EVALUATION OF Sedi-REM MATIC DEVICE USING BD SEDITAINER 1.8 ML TUBE FOR MEASUREMENT OF ERYTHROCYTE SEDIMENTATION RATE

ABSTRACT: Automatic systems for ESR measurement are now used in many laboratories. In this study, it was aimed to compare Sedi-REM Matic reading distance of blood precipitating within BD Seditainer 1.8 ml tube" expressed in millimeter, which also involves two decimals following comma, with reference manual westergren method. Samples used for the study were obtained from hospital referred to the hospital. Patients were randomly selected. All samples were measured within 4 hours after blood sample is drawn. Blood samples of randomly selected patients were concurrently examined in 3 Sedi-REM Matic devices using BD Seditainer 1.8 ml tubes and manually with reference westergren tubes. In post-examination analysis, it was observed that there was no statistically significant difference between 2 methods (p=0,811) and there was a linear relationship at rate of 99,7 percent. In conclusion of present study, we believe that the device can replace reference Westegren method in clinical laboratories.

INTRODUCTION: ESR is a simple and cheap test method, which is used worldwide. When a blood treated with an anticoagulant substance is placed into a vertical tube, erythrocytes tend to precipitate. Measuring precipitation distance of erythrocytes within a particular time is referred as ESR (1). ESR has 3 separate phases:

1. Erythrocytes initially precipitate due to their own weight. Precipitation in this phase is very slow.
2. Cells rapidly form aggregates and precipitation substantially accelerates. The larger aggregate, the faster precipitation.
3. The speed decreases in congestion phase as erythrocytes accumulates at the bottom of the tube in a cluster form.(1,2)

   Therefore, ONE-HOUR SEDIMENTATION determining precipitation rate at first two conditions is VALUABLE. Clinical relevance of half-hour and 2-hour value is low.

Physiologic range of ESR:

		1-hour
• Men:		6 mm – 12 mm
• Women:		11 mm – 18 mm
• Newborn:		2 mm
• Infant	1 – 6 month	12 mm
•	7 - 12 month	10 mm
• Baby:		8 mm

Sedimentation is used for diagnostic and follow-up purposes as an acute phase reactant. Conditions where sedimentation rate increases and decreases are listed.(3)

Diseases increasing sedimentation rate;

1. Inflammations (particularly in exudative ones)
2. Infectious diseases. For example, sepsis, pneumonia, early stage of epidemic hepatitis
3. Tuberculosis. Sedimentation rate increases at activation phases of the disease.
4. Rheumatoid diseases. For Example, Acute Rheumatism
5. Collagen disorders. Lupus Erythematosus, Scleroderma, Periarteritis Nodosa
6. Neoplasm. Sarcoma, Hypernephroma, Acute Leukemia, Malign Reticulosis,
7. Paraproteinemia. Plasmositoma, Waldenström makroglobulinemia
8. Dysproteinemia. Nephrotic syndrome
9. Anemia.
10. Drugs. Oral contraceptives, dextrane and infusion of compositions with polyvinyl alcohol
11. Myokard Infarction. It starts to increase in and after 2-5 days
12. Hypothyroidism.
13. Gastrointestinal disorders. First 24 hours of acute appendicitis, malignant gastric tumors

Diseases decreasing sedimentation rate

1. Polycythemia
2. Congestive heart failure
3. Pertussis without complication
4. Nieman-pick disease

5. Hypercholestrinemia
6. Drugs. Fenilbutosane, cortisone,….

Classical Westergren method used in ESR measurement is reference method determined as GOLD STANDARD in 1997 by "The international council for Standardization in Hematology "(ICSH). (3) Within last 15-20 years, new techniques have been developed. Those techniques were aroused from the need to make accurate measurement using automatic and closed system, self-determination and studying other hematological tests in conjunction with ESR using same sample.(4)

In present study, we compared a new device Sedi-REM MATIC reading only BD SEDITAINER 1.8 ml tubes with classical manual westergren method.

MATERIAL-METHOD: Samples used for the study were obtained from hospital referred to the hospital. Patients were randomly selected. All samples were measured within 4 hours after blood sample is drawn. In this study, "Sedi-REM Matic / Only use for BD Seditainer 1.8 ml tube" device (totally 3 devices were used), which reads and prints sedimentation distance of the blood precipitating within the tubes using "BD Seditainer 1.8 ml" Sedimentation tubes of BD Company in accordance with Reference Westergren method, expressed as mm in 30^{th} minute,60^{th} minute and 120^{th} minute was operated in conjunction with manual westergren pipettes for comparison purposes.

After all tests were performed, Kolmogorov-Smirnov Test, Correlations test, Mann Whitney U Test and Kruskal-Wallis Tests were applied for comparisons.

RESULTS: Samples of totally 800 patients were tested using both Sedi-REM MATİC and Westergren method. Following table lists comparative results.

Number of tests	60-minute reading with Westergren	Difference of reading by Sedi-REM MATİC from Westergren
497	2-18 mm	Lower than 0,9 mm (Result of Sedi-Rem is low in 198 tests; result of westergren method is low in 299 tests)
183	19-25 mm	Between 1-1,5 mm (Result of Sedi-Rem is low in 97 tests; result of westergren method is low in 86 tests)
58	26-40 mm	Between 1,6-2 mm (Result of Sedi-Rem is low in 19 tests; result of westergren method is low in 39 tests)
43	41-75 mm	Between 2,1 - 3 mm (Result of Sedi-Rem is low in 24 tests; result of westergren method is low in 19 tests)
19	76-100 mm üstü	Between 3,1 - 5 mm (Result of Sedi-Rem is low in 12 tests; result of westergren method is low in 7 tests)

Totally 800 Tests

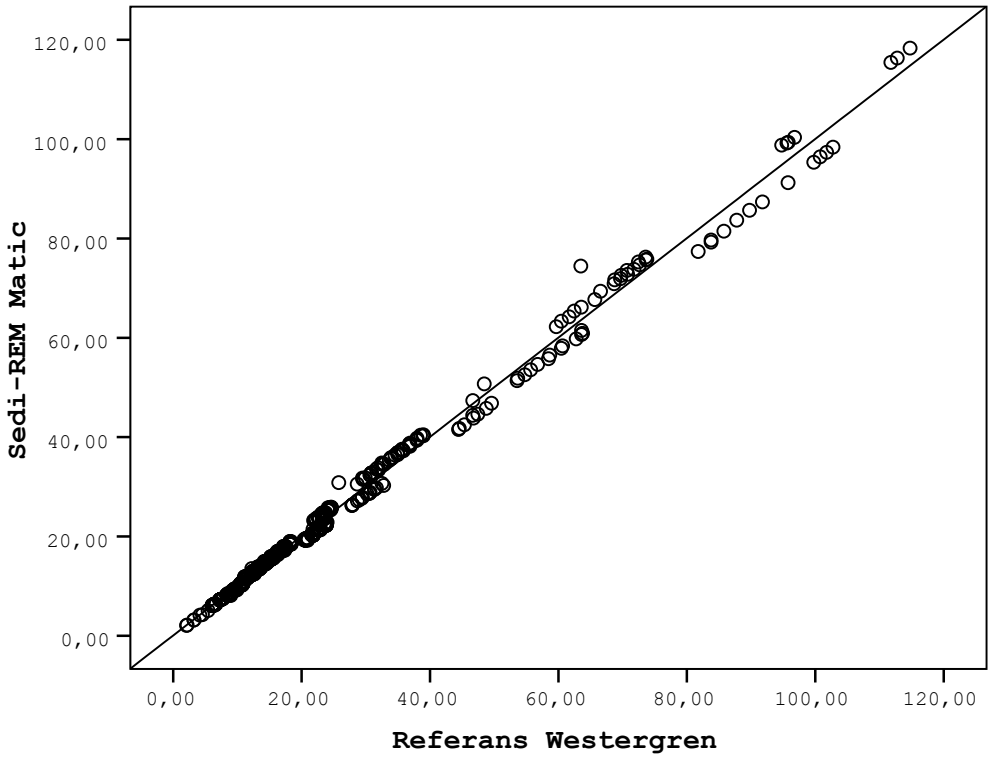

Figure 1 : Graphical view of results obtained by reference westergren method and Sedi-REM Matic demonstrates linear relationship

One-Sample Kolmogorov-Smirnov Test

		Sedi-REM	Westergren
N		800	800
Normal Parameters(a,b)	Mean	20,7764	20,7198
	Std. Deviation	17,14149	17,09818
Most Extreme Differences	Absolute	,231	,258
	Positive	,231	,258
	Negative	-,187	-,187
Kolmogorov-Smirnov Z		6,547	7,293
Asymp. Sig. (2-tailed)		,000	,000

a Test distribution is Normal. b Calculated from data.

Table 1: **Kolmogorov-Smirnov Test** was performed for determining whether data have normal distribution, and as a consequence, it was found that distribution is not normal($p<0.05$).

Correlations

			Sedi-REM	Westergren
Spearman's rho	Sedi-REM	Correlation Coefficient	1,000	**,997(**)**
		Sig. (2-tailed)	.	,000
		N	800	800
	Westergr.	Correlation Coefficient	**,997(**)**	1,000
		Sig. (2-tailed)	,000	.
		N	800	800

** Correlation is significant at the 0.01 level (2-tailed).

Tabe 2 : When it was found that data is not normally distributed for determining relationship between Sedi-REM matic and Reference Westergren Method, **Spearman's rho coefficient** was tested for **non-parametric Correlation coefficient**. As a consequence of the analysis, same sided relationship with rate of 99,7 % was found between Sedi-REM matic and Reference Westergren Method.

Mann Whitney U Test

Ranks

	group	N	Mean Rank	Sum of Ranks
values	Sedi-REM	800	803,26	642605,50
	Westergren	800	797,74	638194,50
	Total	1600		

Test Statistics(a)

	values
Mann-Whitney U	317794,500
Wilcoxon W	638194,500
Z	-,239
Asymp. Sig. (2-tailed)	**,811**

a Grouping Variable: grup

TABLE 3: In order to examine if a difference exists between two methods, **Mann Whitney U Test** was performed. As a consequence of the analysis, p value was found as p=0.811>0.05, there is no difference between Sedi-REM Matic Device and Reference Westergren method.

Kruskal-Wallis Test

Ranks

	device	N	Mean Rank
Sedi-REM	1st device	267	400,54
	2nd device	267	400,63
	3rd device	266	400,33
	Total	800	
Westergr.	1st device	267	399,67
	2nd device	267	401,13
	3rd device	266	400,70
	Total	800	

Test Statistics (a,b)

	Method 1	Method 2
Chi-Square	,000	,006
Df	2	2
Asymp. Sig.	**1,000**	**,997**

a Kruskal Wallis Test
b Grouping Variable: device

TABLE 4 : Kruskal Wallis Test is applied in order to examine whether there is any difference between 3 Sedi-REM Matic devices used in the study. As a consequence of the analysis, no significant difference can be found between 3 Sedi-REM Matic devices (p=1.000). For westergren method, no statistically significant difference can be found between three Sedi-REM Matic devices (p=0.997).

Definitive Statistical Values

Case Summaries

	Values		
group	N	Mean	Std. Deviation
Sedi-REM	800	20,7764	17,14149
Westergr.	800	20,7197	17,09818
Total	1600	20,7481	17,11452

Case Summaries **TABLE 5**

device		Sedi-REM	Westergr.
1st device	N	267	267
	Mean	20,7658	20,7178
	Std. Deviation	17,20264	17,20405
2nd device	N	267	267
	Mean	20,8652	20,8049
	Std. Deviation	17,36526	17,25143
3rd device	N	266	266
	Mean	20,6978	20,6362
	Std. Deviation	16,91672	16,90000
Total	N	800	800
	Mean	20,7764	20,7197
	Std. Deviation	17,14149	17,09818

DISCUSSION: ESR is a simple and cheap test method, which is widely used in clinics. However, it is used for diagnostic and treatment follow-up purposes in many inflammations, malignancies and infections. Westergren ESR method has been regarded as gold standard for more than 70 years. Clinical conditions such as sex, age, anemia, fibrinogen level and thyroid disorders as well as laboratory conditions dilution of the blood, duration of the test and angle of tubes may influence ESR results. Westergren method is a manual one. It is required to dilute blood before transferring it to the pipettes, later blood is mixed and tubes should be vertically placed on a holder using a pump after blood is transferred. Reading is made with eyes. Therefore, it is reported by many different sources that different results may be easily obtained and moreover, there is a non-negligible risk for technician (5). Today, many automatic systems are used as alternative to the Westergren method, regarded as gold standard. Many available devices provide results after reading is completed in 20-30 minutes. In those systems, precipitation is read within shorter times and the result is compared with westergren and thus, test result is obtained.(6) Sedi-REM MATİC performs classical 30-, 60- and 120-minute readings and results are provided at mentioned intervals. A single system may concurrently test 1000 tubes.

In this study conducted using **Seditainer 1.8 ml** tubes of BD company, it was observed that there is no difference between Sedi-REM Matic Device and reference Westergren method (p=0.811). In present study, correlation of new device with westergren was obtained as 99,7 percent. We believe that this result depends on the fact that Sedi-REM

MATIC device and westergren method relies on same principles. In this system, one-to-one corresponding results are obtained rather than estimations and up to 1000 results can be read and printed out due to high number of reader eyes at the end of one hour.

Moreover,

- It was observed that only sedimentation tubes of BD Company can be placed into the device.
- It was observed that all slots operate in a non-dependent manner. That is, a tube can be placed into the device at any time.
- Operating positions and completed positions of all tubes can be visualized on LCD display.
- It was observed that the device offers operation with or without Barcode.
- **In barcode assisted** operation, all patient information is automatically archieved when barcode is scanned.
- **In barcode assisted** operation, it was observed that options of sequential automatic operation or inquiry-based manual operation are possible.
- **In non-barcode operation,** patient details can be entered into the device using keyboard while study is continuing or when it stops.
- Patient details can be inquired from **archive**. All previous **sedimentation results** of the patient **are displayed** or the information **can be printed out**.
- Results are expressed in two decimals following comma.
- When operation of the device ends, results are either presented automatically as results of all patients printed on **A4 paper** or personal information and all previous results of individual patient can be printed on **A5 paper.** Personal results can be independently printed out manually, when test of the patient is completed.

Considering above mentioned features and high number of reader eyes, low device cost, ease of use, compatibility of results with those of Westergren method, we believe that it is a system suitable for laboratories.

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