〈Original Article〉

Evaluation of new Smart Strip instrument for determination of hemoglobin

Miyuki Takayanagi[1)], Kayo Sakamoto[1)], Akino Kondo[1)], Yoshimi Nishioka[1)]
Ruriko Endo[1)], Junki Takamatsu[1)], Makoto Suzuki[2)], Tetsuo Takeuchi[3)],
Ikukatsu Suzuki[4)] and Tamotsu Yashiro[5)]

Summary Before a blood donation for a suitable donor, items are checked as pleasant, safe, and convenient as possible. Among these items are blood specific gravity (SG) or whole blood hemoglobin concentration (Hb conc.). Though the former had long been adopted because of its low cost, the latter is now mainly adopted for a donor's health control. However, the only instrument for determination of Hb conc. was HemoCue Hb 201+ based on colorimetry. However, a new mobile instrument (called Smart Strip) based on amperemetry has been developed. With this instrument, the interference from other blood components was eliminated. Smart Strip was suited for the determinations of Hb at concentrations between 1-20 g/dL. Its within-run precision (C.V.) was 2.6%. A close correlation was found between Smart Strip and other instruments.

Key words: Hemoglobin concentration, Amperemetry, Smart Strip, Whole blood

1. Introduction

In the Japanese blood program, before a blood donation is judged for a suitable donor. It must be checked as pleasant, safe, and as convenient as possible. These checks include body weight, blood pressure and anemia. Among the items checked for anemia are blood specific gravity (SG)[1)] or the concentrations of whole blood hemoglobin (Hb). SG has long been used because of its cost effectiveness. But currently, Hb is used mainly for the donor's health control. In various foreign countries, the mobile instruments of Hb determination were evaluated for introduction to the clinical field[2-4)] and blood programs[5)]. They were mainly comprised of HemoCue systems (HemoCue AB, Ängelholm, Sweden), such as the HemoCue B-Hb[6)], HemoCue Hb 201+[5)], and HemoCue Hb 301[7, 8)]. In Japan, the model HemoCue Hb 201+ was only introduced as an instrument of Hb determination for problems of crisis control. It is expected that other instruments of Hb determination will be developed.

Recently, a new mobile instrument for Hb determination, the Smart Strip, was developed by Nova

[1)]Japanese Red Cross Aichi Blood Center , 539-3, Minami-yamaguchi, Seto, Aichi 489-8555, Japan
[2)]Nagoya Teishin Hospital, 2-2-5, Izumi, Higashi, Nagoya 461-8798, Japan
[3)]Taijyu-kai Akeai Clinic, 970-41, Tabataueno, Ano, Tsu 514-2325, Japan
[4)]Gifu Dental Hygiene Vocational College, 1-25, Toei, Gifu 500-8144, Japan
[5)]Formerly of: Graduate School of Pharmaceutical Sciences, Nagoya City University, 3-1, Tanabe-dori, Mizuho, Nagoya 467-8603, Japan

Received for Publication December 29, 2011
Accepted for Publication January 11, 2012

Biomedical Corp. (MA, USA), and we had a chance to evaluate it with the possibility of introducing it into the Japanese blood program. Besides, so far as authors know, it hasn't reported for same instruments based on amperemetry.

2. Outline of new mobile instrument

The mobile instrument used for evaluation is called Smart Strip.

1. Determination principle

Aspirate a port of sample whole blood (sample WB) by applying the strip to the blood sample. The blood thus aspirated is reacted with a redox mediator, which is changed to a reductive type. Adding electric pressure to that mediator changes it from a reductive type to an oxidative type, by which an oxidative electric current is produced. The current is proportional to the Hb conc. in sample WB. Next, measure the electric current, and calculate its Hb conc. using the regression equation between the oxidative electric current and the Hb conc.

3. Materials and methods

1. Materials

①Chemicals

Citric acid and bilirubin were purchased from Wako Pure Chemical Industries Ltd., Osaka, Japan. The kit for hemoglobin determination {Nescoat Hemokit-N (the cyanmethemoglobin method[9])} was obtained from Alfresa Pharma Corp., Osaka. An anticoagulant sealed in a Venoject Tube was used: VT-050H (sodium heparin) was purchased from Terumo Corp., Tokyo, Japan.

②Human blood

WB was obtained from a healthy human volunteer and treated with sodium heparin. In this study, sample WB was prepared using WB.

③Hb standard

Plasma was obtained from WB by centrifuging (4,000 × *g*, 10 min) and separating the supernatant. An Hb standard was obtained by diluting WB with plasma and the Hb conc. in each Hb standard was measured using the determination kit.

④Apparatus

The absorbance of the solution was measured by a spectrophotometer (Model U-2900, Hitachi High-Technologies Corp., Tokyo). Centrifugation was done by a Model 5922 centrifuge (Kubota Manufacturing Corp., Tokyo).

2. Procedure

The Hb conc. was determined by a Smart Strip using the method described in the manufacturer's instruction manual shown in Fig. 1. For comparison, the Hb conc. was determined by the HemoCue Hb 201+ (the azidemethemoglobin method) as well as a full automatic blood cell counter {Model XE-2100 (the SLS-hemoglobin method), Sysmex Corp., Kobe, Japan}.

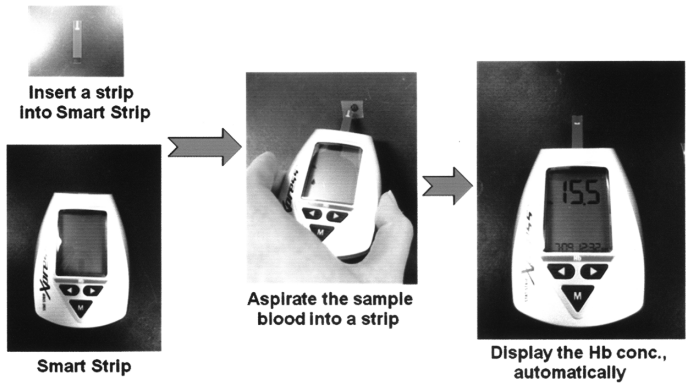

Fig. 1 Procedure for Hb conc. by Smart Strip

3. Methods

In this study, we adopted the following procedures

①Efficiency

Test samples were produced by diluting WB with plasma separated from WB. Using these samples, Smart Strip was evaluated by the linearity of a standard curve, the sensitivity of determination, and reproducibility with the same sample.

②Reliability of results

Using the same WB, Hb conc. was determined using Smart Strip, HemoCue Hb 201+, and XE-2100. We also checked the correlation of these results between Smart Strip and other instruments.

③Influence on determination

We confirmed the effect of samples containing materials such as anticoagulants (trisodium citrate dehydrate and dipotassium EDTA dihydrate), and interfering materials (bilirubin) on Hb determination, using Smart Strip.

④Comparison of handling

We compared the handling of Smart Strip and HemoCue Hb 201+.

4. Results

1. Effect of interfering material

①Anticoagulants

When the final concentration of trisodium citrate dihydrate used as anticoagulant reached 3.2 mg/mL, and was used to quintuply determine the Hb concs. of 12.7, 13.4, and 13.6 g/dL, recoveries by Smart Strip were between 98.4 and 100.0%. When the final concentration of dipotassium EDTA dihydrate used as anticoagulant reached 1.0 mg/mL and was used to quintuply determine the Hb concs. of 14.1, 14.9, and 15.1 g/dL, the recoveries by Smart Strip ranged between 97.9 and 101.4%.

②Bilirubin

When the final concentrations of bilirubin used as an interfering material were 2, 10, and 20 mg/mL, and these were used to triply determine the Hb conc. of 14.4 g/dL. The recoveries by Smart Strip were between 102.0 and 104.6%.

2. Efficiency of Smart Strip

①Accuracy

The calibration curve was linear up to 20 g/dL, with a sensitivity of 1 g/dL. The regression equation of the curve was y=0.98x + 0.69 (n=19, r=0.990) (Fig. 2).

②Precision

Table 1 shows the within-run results of the samples containing 8.1 and 12.3 g/dL of hemoglobin

Table 1 Precision and recovery of Hb determinations by Smart Strip

	Added Hb, g/dL			
	8.1	12.3	4.8	13.9
	Within-run (n=5)		*Between-run* (n=5)	
Mean, g/dL	8.2	12.3	4.9	13.9
S.D., g/dL	0.2	0.5	0.3	0.5
C.V., %	2.6	2.6	5.1	3.9
	Recovery (n=5)			
Mean, %	101.1	100.1	103.1	99.9
S.D., %	2.9	4.4	5.2	3.9

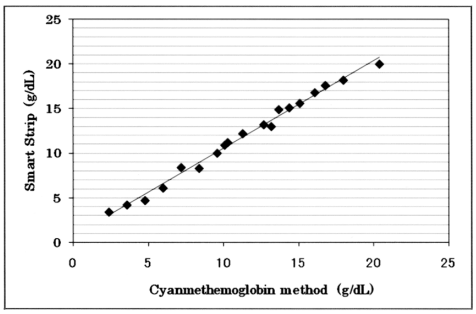

Fig. 2 Calibration curve for Hb by Smart Strip.

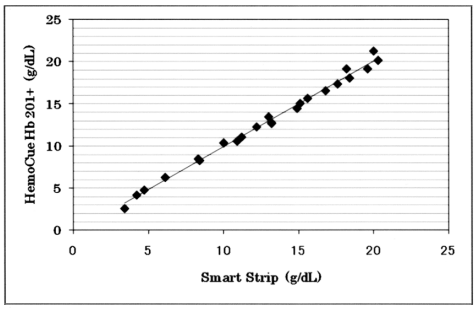

Fig. 3 Correlation between HemoCue Hb 201+ and Smart Strip.

in the 5 respective samples, and gives the between-run results of the samples containing 4.8 and 13.9 g/dL hemoglobin in 5 respective samples. The within-run precision (C.V.) was 2.6%, and the between-run C.V. was 5.1%.

③Comparison of methods

Fig. 3 shows the Hb concs. in the identical samples measured simultaneously by Smart Strip and HemoCue Hb 201+. The correlation between these two methods was good (n=23, r=0.995), with the regression equation of the curve defined by y=1.01x - 0.24.

Fig. 4 shows the Hb conc. in the identical samples simultaneously measured by Smart Strip and XE-2100. The correlation between these two methods was good (n=23, r=0.995), with the regression equation of the curve defined by y=1.01x - 0.55

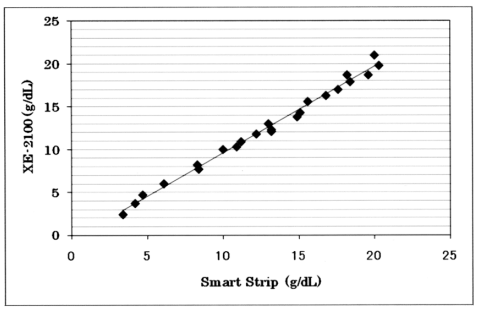

Fig. 4 Correlation between XE-2100 and Smart Strip.

④Differences in handling

We compared some items for Smart Strip and HemoCue Hb 201+, the former used to measure the oxidative electric current as the determination principle, using the 2 μL sample shown in a 2.6% within-run C.V. However, due to the manufacturer's inspection, the latter was based on colorimetry using the 10 μL sample shown in a 1.5% within-run C.V. The other items were almost the same.

5. Discussion

Fig. 5 shows the reaction mechanism for producing the oxidative electric current.

The mobile instrument for Hb determination was conventionally colorimetry[2-9]. However, Smart Strip is a newly established method using amperemetry. The basic mechanism differs from the colorimetry approach used by other instruments. The difference in measuring mechanisms was considered to contribute to crisis control.

The normal reference interval for Hb in healthy Japanese human blood usually ranges between 13.5 and 16.9 g/dL for a man, and between 11.0 and 14.8 g/dL for a woman[10]. For a clinical determination of Hb, the ranges up to 20 g/dL are important. A good correlation was found among the instruments of Smart Strip, HemoCue Hb 201+, and XE-2100. Such results confirm that Smart Strip is a safe and acceptable instrument.

Therefore, Smart Strip is considered to be a highly

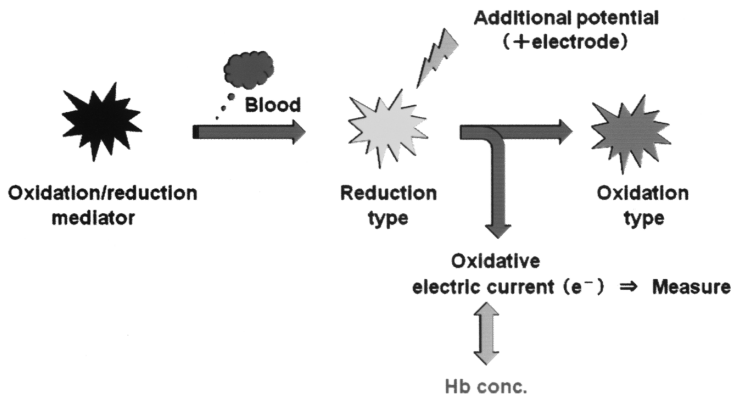

Fig. 5 Mechanism for determination of Hb by Smart Strip.

useful tool for determining the Hb conc. for the blood program in Japan.

Acknowledgements

The authors are greatly indebted to Dr. Yasuyuki Ichimaru and Mr. Noriyuki Wada (Nova Biomedical K.K., Tokyo) for their critical appraisal and useful suggestions.

References

1) Phillips RA, van Slyke DD, Hamilton PB, Dole V, Emerson K Jr and Archibald RM: Measurement of specific gravities of whole blood and plasma by standard copper sulfate solution. J Biol Chem, 183: 305-330, 1950.
2) Montagnac R, Vitry F, Rehn Y, Cotty M and Schillinger F: HemoCue: preliminary considerations about its use in hemodialysis. Nephol Ther, 3: 60-64, 2007.
3) Degarege A, Animut A, Legesse M and Erko B: Malaria severity status in patients with solid-transmitted helminth infection. Acta Trop, 112: 8-11, 2009.
4) Degarege A, Animut A, Legesse M and Erko B: Malaria and helminth co-infection in outpatients of Alaba Kulito Health Center, southern Ethiopia: a cross sectional study. BMC Res Notes, 3: 143, 2010.
5) Mendrone A Jr, Sabino EC, Sampaio L, Neto CA, Schreiber GB, de Alencar Fisher Chamone D and Dorhiac-Liacer PE: Anemia screening in potential female blood donors: comparison of two different quantititative methods. Transfusion, 49: 662-668, 2009.
6) von Schenck H, Falkensson M and Londberg B: Evaluation of "HemoCue," a new device for determining hemoglobin. Clin Chem, 32: 526-529, 1986.
7) Morris LD, Osei-Bimpong A, McKeown D, Roper D and Lewis SM: Evaluation of the utility of the HemoCue 301 haemoglobinometer for blood donor screening. Vox Sang, 93: 64-69, 2007.
8) Ojengbede OA, Okorkwo SN and Morhason-Bello IO: Comparative evaluation of hemoglobin estimation amongst pregnant women in Ibadan: HemoCue-B haemoglobin analyzer versus haemiglobincyanide (standard) method as the gold standard. Afr J Reprod Health, 12: 153-159, 2008.
9) Duchateau NJ: A comparative study of oxyhemoglobin and cyanmethemoglobin determination by photometric and spectrophotometric mettods. Am J Med Technol, 23: 17-26, 1957.
10) Japanese Association of Medical Technologists: The list of reference intervals [Jpn], Bulletin of prompt reports, 17: 7, 2011.