Evaluation of APEL Digital Hemoglobin meter (HG-202) for the Measurement of Blood Hemoglobin Level.

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الخلاصة:

أجريت هذه الدراسة على ثلاثين شخصاً من الأصحاء لغرض تقييم جهازفحص نسبة الهيموغلوبين في الدم(Apel HG-202) وذلك بإتباع طريقتين:أولاً مقارنته بطريقة (Sahli) والتي تعتبر الطريقة القياسية في قياس مستوى الهيموغلوبين لمعرفة مدى دقة الجهاز المراد تقييمه.ثانياً لمعرفة دقة الجهاز أثناء القياسات المتكررة والتي أظهرت نتائجها بان القياسات المتتالية للجهاز متقاربة جداً في ألقيمه ولغرض البرهنة على دقة الجهاز استعملت ألمعادله الاحصائيه:

2SD/mean x100%

والتي تؤكد على أن جهاز (Apel HG-202) يعطي قراءات دقيقه ويمكن استعماله في البحوث الطبية والمستشفيات لغرض قياس مستوى الهيموغلوبين في الدم عند الأصحاء وعند المرضى.

Abstract:

This study was carried out on thirty normal subjects in order to evaluate (Apel Hemoglobin meter HG-202) 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 Apel.

The results of this study indicate that values of Hb measured by Apel HG-202 were slightly higher than that measured by Sahli's method ($p<0.005$)

And the result of random error test indicate that the Apel HG-202is reproducible device which is proved by using the statistical equation (2SD/mean x100%) 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 for the measurement of various physiological and clinical variables. But it is very important to evaluate these automatic instruments before using it in clinical practice or in researches.

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 devices such as measurement of cardiac output by a single breath method (1), 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), measurement of lung function test by Discom-14(7)and evaluation of spirolabII for the measurement of lung function test(8) .

This study was carried out to evaluate Apel hemoglobin meter which is used to measure blood hemoglobin level in normal subjects and in patients with various hematological diseases.

Materials and method:

This study was carried out on thirty normal healthy subjects there age range (20-40 years) with mean ±S.D. (31.40±7.37year) in order to evaluate Apel hemoglobin meter HG-202 (produced by Apel Co.,Ltd. Kawaguchi, Saitama,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 40µℓ blood sample from volunteers, Then blood hemoglobin level test was done by two methods: first Sahli's method using 20 µℓ blood sample, and the second test by Apel hemoglobin meter using the second 20 µℓ blood sample. All the measurements were made at 10 minutes of a steady state (steady state mean that the heart rate in consecutive minute changing by less than 3beats /min.) (3).

Two processes were made for the evaluation Apel hemoglobin meter:-

1. Systematic error

In order to determine the accuracy of Apel hemoglobin meter, a comparison was made between the estimates of Hb performed by using the standard Sahli's method with that measured by Apel hemoglobin meter. Then a comparison was made between the estimates of Hb made using Sahli's method with that of Apel hemoglobin meter on thirty normal subjects.

2. Random error

Thirty normal subjects were involved in this test. Duplicate estimates were made for each subject by using the Apel hemoglobin meter 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 statistical equation:

2SD/mean x100 % (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 Apel hemoglobin meter with that measured by the standard Sahli's method on the same subjects.

The results of this comparison indicate that values of Hb measured by Apel HG-202 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 Apel hemoglobin meter and that by Sahli's method showing a significant correlation in relation to line of identity as shown in figure 2.

Table-1-Evaluation of Apel hemoglobin meter (systematic error)

parameter	Apel hemoglobin meter	Sahli's method	difference	P value
HB	13.16 ± 1.57	12.41 ± 1.55	0.28 ± 0.45	<0.005

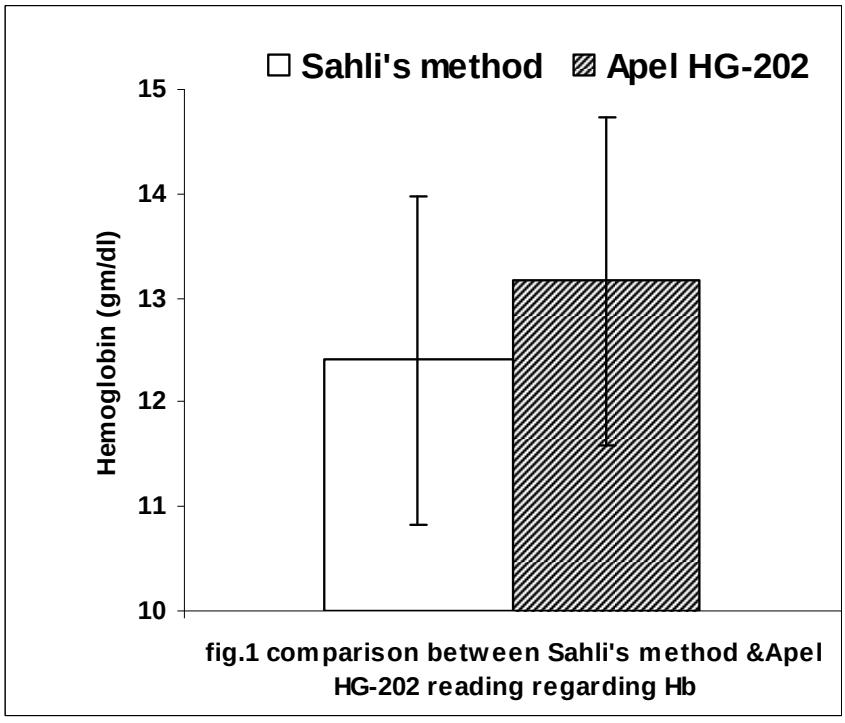

fig.1 comparison between Sahli's method &Apel HG-202 reading regarding Hb

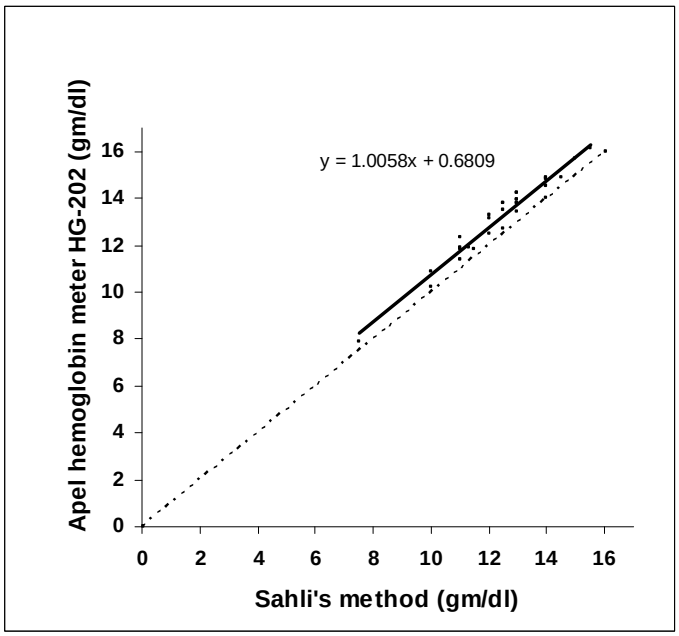

Fig.2 comparison between values of hemoglobin level made by Ape hemoglobin meter with that measured by Sahli's method.

Note:-the doted line is line of identity (line of no change).

-the solid line is the regression line.

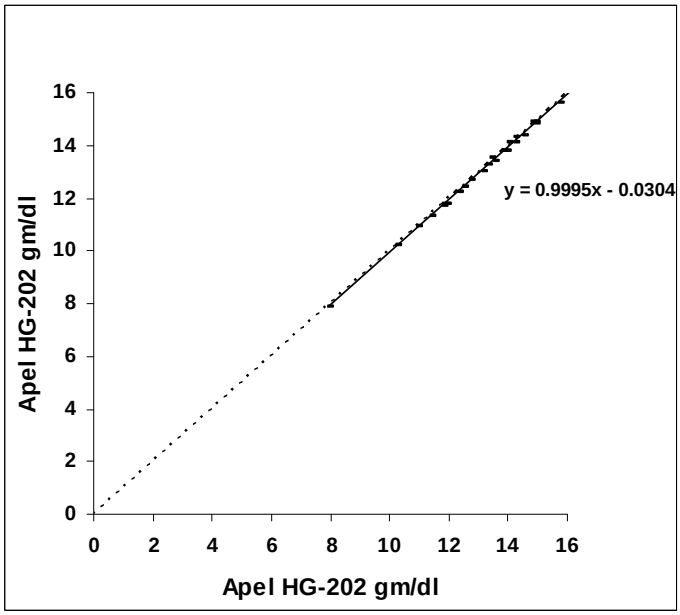

Fig.3: comparison between values of Hb measured by Apel hemoglobin meter (random error).
Note:-the doted line is line of identity (line of no change).
-the solid line is the regression line.

2. Random error

To test the reproducibility of Apel hemoglobin meter, a duplicate estimate have been made in Apel hemoglobin meter on 30 normal subjects 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 Apel hemoglobin meter (random error)

parameter	Mean value	Mean of paired differences	Standard deviation	95%Tolerance limit	P value
Hb	13.16 ± 1.55	0.28	0.45	6.8%	.N.S

N.S= not significant

Discussion:

The results of this study indicate that values of Hb measured by Apel HG-202 where slightly higher than that measured by Sahli's method ($p<0.005$).

However, many investigations shown that the cyanide methemoglobin method (the method employed by Apel HG-202 hemoglobin meter) gives different values of hemoglobin percent of the same subject when measured by Sahli's method ([12]).

Also the regression analysis of estimates hemoglobin level indicates that there is significant correlation in relation to line of identity. This means that Apel hemoglobin meter HG-202 is an accurate device and can be used to measure hemoglobin level in blood ([7, 10]),also the increase in value of Hb measured by Apel HG-202 hemoglobin meter could be due to visual bias and digital preferences.

The random error which test the reproducibility of Apel hemoglobin meter HG-202 was made by taking the differences between pairs of estimates of hemoglobin level in consecutive measurements in Apel hemoglobin meter HG-202, thus the standard deviation of the differences between the pairs of results gives a measure predominantly of the errors of the Apel hemoglobin meter HG-202 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 multiplied by 100% (2SD/mean x100%)([9]),The 95% tolerance limit of Hb is 0.26%.

In conclusion Apel hemoglobin meter HG-202 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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