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An evaluation of clinical accuracy of the EasyTouch blood uric acid self-monitoring system

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Abstract

Objectives: Self-monitoring blood uric acid device is an important tool for patients to efficiently monitor their blood uric acid concentrations. The objective of the present study was to evaluate the accuracy of EasyTouch uric acid monitoring system.

Design and methods: Capillary blood uric acid concentrations measured using EasyTouch and the reference values obtained from COBAS MIRA were performed in the Department of Laboratory Medicine, Wei-Gong Memorial Hospital. Results were evaluated using (1) linear regression analysis, (2) percentage of readings within a defined range of deviation from the reference value, and (3) coefficients of variation (CVs) calculated from 60 measurements in series.

Results: The window of the 177 EasyTouch readings covered a wide range from 0.1785 to 0.6367 mmol/L (3–10.7 mg/dL). Linear regression analysis yielded a regression slope of 0.975, an intercept of 0.0118 mmol/L and an R^2 of 0.8966. Of the EasyTouch readings, 64 (36.2%), 61 (34.5%), 34 (19.2%), 9 (5.08%), and 9 (5.08%) were within the intervals of <5%, 5–10%, 10–15%, 15–17%, and >17%, respectively, of the reference values. Further analysis for the performance of each lot of strips showed that both coefficients of correlation and the percentages of readings within the CLIA's criterion (±17%), respectively, were in a narrow range from 0.8777 to 0.9541 and from 92.1% to 100%. The CVs for the seven lots of strips (lot 1 to lot 7) ranged from 2.93% to 6.33%, 3.2% to 5.9%, 3.64% to 7.0%, 2.84% to 7.6%, 2.68% to 5.42%, 3.03% to 6.93%, and 3.18% to 5.17%, respectively.

Conclusion: EasyTouch is an acceptable diagnostic device which provides accurate uric acid measurements.

Keywords: Uric acid; Self-monitoring system; Linear regression; CLIA

Introduction

Uric acid is known as the major metabolic product of purines in humans. There are two types of purines, which are exogenous (dietary) or endogenous nucleic acids. Normally, a balance between the rate of purine metabolism and the degree of uric acid excretion keeps the concentration of blood uric acid in a range of 0.1785–0.4284 mmol/L (3–7.2 mg/dL) in men and 0.119–0.357 mmol/L (2–6 mg/dL) in women. Under certain circumstances, a disturbance of the balance may occur and lead to an increase or a decrease in blood uric acid concentration. Altered blood uric acid concentrations have been linked to a number of disorders such as (1) gout [1,2]; (2) cardiovascular disease [3–6]; (3) diabetes mellitus [7]; (4) multiple sclerosis [8–10] suggesting that serum uric acid concentration may serve as an important parameter physiologically/pathologically.

For quantitative determination of blood uric acid, uricase (urate oxidase)-based approaches have been used by several studies [11–15]. The widespread use of uricase was based on its specific role in converting uric acid into allantoin [16–

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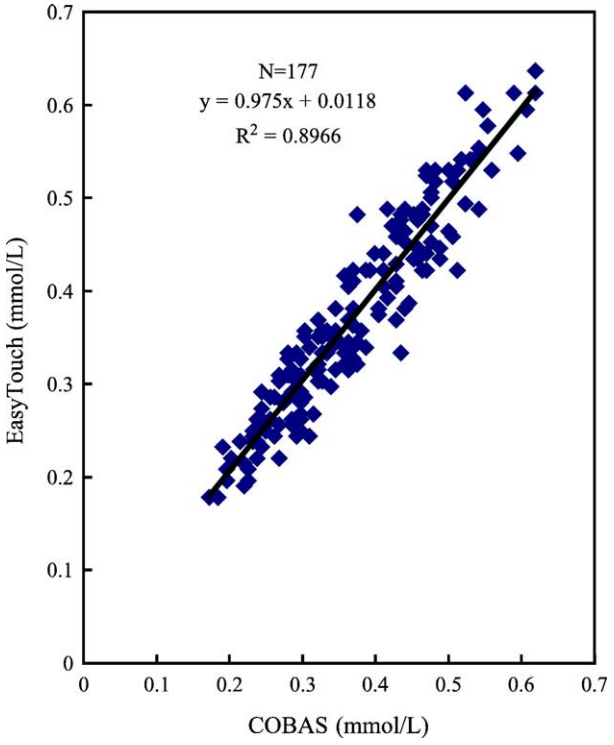

Fig. 1. Linear regression analysis of the EasyTouch monitoring system against the COBAS reference method. A total of 177 EasyTouch readings were plotted.

18]. Recently, EasyTouch (Bioptik Technology Inc., Hsinchu, Taiwan), a new handheld capillary blood bifunctional (glucose/uric acid) self-monitoring system, was introduced into the diagnostic market using the uricase-based electrochemical technique. Since the self-monitoring system is used to improve clinical outcome of in-home patients, it is necessary and important to determine if EasyTouch provides measurements which are equivalent to those obtained from the laboratory reference method. Therefore, the objective of the present study was to determine the clinical accuracy of EasyTouch uric acid monitoring system.

Methods

Patients attending the outpatient clinic of Wei-Gong Memorial Hospital were invited to enroll in the study. Using the EasyTouch uric acid monitoring system, capillary blood uric acid measurement (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. Seven lots of EasyTouch test strips were used. Immediately after finger stick measurement, a venous blood sample was drawn from the patient by a nurse. Serum uric acid from this sample was determined using the COBAS MIRA analyzer (Roche, Taiwan), which served as the reference method. The manufacturer has indicated that the safe range of hematocrit for the measurement of blood uric acid concentrations with EasyTouch was between 30% and 55%. According to this claim, patient's hematocrit was also determined. Measurements from patients with hematocrit of less than 30% or more than 55% were excluded from the present clinical accuracy study. The readings obtained from COBAS were served as the reference values. To evaluate the precision of the EasyTouch monitoring system, 60 measurements for

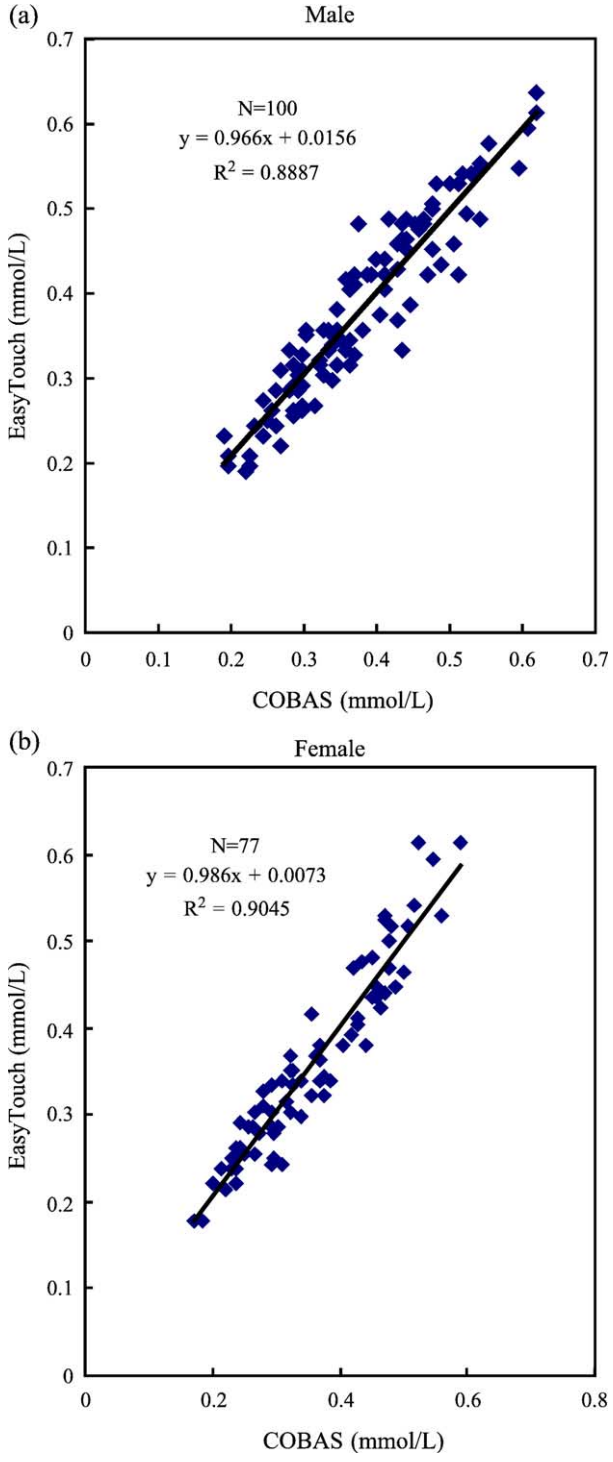

Fig. 2. Linear regression analysis of the EasyTouch readings against the COBAS reference method. (a) males and (b) females were plotted.

Table 1
Number of EasyTouch readings within a defined interval according to the 7 lots of uric acid strips

Strip lots	Percentage deviation from the reference value					Total
	<5%	5–10%	10–15%	15–17%	>17%	
Lot 1	4	4	2	2	0	12
Lot 2	11	7	6	1	2	27
Lot 3	9	17	7	2	3	38
Lot 4	13	10	10	2	1	36
Lot 5	8	15	5	1	1	30
Lot 6	10	5	2	0	1	18
Lot 7	9	3	2	1	1	16
Total	64	61	34	9	9	177

Data are number.

each of the five clinically relevant blood uric acid ranges (0.25–0.29, 0.45–0.48, 0.61–0.67, 0.85–0.90, and 1.10–1.16 mmol/L) were performed for the seven lots of test strips using 20 EasyTouch meters. Four of these meters were used at the Wei-Gong Memorial Hospital.

The clinical accuracy of EasyTouch was assessed by comparing the EasyTouch readings with the COBAS reference values using (1) linear regression analysis and (2) the percentage of readings within a defined range of deviation (<5%, 5–10%, 10–15%, 15–17%, and >17%) from the reference values. The 17% interval was defined by CLIA '88 (Clinical Laboratory Improvement Amendments of 1988) [19] as the allowable error for determination of uric acid concentrations. Further analysis for the performance of each lot of strips, both linear regression and CLIA's criterion were used. Precision of the EasyTouch monitoring system was determined using coefficients of variation (CVs) calculated from the 60 measurements of each uric acid range.

Results

A total of 177 participants, met the criterion of hematocrit concentrations (30–55%), were eligible for the study. Of these participants, 100 (56.5%) were males and 77 (43.5%) were females. The ages of the participants were from 21 to 88 years with the mean age of 61 years. The 177 EasyTouch readings covered a wide range of uric acid concentrations from 0.1785 to 0.6367 mmol/L (3 to 10.7 mg/dL). Over the range of uric acid measurements, EasyTouch correlated well with the COBAS values (a regression slope of 0.975, an intercept of 0.0118 mmol/L and an R^2 of 0.8966; N = 177; Fig. 1). For each lot of strips, linear regression analysis of (1) lot 1 (N = 12) yielded a regression slope of 0.9571, an intercept of 0.0226 mmol/L and an R^2 of 0.9082; (2) lot 2 (N = 27) yielded a regression slope of 0.9911, an intercept of 0.01 mmol/L and an R^2 of 0.888; (3) lot 3 (N = 38) yielded a regression slope of 0.9849, an intercept of 0.0043 mmol/L and an R^2 of 0.8777; (4) lot 4 (N = 36) yielded a regression slope of 1.0484, an intercept of 0.0147 mmol/L and an R^2 of 0.9015; (5) lot 5 (N = 30) yielded a regression slope of 0.8812, an intercept of 0.0486 mmol/L and an R^2 of 0.8798; (6) lot 6 (N = 18) yielded a regression slope of 0.985, an intercept of 0.0141 mmol/L and an R^2 of 0.9173; and (7) lot 7 (N = 16) yielded a regression slope of 0.957, an intercept of 0.0301 mmol/L and an R^2 of 0.9541. Fig. 2 shows the linear regression analysis of males (a regression slope of 0.966, an intercept of 0.0156 mmol/L and an R^2 of 0.8887; N = 100; Fig. 2a) and females (a regression slope of 0.986, an intercept of 0.0073 mmol/L and an R^2 of 0.9045; N = 77; Fig. 2b).

Of the 177 EasyTouch readings, 64 (36.2%), 61 (34.5%), 34 (19.2%), 9 (5.08%) and 9 (5.08%) were within the intervals of <5%, 5–10%, 10–15%, 15–17%, and >17%, respectively, of the reference values (Table 1). Overall, 95% of the 177 EasyTouch readings were within the ±17% of the COBAS reference values. A further analysis for the performance of each lot of the strips showed that 100% (12/12), 92.6% (25/27), 92.1% (35/38), 97.2% (35/36), 96.7 (29/30), 94.4% (17/18), and 93.8% (15/16), respectively, of the EasyTouch readings from lot 1 to lot 7 met the criterion of ±17% interval defined by CLIA '88. The precision of the EasyTouch monitoring system is shown in Table 2. At the five test uric acid ranges, CVs for lot 1 to lot 7 ranged from 2.93% to 6.33%, from 3.2% to 5.9%, from 3.64% to 7.0%, from 2.84% to 7.6%, from 2.68% to 5.42%, from 3.03% to 6.93%, and from 3.18% to 5.17%.

Discussion

EasyTouch is a bi-functional handheld device combined with glucose and uric acid monitoring systems. It was recently introduced into the self-monitoring diagnostic market. Using uricase-based electrochemical detection technique, EasyTouch uric acid monitoring system was developed for rapid determination (less than 25 s) of uric acid concentrations over a wide range (3–20 mg/dl; 0.1785–1.190 mmol/L) using a small amount of capillary whole blood samples (approximately 4 μL). It has been reported previously that constant monitoring of uric acid level was necessary for prevention of gout [2]. Thus, it is necessary that EasyTouch provides accurate readings for in-home patients. In order to determine if EasyTouch is a clinically acceptable device for measuring blood uric acid concentrations, we evaluated the clinical accuracy of the EasyTouch.

Table 2
The CVs (%) for measurements in series for five different uric acid concentration ranges

Lots of strips	0.25–0.29 mmol/L	0.45–0.48 mmol/L	0.61–0.67 mmol/L	0.85–0.90 mmol/L	1.10–1.16 mmol/L
Lot 1	6.33	5.16	3.94	2.93	3.13
Lot 2	5.9	5.2	4	3.6	3.2
Lot 3	7	5.74	4.58	3.64	3.92
Lot 4	7.6	4.94	3.45	3.37	2.84
Lot 5	5.42	4.13	3.43	2.9	2.68
Lot 6	6.93	5.04	4.13	3.37	3.03
Lot 7	5.17	3.94	3.41	3.18	3.19

Linear regression analysis showed that the EasyTouch readings correlated well with the COBAS reference values over the range of uric acid concentrations measured. It is important to note that this good correlation is also observed on each lot of strips, suggesting that the impact of lot-to-lot variability on the accuracy of uric acid reading is minimal.

Other analysis in determining the accuracy of self-monitoring system was expressed by the percentage of deviation from the reference value. The CLIA '88 recommended that uric acid readings should be within the allowable error ($\pm$17%) of the reference values. Only 5% of the EasyTouch readings did not meet the CLIA's criterion suggesting that EasyTouch was an acceptable uric acid monitoring system. The precision study indicated that a lot-to-lot variation was small ($\leq$7.6%). In addition, similarity in the correlation analysis between males and females suggests that the effect of sex difference on the accuracy of uric acid reading is minimal. In conclusion, the present study demonstrates that the uric acid monitoring system of EasyTouch provides accurate uric acid readings.

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