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ORIGINAL ARTICLE

Evaluation of OneTouch Verio®, a new blood glucose self-monitoring system for patients with diabetes

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Abstract

Introduction. Self-monitoring of blood glucose (SMBG) is important in diabetes management. Reliable and user-friendly instruments are essential. OneTouch Verio® is a new blood glucose concentration-measuring system designed to be used by patients with diabetes and healthcare professionals. The objective of the present study was to evaluate the analytical performance of the OneTouch Verio®. ***Method.*** The OneTouch Verio® was evaluated by the Scandinavian evaluation of laboratory equipment for primary healthcare (SKUP) according to a protocol based on ISO 15197 and the American Diabetes Association (ADA) quality goals. Blood samples were collected and measured on the OneTouch Verio® by laboratory personnel and patients with diabetes ($n = 91$, randomized into groups receiving personal training or mail instructions for the OneTouch Verio® system). Results were compared to a validated routine method, imprecision and bias were calculated. User-friendliness was evaluated with a questionnaire. ***Results.*** Quality specifications for blood glucose concentration monitoring systems according to ISO 15197 were fulfilled. The mean coefficients of variation (CV%) of repeatability was 3.4% when tested by laboratory personnel and within the goal of imprecision suggested by ADA. Mean CV% of repeatability for patient self-monitoring was 5.0% and 5.1% in the training- and the mail group, respectively. Total error was 6.4–10.0%. The OneTouch Verio® showed no hematocrit interference or variation between strip lots. ***Conclusion.*** The OneTouch Verio® displayed sufficient analytical quality and satisfactory user-friendliness. It is suitable for point-of-care testing of blood glucose concentration when handled by patients and healthcare professionals.

Key Words: *Blood glucose self-monitoring, diabetes mellitus, point-of-care system, validation, blood glucose*

Introduction

Self-monitoring of blood glucose (SMBG) is an important component in diabetes management helping patients to achieve and maintain optimal blood glucose concentrations. Therefore, reliable and user-friendly instruments are of great importance as the number of diabetes patients is increasing worldwide [1]. The point-of-care instrument should meet the quality goals set for self-testing devices, be easy and rapid to use, portable, inexpensive and provide immediate results. SMBG is recommended by many organizations [2–4].

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OneTouch Verio® (Lifescan Inc., Milpitas, CA, USA) is a new blood glucose monitoring system designed to be used by patients with diabetes and healthcare professionals for measuring glucose concentration in capillary blood. When this study was performed the meter had not been launched into the Scandinavian market yet. In order to get reimbursement for the test strips in Norway, the Norwegian Health Economics Administration (HELFO) requires from the companies to carry out an evaluation that includes a user evaluation among diabetes patients. The OneTouch Verio® has been evaluated by the Scandinavian evaluation of laboratory equipment for primary healthcare (SKUP) according to an evaluation model that has been used by SKUP since 2002 [5]. All data in the present article as well as Figures 2, 3 and Table II are taken from the SKUP report [6] with permission from LifeScan.

ISO15197 is an international standard for evaluating meters designed for glucose monitoring. It recommends that 95% of the individual glucose results fall within 0.83 mmol/L of the designated comparison method at glucose concentrations < 4.2 mmol/L and within 20% at glucose concentrations ≥ 4.2 mmol/L [7]. Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS) has adapted the analytical quality demands to the diabetes patients' self-measurements as follows: 95% of the individual glucose results shall fall within 1.0 mmol/L of the results of the comparison method at glucose concentrations < 4.2 mmol/L and within 25% at glucose concentrations ≥ 4.2 mmol/L. According to the American Diabetes Association (ADA), the imprecision for new glucose devices should be less than 5% for self-monitoring [8]. The total error for meters designed for SMBG should not exceed 10% according to ADA and NOKLUS has suggested a similar goal for glucose instrument used in primary care centers [9].

The aim of the present study was to evaluate the analytical performance and the user-friendliness of the OneTouch Verio® blood glucose concentration measuring system.

Materials and methods

Population

The study population comprised of 91 patients (men $n = 46$, women $n = 45$) with diabetes (type 1 diabetes $n = 30$, type 2 diabetes $n = 58$, impaired glucose tolerance $n = 1$, unclassified $n = 2$) aged 19–81 years (median 59 years). Diabetes treatment: insulin $n = 33$, insulin pump $n = 7$, insulin and tablets $n = 10$, tablets $n = 33$, diet $n = 7$, unspecified $n = 1$. All patients, except two, did regularly perform SMBG (frequency of SMBG: not measuring $n = 2$, less than weekly $n = 6$, 1–3 times per week $n = 7$, 4–6 times per week $n = 10$, 7–10 times per week $n = 16$, > 10 times per week $n = 50$). The patients were recruited in September and October 2010 through advertisements in local newspapers and by mail inquiry to members of The Norwegian Diabetes Association.

The evaluation model

The evaluation model of the OneTouch Verio® system used in the present study is shown in Figure 1. The patients were randomly divided into two groups: A training group and a mail group. The training group ($n = 46$) attended an instruction meeting, where they received personal training from laboratory personnel on how to use the OneTouch Verio® meter. They also received the owner's booklet. Immediately after the instruction, blood samples were collected by the patients and by laboratory personnel for measurements on the OneTouch Verio® meters.

The mail group ($n = 45$) had no personal training in using the OneTouch Verio® system and received the device together with the owner's booklet and an information letter by mail. The information letter was written in the native language but for both groups (training and mail group) the owner's booklet was written in English. Three different lots of test strips were distributed evenly between the patients in the groups.

After three weeks of practicing self-monitoring with the OneTouch Verio® system at home, the patients ($n = 89$) attended a follow-up meeting. For unknown reasons two patients (one with type 1 diabetes and one with type 2 diabetes) did not attend this meeting. At the follow-up meeting, blood sampling and measuring were carried out in the following order:

(1) The laboratory personnel took a first sample for the comparison method;
(2) The laboratory personnel took a sample and measured it on the OneTouch Verio® meter under standardized and optimal conditions, in a hospital laboratory. This was done by keeping the procedure in exact accordance with the protocol and the owner's booklet for the OneTouch Verio system®. The first drop of blood was wiped off before the first measurement and blood was also wiped off between two sets of duplicates. Two laboratory personnel, using two different OneTouch Verio® meters each, carried out all the blood sampling and measuring after thorough training;
(3) The patients took duplicate samples for their assigned OneTouch Verio® meter;
(4) The laboratory personnel took a second sample for the comparison method;
(5) Finally, a venous sample was collected for hematocrit analysis. All samples for measurement on the comparison method and the OneTouch Verio® meters were collected from finger capillaries. The samples measured on the OneTouch Verio® meter by laboratory personnel were

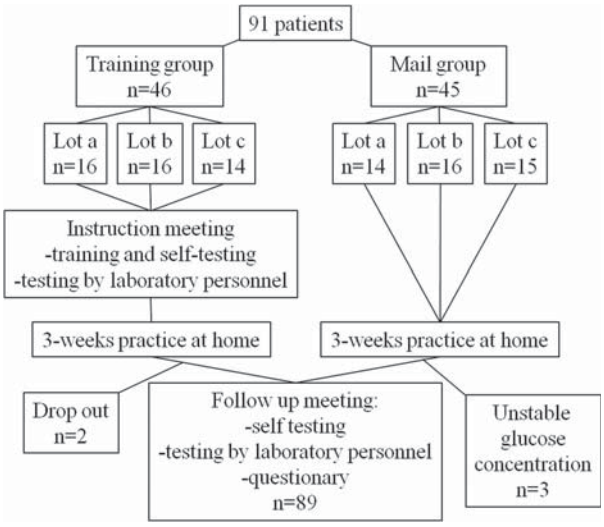

Figure 1. The evaluation model.

compared to samples taken simultaneously and measured using Abbott Architect ci8200 in order to evaluate the bias of the meters used.

The patients were all encouraged to fill in two questionnaires about the user-friendliness and the owner's booklet. Questions about the user-friendliness of the OneTouch Verio® meter were ranked 1–6, where 1 was difficult and 6 was simple. Questions about the owner's booklet were answered yes or no.

The OneTouch Verio® system

The OneTouch Verio® is a monitoring system designed to be used by patients with diabetes and healthcare professionals for measuring blood glucose concentration in capillary blood. It is based on amperometric electrochemical biosensor technology with corresponding dry reagent test strips. The test principle is to convert glucose to gluconolactone by glucose dehydrogenase. The cofactor in the reaction is flavin-adenine dinucleotide (FAD). Every test requires a blood volume of 0.4 µL taken from the fingertip, forearm or palm. The blood is drawn into the test strip by capillary force and blood glucose reacts with the dried reagents on the strip. The meter is designed for whole blood samples but reports plasma glucose concentration. A calibration technique is the basis for plasma-equivalent blood glucose results and the measuring interval is 1.1–33.3 mmol/L. The OneTouch Verio® system does not require user calibration and the results are not affected by hematocrit values from 20–60% according to the manufacturer.

Test strips from three different lots were used to assess lot-to-lot variation, all having the same expiry date. The patients could choose whether to use the OneTouch Mini Lancet Pen with OneTouch Ultra soft lancets, or the lancet pen they usually use. The reproducibility of the OneTouch Verio® meters used was checked with control solutions from the manufacturer.

The comparison method

In the absence of a reference method, a routine method for plasma glucose concentration measurement in the Laboratory at Haraldsplass Diaconal Hospital in Bergen was used as the comparison method. It is a photometric enzymatic method utilizing hexokinase and glucose-6-phosphate dehydrogenase enzymes. This method is implemented on Architect ci8200 System (Abbott Laboratories, IL, USA) and shows traceability equivalent to an internationally accepted reference solution for example supplied by the National Institute of Standards & Technology (NIST) [10].

Blood samples were taken from finger capillary using Microvette Li-heparin tubes (Sarsted AG & Co, Nümbrecht, Germany) and were centrifuged for 3 min at 10,000 *g* before plasma was separated and frozen at − 80°C until the measurement was performed.

Two human serum controls (SERO AS) with target values determined by an isotope-dilution gas chromatography/mass spectrometry method in a reference laboratory in Belgium (Laboratory for analytical chemistry, University of Gent, Belgium) were used. These controls are included in the NOKLUS's External Quality Assessment Program. Reagent and calibrator from Abbott Laboratories were used.

Analytical quality goals

OneTouch Verio® was evaluated according to quality goals presented in Table I.

Statistics

Statistical analyses were performed using Microsoft® Office Excel 2003. All results were examined for outliers according to Burnett [11] and outliers were excluded from the calculations of coefficients of variation (CV%). Student's paired *t*-test was used to compare the mean values of the duplicated samples on the comparison method and on the OneTouch Verio® system. Precision was defined as repeatability and reproducibility, where repeatability of the OneTouch Verio® instrument was calculated in CV% using duplicate measurements and the reproducibility was calculated in CV% using the control solution results. The agreement between the comparison method and the OneTouch Verio® is shown in a Bland-Altman plot [12]. Trueness was expressed as bias by comparing mean values between the comparison method and the OneTouch Verio® results achieved under standardized and optimal conditions. Total error was calculated as $1.96 \times CV$ (two-tailed probability of 0.05).

Table I. Analytical quality for glucose monitoring under optimal conditions defined by American Diabetes Association (ADA), the International Organization for Standardization ISO 15917 and Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS).

	Accuracy (%)	Total error (TE) (%)	Precision (CV, %)
ADA		10	< 5
ISO 15197	20		
NOKLUS	25*	10	

*Analytical quality goals adjusted to the diabetes patients self-measurements.

Results

The comparison method

The trueness of the comparison method (Abbott system) was documented at glucose concentrations 1.8, 4.2, 6.6 and 16.4 mmol/L of NIST SRM 965b reference material and with two human serum control concentrations (4.8 and 11.8 mmol/L). The glucose concentrations of NIST SRM 965b reference material measured with the Abbot system showed bias of − 0.2%, 1.4%, 1.0% and 2.5% for those four concentrations, respectively. Results for the reference material were in agreement with certified target values at the three lowest concentrations. The highest concentration was approximately 0.2 mmol/L above the upper 95% uncertainty limit. Therefore, SKUP did theoretical recalibration and adjusted the comparison method results according to certified NIST targets. The Architect system showed good repeatability. The repeatability expressed as CV% calculated from the differences between the duplicate capillary blood samples corresponded to a CV% of 0.9% (CI 0.7–1.0) ($n = 134$).

Evaluation of hematocrit interference

The hematocrit measured by the Sysmex-system was between 30 and 49% for all measured samples ($n = 82$, data not shown). Glucose measurements with OneTouch Verio® meter were not influenced by hematocrit within this interval.

Evaluation of OneTouch Verio® under optimized and standardized conditions

A small statistically significant positive bias was observed at glucose concentrations below 10 mmol/L. At glucose concentrations above 10 mmol/L the OneTouch Verio® showed good agreement with the comparison method as shown in Table II. The quality specifications for accuracy for blood glucose monitoring systems for self-testing according to ISO15197 (± 20%) were fulfilled (Figure 2). The results for capillary blood samples drawn from the patients by the laboratory personnel showed a repeatability of 3.4% (CI 3.0–3.8%) for duplicate measurements on the OneTouchVerio® meter. The total error was 6.7% (CI 5.9–7.4%) as shown in Table III. This was below the 10% threshold of maximum allowable total error stated by ADA. Since one statistical outlier was found, CV% and total error was calculated without the results from the outlier. On the four meters used by laboratory personnel, the mean of paired measurements showed a difference of glucose concentration less than 0.06 mmol/L between the duplicate results. The reproducibility achieved with the controls on the OneTouch Verio® meters used by the laboratory personnel was 2.8% (data not shown). No significant difference was observed between the three lots of strips used on the OneTouch Verio® meters (data not shown).

Evaluation of the OneTouch Verio® meter in patient self-testing

Out of the 89 patients who attended the follow-up meeting, three had unstable glucose concentrations as measured by the comparison method before and after the blood samplings and were excluded from the calculations. Patient's glucose concentrations were regarded unstable if the difference between the first and the second glucose concentration result exceeded 10% when measured with the comparison method.

It was also stated at the original SKUP report [6] that the conclusions were not dependent on keeping the excluded results. Evaluation of accuracy of the diabetes patients' self-measurement at the follow-up meeting was performed by comparing the results of the first

Table II. The trueness of OneTouch Verio® meter. Table II is taken from the SKUP report [6].

Glucose level group Comparison method (mmol/L)	*n*	Excluded results	Comparison method, mean (mmol/L)	OneTouch Verio®, mean (mmol/L)	Mean deviation from the Comparison method, mmol/L (95% CI)
Low					
< 7	28	0	6.0	6.2	+ 0.27 (+ 0.15 to + 0.39)
Medium					
7–10	32	0	8.0	8.2	+ 0.24 (+ 0.08 to + 0.39)
High					
> 10	26	0	13.3	13.3	+ 0.01 (− 0.25 to + 0.27)

CI, confidence interval.

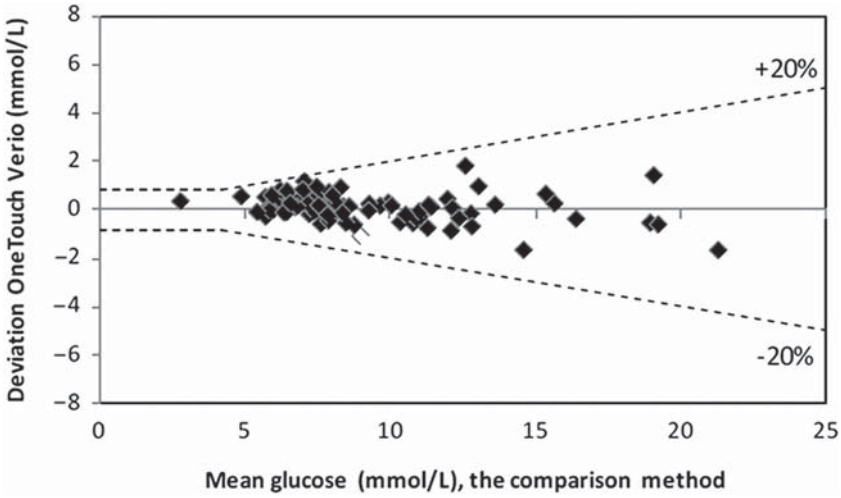

Figure 2. Accuracy measured by the OneTouch Verio® meter under standardized and optimal measuring conditions at the follow-up meeting. The X-axis represents the mean value of the duplicate results on the comparison method. The Y-axis shows the difference between the first measurement on OneTouch Verio® and the mean value of the duplicate results on the comparison method. Stippled lines represent limits suggested in ISO 15197 (± 0.83 mmol/L at glucose concentrations < 4.2 mmol/L and within ± 20% at glucose concentrations ≥ 4.2 mmol/L), $n = 87$. Open symbol represents a statistical outlier excluded from the calculation of repeatability on one meter. Figure is taken from the SKUP report [6].

measurement on the OneTouch Verio® and the mean value of the duplicate results on the comparison method in accordance to the adjusted ISO15197 limits suggested by NOKLUS (25%). These adjusted quality requirements for accuracy for SMBG were attained as shown in Figure 3. When patients in the training group draw the capillary blood samples, the result for the CV% of the repeatability for duplicate samples was 5.0% (CI 4.0–6.1%) and the total error 9.8% (CI 7.8–12%) as shown in Table III. For patients in the mail group the CV% for repeatability was 5.1% (CI 3.6–6.6%) and the total error 10% (CI 7.1–12.9%) (Table III). The CV% for repeatability and the total error in the training- and mail group were not statistically significantly different (Table III). There was no significant difference in CV% of repeatability between the training group before and after three weeks of practicing at home (data not shown).

The reproducibility achieved with the control solutions on the patients' meters used by the laboratory personnel showed a CV% of approximately 3%. All control results were within the control range printed on the control solution vial.

Evaluation of the user-friendliness of the OneTouch Verio® meter

The questionnaire about the user-friendliness and the owner's booklet for the OneTouch Verio® meter were filled in by 89 patients. The majority of the patients did not experience difficulties using the OneTouch Verio® meter according to the answers from the questionnaire. The meter was scored a mean of 5.4 on a scale from 1–6. A total of 11% of the patients had experienced technical problems with the OneTouch Verio® meter (89% responded). However, the written comments indicated that the problems were related to error codes instead of really being technical ones. The owner's booklet was read by 81% of the patients and 85% of the patients were satisfied with the booklet (95% responded).

Discussion

The analytical performance of the OneTouch Verio® was within the suggested ISO 15197 limits both when performed by the training group and the mail group of patients, and by the laboratory personnel. When tested by laboratory personnel, the mean CV% of repeatability was 3.4% and within the goal of imprecision CV% (< 5%) suggested by ADA. When tested by diabetes patients, the mean CV% of repeatability was 5.0% and 5.1% in the training group and the mail group, respectively. This is just above the limit suggested by ADA but indicates that the imprecision of the OneTouch Verio® when handled by patients is sufficient irrespective of whether they receive personal training or are instructed by written material alone.

Table III. Repeatability and calculated total error (TE) of OneTouch Verio®. Results achieved by laboratory personnel, training group and mail group patients.

	n	Mean glucose (mmol/L)	CV% (95% CI)	TE % = 1.96 × CV (95% CI)
Laboratory personnel	270	9.1	3.4 (3.0 – 3.8)	6.74 (5.9–7.4)
Training group	90	9.1	5.0 (4.0 – 6.1)	9.8 (7.8–12.9)
Mail group	45	9.6	5.1 (3.6 – 6.6)	10.0 (7.1–12.9)

CI, confidence interval; CV, coefficients of variation.

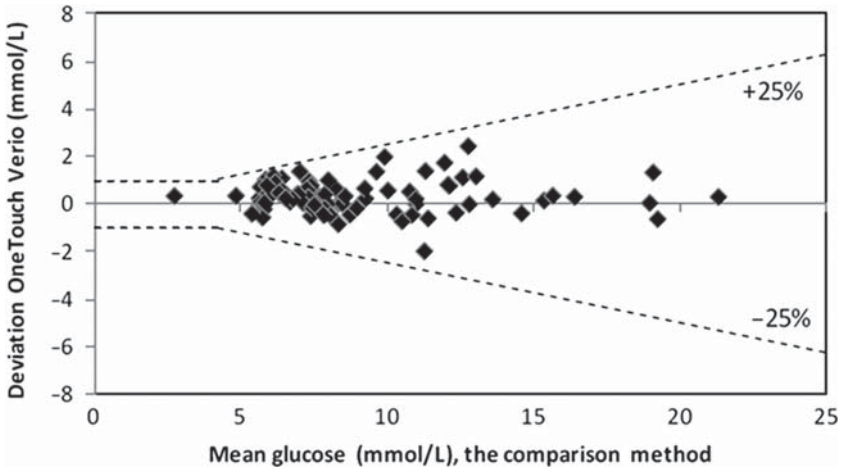

Figure 3. Accuracy, self-measurements by patients at the follow-up meeting. Stippled lines represent adjusted ISO limits suggested by NOKLUS (± 0.83 mmol/L at glucose concentrations < 4.2 mmol/L and within ± 25% at glucose concentrations ≥ 4.2 mmol/L), $n = 87$. The X-axis represents the mean value of the duplicate results on the comparison method. The Y-axis shows the difference between the first measurement on OneTouch Verio® and the mean value of the duplicate results on the comparison method. Figure is taken from the SKUP report [6].

The fact that the mean CV% of repeatability was slightly higher when tested by patients and that the performance was marginally better when tested by the laboratory personnel could be due to pre-analytical causes. For example, some of the patients did not wipe off the first drop of blood when performing the testing, and all the patients did not use the same lancet pen. The majority of the patients (85%) reported that they were satisfied with the owner's booklet, although it was written in English.

No statistically significant difference in repeatability was observed between the training group before and after three weeks of practice at home, nor between the mail group and the training group. This suggests that the given personal training did not improve patient handling of the OneTouch Verio® meter and implicates that written instruction in how to use the meter fully satisfies the need of information before self-monitoring, at least when the patient population is familiar with the SMBG testing at home as was the case in this evaluation. This also indicates a possible cost reducing effect by implementing the OneTouch Verio® system into patient settings.

Lot-to-lot variation has previously been observed as a problem [5,13], but in the present study there was no variation between lots. The hematocrit may influence the blood glucose measurements critically, especially in meters designed for self-monitoring [5]. According to the manufacturer, the glucose concentration measurements of the OneTouch Verio® meter are not influenced by hematocrit values from 20–60%. This has also been shown by Musholt et al. [14]. In this setting the glucose concentration measurements were not influenced by hematocrit values between 30–49%. In the study population there were no values beyond this hematocrit interval.

The limitation of the present study is the relatively low sample size. Furthermore, the results cannot immediately be generalized to patients who are naïve to SMBG.

In conclusion, the OneTouch Verio® system displayed an acceptable analytical quality, satisfactory user-friendliness and was found to be fit-for-purpose. It is suitable for point-of-care testing of blood glucose concentration when handled by patients and healthcare professionals.

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Declaration of interest: The authors report no conflict of interest. The authors alone are responsible for the content and writing of the article.

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