

The agreement between hematological indices obtained from two laboratories

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Abstract

Introduction: Agreement between hematological indices obtained by different laboratories has been shown to be unsatisfactory in the past.

Objectives: To evaluate the agreement between the hemoglobin concentrations (Hb) and between the hematocrits obtained from two laboratories.

Method: Consecutive pregnant women (n = 350), with gestations between 12 to 20 weeks, presenting to the Academic Obstetric Unit at the Teaching Hospital Mahamodera Galle (THMG), from 10 November 2014 to 13 January 2015 had their Hb and hematocrit measured by flow-cytometry and hydro-dynamic focusing methods at the Durdan's Hospital Laboratory, Galle (DHLG) and the colorimetric method at the laboratory of the THMG (THMGL). The agreement between the Hb values and between the hematocrit values obtained from the two laboratories were assessed by comparison of means, Pearson's correlation, and the calculation of the limits of agreement and the clinical limits of indifference.

Results: No significant differences were seen between the mean Hb values and between the mean hematocrit values obtained from the two laboratories. Strong, positive correlations were seen between the Hb values as well as between the hematocrit values obtained from the two laboratories ($r=0.86$, $p < 0.01$ and $r=0.83$, $p < 0.01$ respectively). The limits of agreement and the clinical limits of indifference between the Hb as well as between the hematocrit values obtained from the two laboratories were satisfactory, but individual differences of $> 10\%$ were seen in 6.6% of results

Conclusion: Although there was good agreement between the Hb values as well as between the hematocrit values obtained from the two laboratories, individual differences of $> 10\%$ were seen in 6.6% of cases.

Key words: Agreement, Hematological indices, Anemia, Iron deficiency, Pregnancy, Sri Lanka

INTRODUCTION

One of the challenges faced by clinicians is when laboratory investigations do not match the clinical impression of a patient's condition, and when the investigation is repeated, significant intra

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and inter laboratory variations are seen. It is not uncommon for a pregnant woman who appears to be clinically very pale and anemic at 38 weeks gestation and therefore appears to need a blood transfusion prior to the onset of labor, to be found to have a hemoglobin concentration (Hb) of 10g/dl on checking her full blood count (FBC), and in which case a blood transfusion would not be indicated. Similarly, it is not uncommon for a pregnant woman to be referred to a teaching hospital from a peripheral hospital where a FBC has shown her Hb to be 8 g/dl at 38 weeks gestation, and when the FBC is repeated at the teaching hospital, the Hb is found to be 10 g/dl. A previous study carried out on pregnant women presenting for

antenatal care to the Academic Obstetric and Gynaecology unit at the Teaching Hospital Mahamodera Galle (THMG) demonstrated that hematological indices obtained from different laboratories using different methods of measurement, significantly differed from each other¹. Therefore the objective of the current study was to assess the agreement between Hb measurements as well as between hematocrit measurements obtained from two laboratories using two different methods.

METHOD

Samples of blood were obtained from 350 consecutive pregnant women with gestations between 12 to 20 weeks, presenting to the antenatal clinic of the Academic Obstetrics and Gynaecology unit at the THMG, Sri Lanka from 10th November 2014 to 13th January 2015. Subjects who were recruited for a study on the rate of anemia and iron deficiency in pregnancy, were used for the current study too. When venous blood was drawn for the routine antenatal investigations including the Full blood count (FBC) at the THMG, an additional five ml of blood was obtained for FBC and serum ferritin (SF) assay and sent to the Durdan's Hospital Laboratory, Galle (DHLG), for the study on the rate of anemia and iron deficiency in pregnancy, as facilities for assessment of SF were not available in the THMG laboratory. The hemoglobin concentration (Hb) and the hematocrit were measured by flow-cytometry and hydro-dynamic focusing methods using a Sysmex-XS-500i System (Diamond Diagnostics, Holliston, USA) in the DHLG and the Colorimetric method using a Mindray BC-5800 Hematology Analyzer (Mindray, Shenzhen, China) at the THMG.

Continuous variables with parametric distributions are presented as means with 95% confidence intervals (CI). Ordinal variables are presented as medians with inter-quartile ranges. Nominal variables are presented as percentages. The



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Table 1. Characteristics of the study population. (n=350)

Age in years	Range	13 - 42
	Mean (95% CI)	27.4 (26.7 – 28)
	SD	6.1
Gestational age	Range	12 - 20
	Mean (95% CI)	15.9 (15.7 – 16.2)
	SD	2.6
Parity	Range	1 – 6
	Median (IQR)	1 (1 – 2)
Education	Grade 1-5	18 (5%)
	Grade 6-10	57 (16%)
	O/L qualified	114 (33%)
	Up to A/L	89 (25%)
	A/L qualified	44 (12%)
	Diploma or Degree	25 (7%)
Occupation	Housewife	265(76%)
	Professional	22 (6%)
	Skilled worker	15 (4%)
	Others	48(14%)
Monthly family income in thousand rupees	Median (IQR)	25 – 30 (20 – 40)
	Range	10 – 100
Gestational age at registration 12-16 weeks		213 (60.9%)
Received iron supplements before registration between 12-16 weeks		23(6.5%)
Gestational age at registration 17-20 weeks		137 (39.1%)
Received iron supplements before registration between 17-20 wks		34 (9.7%)

Table 2. Hematological indices obtained from two laboratories (n=350)

		Durdans Hospital Laboratory, Galle	Laboratory of Teaching Hospital Mahamodara Galle	p *
Hemoglobin g/dl	Mean (95% CI)	11.6 (11.4-11.7)	11.6 (11.4-11.7)	0.598
	Range	8.7-13.9	9.4-13.9	
Hematocrit %	Mean (95% CI)	33.8 (33.3-34.2)	34.0 (33.6-34.5)	0.750
	Range	29.4-43.2	28-4	
Serum Ferritin µg/L	Mean (95% CI)	47.7 (42.3-53.1)	-	-
	Range	9.1-154.9		

* by comparison of means using t-test

agreement between the Hb and hematocrit results obtained from THMGL and the DHLG were assessed using comparison of means using the t test, Pearson's Correlation Coefficient, Bland Altman's method of limits of agreement, based on the comparison of the individual differences between two measurements against the average of the two measurements [2] and the clinical limits of indifference described by Indrayan [3]. In Indrayan's method the clinically tolerable maximum individual difference between the two measurements must be pre-defined either as an absolute value or as a percentage difference. The clinically tolerable maximum individual difference between the two laboratories was considered to be a difference of 10% more or 10% less than the Hb and hematocrit values obtained from the DHLG.

The Statistical Package for Social Sciences (SPSS version 20) was used for data analysis. Approval for the study was obtained from the Ethical Review Committee, Faculty of Medicine, University of Ruhuna and the Director of the (THMG), and informed written consent was obtained from all the participants of the study.

RESULTS

The characteristics of the study population are shown in Table 1. There were no significant differences between the mean Hb values obtained from the two laboratories as well as the mean hematocrit values obtained from the two laboratories (Table 2). There were very good positive correlations between the Hb values obtained from the two laboratories as well as the hematocrit values obtained from the two laboratories. ($r = 0.86$, $p < 0.001$ and $r = 0.83$, $p < 0.001$ respectively)

The limits of agreement between the Hb values obtained by the two laboratories and the limits of agreement between the hematocrit values obtained by the two laboratories had 95% CI ranging from -0.99 g/dl to +0.99g/dl and -3.36% to +3.00 % respectively. (Table 3, Figures 1 and 2). The Hb values obtained from the THMGL were > 10% lower than the Hb values from the DHLG in eight subjects and > 10% higher than the Hb values from the DHLG in two subjects (Figure

Table 3. The limits of agreement between the hemoglobin and hematocrit values obtained from two laboratories⁵. (n- 350)

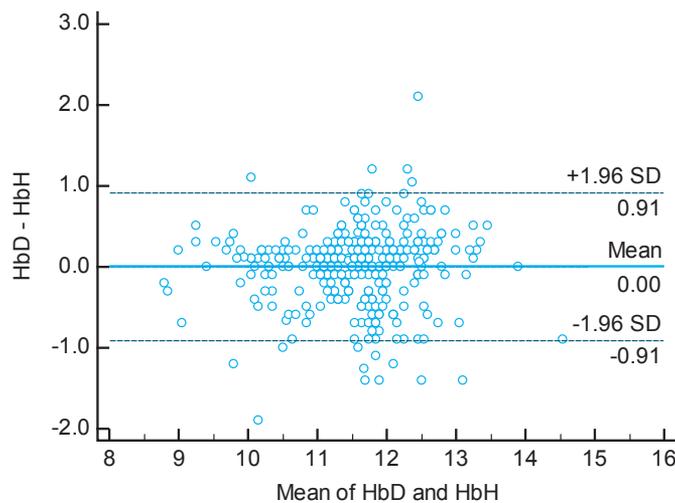
	Upper limit of agreement (95% Confidence Interval)	Lower limit of agreement (95% Confidence Interval)
Hb DHLG vs Hb THMGL	0.91(0.82 to 0.99)	-0.91 (-0.99 to -0.82)
Hct DHLG vs Hct THMGL	2.73 (2.46 to 3.00)	-3.10 (-3.36 to -2.83)

Hb=Hemoglobin, Hct =Hematocrit

DHLG = Durdans Hospital Laboratory Galle.

THMGL = Laboratory of Teaching Hospital Mahamodera Galle.

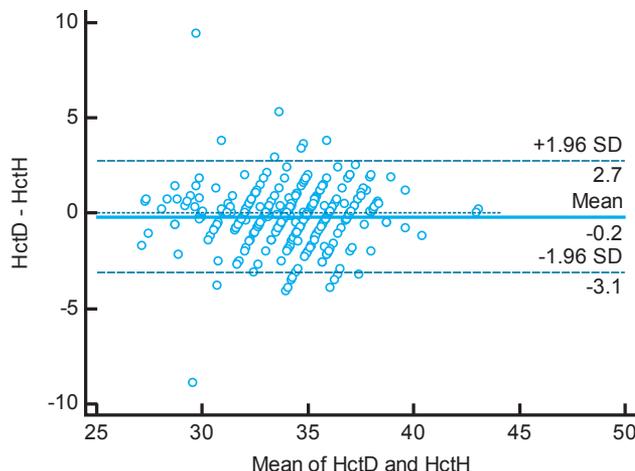
Figure 1. The limits of agreement between the hemoglobin values obtained by two laboratories⁵ (n- 350)



HbD = Hemoglobin values from the Durdans Hospital Laboratory Galle

HbH = Hemoglobin values from Laboratory of Teaching Hospital Mahamodera Galle

Figure 2 The limits of agreement between the hematocrit values obtained by two laboratories⁶ (n- 350)



HctD = Hematocrit values from the Durdans Hospital Laboratory Galle

HctH = Hematocrit values from Laboratory of Teaching Hospital Mahamodera Galle

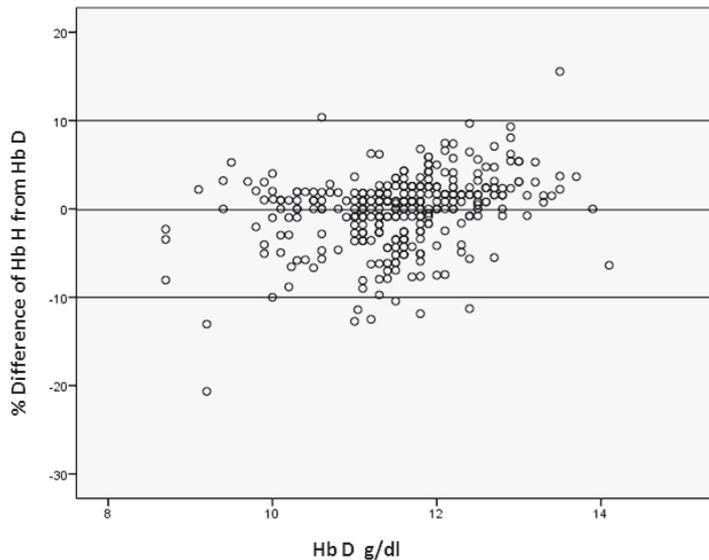
3). The hematocrit values obtained from the THMGL were > 10% lower than the hematocrit values from the DHLG in four subjects and > 10% higher than the hematocrit values from the DHLG in nine subjects (Figure 4).

DISCUSSION

Although the agreement between hematological indices obtained from different laboratories in Galle have been shown to be unsatisfactory in the past [1], they currently appear to have better agreement. This could be due to improvements in the techniques currently used in different laboratories to measure hematological indices as well as the adoption of quality assurance measures. Although comparisons of the means of Hb obtained by the two laboratories and the means of hematocrit obtained by the two laboratories demonstrated near perfect agreement, and very good correlations were seen between the Hb values obtained by the two laboratories as well as the hematocrit values obtained by the two laboratories, these are not reliable methods of assessing agreement between two measurements of the same parameter obtained by two laboratories [2, 3]. Although the limits of agreement (also referred to as limits of disagreement) were narrow, assessment of the clinical limits of indifference demonstrated that in a few instances significant differences were seen between the Hb values obtained from the two laboratories, as well as between the hematocrit values obtained from the two laboratories, from the same sample of blood taken from a patient. Therefore the importance of repeating the FBC and also taking into consideration the clinical picture, needs to be stressed.

The strength of this study is the fact that not only the recommended Bland Altman method of obtaining the limits of agreement (or disagreement) between two results, but also Indrayan's method of setting up of pre-determined clinical limits of individual differences between two results, which could be tolerated without a risk to affecting changes in patient management, were also used to assess the agreement of results from the two laboratories. Indrayan's method also enables the assessment of small and big individual differences as well as a proportional bias, which are not possible with the Bland Altman method. The

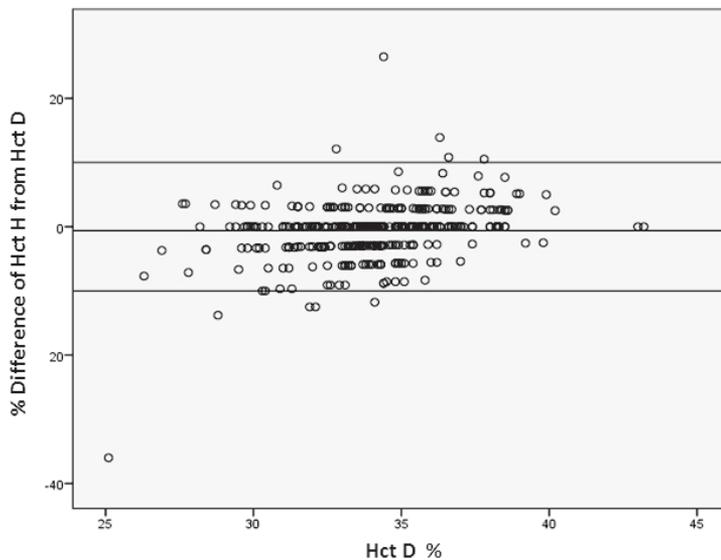
Figure 3. The clinical limits of indifference between the hemoglobin values obtained from two laboratories⁶ (n- 350)



HbD = Hemoglobin values from the Durdans Hospital Laboratory Galle

HbH = Hemoglobin values from Laboratory of Teaching Hospital Mahamodera Galle

Figure 4. The clinical limits of indifference between the hematocrit values obtained from two laboratories⁶ (n- 350)



HctD = Hematocrit values from the Durdans Hospital Laboratory Galle

HctH = Hematocrit values from Laboratory of Teaching Hospital Mahamodera Galle

consideration that a difference of Hb > 10% could affect the clinical management of chronic anemia or acute blood loss while a difference of > 10% in hematocrit could affect the clinical management of other conditions such as dengue hemorrhagic fever, was the basis for the setting of these clinical limits of indifference for the application of Indrayan’s method.

In conclusion, although overall agreement between the Hb values as well as between the hematocrit values obtained from the two laboratories were good, individual differences of > 10% were seen in 6.6 % of cases.

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