Performance Evaluation of B. Braun Omnitest 5 Blood Glucose Monitoring System for Self-Monitoring of Blood Glucose

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Background: We evaluated the accuracy of the B. Braun Omnitest 5 blood glucose monitoring system (BGMS; Infopia Co. Ltd., Korea), which was recently developed for self-monitoring of blood glucose.

Methods: Precision was assessed according to Clinical and Laboratory Standards Institute guideline EP5-A3 with control materials containing low, normal, and high levels of glucose. Linearity was evaluated over the range of 52.5–548.0 mg/dL prepared from patient samples. For system accuracy, 100 capillary blood samples measured by the B. Braun Omnitest 5 BGMS were compared to plasma-equivalent blood glucose values of the fingertip blood samples measured by the YSI 2300 STAT PLUS glucose analyser (YSI Life Sciences, USA). Accuracy was evaluated according to the International Organization for Standardization (ISO) 15197: 2013 criteria.

Results: The range for the total coefficient of variation (%) was 1.5%–4.9% for three lots of strips. Both within-run precision and within-laboratory precision fulfilled the manufacturer's claim. ISO 15197: 2013 states that more than 95% of blood glucose measurement values must be within ± 15 mg/dL for ranges below 100 mg/dL and $\pm 15\%$ for ranges above 100 mg/dL. Each of B. Braun Omnitest 5 lots satisfied ISO 15197: 2013, as 98.5% (197/200), 97.0% (194/200), and 99.5% (199/200) of values were within range. In consensus error grid analysis, respectively, 99.5%, 99.0%, and 100.0% of measurement values of each lot were within zone A, indicating that an average of over 99.0% of values were within zone A.

Conclusions: B. Braun Omnitest 5 provided reliable results and satisfied the ISO 15197: 2013 accuracy criteria. This test is an appropriate BGMS for the self-monitoring of blood glucose. (J Lab Med Qual Assur 2016;38:234-242)

Key Words: Blood glucose monitoring system, Self-monitoring of blood glucose, Accuracy, Evaluation

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INTRODUCTION

Diabetes is a major worldwide health epidemic that affected nearly 415 million people in 2015. Poorly managed diabetes leads to serious complications and early death in most countries, but with good self-management and health professional support, people with diabetes can live long, healthy lives [1]. Complications related to both

type 1 and type 2 diabetes can be reduced by better regulation of blood glucose [2]. Self-monitoring of blood glucose (SMBG) enables diabetes patients to effectively control their blood glucose levels. Moreover, management of diabetes through diet, exercise, and chemical treatment can delay degeneration of the disease or arrival of complications. The blood glucose test thus is considered one of the most important point-of-care tests [3,4].

The analytical performance of blood glucose monitoring systems (BGMSs) is critical because their accuracy can affect decisions regarding glycaemic control, such as insulin dosage [5].

The International Organization for Standardization (ISO) 15197: 2013 standard recommends that two minimum criteria be fulfilled for a system to be considered accurate [6]. One criterion specifies that the overall difference in 95.0% of values should be within ± 15 mg/dL for concentrations <100 mg/dL and $\pm 15\%$ for those ≥ 100 mg/dL; the other is that 99.0% of measured values fall within zones A and B of the consensus error grid (CEG) for type 1 diabetes.

The B. Braun Omnitest 5 BGMS (Infopia Co. Ltd., Anyang, Korea) was recently developed for SMBG. It is composed of B. Braun Omnitest 5 Blood Glucose Test Strips and a B. Braun Omnitest 5 Blood Glucose Test Meter, and adopts the GDH-FAD (flavin adenine dinucleotide-dependent glucose dehydrogenase) method and bio-sensor technology with electrochemical components to determine glucose levels. Designed to provide plasma-calibrated glucose values to patients in self-testing, the B. Braun Omnitest 5 BGMS requires a relatively small volume of whole blood (0.5 μ L) for analysis and requires approximately 5 seconds for measurement.

The purpose of this study was to assess the performance of the B. Braun Omnitest 5 BGMS for SMBG.

MATERIALS AND METHODS

1. Subject

The study was conducted from November 3–30, 2015 at the Hanil General Hospital, a 500-bed general hospital in Seoul, Korea. Subjects who had received a diagnosis of type 1 or type 2 diabetes were recruited from the Division of Endocrinology at Hanil General Hospital. A total of 120 subjects were enrolled in this study; however, data analysis was performed on capillary blood samples from 100 different subjects because 20 subjects were excluded based on the exclusion criteria of the study. Data were excluded from statistical analysis if (1) a handling error occurred, (2) no reference value was available, (3) a

technical error occurred, (4) haematocrit value was outside the validated range of the respective BGMS, (5) the drift between the first and second reference measurement was >4 mg/dL at blood glucose concentrations ≤ 100 mg/dL, or $>4\%$ at blood glucose concentrations >100 mg/dL, or (6) the maximum number of samples in a given blood glucose concentration category was already reached.

All subjects provided written informed consent, and the study protocol was conducted with institutional review board approval of Hanil General Hospital (KMC-2015-ME-001).

2. Methods

1) Precision

Precision testing was conducted in accordance with Clinical and Laboratory Standards Institute (CLSI) EP05-A3 [7]. Glucose levels were measured in duplicate in each run, and two runs per day for 20 days were performed for three concentrations of control materials. B. Braun Omnitest 5 glucose control solution was supplied by the manufacturer. The calculated total coefficients of variation (CV) and SD were compared with the manufacturer's claims for precision.

2) Linearity

Linearity testing was conducted in accordance with CLSI EP06-A [8]. During linearity testing, specimens with the highest and lowest glucose concentrations were selected from the EDTA-containing whole blood specimens remaining after routine testing (elapsed time until completion of the test was less than 1 hour). The two specimens were mixed at ratios of 5:0, 4:1, 3:2, 2:3, 1:4, and 0:5, and these six concentrations were then measured in quadruplicate.

3) Method comparison and system accuracy

Finger-stick extraction of blood was performed on each subject using a lancing device and their blood glucose levels were tested using Meter 1 and Meter 2 to test the same drop of blood. Capillary blood samples were collected into two capillary tubes of blood for measurement of haematocrit levels and the YSI 2300 STAT PLUS (YSI

Life Sciences, Yellow Springs, OH, USA) glucose reference measurement. Using one tube, haematocrit was analysed using the ADVIA 2120i Automated Hematology System (Siemens, Munich, Germany). Glucose measurement of the B. Braun Omnitest 5 BGMS was found to be within the valid haematocrit range of 20%–60%. All data from haematocrit measurements fell within this claimed range. The other tube was then immediately centrifuged at 2,260 g for 5 minutes. Glucose levels were measured by glucose oxidase assay on the YSI 2300 STAT PLUS in duplicate. The ISO 15197 standard specifies that the blood glucose concentrations of blood samples should be distributed as follows: 5% <50 mg/dL, 15% ≥50 to <80 mg/dL, 20% ≥80 to <120 mg/dL, 30% ≥120 to <200 mg/dL, 15% ≥200 to <300 mg/dL, 10% ≥300 to <400 mg/dL, and 5% >400 mg/dL.

If sufficient numbers of native samples with blood glucose concentrations <50 mg/dL were not available, adjusted capillary blood samples were prepared as follows: blood samples were collected in lithium heparin tubes, incubated at 25°C to allow for glycolysis, and gently mixed before testing. If sufficient numbers of native samples with blood glucose concentrations >400 mg/dL were not available, additional samples were prepared as follows: blood samples were collected in lithium heparin tubes, supplemented with concentrated glucose solution (40,000 mg/dL glucose in 0.9% NaCl), and gently mixed before testing [9]. In this study, the blood samples were distributed into different concentration categories based on the mean blood glucose reference values of the reference method (Table 1).

Native capillary samples were used at blood glucose concentrations of >50 mg/dL to ≤400 mg/dL and adjusted capillary blood was used at blood glucose concentrations of ≤50 mg/dL and >400 mg/dL in this study.

Tests using the B. Braun Omnitest 5 BGMS were performed by a well-trained technician to minimize user error and inter-user variance. BGMS tests were performed with three reagent system lots (F2QF03, F2QF04, and F2QF05). Two samples were excluded because of haemolysis and 18 samples were excluded because the concentration category was already filled. To

minimize the time between the duplicate measurements, two measurements were performed for each reagent system lot.

Estimated differences with 95% confidence intervals between the test and reference methods were derived from the linear regression method [10]. In addition, CEG analysis was performed and system accuracy was evaluated in conformance with the ISO 15197: 2013 standard.

The accuracy of the reference instrument was verified in accordance with the National Institute of Standards and Technology (Gaithersburg, MD, USA) reference material. Measurements taken by the reference method were performed at the clinical laboratory of Hanil General Hospital.

3. Statistical Analysis

System accuracy was assessed by comparing the BGMS measurement results with the respective mean result of the reference measurements. The data obtained from the B. Braun Omnitest 5 were plotted against the YSI 2300 STAT PLUS reference values and linear regression and CEG analyses were performed. Minimum system accuracy criteria were applied according to the ISO 15197: 2013 standard, by which the BGMS should meet the following criteria. (1) Criterion A: 95.0% of the measured glucose values should fall within either ±15 mg/dL of the average comparison measurement result at glucose concentrations

Table 1. Capillary samples for the evaluation of system accuracy according to International Organization for Standardization 15197: 2013 standard

Concentration category	Percentage of samples (%)	Glucose concentration (mg/dL)	Sample type
1	5	≤50	Adjustment
2	15	>50–≤80	Native
3	20	>80–≤120	Native
4	30	>120–≤200	Native
5	15	>200–≤300	Native
6	10	>300–≤400	Native
7	5	>400	Adjustment

<100 mg/dL or within 15% at glucose concentrations $\geq$ 100 mg/dL. Each lot should pass acceptability criterion A. (2) Criterion B: 99.0% of individual glucose measured values should fall within zones A and B of the CEG [11].

Microsoft Excel 2010 (Microsoft Co., Redmond, WA, USA) was used for data analysis.

RESULTS

1. Precision

The range for total CV was 1.5%–4.9% for the three lots of strips. In terms of both within-run precision and within-laboratory precision, the manufacturer's claims were fulfilled (Table 2): SDs for each glucose concentration

<100 mg/dL should be below 5 mg/dL and CV for each glucose concentration $\geq$ 100 mg/dL should be below 5%.

2. Linearity

Over the concentration range of 52.5–548.0 mg/dL, the coefficients of determination (R^2) with the three reagent system lots were 0.9963, 0.9986, and 0.9962 (Fig. 1).

3. Method Comparison and System Accuracy

The glucose reference values ranged from 35 to 482 mg/dL. Two test strips from three individual strip lots (F2QF03, F2QF04, and F2QF05) were tested for each patient, for a total of 200 glucose meter results per lot. Statistics showing combined lot agreement of the B.

Table 2. Precision of B. Braun Omnitest 5 blood glucose monitoring system by using three levels of control material on three lots

Strip lot	Control solution (mg/dL)	Test result (n=80)				Claim of manufacturer	
		Within-run precision		Within-laboratory precision		Within-laboratory precision	
		SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
F2QF03	Level 1 (35–65)	1.6	2.9	2.2	4.0	<5.0	
	Level 2 (102–136)	2.2	2.0	3.2	2.9		<5.0
	Level 3 (295–399)	4.9	1.7	6.2	2.2		<5.0
F2QF04	Level 1 (35–65)	1.5	2.8	1.6	2.9	<5.0	
	Level 2 (102–136)	2.8	2.7	3.4	3.2		<5.0
	Level 3 (295–399)	5.1	1.8	6.8	2.4		<5.0
F2QF05	Level 1 (35–65)	1.9	3.5	2.3	4.1	<5.0	
	Level 2 (102–136)	3.2	2.7	4.1	3.5		<5.0
	Level 3 (295–399)	4.5	1.5	6.4	2.2		<5.0

Fig. 1. Linearity of glucose concentrations measured by the three reagent system lots, B. Braun Omnitest 5. (A) F2QF03. (B) F2QF04. (C) F2QF05.

Braun Omnitest 5 BGMS results are shown in Table 3 and Fig. 2. When applying the system accuracy criteria of ISO 15197: 2013, 100% (54/54), 100% (54/54), and 100% (54/54) of B. Braun Omnitest 5 BGMS values were within ± 15 mg/dL (<100 mg/dL) for the three strip lots (F2QF03, F2QF04, and F2QF05), respectively. Additionally, 97.9% (143/146), 95.9% (140/146), and 99.3% (145/146) were within $\pm 15\%$ (≥ 100 mg/dL) of the

average reference value. For the overall concentrations, 98.5% (197/200), 97.0% (194/200), and 99.5% (199/200) of specimens met these criteria (Table 4, Fig. 3). In CEG analyses, 100% of the values were within zones A and B of the consensus error grid for the system (Table 5, Fig. 4).

Table 3. Method comparison between B. Braun Omnitest 5 blood glucose monitoring system, and YSI 2300 STAT PLUS auto analyser (N=200)

Strip lot	Linear regression	95% CI slope	95% CI intercept	R^2	No.
F2QF03	$y=0.9454x+3.6801$	(0.931–0.960)	(0.761–6.599)	0.9887	200
F2QF04	$y=0.9299x+4.5905$	(0.916–0.943)	(1.807–7.374)	0.9893	200
F2QF05	$y=0.9436x+5.1553$	(0.931–0.956)	(5.658–7.653)	0.9916	200

Abbreviation: CI, confidence interval.

Fig. 2. Scatter plot of expected and measured glucose levels from method comparison test of Omnitest 5 blood glucose monitoring system (200 data points, duplicate measurements on a sample with each test strip lot, are shown). Solid lines indicate the limits stipulated in the International Organization for Standardization 15197: 2013. (A) F2QF03. (B) F2QF04. (C) F2QF05.

Table 4. System accuracy between B. Braun Omnitest 5 blood glucose monitoring system and YSI 2300 STAT PLUS auto analyser (N=200)

BG system	Strip lot	International Organization for Standardization 15197: 2013		BG concentration <100 mg/dL			BG concentration ≥ 100 mg/dL		
		No.	Total	Within ± 15 mg/dL	Within ± 10 mg/dL	Within ± 5 mg/dL	Within $\pm 15\%$	Within $\pm 10\%$	Within $\pm 5\%$
B. Braun Omnitest 5	F2QF03	200	(98.5)	(100.0)	(94.4)	(77.8)	(97.9)	(88.4)	(57.0)
	F2QF04	200	(97.0)	(100.0)	(92.6)	(57.4)	(95.9)	(84.9)	(44.5)
	F2QF05	200	(99.5)	(100.0)	(90.7)	(57.4)	(99.3)	(90.49)	(52.1)

Values are presented as number or (%).

Abbreviation: BG, blood glucose.

Fig. 3. Absolute difference plot between the blood glucose concentration results measured by the systems and respective comparison values measured with YSI 2300 STAT PLUS (200 data points, duplicate measurements on a sample with each test strip lot, are shown). Solid lines indicate the limits stipulated in the International Organization for Standardization 15197: 2013. (A) F2QF03. (B) F2QF04. (C) F2QF05.

Table 5. Consensus error grid analysis of glucose levels measured by B. Braun Omnitest 5 blood glucose monitoring system against YSI 2300 STAT PLUS auto analyser (N=200)

Blood glucose system	Strip lot	Consensus error grid zone				
		Zone A	Zone B	Zone C	Zone D	Zone E
B. Braun Omnitest 5	F2QF03	199/200 (99.5)	1/200 (0.5)	0/200 (0)	0/200 (0)	0/200 (0)
	F2QF04	198/200 (99.0)	2/200 (1.0)	0/200 (0)	0/200 (0)	0/200 (0)
	F2QF05	200/200 (100.0)	0/200 (0)	0/200 (0)	0/200 (0)	0/200 (0)

Values are presented as number (%).

Fig. 4. Consensus error grid analysis of capillary blood glucose results. Each specimen was measured in duplicate by each method. Zone A, clinically accurate (no effect on clinical action); zone B, clinically acceptable (altered clinical action-little or no effect on clinical outcome); zone C, altered clinical action-likely to affect clinical outcome; zone D, altered clinical action-may have significant medical risk; and zone E, altered clinical action-may have dangerous consequences. (A) F2QF03. (B) F2QF04. (C) F2QF05.

DISCUSSION

Accurate performance of glucose meters is the most critical factor of glycaemic control for a diabetic patient. Hence, the criteria for the performance evaluation of glucose meters have become more stringent as required by regulatory agencies [12]. Most glucose meters are calibrated using capillary blood, after which reference equipment is employed to calibrate the plasma. Therefore, the glucose meter and reference equipment should utilise capillary blood for accurate performance evaluation. The blood glucose concentration levels and quantities manipulated in the evaluation should be in compliance with ISO 15197. Occasionally, it is difficult for the subject (participant who donates the blood) to measure the capillary blood with the reference equipment. Thus, in common domestic evaluations, the blood glucose meter is evaluated using capillary blood, whereas the reference equipment is assessed using venous blood [13,14]. Nevertheless, this study evaluated ISO 15197: 2013 by employing capillary blood for both the evaluation criteria and the exclusion criteria applied in data analysis.

Upon measurement of the capillary blood collected from participants, the blood sample was tested again using the reference equipment. For glucose concentrations below 100 mg/dL, the difference between two measurements determined using the reference equipment should be less than 4 mg/dL and should be within the range of max bias $\pm 4\%$ for glucose concentrations above 100 mg/dL. Otherwise, the subject should be excluded from the analysis. This is to minimize variance in the reference equipment. ISO 15197 states that samples with glucose concentrations under 50 mg/dL and over 400 mg/dL can be replaced with manipulated blood during evaluation. However, this is done for extreme cases of patients with severe hypoglycaemia. Blood samples can be manipulated by decreasing sugar levels by approximately 7 mg/dL each hour, and samples of 50 mg/dL glucose concentration can be produced through glycolysis after collecting capillary blood. When glucose concentration exceeds 400 mg/dL, a 40,000 mg/dL stock solution is prepared for addition into the blood. After setting the target for blood glucose

concentration, the blood glucose concentration in the collected sample is measured. The formula applied multiplies the difference in blood glucose concentrations (current volume subtracted from target volume) and divides the product by the stock concentration. With the exception of the sample described above, all blood samples were evaluated utilizing non-manipulated blood.

In blood glucose measurement, Parkes proposed consensus error grid analysis techniques in the 2000s to improve the error grid analysis techniques first introduced by Clarke in the mid-1980s [11]. Consensus error grid analysis is a method that plots measured values in 5 error regions (zone A, B, C, D, and E). Based on the consensus of survey participants, glucose results in zones A and B lead to little or no effect on clinical outcome, whereas results in zones C to E lead to an increased risk of an adverse outcome. Evaluation of a BGMS requires the use of the prevailing method of error grid analysis, as regression analysis and the absolute value of the difference or percentage techniques analyse the measurement error from different concentrations with the same standard and do not reflect the importance of measurement values according to blood glucose concentration.

Hence, the ISO/DIS 15197: 2013, consensus error grid analysis is required and 99% of measurement values must be within zone A or B. Consensus error grid analysis demonstrated no risk of adverse effects of medical decisions in treatment, as outlier values of the B. Braun Omnitest 5 measurements were within zone B. A similar pattern of difference was observed in comparisons between the B. Braun Omnitest 5 BGMS and YSI 2300 Stat Plus. All 600 tests fell in zone A or B of the consensus error grid. Thus, differences in results would not affect clinical actions (for zone A) or have little or no effect on clinical outcomes, even with altered clinical action (for zone B).

In addition to the accuracy test, comprehensive assessment of precision and linearity showed that the diagnostic equipment and other factors displayed outstanding performance.

In conclusion, the B. Braun Omnitest 5 provided reliable results and satisfied the ISO 15197: 2013 accuracy criteria, demonstrating good performance in terms of

precision and linearity. Therefore, the B. Braun Omnitest 5 is expected to be useful in self-testing by a BGMS.

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자가혈당측정기 B. Braun Omnitest 5 성능평가

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배경: 최근 자가혈당측정기로 개발이 완료된 B. Braun Omnitest 5 (Infopia Co. Ltd., Korea)의 성능평가를 진행하였다.

방법: 정밀도평가는 정도관리물질 3농도를 이용하여 Clinical and Laboratory Standards Institute EP5-A3에 따라 평가하였다. 직선성은 환자의 혈액을 이용하여 52.5-548.0 mg/dL의 농도까지 평가하였으며, 정확도 평가는 100명의 참여자의 손끝 모세혈을 이용하여 평가하였다. International Organization for Standardization (ISO) 15197: 2013 정확성 평가기준에 따라 평가하였으며, 기준장비로는 YSI 2300 STAT PLUS 혈당측정기(YSI Life Sciences, USA)를 이용하였다.

결과: 총 3개의 lot에서 평가된 모든 항목의 변이개수는 1.5%-4.9%를 나타내었으며 이는 검사 내 정밀도, 검사실 내 정밀도 모두 제조사의 요구를 만족하였다. ISO 15197: 2013에서는 측정된 혈당 값과의 허용 차이가 100 mg/dL 미만의 검체에서는 95.0%의 결과가 오차범위 ± 15 mg/dL 안에, 100 mg/dL 이상의 검체에서는 95.0%의 결과가 $\pm 15\%$ 이내에 들것을 권고하고 있는데, B. Braun Omnitest 5의 평가결과 ISO 15197: 2013의 기준을 만족하였으며 각 lot별로 98.5% (197/200), 97.0% (194/200), 그리고 99.5% (199/200)의 결과를 보여주었다. Consensus error grid 분석에서는 각각 99.5%, 99.0%, 100.0%의 측정값이 zone A에 만족하였으며, 3 lot 평균 99.0%가 A영역 내에 포함되었다.

결론: B. Braun Omnitest 5는 신뢰할 만한 평가결과를 나타냈으며 ISO 15197: 2013 정확성 기준을 만족하였고, 재현성 및 직선성에서도 만족할 만한 성능을 보여주었다. 따라서 B. Braun Omnitest 5는 자가혈당측정기로서 적절한 혈당측정시스템으로 평가된다.

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