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Clinical evaluation of a novel test strip technology for blood glucose monitoring: Accuracy at hypoglycaemic glucose levels

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ABSTRACT

Aim: To evaluate OneTouch® Verio™ test strip performance at hypoglycaemic blood glucose (BG) levels (<3.9 mmol/L [<70 mg/dL]) at seven clinical studies.
Methods: Trained clinical staff performed duplicate capillary BG monitoring system tests on 700 individuals with type 1 and type 2 diabetes using blood from a single fingerstick lancing. BG reference values were obtained using a YSI 2300 STAT™ Glucose Analyzer. The number and percentage of BG values within ±0.83 mmol/L (±15 mg/dL) and ±0.56 mmol/L (±10 mg/dL) were calculated at BG concentrations of <3.9 mmol/L (<70 mg/dL), <3.3 mmol/L (<60 mg/dL), and <2.8 mmol/L (<50 mg/dL).
Results: At BG concentrations <3.9 mmol/L (<70 mg/dL), 674/674 (100%) of meter results were within ±0.83 mmol/L (±15 mg/dL) and 666/674 (98.8%) were within ±0.56 mmol/L (±10 mg/dL) of reference values. At BG concentrations <3.3 mmol/L (<60 mg/dL), and <2.8 mmol/L (<50 mg/dL), 358/358 (100%) and 270/270 (100%) were within ±0.56 mmol/L (±10 mg/dL) of reference values, respectively.
Conclusion: In this analysis of data from seven independent studies, OneTouch Verio test strips provide highly accurate results at hypoglycaemic BG levels.

1. Introduction

Hypoglycaemia is a frequent complication of diabetes management that causes recurrent morbidity and it is potentially fatal [1]. Intensive therapeutic strategies which may decrease the risk of hyperglycaemia-related complications can increase the risk of hypoglycaemia [2,3]. Medical consequences of hypoglycaemia include a cycle of recurrent hypoglycaemic episodes, often resulting in hypoglycaemia unawareness [4].

Greater attention to interventions that reduce hypoglycaemic events could have a major positive impact on overall diabetes management. Blood glucose monitoring systems (BGMSs) allow individuals with diabetes to keep track of their blood glucose and to take appropriate action if blood glucose levels deviate from target ranges [5]. In order to obtain optimal benefit, users of these systems need to be adequately trained to collect, interpret, and respond to the test results. More importantly and perhaps as a starting point, BGMSs need to be

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sufficiently accurate (i.e., deviating only slightly or within acceptable limits from the actual or reference value).

Most previous studies of BGMS-performance show data at normoglycaemic or hyperglycaemic ranges. Limited data from small studies indicate that BGMSs may be insufficiently accurate at clinically relevant low blood glucose levels (<3.9 mmol/L [<70 mg/dL]) [6,7]. Consequently, it has been suggested that separate performance criteria may be needed in the low blood glucose ranges [7,8]. As new technologies for BGMSs are introduced, accuracy of systems using these technologies needs to be established, particularly in the clinically important hypoglycaemic blood glucose range.

The current analysis evaluated the accuracy of OneTouch® Verio™ (LifeScan, Inc., Milpitas, CA, USA) test strips at hypoglycaemic blood glucose levels (<3.9 mmol/L [<70 mg/dL]) in seven separate clinical studies.

2. Methods

Data from seven clinical studies, which were each designed and performed in accordance with the International Organization for Standardization ISO 15197:2003 system accuracy testing guidelines [9], were included in this analysis. The purpose of each study was to verify the accuracy of a new or existing (commercially available) BGMS. The studies were performed from June 2009 to June 2011 at two sites in the UK, Edinburgh Royal Infirmary and Birmingham Heartlands Hospital. The design of the seven studies was identical; however, the type of meter used varied. Patients known to have type 1 or type 2 diabetes visiting one of the clinics for their regular appointment were approached to participate in the study. All participants provided informed consent; no other inclusion criteria applied.

In total, five different meters were used from LifeScan, Inc.: OneTouch® Verio™; OneTouch® Verio™Pro; OneTouch® Verio™IQ; and two meters in development (hereafter referred to as Experimental meters 1 and 2). The Verio meter was used in three studies; all other meters were used in one study. All five meters used the same OneTouch Verio test strip and the same glucose measurement algorithm and are, therefore, considered to be performance equivalent. This allowed for pooling of data over the seven studies.

The OneTouch Verio test strips used in this analysis are designed to minimize user and analytical errors. The strip itself incorporates gold and palladium electrodes, separated by a thin (nominal thickness 95 μM) plastic spacer. The strip can be defined as a ''side-fill strip'', as blood can be applied on either side of the strip. The architecture provides quick-wicking action, and the user can assess visually whether the strip is filled correctly. The strip uses flavin-adenine dinucleotide-dependent glucose dehydrogenase (FAD-GDH), a complex waveform, and a proprietary algorithm, which allow it to provide more accurate results than previous strips. The strip is not sensitive to interference by hematocrit (over a range of 19–61%) and is not affected by presence of internal or external substances (with the exception of maltose) [10,11]. The five meters are calibrated to provide plasma-equivalent glucose results and do not require coding by the user. In addition, the strip has a wide dynamic range (1.1–33.3 mmol/L [20–600 mg/dL]), and requires a small blood volume (0.4 μL).

In each clinical study, blood glucose testing, including fingertip lancing was performed by trained clinic staff using capillary blood samples from 700 individuals with diabetes. All studies were conducted according to protocol, which was approved by the relevant Research Ethics Committees and each participant gave informed consent. For each participant, duplicate blood glucose meter tests were performed with strips drawn from multiple test-strip lots (three or four lots per study, resulting in six or eight measurements per participant), using blood from a single fingertip lancing Comparative testing was performed with the YSI® 2300 STAT™ Glucose Analyzer (Yellow Springs Instrument Co, Inc. Yellow Springs, OH, USA) before and after testing with the OneTouch Verio test strips, using capillary blood samples from the same lancing. Blood was collected in Microvette Lithium Heparin collection tubes, which were centrifuged to separate the plasma fraction used for YSI testing. If one lancing did not provide enough blood for all analyses, a second lancing was performed. No more than two lancings were performed per participant. For accuracy assessment, blood glucose measurements from each BGMS were evaluated against the mean of reference values obtained from the YSI 2300 STAT Glucose Analyzer before and after strip testing. A summary of the seven studies is shown in Table 1. All studies were conducted according to protocol, which was approved by the relevant Research Ethics Committees.

Table 1 – Overview of studies included.

Study	Centre	Study dates	BGMS[a]	Patients, *n*	Strip lots, *n*	Measurements, *n*
1	Edinburgh Royal Infirmary, UK	June 8–July 3, 2009	OneTouch Verio	100	3	600
2	Edinburgh Royal Infirmary, UK	June 2–23, 2010	OneTouch VerioPro	100	4	800
3	Birmingham Heartland Hospital, UK	July 20–August 3, 2010	OneTouch VerioIQ	100	4	800
4	Birmingham Heartland Hospital, UK	April 15–May 9, 2011	Experimental meter 1[b]	100	4	800
5	Birmingham Heartland Hospital, UK	May 23–June 17, 2011	Experimental meter 2[b]	100	4	800
6	Birmingham Heartland Hospital, UK	February 1–March 4, 2011	OneTouch Verio	100	4	800
7	Birmingham Heartland Hospital, UK	May 23–June 17, 2011	OneTouch Verio	100	4	800

[a] All BGMSs used OneTouch Verio test strips and are technically equivalent (but with different user interfaces). Studies 2–5 included the OneTouch Verio BGMS as a control.

[b] Experimental meters 1 and 2 are currently in development. They are designed to provide enhanced data management and transfer capabilities.