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Clinica Chimica Acta 349 (2004) 135–141



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Accuracy of the EasyTouch blood glucose self-monitoring system: a study of 516 cases

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Received 29 April 2004; received in revised form 10 June 2004; accepted 15 June 2004

Abstract

Background: Self-monitoring blood glucose device is an important tool for diabetes patients to efficiently control their blood glucose concentrations. We evaluated the accuracy of EasyTouch glucose monitoring system.

Methods: Capillary blood glucose concentrations measured using EasyTouch and the reference values obtained from Yellow Springs Instruments (YSI) 2300 STAT were performed in the Department of Laboratory Medicine, Wei-Gong Memorial Hospital. Results were evaluated using (1) linear regression analysis, (2) Clarke Error Grid analysis, (3) percentage of readings within a defined range of deviation from the reference value, (4) bias plots, and (5) coefficients of variation (CVs) calculated from 60 measurements in series.

Results: The window of the 516 EasyTouch readings covered a range from 42 to 555 mg/dl. Linear regression analysis yielded a regression slope 0.9972, intercept 1.899 mg/dl, r^2 0.9571, and Syx 14.89 mg/dl. A Clarke Error Grid analysis showed 100% of the EasyTouch readings in clinically acceptable zones A and B. Of the EasyTouch readings, 98.3%, 91.9%, 78.3% and 46.9% were found within $\pm 20\%$, $\pm 15\%$, $\pm 10\%$, and $\pm 5\%$, respectively, of the reference values. Further analysis showed that the percentage of EasyTouch readings within the defined intervals was similar in three glucose ranges (≤ 100 , 101–200, and ≥ 201 mg/dl). The CVs for the four lots of strips (lot 1 to lot 4) ranged from 3.5 to 5.5%, 2.1 to 4.8%, 1.8 to 3.6%, and 3.0 to 5.7%, respectively.

Conclusions: EasyTouch provides high accurate and precise glucose readings over a wide range of glucose concentrations.

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Keywords: Diabetes mellitus; Glucose self-monitoring system; Clarke Error Grid analysis; Home testing; Point-of-care testing

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doi:10.1016/j.cccn.2004.06.010

1. Introduction

Diabetes mellitus (DM) and its related complications have been known to be the major health problems worldwide. The annual deaths associated with DM was estimated to be approximately 4 million [1]. The cost burden for DM in the US was estimated to be 132 billion in 2002 [2]. Considerable efforts regarding diabetes have been focused on the improvement of clinical outcome and on the reduction of economic burden. It has been reported that the maintenance of near-normal blood glucose level was important in reducing the risk or slowing the progress of diabetes-related complications/deaths [1,3]. Thus, self-monitoring blood glucose device was recommended as one of the important tools for diabetic patients to control their blood glucose levels [4–8].

Over the past few years, many handheld glucose meters have been developed and introduced into the self-monitoring diagnostic market. The clinical accuracy of many of them has been evaluated [9–16]. Recently, EasyTouch, a new handheld capillary blood glucose/uric acid monitoring system (Bioptik Technology, Hsinchu, Taiwan), has been introduced into the diagnostic market. The objective of the present study was designed to determine the clinical accuracy of EasyTouch glucose monitoring system.

2. Materials and methods

2.1. Subjects and blood glucose measurements

Patients with diabetes attending the outpatient clinic of Wei-Gong Memorial Hospital were invited to enroll in the study. Using EasyTouch glucose monitoring system, capillary blood glucose measurements (finger stick) was performed in the Department of Laboratory Medicine of Wei-Gong Memorial Hospital by a trained technician according to the manufacturer's instructions to avoid errors made by patients. Four lots of EasyTouch test strips were used. Immediately after finger stick measurement, venous blood sample of diabetic patient was drawn by a nurse. Plasma glucose from this sample was determined using the Yellow Springs Instruments (YSI) 2300 STAT blood glucose analyzer, which served as the reference method. According to the manufac-

turers' claims, patient's hematocrit, a selection criterion of the present study, was also determined. Measurements from patients with hematocrit of <30% or >55% were analyzed but excluded from the present clinical accuracy study. To evaluate the precision of the EasyTouch monitoring system, 60 measurements for each of the six clinically relevant blood glucose ranges (43–56, 83–90, 148–158, 245–264, 354–371, and 422–470 mg/dl) were performed for the four lots of test strips using 20 EasyTouch meters. Four of these meters were used at the Wei-Gong Memorial Hospital.

2.2. Data analysis

The clinical accuracy of EasyTouch was assessed by comparing the EasyTouch readings with the YSI reference values using (1) linear regression analysis, (2) Clarke Error Grid analysis [17,18], and (3) the percentage of readings within a defined range of deviation from the reference value. The *x*-axis and the *y*-axis of the Error Grid analysis were defined as the reference values and the EasyTouch readings, respectively. The resulting graphic display of the Clarke Error Grid analysis was divided into different zones: (1) zone A: clinically accurate; (2) zone B: error $>\pm 20\%$ but would lead to benign or no treatment; (3) zone C: overcorrection of the true glucose value; (4) zone D: dangerous failure to detect and treat; (5) zone E: erroneous treatment. The percentage of readings within a defined deviation range (<5%, 5–10%, 10–15%, 15–20%, and >20%) of the reference values was analyzed for each of the glucose range (≤ 100 , 101–200, and ≥ 201 mg/dl). Precision of the EasyTouch monitoring system was determined from the 60 measurements of each glucose range.

3. Results

A total of 516 patients, met the criterion of hematocrit concentrations (30–55%), were eligible for the study. Of these participants, 246 (47.7%) were males and 270 (52.3%) were females (age range 16 to 83 y). The 516 EasyTouch readings covered a wide range of glucose concentrations from 42 to 555 mg/dl (65 readings (12.6%) ≤ 100 mg/dl, 314 readings (60.8%) 101–200 mg/dl, 112 readings (21.7%) 201–

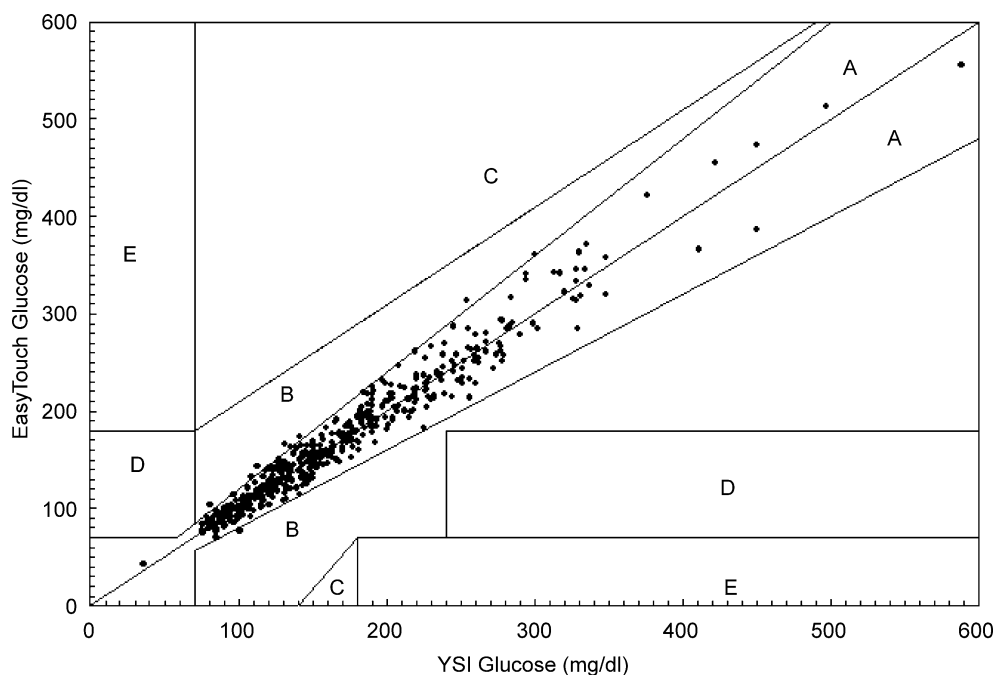


Fig. 1. Error grid analysis of the EasyTouch monitoring system. EasyTouch readings were plotted against the YSI reference method.

300 mg/dl, 19 readings (3.7%) 301–400 mg/dl, 5 readings (0.9%) 401–500 mg/dl, and 1 reading (0.19%) ≥ 501 mg/dl). Over the range of glucose readings, EasyTouch correlated well with the YSI values (slope 0.9972, intercept 1.899 mg/dl, r^2 0.9571, Syx 14.89 mg/dl). A Clarke Error Grid analysis showed that 507 readings (98.3%) fell within zone A and 9 readings (1.7%) fell within zone B (Fig. 1). All readings falling on zone B were near the A/B border. There were no readings in the C, D, or E zones. Of the EasyTouch readings, 98.3%, 91.9%, 78.3% and 46.9% were within $\pm 20\%$, $\pm 15\%$, $\pm 10\%$, and $\pm 5\%$, respectively, of the reference values. The total readings were separated into three glucose ranges (≤ 100 , 101–200, and ≥ 201 mg/dl) for further analysis

(Table 1). The percentage of the readings deviating from the reference values within the defined interval was similar in the three glucose ranges: (1) nearly half of the readings (41.5–49.6%) were within 5% interval; (2) around one-third (30.6–35.4%) of the readings were within 5–10% interval; (3) about one-eighth (11.7–14.3%) of the readings were within 10–15% interval; (4) approximately one-fifteenth (5.8–7.7%) of the readings were within 15–20% interval; and (5) $< 2\%$ (1.5–1.9%) of the readings were $> 20\%$ of the reference values.

The manufacturer has indicated that the safe range of hematocrit for the measurement of blood glucose concentrations with EasyTouch was between 30% and 55%. According to this claim, 86 patients were not

Table 1

Number and percentage of EasyTouch readings within a defined interval according to the different glucose concentration ranges

Percentage deviation from the reference value						
Glycemic ranges	<5%	5–10%	10–15%	15–20%	>20%	Total
<100 mg/dl	27(41.5%)	23(35.4%)	9(13.8%)	5(7.7%)	1(1.5%)	65
101–200 mg/dl	147(46.8%)	96(30.6%)	45(14.3%)	20(6.4%)	6(1.9%)	314
>201 mg/dl	68(49.6%)	43(31.4%)	16(11.7%)	8(5.8%)	2(1.5%)	137
Total	242	162	70	33	9	516

Data are number or %.

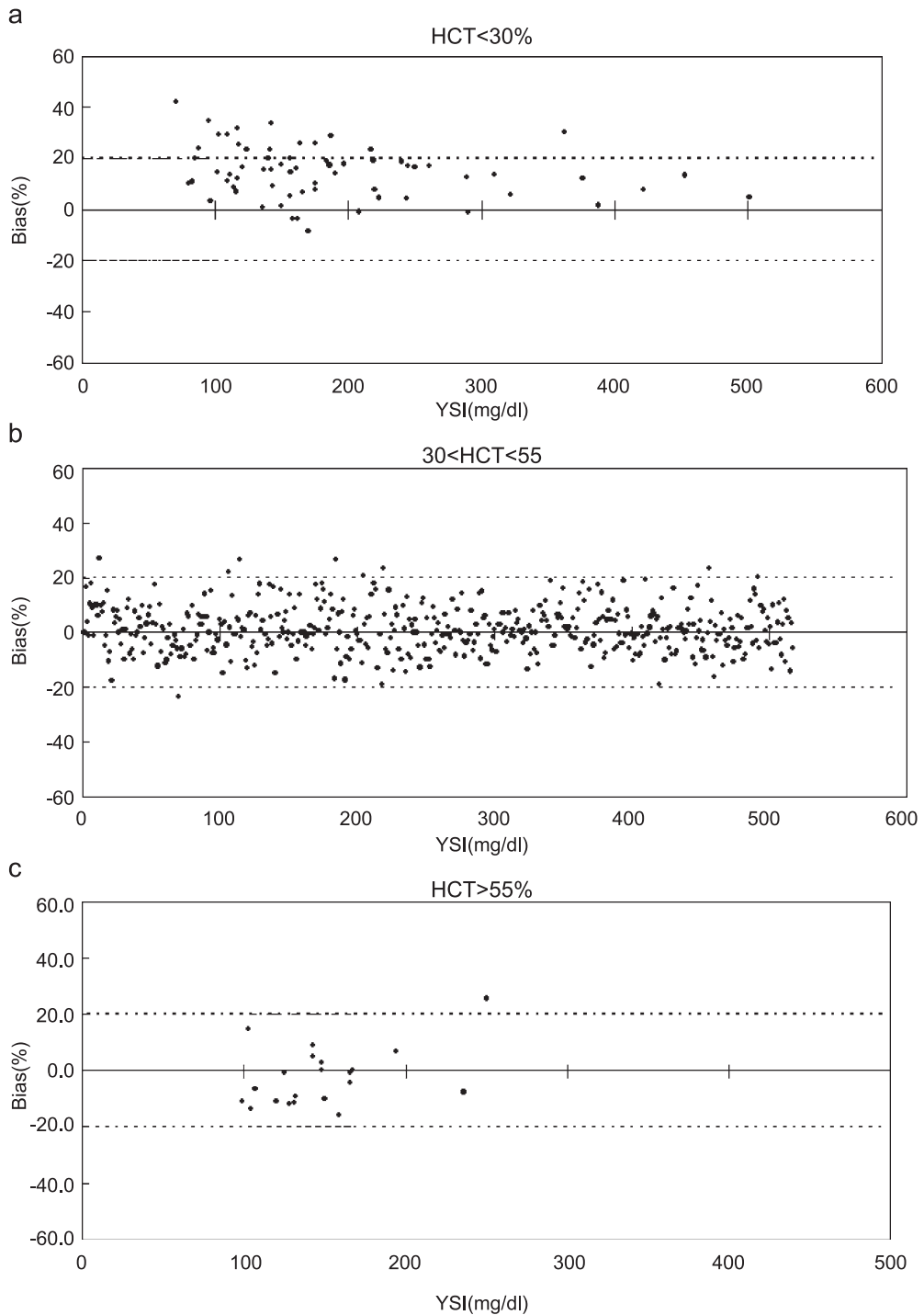


Fig. 2. Bias plots showing the effect of hematocrit on the EasyTouch glucose readings: (a) low hematocrit (<30%); (b) normal hematocrit (30–55%); (c) high hematocrit (>55%).

Table 2
The CVs (%) for measurements in series for six different glucose concentration ranges

Lots of strips	43–56 mg/dl	83–90 mg/dl	148–158 mg/dl	245–264 mg/dl	354–371 mg/dl	422–470 mg/dl
1	5.33	4.73	4.04	4.50	5.52	3.48
2	4.80	4.18	3.07	2.28	2.10	2.96
3	3.09	3.17	2.06	3.64	1.82	3.56
4	5.61	5.75	3.04	3.46	2.97	3.38

eligible for the study. Of these patients, 65 had low hematocrit (<30%) and 21 had high hematocrit (>55%). The effect of hematocrit on glucose readings was demonstrated using bias plots (Fig. 2). The EasyTouch readings relative to the YSI reference values under the conditions of hematocrit <30% showed unacceptable results (approximately 26% of the EasyTouch readings >20% of the reference values) with a pronounced (92.3%) positive bias (Fig. 2a). Under the conditions of normal (30–55%; Fig. 2b) and high (>55%; Fig. 2c) hematocrits, respectively, 98.3% and 95.2% of the EasyTouch readings were within $\pm 20\%$ interval of the reference values. The precision of the EasyTouch monitoring system is shown in Table 2. At the six test glucose ranges, coefficients of variation (CVs) for lot 1 to lot 4 ranged from 3.48% to 5.52%, from 2.10% to 4.80%, from 1.82% to 3.56%, and from 2.97% to 5.75%.

4. Discussion

EasyTouch is a bifunctional handheld device containing glucose and uric acid monitoring systems. It was recently introduced into the self-monitoring diagnostic market. Using electrochemical detection technique, EasyTouch glucose monitoring system was developed for rapid determination (<25 s) of glucose concentrations over a wide range of glucose concentrations (20–600 mg/dl) from a small amount of capillary whole blood samples (approximately 4 μ l). In order to determine if EasyTouch is a clinically acceptable device for measuring blood glucose concentrations, we evaluated the clinical accuracy of the EasyTouch. The 516 EasyTouch readings covered a wide range of glucose concentrations (42 to 555 mg/dl) suggesting that this study population was sufficient to represent a larger population of diabetic patients. Linear regression analysis showed that the EasyTouch readings correlated very well with the YSI reference

values over the range of glucose concentrations measured. The error grid analysis showed that EasyTouch glucose monitoring system had 100% of measurements in zones A and B suggesting that EasyTouch is a clinically acceptable device for blood glucose measurements.

Other analysis in determining the accuracy of self-monitoring system was expressed by the percentage of deviation from the reference value. One standard for accuracy evaluation was proposed by the International Organization for Standardization (ISO), which recommended that 95% of the measurements should be within $\pm 20\%$ of the reference values for glucose concentrations >100 mg/dl and within ± 20 mg/dl for glucose values <100 mg/dl [19]. Our results showed that 98.3% of the EasyTouch readings were within $\pm 20\%$ interval indicating that EasyTouch met the accuracy criteria proposed by ISO. The other standard for accuracy evaluation was proposed by the American Diabetes Association (ADA), which recommended that 100% of readings should be within $\pm 5\%$ of the reference values [20]. However, none of the glucose meters can reach this stringent goal [21–23]. The accuracy of self-monitoring glucose meters reported previously showed: (1) 56% and 74% of the readings were within $\pm 10\%$ and $\pm 15\%$, respectively, of the reference values [24]; (2) 45.6%, 25%, 14% of readings deviated from the reference values by >10%, 15%, and 20%, respectively [25]; (3) only 15–25% of the readings reached the criteria of within $\pm 5\%$ of the reference method [13]. An improvement on the newer generation of self-monitoring meters was evident on a previous study, which indicated an increase from about 33% (older meters) to approximately 50% (newer meters) of readings within $\pm 5\%$ of the reference values [22]. The present study showed that about 50% of the EasyTouch readings met the ADA stringent goal ($\pm 5\%$) suggesting that EasyTouch is an improved monitoring system. In addition, self-monitoring glucose meters have been

classified into groups of good, acceptable, and unacceptable for clinical use [26]. The “good” meters was defined if >60% of the readings within $\pm 10\%$ of the reference value. Thus, EasyTouch should be classified as a “good” meter based on the result that EasyTouch had 78% of the readings within $\pm 10\%$ interval. Besides, the percentage of readings within the defined interval was similar in three glucose concentration ranges (low, medium and high) suggesting that the system performance of EasyTouch was consistent over a wide range of glucose concentrations.

It should be noted that the manufacturer has limited a hematocrit range (30–55%) for the best performance of EasyTouch glucose monitoring system. With respect to the reference values, low hematocrit was associated with overestimation of glucose concentrations. No observable influence on the EasyTouch measurement was evident at the high hematocrit. The CVs between the EasyTouch measurements and the YSI reference values were within the satisfactory interval (<6%) suggesting that EasyTouch monitoring system provided precise measurements. In conclusion, we demonstrated that EasyTouch is a device providing high accurate and precise glucose readings and should be rated as “improved meter” or “good meter”.

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