Evaluation of Sysmex Automated Hematological Analyzer (KX-21N) for the measurement of Blood Hemoglobin Level

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الخلاصة:

أجريت هذه الدراسة على عشرين شخصا من الأصحاء لغرض تقييم جهاز فحص نسبة الهيموغلوبين في الدم (Sysmex KX-21N) وذلك بإتباع طريقتين: أولا مقارنته بطريقة (Sahli) والتي تعتبر الطريقة القياسية في قياس مستوى الهيموغلوبين لمعرفة مدى دقة الجهاز المراد تقييمه. ثانيا لمعرفة دقة الجهاز أثناء القياسات المتكررة و التي أظهرت نتائجها بان القياسات المتتالية للجهاز متقاربة جدا في القيمة و لغرض البرهنة على دقة الجهاز استعملت المعادلة الإحصائية: (2SD/mean x 100%)

والتي تؤكد على أن جهاز يعطي قراءات دقيقة ويمكن استعماله في البحوث الطبية والمستشفيات الغرض منه قياس مستوى الهيموغلوبين في الدم عند الأصحاء وعند المرضى.

Abstract:

This study was carried out on twenty normal subjects (women) in order to evaluate (Sysmex Automated Hematological Analyzer KX-21N) for the estimation of blood hemoglobin level.

Two processes where used for evaluation, the first is the systematic error to determine the accuracy of the device by comparison with the standard device (the Sahli's) and the second process is to test the random error or reproducibility of Sysmex.

The result of this study indicate that values of Hb measured by Sysmex KX-21N were slightly higher than that measured by Sahli's method ($P<0.005$)

And the result of random error test indicates that the Sysmex KX-21N is reproducible device which is improved by using the statically equation:
(2SD/mean x 100%) to determine 95% tolerance limit of the device which indicate that the device is greatly reproducible.

Introduction:

The electronic techniques have been widely used in clinical practice. Most of these electronic techniques carried out by using different types of automatic electronic and computerized devices fort the measurement of various physiological and clinical variables. But it is very important to evaluate any automatic instruments before using it in clinical practice or in researchers.

Two processes have been used to evaluate any automatic electronic device: the first is to determine its systematic error (accuracy of device) and the second process is to test its random error (reproducibility). These processes of evaluation have been used to evaluate different automatic and electronic device such as measurement of cardiac output by a single breath method (1), measurement of blood pressure by automatic

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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), measurement of lung function test by Discom-14 (7) and evaluation of Spiro labII for the measurement of lung function test (8).

This study was carried out to evaluate Sysmex Automated Analyzer KX-21N which is used to measure different parameters of blood one of them blood hemoglobin level in normal subject and in patient with various hematological diseases.

Material and method:

This study was carried out on twenty normal healthy women there age (19-45 years) with mean ±S.D. (34.2±5.3 years) in order to evaluate Sysmex Automated hematological analyzer KX-21N which produced by (Sysmex corporation. Wakinohama-Kaigandori, Chuo-Ku, and Kobe, Japan) by comparison with standard technique for measurement of hemoglobin level in blood which is the Sahli (made by Marienfeld co., Ltd, Germany)

The measurements where made by taking 70 µl blood samples from volunteers, then blood hemoglobin level test was done by two methods: first Sahli's method using 20µl blood sample, and the second test by Sysmex automated analyzer using the second 50µl blood sample. All the measurements were made at 10 minutes at a steady state (steady state mean that the heart rate in consecutive minute changing by less than 3 beats/ min.) (3).

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

1- Systematic error

In order to determine the accuracy of Sysmex automated analyzer KX-21N, a comparison was made between the estimates of Hb performed by using the standard Sahli's method with that measurement by Sysmex automated analyzer KX-21N. Then a comparison was made between the estimates of Hb made using Sahli's method with that Sysmex automated analyzer KX-21N on twenty normal women.

2- Random error

Twenty normal women were involved in this test. Duplicate estimates were made for each subject by using the Sysmex automated analyzer KX-21N then the paired differences of each two estimates was determined in order to test the reproducibility or repeatability of this device and using 95% tolerance limit by the statically equation:
2SD/mean **x** 100% (9).

Result:

The result of this study concerning the evaluation is as follows:

1- Systematic error

Comparison have been made between values of Hb level measured by Sysmex automated analyzer KX-21N with that measured by the standard Sahli's method on the same women. The results of this comparison indicate that values of Hb measured by Sysmex automated analyzer KX-21N were slightly higher than that measured by Sahli's method
($P<0.005$) (Table 1, figure 1). The regression analysis of the estimates of Hb level made by Sysmex automated analyzer KX-21N and that by Sahli's method showing a significant correlation in relation to line of identify as.

Table- 1- Evaluation of Sysmex automated analyzer KX-21N (systematic error)

Parameter	Sysmex automated analyzer	Sahli's method	difference	P value
Hb	11.3±0.868	10.1±0.865	0.12±0.44	<0.005

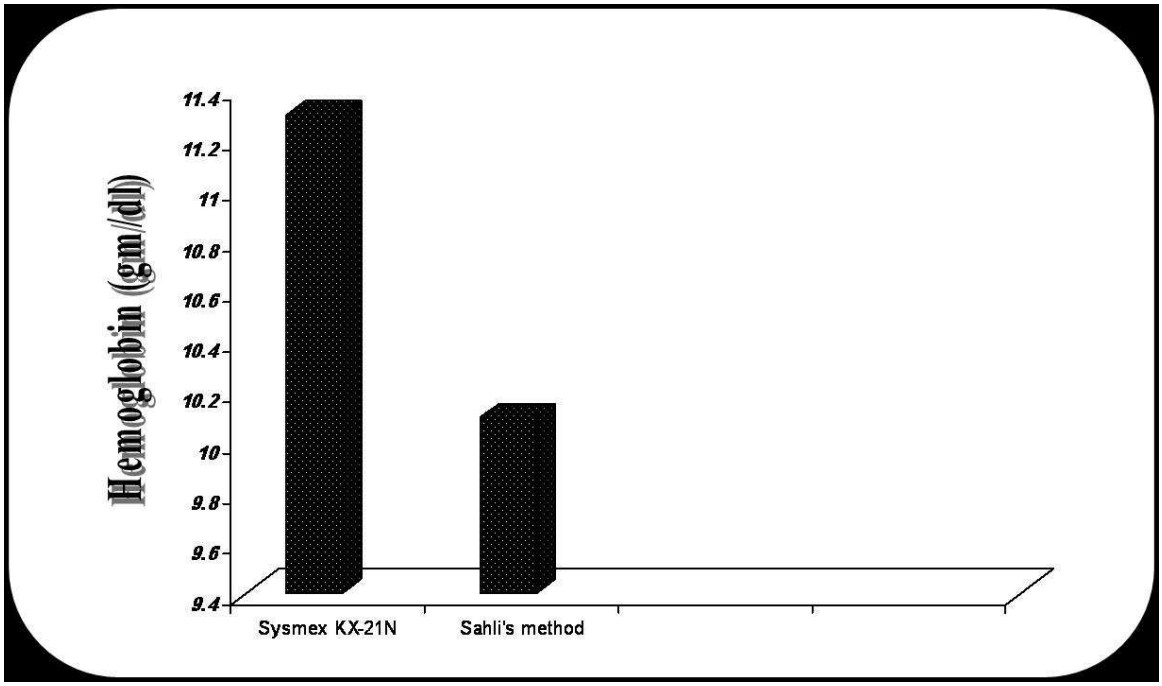

Fig.1 comparison between Sahli's method & Sysmex automated analyzer KX-21N reading regarding Hb

2- Random error

To test the reproducibility of Sysmex automated analyzerKX-21N, a duplicate estimate have been made in Sysmex automated analyzer KX-21N on 20 normal women and then a paired difference between each two estimates have been made, and taken 95% tolerance limit by taking:

2SD/mean **x** 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
Hb	11.5 ± 0.623	0.12	0.44	7.6%	N.S.

N.S. = not significant

Discussion:

The result of this study indicate that values of Hb measured by Sysmex automated analyzer KX-21N where slightly higher than measured by Sahli's method ($P<0.005$).

However, many investigations shown that the acid fast hematite method (the method employed by Sahli's method) gives different values of hemoglobin percent of the same subject when measured by Sysmex automated analyzer KX-21N which using (non-cyanide hemoglobin analysis method) (12). The regression analysis of estimates hemoglobin level indicates that there is significant correlation in relation to line of identity. This means that Sysmex automated analyzer KX-21N is an accurate device and can be used to measure hemoglobin level in blood (7, 10); also the increase in values of Hb by Sysmex automated analyzer KX-21N could be due to visual bias and digital preferences.

The random error which test the reproducibility of Sysmex automated analyzer KX-21N was made by taking the differences between pairs of estimates of Hb level in consecutive measurements in Sysmex automated analyzer, thus the standard deviation of the differences between the pairs of result gives a measure predominantly of the errors of the Sysmex automated analyzer KX-21N and would not be greatly influenced by variation of hemoglobin level (2).

The 95% tolerance limit which is calculated by taken two standard deviations divided by mean of estimated value multiply by 100% (2SD/mean x 100%) (9), the 95% tolerance limit of Hb equal to 7.6%.

In conclusion Sysmex automated analyzer KX-21N is simple, portable, easily handling device; it is reproducible and accurate device for the measurement of blood hemoglobin level in normal subjects and in patients.

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