Original Aticle

Evaluation of Hemoglobin Screening Methods in Prospective Blood Donors by Using Hemoglobin Photometers

Kulvara Kittisares, Parichart Permpikul, Janejira Kittivorapart, Usanee Siriboonrit, Waraporn Meesamat, Amporn Vongpattaranon, Phayom Dareepat

Department of Transfusion Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University

Abstract:

Objectives: *This study aims to evaluate the current hemoglobin screening methods for prospective blood donors in Thailand.* ***Materials and Methods:*** *Fingerstick capillary blood samples and venous blood samples were obtained from blood donors and measured hemoglobin concentration by two hemoglobin photometers (Hemocue 301 and DiaSpectT System) and Sysmex XS800i.* ***Results:*** *The comparison analysis showed a good correlation between both hemoglobin screening methods and the venous-Sysmex method (the gold standard), for fingerstick-Hemocue 301 r = 0.87 and r^2 = 0.75 and for fingerstick-DiaSpectT r = 0.84 and r^2 = 0.70. The mean hemoglobin concentration of the venous-Sysmex method was 14.24 ± 1.21 g/dL (11.5-17.7 g/dL). The mean hemoglobin concentration of fingerstick-Hemocue 301 method was 14.75 ± 1.28 g/dL (difference 0.51 ± 0.65 g/dl, p < 0.01). The mean hemoglobin concentration of fingerstick-DiaSpectT method was 14.27 ± 1.35 g/dl (difference 0.03 ± 0.74 g/dL, p = 0.52).* ***Conclusion:*** *Hemoglobin concentration from the hemoglobin screening methods by hemoglobin photometers had a good correlation with the result from the gold standard method, but there was variation of accuracy according to the types of hemoglobin photometers.*

Keywords : ● *Blood donation* ● *Hemoglobin screening* ● *Hemoglobin photometer* ● *Capillary hemoglobin*

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Introduction

To prevent the donation from pre-existing anemic donors and unacceptable anemia in blood donors after donation, hemoglobin concentration screening before blood donation is an important step in the donation process. Appropriate method and cut off value of hemoglobin are crucial points to be considered. This step of blood donation affects both the quality of blood components and blood donors' health. Undetectable inappropriate hemoglobin screening methods can cause anemia in blood donors, decrease the donor return rate and loss of blood donors from the donor pools[1]. On the other hand, false low hemoglobin screening methods cause loss of appropriate donors. Accuracy of the hemoglobin screening methods should be evaluated. In Thailand, the fingerstick capillary blood are used for hemoglobin concentration measurement before donation as a screening method[2]. In the past, the CuSO4 specific gravity method was commonly applied to measure hemoglobin concentration for screening blood donors. Hemoglobin photometers were introduced to blood collection work and widely used in the blood centers around the world because of its portability,

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Requests for reprints should be addressed to Kulvara Kittisares, M.D., Department of Transfusion Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University, 2 Pranok Rd., Bangkok-noi, Bangkok 10700, Thailand. Tel +6624198081 fax +6624128419

Email kulvara.kit@mahidol.ac.th

convenience and power to discriminate unacceptable blood donors[3-9]. There were a number of studies about accuracy of hemoglobin photometers, mostly reported a good correlation with the gold standard, venous hemoglobin measured by automated hemoglobin analyzers[5-7]. However, there was varied accuracy of hemoglobin concentration results[3-7]. In Thailand, Hemocue was the first hemoglobin photometer introduced to the blood centers since 2007. However, there were several studies reported significant high hemoglobin concentration results measure by Hemocue, varied from 0.24 to 0.78 g/dL higher than the gold standard, which caused a significant percentage of blood donations from unacceptable donors[3,4,7].

In this study, we were interested in the accuracy of two types of hemoglobin photometers, Hemocue 301 hemoglobin photometer (HemoCue, Angelholm, Sweden) and DiaSpectT System hemoglobin photometer (DiaSpectT System, Medical GmbH, Germany), which were currently used in Thailand and the correlation between these screening methods and the gold standard method.

Materials and Methods

Prospective blood donors who attended the blood donation center at Department of Transfusion Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University (Bangkok, Thailand) were enrolled to the study during December 2011 to February 2012. Donors who did not meet the institute's standard criteria for blood donation were excluded. Autologous blood donors were also excluded from the study. Informed consents were attained from participated blood donors.

The participated blood donors were allocated into two groups to minimize effect of difference between second and third drops of fingerstick blood samples. Capillary blood samples were obtained by the fingerstick method from donors when they were in sitting position. Fingerstick was done at any lateral site of the tip of index or middle finger by a disposable lancet. The first drop of blood was discarded. From 125 donors, the second drops of capillary blood were collected and tested by Hemocue 301 and the third drops were tested by DiaSpectT. From 127 donors, the second drops were tested by DiaSpectT and the third drops were tested by Hemocue301. Only the donors whose hemoglobin more than 12.5 g/dL by Hemocue301 tests went on blood collection process. The blood collection was done by standard technique while the donor was in semi-Fowler's position on a blood donation chair. Two milliliter of EDTA blood was obtained from a diversion pouch bag and used as venous blood sample. The venous blood samples were tested by Hemocue 301 hemoglobin photometer, DiaSpectT system hemoglobin photometer and automated hemoglobin analyzer, Sysmex XS800i.

Statistical analysis was performed using SPSS (version 17.0, Chicago, Ill., USA) under MUIT network. Characteristics of the donors were shown as percentage and mean ± SD. Unpaired sample *t*-tests was used to determine significance of difference between the second drops and the third drops. The hemoglobin concentration of venous blood sample measured by SysmexXS800i was considered as the gold standard. Paired sample *t*-tests were used to determine significance of difference between the hemoglobin photometer methods and the gold standard method. Linear regression analysis was performed to determine the strength of the relationship between the screening methods (fingerstick-Hemocue 301 and fingerstick-DiaspectT) and the gold standard method. A p-value of < 0.05 was considered significant. All procedures were approved by the Siriraj Institutional Review Board.

Results

Two hundred fifty three blood donors were enrolled to this study. One blood donor whose capillary hemoglobin measured by Hemocue 301 less than 12.5 g/dL was deferred and excluded from statistical analysis. All were healthy donors who met Siriraj Blood

Donation Center's standard criteria for blood donation. No immediate complication was seen during the fingerstick sampling and the collection process.

Characteristics of the donors are shown in Table 1. There was no significant difference between the mean of hemoglobin of the second and the third drops of fingerstick capillary blood samples, as shown in Table 2. The comparison analysis showed a good correlation between both hemoglobin screening methods and the venous-Sysmex method (fingerstick-Hemocue 301 r = 0.87 and r^2 = 0.75 and fingerstick-DiaSpectT r = 0.84 and r^2 = 0.70). The linear regression equations for fingerstick-Hemocue 301 (Y = 2.103 + 0.823X) and fingerstick-DiaspectT (Y = 3.47 + 0.755X) were calculated as shown in Figure 1. The mean of hemoglobin concentration of fingerstick and venous blood samples measured by the two hemoglobin photometers (HemoCue 301 and DiaSpectT) and by the automate hemoglobin analyzer (Sysmex XS800i) are demonstrated in Table 3. The mean hemoglobin concentration from fingerstick-Hemocue 301 method was 14.75 ± 1.28 g/dL significantly higher than the venous-Sysmex method with the mean difference of 0.51 ± 0.65 g/dL ($p < 0.01$). The mean of hemoglobin concentration from fingerstick-DiaSpectT method was 14.27 ± 1.35 g/dL, not significantly different from the

Table 1 Characteristics of the blood donors, n = 252

Male donors	159 (63.09%)
First time donors	73 (28.97%)
Age, mean(year)	39.87 (18-60)
Weight, mean(kilogram)	68.47 (50-120)
Number of donations, mean	10.58 (1-119)

Table 2 Comparison of hemoglobin concentration in the second drops and the third drops of fingerstick capillary blood samples

Methods	Hemoglobin concentration mean ± SD (g/dL)		p
	2nd drop	3rd drop	
HemoCue301	14.77 ± 1.28	14.73 ± 1.29	0.89
DiaSpectT	14.20 ± 1.32	14.35 ± 1.37	0.37

2nd drop = Hemocue301 and 3rd drop = DiaSpectT, n = 125

2nd drop = DiaSpectT and 3rd drop = Hemocue301, n = 127

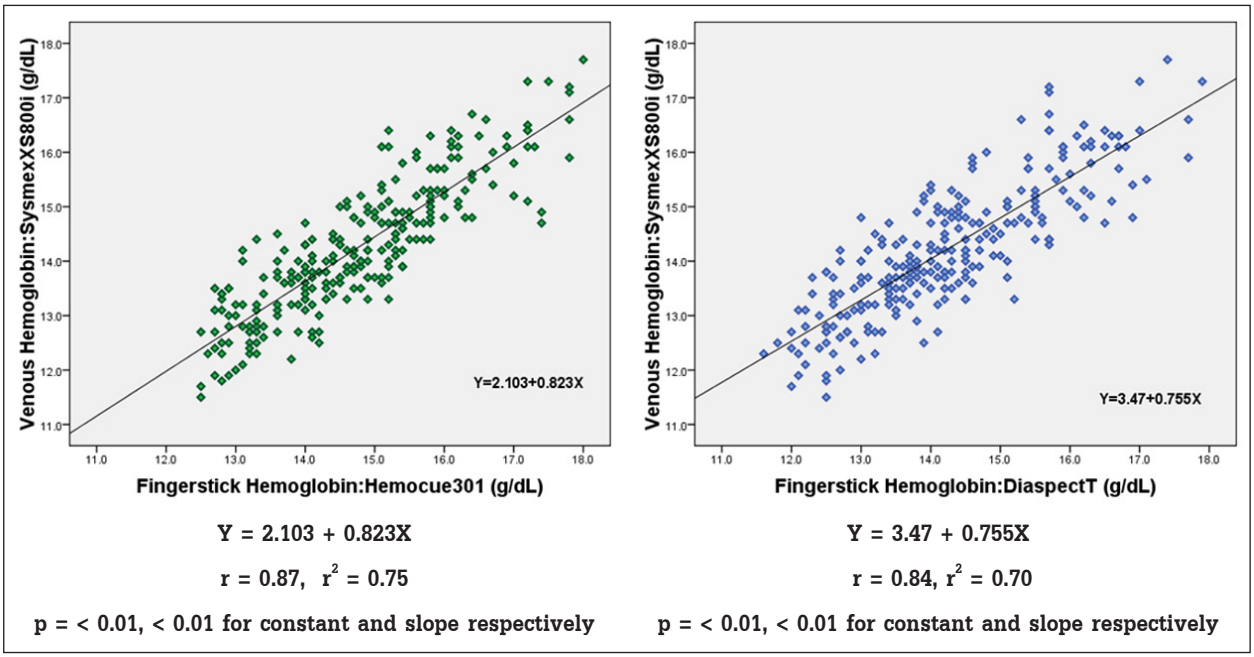

Figure 1 Linear regression analysis of fingerstick hemoglobin versus venous hemoglobin

Table 3 Hemoglobin concentration of fingerstick and venous samples measured by 3 different methods, n = 252

Sample	Method	Hemoglobin Mean ± SD (g/dL)	Min-Max (g/dL)	Mean difference from Sysmex XS800i (g/dL)	p-value
Fingerstick	HemoCue301	14.75 ± 1.28	12.5-18.0	0.51 ± 0.65	< 0.01
	DiaSpectT	14.27 ± 1.35	11.6-17.9	0.03 ± 0.74	0.52
Venous	HemoCue301	14.98 ± 1.23	12.4-18.6	0.74 ± 0.24	< 0.01
	DiaSpectT	14.37 ± 1.23	11.6-17.6	0.12 ± 0.25	< 0.01
	SysmexXS800i	14.24 ± 1.21	11.5-17.7	N/A	N/A

N/A = not applicable

venous-Sysmex method with the mean difference of 0.03 ± 0.74 g/dL (p = 0.52). The mean hemoglobin concentration of venous-Hemocue 301 method was 14.98 ± 1.23 g/dL, significantly higher than the venous-Sysmex method with the mean difference of 0.74 ± 0.24 g/dL (p < 0.01). Likewise, the mean hemoglobin concentration of venous-DiaSpectT method was 14.37 ± 1.23g/dL, also significantly higher than the venous-Sysmex method with the mean difference of 0.12 ± 0.25 g/dL (p < 0.01).

In this study, which the fingerstick-Hemocue301 method was used as a screening method, 14 donors (5.5%) had venous hemoglobin < 12.5 g/dL (mean 12.08 g/dL, range 11.5-12.40 g/dL).

Discussion

Both hemoglobin photometers were evaluated by using the blood samples from the same donors. Therefore, blood donors were allocated into two groups to minimize effect of difference between second and third drops of fingerstick blood samples. In the first group of donors, the second drop was tested by Hemocue 301 and the third drop was tested by DiaspectT. In the second group, the second drop was tested by DiaspectT and the third drop was tested by Hemocue 301. No significant difference between the mean of hemoglobin of the second and the third drops was demonstrated, and then the results from both second and third drops can be used for analysis.

The hemoglobin concentration of the screening methods, both fingerstick-Hemocue 301 and fingerstick-DiaspectT, had a good correlation with the gold standard (the venous-Sysmex), r = 0.87 and r = 0.84 respectively. However, as found in several reports[3,4,6], the capillary hemoglobin concentration measured by Hemocue 301 was significantly higher than the gold standard with the mean difference of 0.51 ± 0.65 g/dL. Therefore, we found a considerably number of blood donors (5.5%) who had venous blood hemoglobin less than 12.5 g/dL. A good accuracy was demonstrated in the results from DiaSpectT. The mean hemoglobin concentration of fingerstick-DiaspectT method was not significantly different from the mean of the gold standard method. However, when hemoglobin concentration from fingerstick-DiaSpectT at 12.5 g/dL was used as a cut off value, 8 (3.17%) donors whose venous-Sysmex hemoglobin < 12.5 g/dL were eligible to donate and 7 (2.78%) donors whose venous-Sysmex hemoglobin ≥ 12.5 g/dL were not eligible. Both hemoglobin photometers provided the results with good relation to the venous blood hemoglobin that can facilitate prospective donor screening, however, there was variation in term of accuracy, not only accept donors with hemoglobin < 12.5 g/dL , but also exclude donors with hemoglobin ≥ 12.5 g/dL. Validation and quality control of hemoglobin photometers should be implemented when a hemoglobin screening method by using hemoglobin photometer was employed.

The different types of blood samples (capillary VS venous) and the different donor positions (sitting VS semi-Fowler's position) had an effect on fluid component of the blood samples. These two factors

might be an explanation for the deviation of results. In comparison, the means of hemoglobin concentration of venous blood were higher than the means hemoglobin concentration of fingerstick capillary blood samples measured by corresponding hemoglobin photometers (venous VS fingerstick; Hemocue 301 14.98 ± 1.23 g/dL VS 14.75 ± 1.28 g/dL, DiaspectT 14.37 ± 1.23 g/dL VS 14.27 ± 1.35 g/dL). From this observation, capillary blood samples taken when donors were in sitting position might have higher hemoglobin concentration than venous blood samples taken when donors were in semi-Fowler's position. This assumption was not complied with previous reports which capillary blood sample had higher hemoglobin concentration than venous blood[3,10-11].

In conclusion, hemoglobin concentration from the hemoglobin screening methods using fingerstick capillary blood samples measured by hemoglobin photometers had a good correlation with hemoglobin concentration from the gold standard method, venous blood sample measured by automated hemoglobin analyzers. However, there was variation of accuracy according to the type of hemoglobin photometers. To prevent the donation from pre-existing anemic donors and unacceptable anemia after blood donation, blood centers have to consider implementation of the proper hemoglobin screening methods.

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การประเมินวิธีตรวจคัดกรองค่าฮีโมโกลบินในผู้บริจาคโลหิตด้วยเครื่องอ่านค่าฮีโมโกลบิน

กุลวรา กิตติสาเรศ ปาริชาติ เพิ่มพิกุล เจนจิรา กิตติวรภัทร อุษณีย์ ศิริบุญฤทธิ์ วราภรณ์ มีสมรรถ อำพร วงศ์ภัทรนนท์ และ พยอม ดะรีพัตร์

ภาควิชาเวชศาสตร์การธนาคารเลือด คณะแพทยศาสตรศิริราชพยาบาล มหาวิทยาลัยมหิดล

วัตถุประสงค์ *เพื่อประเมินวิธีการตรวจคัดกรองฮีโมโกลบินในผู้บริจาคโลหิตด้วยเครื่องอ่านค่าฮีโมโกลบิน* ***วัสดุและวิธีการ*** *ผู้บริจาคที่จะบริจาคเลือดจะได้รับการตรวจค่าฮีโมโกลบินก่อนการบริจาคเลือดโดยเก็บตัวอย่างเลือดการเจาะปลายนิ้วและจากหลอดเลือดดำ แล้วนำไปวัดค่าฮีโมโกลบินด้วยเครื่องอ่านค่าฮีโมโกลบินได้แก่ Hemocue 301และ DiaSpect T และนำมาเปรียบเทียบกับเครื่อง SysmexXS 800i ซึ่งกำหนดให้เป็นวิธีมาตรฐาน* ***ผลการศึกษา*** *ผลจากการตรวจคัดกรองจากทั้งสองวิธีมีความสัมพันธ์ที่ดีกับผลการตรวจด้วยวิธีมาตรฐาน (fingerstick-Hemocue 301 r = 0.87 and r^2 = 0.75 และ fingerstick-DiaSpectT r = 0.84 and r^2 = 0.70) ค่าเฉลี่ยฮีโมโกลบินที่ตรวจด้วยวิธีมาตรฐานคือผลที่ได้จากเก็บตัวอย่างเลือดจากหลอดเลือดดำและตรวจด้วยเครื่อง SysmexXS800i คือ 14.24 ± 1.21 กรัมต่อเดซิลิตร ผลจากการตรวจคัดกรองวิธีที่หนึ่งคือค่าเฉลี่ยฮีโมโกลบินที่ได้จากเก็บตัวอย่างเลือดจากเจาะปลายนิ้วและตรวจด้วยเครื่อง Hemocue Hb301 เท่ากับ 14.75 ± 1.28 กรัมต่อเดซิลิตร ความแตกต่างจากวิธีมาตรฐาน 0.51 ± 0.65 กรัมต่อเดซิลิตร, p < 0.01 ผลจากการตรวจคัดกรองวิธีที่สองคือค่าเฉลี่ยฮีโมโกลบินที่ได้จากเก็บตัวอย่างเลือดจากเจาะปลายนิ้วและตรวจด้วยเครื่อง DiaSpect T เท่ากับ 14.27 ± 1.35 กรัมต่อเดซิลิตร ความแตกต่างจากวิธีมาตรฐาน 0.03 ± 0.74 กรัมต่อเดซิลิตร, p = 0.52* ***สรุป*** *ผลจากการตรวจคัดกรองฮีโมโกลบินด้วยเครื่องอ่านค่าฮีโมโกลบินในผู้บริจาคเลือดมีความสัมพันธ์ที่ดีกับผลการตรวจฮีโมโกลบินวิธีมาตรฐาน แต่ความแม่นยำของผลการตรวจคัดกรองฮีโมโกลบินแตกต่างกันตามชนิดของเครื่องตรวจฮีโมโกลบิน*

Keywords : ● *Blood donation* ● *Hemoglobin screening* ● *Hemoglobin photometer* ● *Capillary hemoglobin*

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