Accuracy of the FreeStyle Method: Measuring Blood-Glucose by Skin-Prick Blood Extraction From Forearm

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Objectives. Self-measurement of blood glucose levels by the established monitoring systems is accurate but not readily accepted by patients because the finger prick is painful. A new system which involves blood sample collecting at an alternative and less painful site, the forearm, has been developed to facilitate frequent blood glucose measurement. The purpose of this study was to evaluate the accuracy of this new blood glucose monitoring system: the FreeStyle method.

Methods. Venous blood samples were drawn from 93 fasting and 93 nonfasting outpatients with diabetes. Plasma was extracted by a standard laboratory method for glucose measurement. Capillary blood was then obtained from each patient by skin prick on the fingertip and forearm. Blood glucose was measured by two standard blood glucose meters, the Glucometer Elite and the Glucotrend 2, and the FreeStyle system. The data were compared with a reference laboratory method. Each patient was also asked to comment on the pain associated with the skin prick at both sites. The accuracy of self-monitoring systems was evaluated by statistical and clinical analyses.

Results. Linear regression analysis of the FreeStyle data from fasting patients revealed an intercept of −9.87 mg/dL, a slope of 0.96, and a correlation coefficient (r) of 0.966. Furthermore, error grid analysis (EGA) demonstrated that all of the data fell within zones A (81%) and B (19%), which define clinically acceptable results. Linear regression analysis of the FreeStyle data from nonfasting subjects revealed an intercept of 26.41 mg/dL, a slope of 0.81, and a correlation coefficient (r) of 0.938. EGA revealed that 81% of the data fell within zone A, 17% within zone B and 2% within zone D. The relative standard deviation (RSD) for FreeStyle was similar to the RSD for the two standard meters and the reference laboratory method. Ninety-seven percent of the patients reported that they experienced less pain from the forearm skin prick than from skin prick at the fingertip.

Conclusions. The FreeStyle blood glucose monitoring system which requires forearm skin prick for blood extraction is sufficiently accurate for home use. However, caution must be taken because of its potential failure to detect hypoglycemia and because the accuracy is reduced during rapid change of blood glucose levels. **(Mid Taiwan J Med 2003;8:214-24)**

Key words

accuracy, blood glucose meter, error grid analysis (EGA), FreeStyle, self-monitoring of blood glucose (SMBG)

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INTRODUCTION

Analysis of data obtained from the Diabetes Control and Complication Trial (DCCT) and the United Kingdom Prospective Diabetes Study

(UKPDS) has clearly demonstrated that improved glycemic control significantly reduces microvascular and, probably, macrovascular complications of type 1 and type 2 diabetes [1-3]. To achieve optimal glycemic control, intensive therapeutic regimens and frequent blood glucose monitoring are necessary. However, daily frequent plasma glucose measurement by venepuncture in hospital is difficult because of poor patient compliance. Hence, self-monitoring of blood glucose (SMBG) is an important component of any treatment plan for patients with diabetes mellitus because it facilitates frequent measurement of blood glucose, appropriate real-time adjustment of treatment regimens, and achieves near-normal blood-glucose levels [1,4-6].

SMBG most commonly involves pricking a finger with a lancet device to obtain a small blood sample, applying a drop of blood onto a reagent strip, and determining the glucose value by inserting the strip into a reflectance photometer for an automated reading. The actual number of SMBG systems in use is unknown, but it is estimated that up to 15% of the 16 million patients with diabetes mellitus self-monitor their blood glucose in the USA [7,8]. In 1997, the worldwide market for hand-held blood glucose meters and supplies was estimated to be $2.05 billion, with a growth rate of 11% per year [9].

The SMBG must be accurate enough to be a reliable method for clinical practice. However, none of the SMBG systems meet this requirement. In a study which compared analytic error of glucose monitoring with 18 blood glucose meters, the imprecision at the mean glucose concentration of 160 mg/dL gave coefficients of variation (CV) ranging from 5.2% to 22.8% and the incidence of significant error (> 15% deviation from reference method) varied from 6% to 76% [10]. Whereas, in another study which evaluated the performance of three blood glucose meters, the majority of blood glucose determinations with blood glucose meters were clinically acceptable [11].

For most patients, frequent blood-glucose measurement is not readily acceptable because the standard SMBG systems rely on painful fingertip skin pricks [12]. Thus, to foster the required measurement frequency, a new system has been developed which analyzes blood samples from the forearm, an alternative to and less painful site than the fingertip. This system, known as FreeStyle, is precise (CV < 5.6% as blood glucose level from 44 to 436 mg/dL) and accurate (slope 0.931, intercept 8.1 mg/dL and correlation coefficient 0.984 as blood glucose level from 51 to 487 mg/dL) at any altitude, at low or high ambient temperature, and at any hematocrit level encountered in clinical practice [13,14].

The purpose of this study was to evaluate the accuracy of the FreeStyle SMBG system, to prove that forearm skin pricks are less painful, and to show that the new system is easy to use.

MATERIALS AND METHODS

Patient Population

A total of 186 diabetic outpatients (6 type 1 and 180 type 2) were enrolled in the study. Patients ranged in age from 16 to 87 years (55.2 ± 9.9 years); 56% were women. Exclusion criteria that may affect blood glucose measurements included pregnancy, skin lesions, severe anemia or polycythemia, marked hyperlipidemia, hyperbilirubinemia and hyperuricemia, and the use of acetaminophen or ascorbic acid in the previous 72 hours. Written informed consent was obtained from all patients before commencement of the study.

SMBG Systems and Reference Method

Three SMBG systems, the Glucometer Elite (Bayer Corp., Mishawaka, IN, USA), the Glucotrend 2 (Roche Diagnostics GmbH, Mannheim, Germany) and the FreeStyle (TheraSence Inc., Alameda, CA, USA), measured blood glucose values. Each system was composed of a meter for blood glucose measurement and a lancet device for blood extraction by skin pricking. All three systems measure blood glucose values by an electrochemical method and are plasma-reference meters that allow direct

comparison with reference laboratory values. The Glucometer Elite and Glucotrend 2 represented standard SMBG systems, which analyze blood samples obtained from the fingertip; 3 to 5 μL of blood is typically needed to ensure accurate measurement. These two systems measure capillary whole blood glucose and can detect blood glucose values ranging from 10 to 600 mg/dL. The Glucometer Elite provides a reading of glucose level in 30 seconds and the Glucotrend 2 in 15 seconds. The readings are not affected by hematocrit as the effective operating range is 20% to 70%. The precision as well as the accuracy of these two meters have already been documented [15,16]. The overall imprecision (CV) of the Glucometer Elite is < 4% in the range from 60 to 360 mg/dL. The accuracy is represented against reference laboratory method as slope 1.02, intercept −3.16 mg/dL and correlation coefficient (*r*) 0.990 in the range from 53 to 419 mg/dL. The Glucotrend 2 is also precise (CV < 3%) and accurate (slope 0.98, intercept 1.45 mg/dL, with mean deviation from the reference laboratory method of < 4%) within its measuring range. The FreeStyle system also measures capillary whole blood glucose but, unlike the other two systems, blood collection is from the forearm. Furthermore, only 0.3 μL of blood is required to accurately detect blood glucose values ranging from 20 to 500 mg/dL. The reading response time is 15 seconds and the result is not affected by hematocrit [13,14]. The results obtained from these three meters are not affected by altitude and ambient temperature. For each glucose meter, if the measured glucose levels are not within its detectable range, the meter will show "Lo" or "Hi" representing low or high glucose values.

Before evaluating the accuracy, the three glucose meters were examined for precision, linearity, and reproducibility. Precision was assessed according to the readings of 20 replicates with glucose levels of 50, 150 and 300 mg/dL. Linearity was then determined by these readings and the results obtained by detecting an additional solution with a glucose level of 450 mg/dL. In other words, linearity ranging from 50 to 450 mg/dL was examined. Reproducibility was examined by analyzing the readings of the two successive measurements on two different fingers or on two different sites of the same forearm from 30 volunteers for each SMBG system.

The GA 03R (A&T, Tokyo, Japan), an automated glucose analyzer, was the reference laboratory method to measure plasma glucose values. This system measures plasma glucose by a GOD immobilized membrane/oxygen electrode peak acceleration method and has a measurement range of 0 to 5000 mg/dL. Precision was determined at three different glucose concentrations (50, 150 or 300 mg/dL) and the CV was 4.2%, 3.1% and 3.5%, respectively. Measurements are reproducible at low concentrations ($R \leq 5$ mg/dL) and is linear to high concentrations (5000 mg/dL). The quality of analysis is stable if the system is installed in an environment with a temperature and humidity range from 15°C to 30°C and 40% to 48% RH, respectively.

Procedure

Patients were randomly assigned to a fasting or a nonfasting group (93 patients in each). Patients in the fasting group were not allowed any food or fluid intake, except water, for at least six hours before glucose measurement, while the nonfasting patients ate a meal three hours prior to the procedure.

Blood was first drawn from each subject at the antecubitus by venepuncture. The blood sample was centrifuged immediately, and glucose measurement of the extracted plasma was performed within 30 minutes by the reference laboratory method. Blood was then extracetd by both fingertip and forearm skin pricks and directly analyzed by the three tested glucose meters within five minutes of the venepuncture. Hence, three capillary blood glucose results were generated for each subject from the three meters, and the results were separately compared with the plasma analog generated from the reference laboratory method. The order of the skin pricks and glucose measurements were randomized, and all procedures were uniformly performed and the

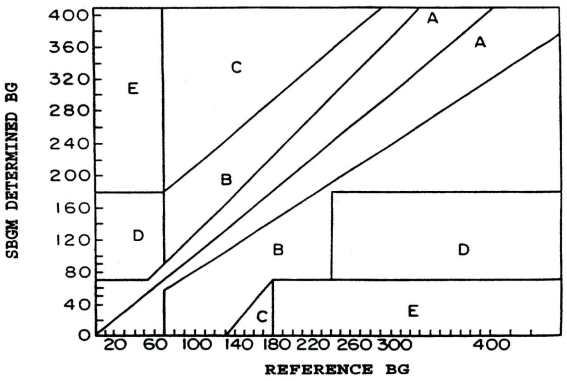

Fig. 1. Error grid analysis (EGA) to evaluate clinical implications of patient-generated blood glucose values. "Copyright © 1987 American Diabetes Association From Diabetes Care, Vol. 10, 1987;622-628. Reprinted with permission from the American Diabetes Association".

data recorded by one trained healthcare professional. When a second venepuncture or skin prick was required to obtain sufficient blood volume, the percentage was recorded. After the procedure, each patient was asked to evaluate the level of pain experienced.

Statistical and Clinical Analysis

Precision was represented as coefficient of variation. Linearity and reproducibility were analyzed by simple linear regression analysis and paired-*t* test, respectively. Statistical accuracy of the results from all methods was evaluated by the multiple comparison test. We then calculated the relative standard deviation (RSD) and performed simple linear regression analysis. Clinical accuracy was evaluated by percentage deviation from the reference method [(meter result – reference result)/reference result × 100%] and error grid analysis (EGA, Fig. 1) [17]. Statistical significance was defined as $p < 0.05$.

The EGA was developed by Clarke et al in 1987 for the evaluation of the clinical implications of blood glucose meter-generated values and was adopted by several studies [11,13,14,18,19]. The reference blood glucose values and those generated by the monitoring system were plotted along the x and y axes, respectively. The diagonal represents perfect agreement between the two, with data points above and below this line representing overestimates and underestimates, respectively. This method is based on assumptions that reflect clinical practices: 1) the target blood glucose values are between 70 and 180 mg/dL, 2) patients will attempt to correct blood glucose readings that are above or below the target range but not those readings that are within the target range, 3) corrective treatment by the patient is inappropriate if such treatment results in blood glucose values outside of the target range, and 4) failure to treat blood glucose values < 70 or > 240 mg/dL is inappropriate.

Based on these assumptions, the grid is divided into five zones, each reflecting varying categories of accuracy and inaccuracy of the glucose estimates. Zone A represents glucose values that deviate from the reference by no more than 20% or are in the hypoglycemic range, < 70 mg/dL, when the reference is also < 70 mg/dL. Values falling within this range are deemed clinically accurate, as they would result in clinically correct treatment decisions. Zone B represents values that deviate from the reference by more than 20%, but would lead only to clinically benign decisions. Zone C readings are those that would result in overcorrection of preexisting, acceptable blood glucose values. Zone D represents errors that would result in failure to detect or treat dangerously low levels. Actual glucose values are outside of the target range, but blood glucose meter-generated values are within the target range. Zone E readings would result in erroneous treatment. Blood glucose meter-generated values within this zone are opposite the reference values, and the corresponding treatment decision would therefore be inappropriate. In summary, values in zones A and B are clinically acceptable, whereas values in zone C, D, and E are potentially dangerous errors, and therefore clinically significant.

RESULTS

As shown in Table 1, the FreeStyle system as well as the other two standard SMBG systems were precise, linear, and reproducible.

In the fasting group, the range of plasma glucose values was 66 to 353 mg/dL (mean ± SD:

Table 1. Precision, linearity and reproducibility of three SMBG systems

	Glucometer Elite	Glucotrend 2	FreeStyle
Precision (CV, %)			
50 mg/dL	4.7	6.0	2.9
150 mg/dL	2.3	3.5	3.9
300 mg/dL	1.7	5.5	2.6
Linearity (50-450 mg/dL)			
Intercept (mg/dL)	2.01	1.17	4.54
Slope	1.03	1.00	1.01
Correlation coefficient (*r*)	0.998	0.998	0.999
Reproducibility			
Mean ± SD (first)	165.2 ± 72.1	155.9 ± 74.0	157.0 ± 70.0
Mean ± SD (second)	161.2 ± 73.2	156.0 ± 75.1	156.2 ± 71.9
Correlation coefficient (*r*)	0.946	0.998	0.999

Mean ± SD: mg/dL.

Table 2. Blood glucose values generated from three SMBG systems and the reference laboratory method

	Fasting (n = 93)		Nonfasting (n = 87)	
	Mean ± SD (mg/dL)	RSD (%)	Mean ± SD (mg/dL)	RSD (%)
Glucometer Elite	164.5 ± 53.3	32.4	248.6 ± 104.7	42.1
Glucotrend 2	148.3 ± 51.0	34.4	238.8 ± 104.6	43.8
FreeStyle	150.8 ± 54.5	36.1	219.2 ± 87.6	40.0
Reference laboratory method	167.5 ± 54.9	32.8	237.7 ± 101.3	42.5

RSD = (SD / |mean|) ×100%. Fasting: 3 SMBG systems *vs* reference laboratory for mean glucose values ($p < 0.05$). Both Glucotrend 2 and FreeStyle *vs* Glucometer Elite ($p < 0.05$). Nonfasting = no significant difference between the four methods was found (ANOVA, $p = 0.269$).

167.5 ± 54.9 mg/dL, RSD: 32.8%), according to the reference laboratory method, while the blood-glucose range from the blood glucose meters was 68 to 321 mg/dL (164.5 ± 53.3 mg/dL, 32.4%) for Glucometer Elite, 56 to 333 mg/dL (148.3 ± 51.0 mg/dL, 34.4%) for Glucotrend 2, and 66 to 340 mg/dL (150.8 ± 54.5 mg/dL, 36.1%) for FreeStyle, respectively. The means of related sample values for each meter were found to differ significantly by the multiple comparison test ($p < 0.05$) from the laboratory reference values. In addition, there was also a statistically significant difference ($p < 0.05$) between the Glucotrend 2, FreeStyle and Glucometer Elite systems. In the nonfasting group, the range of plasma/blood glucose values generated from the reference method, Glucometer Elite, Glucotrend 2, and FreeStyle was 70 to 802 mg/dL (237.7 ± 101.3 mg/dL, 42.5%), 73 to 554 mg/dL (248.6 ± 104.7 mg/dL, 42.1%), 75 to 598 mg/dL (238.8 ± 104.6 mg/dL, 43.8%), and 71 to 430 mg/dL (219.2 ± 87.6 mg/dL, 40.0%), respectively (Table 2). The difference was not statistically significant (ANOVA, $p = 0.269$) when related values of each meter and reference laboratory were compared. However, the RSD for the FreeStyle system was very similar to those for the two standard meters and reference laboratory method in both fasting (36.1% *vs* 32.4% to 34.4%) and nonfasting groups (40.0% *vs* 42.1% to 43.8%). Ten out-of-range meter readings, indicated as "Hi", were recorded for six nonfasting patients. The corresponding results from the reference method were also markedly elevated (513 to 802 mg/dL). All of the plasma/blood glucose measurement readings for these six subjects were discarded from this study.

The glucose values obtained by the SMBG systems and the corresponding results from the reference laboratory method are depicted in Fig. 2. For the fasting group, simple linear regression analysis revealed intercepts of 5.32, −2.33 and −9.87 mg/dL, slopes of 0.95, 0.90 and 0.96 and correlation coefficients (*r*) of 0.979,

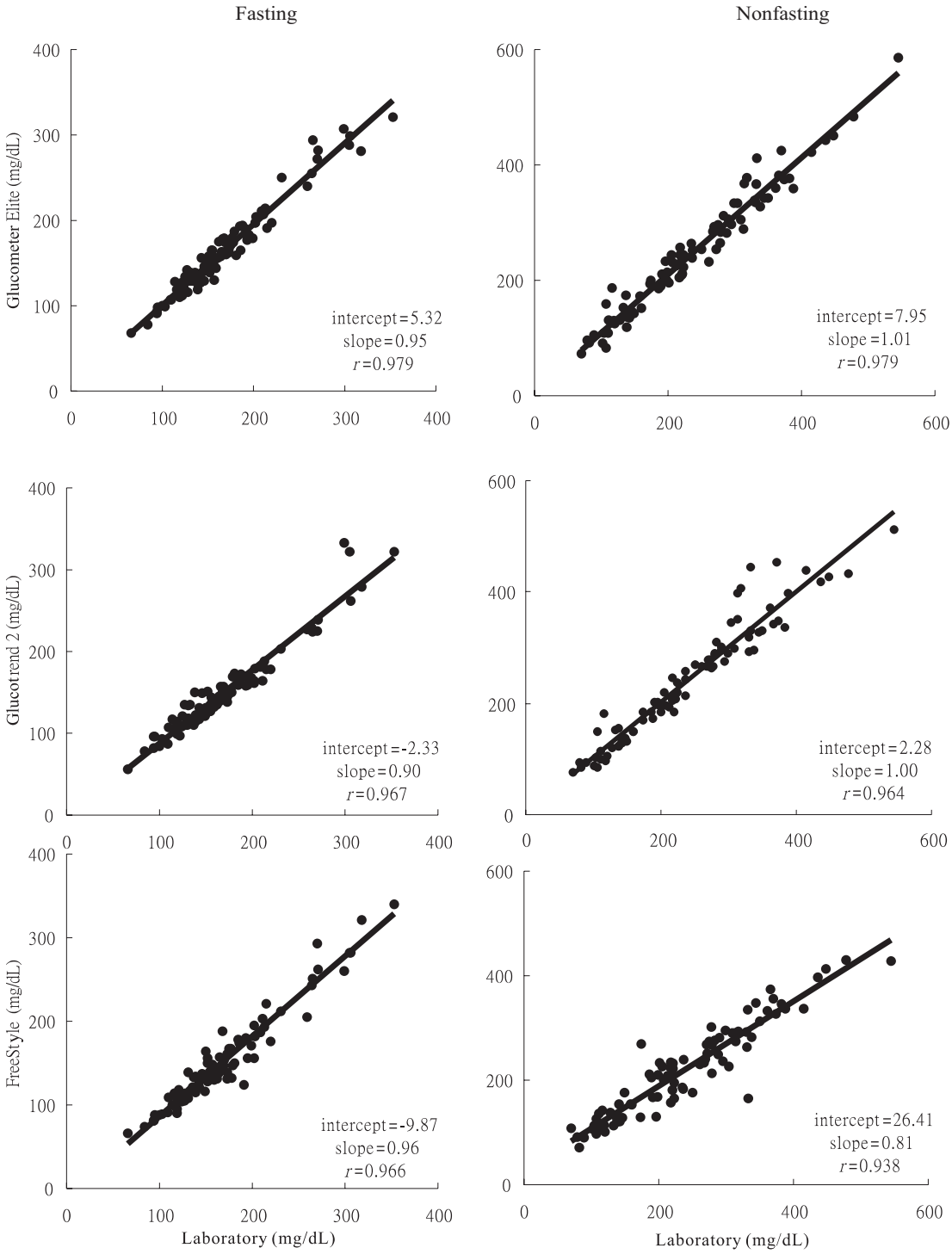

Fig. 2. Correlation between SMBG-generated blood glucose values and reference laboratory-based plasma glucose values.

0.967 and 0.966 for the Glucometer Elite, Glucotrend 2 and FreeStyle, respectively. For the nonfasting group, the respective results were: intercepts, 7.95, 2.28 and 26.41 mg/dL; slopes, 1.01, 1.00 and 0.81; and, correlation coefficients (*r*), 0.979, 0.964 and 0.938.

According to percentage deviation analysis, 59% of the Glucometer Elite blood glucose values were within 5% of the reference laboratory values and 100% were within 20%, with analogous

Table 3. Percentage deviation of SMBG values from laboratory values

Deviation (%)	Fasting (n = 93)			Nonfasting (n = 87)		
	Glucometer Elite (%)	Glucotrend 2 (%)	FreeStyle (%)	Glucometer Elite (%)	Glucotrend 2 (%)	FreeStyle (%)
≤ ±5	59	12	17	44	39	28
≤ ±10	85	27	40	71	69	46
≤ ±15	98	53	65	85	87	67
≤ ±20	100	80	81	95	92	81

Percentage deviation = (meter – laboratory)/laboratory × 100%. ADA criterion: ≤ ±5%, NCCLS criterion: ≤ ± 20%.

Table 4. Summary of error grid analysis of three SMBG systems

Zone	Fasting (n = 93)			Nonfasting (n = 87)		
	Glucometer Elite (%)	Glucotrend 2 (%)	FreeStyle (%)	Glucometer Elite (%)	Glucotrend 2 (%)	FreeStyle (%)
A	100	80	81	95	92	81
B	0	20	19	5	8	17
C	0	0	0	0	0	0
D	0	0	0	0	0	2
E	0	0	0	0	0	0

Zone A+B: clinically acceptable values. Zone D: potentially dangerous error.

percentages of 12% and 80% for the Glucotrend 2, and, 17% and 81% for the FreeStyle in the fasting group. In the nonfasting group, the 5% and 20% deviations were 44% and 95% for the Glucometer Elite, 39% and 92% for the Glucotrend 2, and, 28% and 81% for the FreeStyle, respectively (Table 3).

EGA of the fasting data generated by the three tested instruments revealed: 100% of Glucometer Elite glucose values fell within zone A; 80% of the Glucotrend 2 readings were within zone A and 20% were within zone B; and, 81% of the FreeStyle data fell within zone A and 19% within zone B. Analogous analysis for the nonfasting group revealed: 95% of the Glucometer Elite data fell within zone A and 5% within zone B; 92% of the Glucotrend 2 values were within zone A and 8% were within zone B; and, 81% of FreeStyle results were within zone A, 17% zone B, and 2% (two reading pairs) in zone D (Table 4). The glucose values for the two reading pairs within zone D, reported by the FreeStyle/reference laboratory method, were 179/250 mg/dL and 108/70 mg/dL. In summary, almost all of the glucose values in both groups fell within the clinically acceptable category.

About 97% of patients reported feeling less pain during the forearm skin prick than during the fingertip analog, with 43% of them indicating that the experience was almost painless (data not shown). Less than 4% of the patients needed a second skin prick to obtain sufficient blood for glucose measurement with the FreeStyle method. This does not exceed the percentage for the two standard SMBG systems or venepuncture (data not shown).

DISCUSSION

The accuracy of blood glucose (SMBG) meters is an important consideration because potentially significant treatment decisions and changes in pharmacotherapy may be based on the values obtained from these devices [1-3]. Our study suggests that the new SMBG system, FreeStyle, is a reliable instrument for measuring blood glucose values.

Precision and linearity of an SMBG system and a reference laboratory method must be identified before evaluating the accuracy of an SMBG system [20,21]. In our study, precision and linearity were examined with control solutions containing various concentrations of

glucose and determined to be excellent for the FreeStyle system as well as the two standard SMBG systems and the reference laboratory method. Reproducibility of the FreeStyle system was simultaneously determined by checking two successive whole blood glucose values from 30 volunteers. The results show that the FreeStyle system is as reproducible as the two standard SMBG systems.

The statistical accuracy of the blood glucose meters was evaluated by multiple comparison test, calculation of relative standard deviation (RSD), and simple linear regression based on previous studies. Although FreeStyle differed significantly from the two standard meters and the reference laboratory method in fasting state by multiple comparison test, the data of the nonfasting group did not show statistical difference. In addition, the FreeStyle system also had very similar RSD to the two standard meters and reference laboratory method in both fasting and nonfasting states. It is therefore difficult to evaluate the accuracy of the FreeStyle system by this statistical method. A good and acceptable correlation was demonstrated between the results from FreeStyle and the reference laboratory method in both fasting and nonfasting state (r = 0.966 and 0.938, respectively) according to linear regression analyses. The correlation coefficients generated from the two standard meters were modestly better than that generated from FreeStyle. However, the results of linear regression analysis for all the three meters were not perfect because the (r) values did not reach 1.00, the intercepts were not zero, and none of the slopes were as good as 1.00. The imperfect results of both statistical analyses are associated with glucose meter type, the reagents used, calibration factors, and the proficiency of the operator [21]. The most noticeable result in this study was the markedly elevated intercept (26.41 mg/dL) and low slope (0.81) generated by linear regression from the FreeStyle system, but not from Glucometer Elite and Glucotrend 2, in nonfasting patients; a similar condition was also reported by Geoff McGarraugh et al [14]. This phenomenon is due to a lag in the forearm response to a rapid change in glucose level after a meal or glucose challenge and is further complicated by the large difference in glucose levels (up to 20–70 mg/dL) in capillary and vein, the respective sources of blood samples for the FreeStyle and reference laboratory methods [14,21,22].

Statistical analysis is not the only way to evaluate the clinical accuracy of blood glucose meters because the difference between the meter values obtained and the laboratory standards are probably not clinically meaningful. Therefore, percentage deviation of meter glucose values from the reference method and EGA were used in this study.

Recent studies have shown that capillary blood glucose values obtained by SMBG systems may have some degree of deviation from corresponding laboratory results [10,11]. In fact, the 1996 American Diabetes Association (ADA) Clinical Practice Recommendations review of blood glucose meters already cited performance variability as one of the main problems with this form of glucose monitoring [20]. The ADA has recommended that glucose meters should deviate by no more than 5% from the reference laboratory standard [20,21,23]. However, investigation of an outpatient population revealed that these readings commonly deviate by more than 5% from those of a reference standard [24]. In another study, six blood glucose meters were evaluated and none of them met the ADA criteria of < 5% deviation [25]. On the other hand, the National Committee for Clinical Laboratory Standards (NCCLS) allows the difference between readings from blood glucose meters and the corresponding laboratory results for fasting individuals to deviate up to ±20% [20,21,23]. Although the FreeStyle meter (17% readings ≤ 5% deviation and > 80% readings ≤ 20% deviation) did not meet the ADA recommendation in our study, it did meet the NCCLS criterion. Furthermore, although the performance was inferior to that of the Glucometer Elite, the results obtained were superior to those of the Glucotrend 2 in fasting patients.

In this study, we evaluated the clinical significance of meter deviation from the reference laboratory by EGA. EGA of the fasting data revealed good clinical results for the FreeStyle data in comparison with the reference laboratory method (100% within clinically acceptable zones A and B). However, there were two pairs of nonfasting values which fell within zone D (179/250 mg/dL and 108/70 mg/dL). This condition is not surprising as larger glucose variation has been demonstrated between nonfasting capillary and venous blood samples [21,22]. This appears to indicate that FreeStyle fails to detect uncontrolled blood glucose values in accordance with the EGA standards. In practice, however, it is a benign error and seldom induces acute hyperglycemic complications when the blood glucose meter reading is 179 mg/dL and the actual plasma glucose level is 250 mg/dL, even when no additional hypoglycemic agent is added to the patient's usual therapeutic regimen. However, there is a potential risk of developing hypoglycemia when the blood glucose meter reading is 108 mg/dL and the actual plasma glucose level is 70 mg/dL. The latter error, which has been reported by others as well, is produced by the reduced level of blood perfusion which results in a lag of response to falling glucose levels in the forearm and can be ameliorated by rubbing the test site [14,26].

Frequent monitoring of blood glucose is very important because it enables patients and clinicians to adjust therapeutic regimens and achieve optimal glucose control. There are some barriers to effective SMBG, however, including operator error and decreased frequency of compliance because of the discomfort and inconvenience associated with the established methods [12,27]. In our study, to avoid the influence of operator error on accuracy of blood glucose measurement, all monitoring procedures involving blood glucose meters were uniformly performed by the same healthcare professional. Thus, the results of our study reflect the accuracy of the FreeStyle system. Our data also showed that the discomfort and inconvenience associated with the forearm skin prick was markedly reduced in comparison with the fingertip analog. It seems reasonable to assume that this pain reduction is probably the result of the much lower density of sensory nerve endings in the forearm [19]. Furthermore, the number of second skin pricks required for extraction of adequate blood volume was also quite modest with the FreeStyle meter.

In summary, the FreeStyle system is precise and reproducible compared with standard SMBG systems. The linearity, by assessing glucose levels between 50 to 450 mg/dL, is also similar to standard systems. Although its upper display limit (500 mg/dL) is lower than the upper measuring range of the Glucometer Elite and the Glucotrend 2 (600 mg/dL), the FreeStyle is still useful for clinical application. Finally, the FreeStyle is accurate, both statistically and clinically, and corresponds well with the laboratory method for patients in a fasting state. However, its accuracy decreased in the nonfasting state.

There was a limitation in this study: we did not evaluate the accuracy of the SMBG systems at low blood glucose values, and, therefore, can not comment on the accuracy of the FreeStyle in detecting hypoglycemia. The patients enrolled in this study were outpatients and hypoglycemia is rarely encountered in this setting.

In conclusion, the FreeStyle system is sufficiently accurate for home monitoring of blood glucose, at least in the fasting state. However, caution must be taken because of its potential failure to detect hypoglycemia. There are no technical difficulties associated with the forearm skin prick and blood extraction and, with proper education, self-monitoring is easily performed by the patient. Additionally, the FreeStyle is particularly attractive for children and for people hoping to avoid sore or callused fingers. The forearm skin prick is much less painful than the finger pinprick and was even reported to be painless by a substantial portion of the patient population.

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經由手臂採血施行自我血糖監測之準確性

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目的 經由手指採血做自我血糖監測雖然夠準確，但由於較疼痛，常不被病人接受，爲了加強糖尿病人施行自我血糖監測的意願，一種新的血糖機經由較不疼痛的部位(手臂)採血，已經被開發出來了，這篇研究的目的即在於評估這種血糖機－利舒坦(FreeStyle)的準確性。

方法 從門診收集93位空腹和93位非空腹的糖尿病病人，先抽取靜脈血，以標準的檢驗室方法檢測其血漿糖值，隨後再分別於手指和手臂上採血，用三種不同的血糖機：易你測(Glucometer Elite)、固可全(Glucotrend 2)及利舒坦(FreeStyle)檢測其血糖值，再將血糖機得到的數值和檢驗室的結果做比對；統計學上的準確性是以簡單線性迴歸的方法及相對標準偏差做分析，而臨床上的準確性則以Error grid analysis (EGA)做評估。每位病人並同時被詢問關於在手指和手臂上採血的疼痛度。

結果 在空腹的病人，以簡單線性回歸分析顯示利舒坦的結果爲：截距-9.87毫克/百毫升，斜率0.96和相關係數0.966，Error grid analysis則顯示利舒坦的檢測值均落於臨床上可接受的A區和B區；至於非空腹的病人，其結果爲：截距26.41毫克/百毫升，斜率0.81和相關係數0.938，而有81%、17%和2%的檢測值分別落於A區、B區和D區。利舒坦的相對標準偏差值與易你測、固可全及檢驗室方法得到的結果相近。大約有97%的病人認爲在手臂上採血比在手指上採血較不疼痛。

結論 利用新的血糖機－利舒坦在手臂上採血做血糖檢測，其準確性是足夠的，可以推薦給糖尿病病人做自我血糖監測。不過，由於其偵測低血糖的能力有潛在的瑕疵，而且血糖值變動較大時，其準確度亦會降低，因此在使用時仍須小心。（中台灣醫誌 **2003;8:214-24**）

關鍵詞

準確性，血糖機，error grid analysis (EGA)，利舒坦，自我血糖監測

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