

Assessment of Computer Assisted Technique for Measurement of Red Blood Cell Count by Automated Blood Analyzer (Sysmex KX-21N) in Comparison with the Conventional Method

*Yasar M.H. Al-Shamma MB.Ch.B. , Ph.D. (UK)

*Fouad Shareef Dleikh (MSc. , Ph. D).

*Nagam Yehya Gafel (MSc.)

*Sami R. Al-Katib (MSc. , Ph.D).

**Amal Salih Mehdi (MB.Ch.B. , DCH)

* Department of Physiology. Kufa College of Medicine.

** Unite of neonatology. Hilla Teaching Hospital.

الخلاصة

أجريت هذه الدراسة على عشرين شخصاً من الاصحاء لغرض تقييم جهاز (Sysmex automated blood analyzer) (KX21N) في قياس عدد كريات الدم الحمر وذلك بإتباع طريقتين، الأولى مقارنته بالطريقة التقليدية والتي تعتبر الطريقة القياسية في تعداد كريات الدم الحمر لمعرفة مدى دقة الجهاز المراد تقييمه وثانياً لمعرفة دقة الجهاز اثناء القراءات المتكررة والتي أظهرت نتائجها بان القياسات المتتالية للجهاز متقاربة جدا في القراءات المتكررة ولغرض البرهنة على دقة الجهاز استخدمت المعادلة الإحصائية التالية : $2SD/mean \times 100\%$ وقد أكدت هذه المعادلة على ان الجهاز المذكور والمستخدم في قياس تعداد كريات الدم الحمر قد أعطى قراءات متقاربة جدا ويمكن اعتماده في البحوث الطبية والمستشفيات لغرض قياس عدد كريات الدم الحمر عند الأشخاص الطبيعيين وعند المرضى كذلك.

Summary

This study was performed on twenty normal females in order to assess the accuracy of (Sysmex automated hematology analyzer KX-21N) for estimation of red blood cell count (RBCs). Two processes were used for this evaluation, the first is by calculating the systematic error to determine the accuracy of this device by comparison with the standard method and the second process is by testing the random error or reproducibility of the device.

The results of this study indicate that values of RBCs count measured by Sysmex automated analyzer were slightly higher than that measured by the standard methods, although they were statistically not significant.

The results of the random error which was improved by the statistical equation : $(2 SD/mean \times 100\%)$ indicate that the Sysmex automated hematology analyzer was accurate and reproducible and can be used in routine service and research.

Introduction

Automated blood analyzer is one of the recently developed electronic and computerized device for measurement of various blood parameters. However, it is very important to evaluate this instrument before using it in clinical practice or for research purposes. Nowadays electronic technique become preferable technique than the conventional one although the last one remains as accurate and standard method with minor errors⁽¹⁾.

Two processes have been used to assess the validity of any automatic electronic device: the first is called "evaluation of the accuracy of the device and the second process is to test the random error (reproducibility). These processes of evaluation have been used to assess different electronic devices such as measurement of blood pressure by automatic computerized blood pressure machine^(2, 3), estimation of blood glucose

level by electronic monitor device⁽⁴⁾, estimation of different blood parameters by MS9 hematology device^(5,6), and measurement of lung function test by Discom-14⁽⁷⁾.

This study was performed to evaluate the automated blood analyzer (Sysmex KX-21N) for measurement of red blood cell (RBCs) count in comparison with the conventional method in normal subjects and in patients with various hematological diseases.

Materials and Methods

This study was carried on twenty normal healthy women, their age was (19-45) with mean \pm SD (34.2 ± 5.3) in order to evaluate the automated blood analyzer (Sysmex-KX21N) which produced by (Sysmex corporation, Wakinoama-Kaigandori, Chui-Ku, and Kobe, Japan) for measurement red blood cell count want in comparison with the standard and conventional technique.

The measurements were made by taking 70 μ l of blood sample from volunteers, then the red blood cell count was done by 2 methods : the first method by the standard technique using 20 μ l of blood sample⁽⁹⁾, and the second test by the Sysmex automated analyzer using 50 μ l of the blood sample. All measurements were made at 10 minutes a steady state (steady state means that the heart rate changing by less than (2-3) beat per minute in successive measurement)⁽³⁾.

Two processes were made for the evaluation of Sysmex automated hematology analyzer (KX-21N) :

1. Systemic error

In order to determine the accuracy of Sysmex automated analyzer KX-21N, a comparison was made between the estimation of RBCs count by this instrument with that performed by using the standard technique. A comparison was made between the count of RBCs obtained by the standard method with that of Sysmex automated analyzer (KX-21N) on twenty normal females.

2. Random error

A duplicate estimates were made for each women involved in the study, by using the Symex automated analyzer (KX-21N), then the paired differences of each two estimates was determined in order to test the reproducibility of this device and by using 95% tolerance limit by the statistical equation : $2 \text{ SD}/\text{mean} \times 100\%$ ⁽¹⁰⁾.

Results

The result of this study concerning the evaluation of the comparison between the standard method and computer assisted technique for measurement of RBCs count was as following :

1. Systematic error

Comparison have been made between values of RBCs count measured by Sysmex automated analyzer KX-21N with that measured by the manual method on the same women. The results of this comparison indicate that values of RBCs count measured by automated hematology analyzer were slightly higher than that measured by standard or traditional method (Table 1 , Figure 1). However, statistical analysis indicates a non significant differences ($P > 0.05$) among their mean values.

Table (1) : Evaluation of RBCs count by Sysmex automated analyzer KX-21N (systematic error)

Parameter	Sysmex automated analyzer	Standard method	Difference	P value
RBCs count	5.53±0.35	5.17±0.37	0.64±0.22	P>0.05

* Values are mean ± standard deviation.

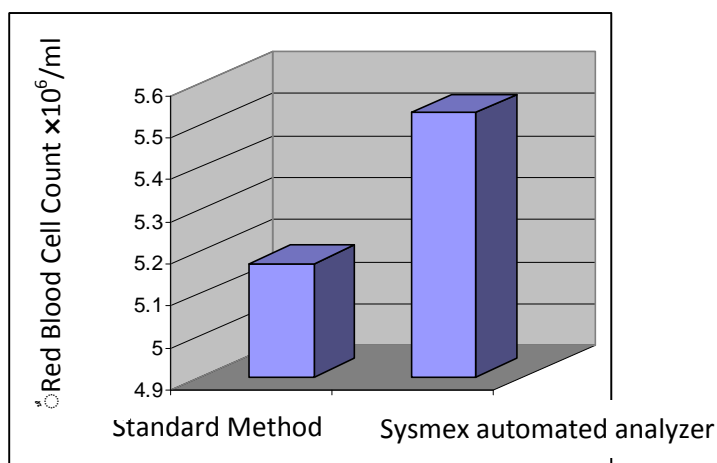


Figure (1) : Comparison between standard method and Sysmex automated analyzer regarding RBCs count.

2. Random error

To test the reproducibility of electronic measurement of RBCs count by Sysmex automated analyzer KX-21N, a duplicate estimate have been made on 20 normal females and then a paired difference between each two estimates have been made and taken 95% tolerance limit by the following equation :
 $2 \text{ SD}/\text{mean} \times 100\%$, as shown in table (2) :

Table (2) : Evaluation of Sysmex automated analyzer (random error)

Parameter	Mean value	Mean of paired differences	Standard deviation	95% tolerance limit	P value
RBCs count	5.53±0.37	0.64	0.22	7.9%	NS

NS : not significant .

Discussion

The results of this study indicate that values of RBCs count measured by Sysmex automated blood analyzer were slightly higher than that measured by the conventional method. However, many investigators have shown that the standard method for calculation of RBCs count give different values of RBCs count for the same subject. This variation in the results of the conventional method could be related to

visual bias, digital preferences and the subjective elements inherent in the standard analysis process⁽¹²⁾.

The random error which test the reproducibility of the Sysmex automated blood analyzer was made by taking the differences between pairs of estimates for RBCs count in consecutive measurements, thus the standard deviation of the differences between pairs of the results gives a measure predominately of the errors of the Sysmex automated analyzer and would not be greatly influenced by variation in the count of RBCs⁽⁸⁾.

The 95% tolerance limit⁽¹¹⁾ which is calculated by taken two standard deviations divided by mean value of RBCs count and multiplied by 100% ($2 \text{ SD}/\text{mean} \times 100\%$), the 95% tolerance limit for RBCs was 7.9%.

In conclusion, the Sysmex automated blood analyzer, was reproducible and can provide sufficiently accurate values for RBCs count and acceptable for use in routine service and research. It's performance was comparable to the conventional standard method^(7,10).

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