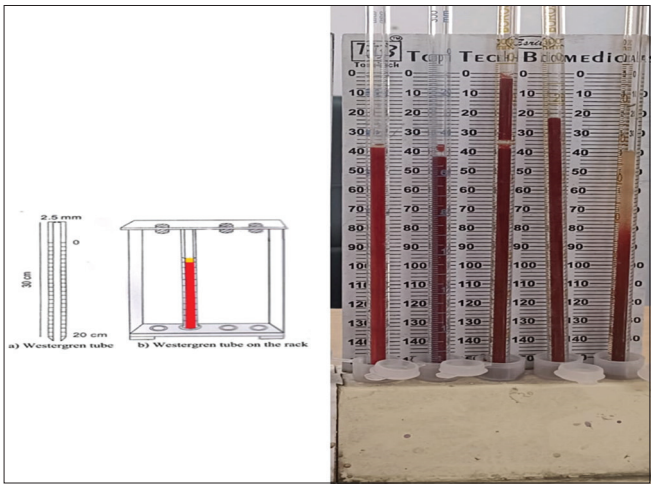

Fig. 2: ESR estimation by manual westergren method.

RESULTS

A total of 100 samples were gathered for the evaluation of ESR. The automated ESR test was conducted using the TEST 1 analyzer (ALIFAX SPA), and ESR measurements were also taken using a manual method.

A total of 100 samples were taken for ESR estimation using both the Automated (TEST1) and Manual (WESTERGREN) methods. Out of the 100 patients, 65 were male and 35 were female, giving a male-to-female ratio of 1.8:1. The mean ESR for females was 41.88 mm/h using the Automated method and 44.31 mm/h using the Manual method. The mean ESR for males was 32.16 mm/h for the Automated method and 35.18 mm/h for the Manual method (Table 1).

A total of 100 samples were estimated for ESR by both method manual (Westergren) and automated (TEST 1). Based on a reading of ESR, three groups were made: Group (1) ESR 1 to 30 Group (2) ESR 31 to 60, and Group (3) ESR>60. The mean ESR of group 1 for the automated method and manual method is 21.34 mm/h and 24.69 mm/h, respectively. The mean ESR of group 2 for the automated method and manual method is 43.42 mm/h and 45.39 mm/h, respectively. The mean ESR of group 3 for the automated method and manual method is 79.16 mm/h and 81.83 mm/h, respectively. These findings are summarized in Table 2.

The Pearson's correlation coefficient between the two methods in this study is 0.94, indicating a strong positive correlation between the Automated (TEST1) and Manual (Westergren) methods for ESR estimation which is tabulated below in Table 3.

DISCUSSION

ESR is not specific to any particular condition but serves a clinical purpose in disorders marked by elevated acute-phase proteins. In conditions like rheumatoid arthritis or tuberculosis, ESR can indicate disease progression and is particularly useful in diagnosing temporal arteritis and polymyalgia rheumatica. It is frequently employed in cases where multiple myeloma is suspected; however, a normal ESR result does not rule out the diagnosis in cases of non-secretory or light chain type myeloma [8].

Table 1: Mean±SD ESR for females and males for the automated and manual method

	n	Automated Mean±SD (mm/h)	Westergren Mean±SD (mm/h)
Total	100	35.57±20.63	38.38±21.54
Female	35	41.88±23.52	44.31±22.40
Male	65	32.16±18.19	35.18±20.54

Table 2: Evaluation of results (Mean±SD ESR) of various groups by manual and automated methods (n=100)

ESR	n	Automated Mean±SD (mm/h)	Westergren Mean±SD (mm/h)
1–30	55	21.34±5.67	24.69±8.35
31–60	33	43.42±6.89	45.39±9.22
>60	12	79.16±20.63	81.83±21.54

Table 3: Pearson's correlation between Westergren and automated method

Methods	Correlation coefficient
Automated method and Westergren method	0.94

In recent years, laboratories have increasingly adopted advanced automated instruments over the traditional Westergren method. This shift is motivated by several advantages: decreased risk of laboratory personnel exposure to infectious diseases, the convenience of using EDTA tubes already allocated for CBCs without additional sampling, and quicker turnaround times. Moreover, automation enhances precision by reducing the likelihood of human error, improves cost-effectiveness, and enables seamless integration of instruments with laboratory middleware [9].

Since 1990s, numerous automated systems have been introduced and compared for their performance against each other and the established Westergren method. Some of these systems include the Ves-matic 60 from Menarini Diagnostics S.r.l. in Milan, Italy, Sediscan from Becton Dickinson in Meylan Cedex, France, Sedimatic from Technicon International Inc. in Tokyo, Japan, and the TEST 1 automated ESR analyzer from Alifax S.p.A in Polverara, Italy, among others. While these automated techniques offer advantages such as reduced biohazard risks, faster processing times, and quicker results, it remains crucial to validate these instruments against the standard Westergren's method to ensure their reliability for routine use and potential replacement of the standard ESR method in hospital settings [10].

The ICSH has established a protocol for evaluating alternative methodologies in comparison to the reference method. New technologies should be tested across a range of ESR values from 2 to 120 mm/h. In this comparison, 95% of the differences should be 5 mm or less, with larger differences linked to higher ESR values. The recommended statistical methods for ESR evaluations include the coefficient of correlation, Passing-Bablok regression, and the Bland-Altman statistical approach [6].

In this study, most differences in ESR values were 5 mm or less in Groups 1 and 2, while differences greater than 5 mm were observed in Group 3, as outlined in the ICSH guidelines.

In this study to compare the accuracy of ESR measurement by automated method (TEST 1) and manual method (Westergren method), we have taken 100 random samples from routine hospital practice. The ESR means obtained were 38.38 mm/h for the gold-standard Westergren method and 35.57 mm/h for Test 1.

In earlier research, authors observed a strong correlation and agreement between the two methods. Mohanvir *et al*. (2018) reported a correlation coefficient of 0.99 when comparing the Westergren and automated techniques [11]. Similarly, Hina *et al*. (2019) conducted a related study and found a significant strong correlation (r=0.945) between the Westergren and automated methods for estimating ESR [12]. Manoj (2022) also noted a strong correlation (r=0.9058) between these two methods, aligning with the current study's findings [13]. In addition, Michele *et al*. (2024) reported a correlation coefficient of 0.96 for the Westergren and VES-MATIC 5 methods, and a coefficient of 0.93 for the Westergren and Test 1 methods [14].

CONCLUSION

The results of this study revealed a significant correlation between the Westergren method and the automated approach for estimating ESR. Both methods are equally reliable and appropriate for this purpose.

CONSENT

This study was done after obtaining informed consent from all the participants involved.

ETHICAL APPROVAL

Ethical approval was obtained from the Institutional Ethics Committee before the study.

CONFLICTS OF INTERESTS

Nil.

AUTHORS CONTRIBUTION

All authors have equal contributions in the preparation of this manuscript.

AUTHORS FUNDING

Nil.

REFERENCES

1. International Council for Standardization in Hematology. ICSH recommendations for measurement of erythrocyte sedimentation rate. International Council for Standardization in Haematology (Expert Panel on Blood Rheology). J Clin Pathol. 1993;46(3):198-203. doi: 10.1136/jcp.46.3.198, PMID 8463411
2. Osei-Bimpong A, Meek JH, Lewis SM. ESR or CRP? A comparison of their clinical utility. Hematology. 2007;12(4):353-7. doi: 10.1080/10245330701340734, PMID 17654065
3. Wu LA, Tan SL, Wright RS, Kopecky SL, Burritt MF, Santrach PJ, *et al*. Prognostic value of the erythrocyte sedimentation rate in patients with unstable angina. Arch Pathol Lab Med. 2002;126(7):772. doi: 10.5858/2002-126-0772-PVOTES, PMID 12125644
4. Arikan S, Akalin N. Comparison of the erythrocyte sedimentation rate measured by the micro test 1 sedimentation analyzer and the conventional Westergren method. Ann Saudi Med. 2007;27(5):362-5. doi: 10.5144/0256-4947.2007.362, PMID 17921682
5. National Committee for Clinical Laboratory Standards. Reference and Selected Procedures for the Erythrocyte Sedimentation Rate (ESR) test (H2-A4). Wayne, PA: NCCLS; 2000.
6. Jou JM, Lewis SM, Briggs C, Lee SH, De La Salle B, McFadden S, *et al*. ICSH review of the measurement of the erythrocyte sedimentation rate. Int J Lab Hematol. 2011;33(2):125-32. doi: 10.1111/j.1751-553X.2011.01302.x, PMID 21352508
7. Kratz A, Plebani M, Peng M, Lee YK, McCafferty R, Machin SJ, *et al*. ICSH recommendations for modified and alternate methods measuring the erythrocyte sedimentation rate. Int J Lab Hematol. 2017;39(5):448-57. doi: 10.1111/ijlh.12693, PMID 28497537
8. Osei-Bimpong A, Burthem J. Supplementary Techniques Including Blood Parasite Diagnosis. In: Dacie and Lewis Practical Hematology. Amsterdam, Netherlands: Elsevier; 2012. p. 101-21.
9. Lapić I, Piva E, Spolaore F, Tosato F, Pelloso M, Plebani M. Automated measurement of the erythrocyte sedimentation rate: Method validation and comparison. Clin Chem Lab Med. 2019;57(9):1364-73. doi: 10.1515/cclm-2019-0204, PMID 30939112
10. Subramanian A, Rangarajan K, Pandey RM, Gandhi JS, Sharma V, Bhoi SK. Evaluation of an automated erythrocyte sedimentation rate analyzer as compared to the Westergren manual method in measurement of erythrocyte sedimentation rate. Indian J Pathol Microbiol. 2011;54(1):70-4. doi: 10.4103/0377-4929.77328, PMID 21393881
11. Kaur M, Mittal A, Puri A. Conventional ESR V/S automated VES MATIC 20/20 plus new ESR- A comparative study of 100 cases. Ann Int Med Dent Res. 2018;4(2):PT34-6.
12. Mushtaq H, Mehmood T, Khan I, Razvi N. Correlation between automated and the westergren method for determination. J Bahria Univ Med Dent Coll. 2019;9(2):109-12. doi: 10.51985/JBUMDC2018101
13. Kahar MA. Comparison of alternate erythrocyte sedimentation rate measurement by automated Celltac α+(MEK 1305) and reference Westergren method. J Hematol Allied Sci. 2022;2(2):39-45. doi: 10.25259/JHAS_12_2022
14. Cennamo M, Giuliano L, Arrigoni G, Fardone V, Russo R, De Tomasi LM, *et al*. Method comparison of erythrocyte sedimentation rate automated systems, the VES-MATIC 5 (DIESSE) and test 1 (ALIFAX), with the reference method in routine practice. J Clin Med. 2024;13(3):847. doi: 10.3390/jcm13030847, PMID 38337540