

Evaluation of One Touch Horizon — A Highly Affordable Glucose Monitor

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Abstract

Background and objective : Despite the growing evidence on the benefits of self-monitoring in diabetes, the use of these meters has been low in developing countries, particularly India. Cost seems to be the major constraint. The aim of the present study is to evaluate the accuracy of One Touch HORIZON an affordable glucose meter with laboratory assessment of blood glucose.

Methods : 100 subjects with diabetes over the age of 18 years were recruited from the MV Diabetes Specialities Centre, Chennai. All the study subjects had their fasting blood tested for glucose in One Touch HORIZON by finger prick. Fasting blood glucose was also assessed in YSI 2300 STATPLUS (Yellow Springs Instruments, Ohio, USA) glucose analyzer. The Parke's Error Grid model was used to assess the accuracy of the meter against YSI plasma glucose values.

Results : Of the total 100 study subjects, 97 were Type 2 diabetic subjects and three were Type 1 diabetic subjects. 62% of the study subjects were males. 89% did not perform SMBG and only 2% of the diabetic subjects performed SMBG daily. The Parke's Error Grid analysis revealed 97% of results to be in Zone A when patient performed the test, 99 - 100% in Zone A when clinical staff performed the test indicating excellent accuracy and precision.

Conclusion : One Touch HORIZON meter is an affordable meter with good accuracy and precision, specifically designed to cater to the needs of diabetic patients in developing countries. ©

Two landmark studies, the Diabetes Control and Complications Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) have clearly documented that maintenance of near normal blood glucose values by intensive therapy reduces the incidence of diabetes complications, particularly microvascular complications.^{1,2} Tight diabetes control however mandates regular monitoring of blood glucose levels to achieve the target. In the intensive therapy group of the DCCT, self-monitoring of blood glucose [SMBG] was performed at least four times per day.¹ An observational study on 807 type 1 diabetic patients showed that SMBG was associated with improved glycemic control.³ The Auto-Surveillance Intervention Active (ASIA) study showed similar observations in type 2 diabetic subjects.⁴ Importance of self-monitoring of blood glucose has led to the invention of several blood glucose meters that have been extensively evaluated and used all over the world as they are accurate and precise.⁵

However, despite the growing evidence on the benefits of

self-monitoring in diabetes, the use of these meters has been exceedingly low in developing countries in contrast to developed countries. In USA, as early as 1989, 26% of type 2 diabetic subjects and 40% of type 1 diabetic subjects performed SMBG at least once daily.⁶ During the last decade, the usage of SMBG has tremendously increased as seen in the recent Fremantle Diabetes Study, where 73.8% of diabetic subjects performed SMBG.⁷ In contrast, in the CURES study, the methodology of which has been reported elsewhere,⁸ we found that less than 0.2 % of the diabetic subjects possess a glucometer and virtually none tested blood sugars daily [unpublished data]. One of the major barriers to perform SMBG in developing countries is the cost of the meter. Other factors include unawareness of the benefits of monitoring or the complications of the disease and inability to learn due to psychological or social barriers. However cost was the major deterrent for over 60% of the population. This emphasizes the need for an affordable glucose meter. The appendix traces the development of the One Touch HORIZON, a new affordable glucose meter specifically developed to cater to the needs of developing countries like India. This study evaluates the accuracy of One Touch HORIZON in comparison to laboratory assessment of blood glucose.

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Received : 12.6.2004; Revised : 23.7.2004; Accepted : 10.9.2004

MATERIAL AND METHODS

Study site: The study was conducted on 300 study subjects recruited at three centres - two in the UK and one in India (the Madras Diabetes Research Foundation and the M.V.Diabetes Specialities Centre at Chennai). However this paper only deals with data on the 100 subjects recruited at the Chennai centre.

Study subjects: Type 1 or Type 2 diabetic subjects who satisfied the inclusion-exclusion criteria were included for the study i.e. study patients should be at least 18 years of age and must be fasting at the time of blood draw. Pregnant women were excluded from the study.

One Touch HORIZON glucose monitoring system: This meter was developed keeping in mind the need to maximize the ease of use for patients while at the same time limiting the cost of the device. A picture of the meter is shown in Fig. 1.

Standard laboratory test for glucose assessment: In order to maintain uniformity among all study centres, YSI 2300 STATPLUS (Yellow Springs Instruments, Ohio, USA) glucose analyzer was used for laboratory assessment of plasma glucose values. For this analysis, blood from the finger prick was collected using a capillary tube.

Study design: The study was conducted in three steps, in step 1 all study patients tested their blood glucose level in the One Touch HORIZON glucometer by themselves. In step 2, from the same finger prick, the clinical staff of the centre loaded the sample on the One Touch HORIZON test strip. In step 3, on the same patients, a clinic staff performed another finger prick and then performed the blood glucose assessment using both One Touch HORIZON and YSI machines.

The total testing time from performing finger prick to measuring blood glucose values using both One Touch HORIZON and YSI did not exceed 10 minutes.

Sample size calculation: In line with NCCLS (Section Ep9) and ISO/FDIS 15197 guidance documents, a minimum sample size of 50 patients will provide sufficient quantitative data to compare the clinical accuracy of the test systems and reference instruments. We set a target of 100 patients who had to be recruited within a week's time.

Statistical analysis: The results obtained from the One Touch HORIZON glucometer were plotted on a Parke's Error grid method for assessment. This error grid is created to identify if the discrepancies in the assessment of blood glucose by new devices affect the clinical action taken for the disease. Parke's grid method has eight zones, Zone A represents no effect on clinical action, Zone B represents

altered clinical action but little or no effect on clinical outcome, Zone C represents altered clinical action which was likely to affect clinical outcome, Zone D represents altered clinical action which could have a significant medical risk and Zone E represents altered clinical action which could have dangerous consequences.⁹

RESULTS

Table 1 presents the demographic details of the study subjects. 62% of the study population was males. There were 97 Type 2 and three Type 1 diabetic subjects. Oral hypoglycemic agents were the most common therapy followed by diet and exercise and insulin. 89% of patients did not perform SMBG at all and only 2% of diabetic subjects performed SMBG daily.

Fig. 2 shows the age distribution and duration of diabetes distribution in the study population. The mean age was 54 ± 13 years and the mean duration of diabetes was 11.7 ± 6.4 years.

The Parke's Error Grid model was used to assess the accuracy of the meter against YSI plasma glucose values and the results are shown in Fig. 3. When tests were entirely performed by the patients 97% of the results were in ZONE A indicating excellent accuracy and good clinical utility (Fig. 3A). When the clinical staff performed the tests, 99% - 100% of the results fell ZONE A reflecting excellent accuracy and precision [Figs. 3B and 3C].

DISCUSSION

The One Touch HORIZON glucometer evaluated in this study is a new product specifically designed to meet the needs of developing countries. The meter was evaluated against laboratory blood glucose assessment. The study findings indicate that One Touch HORIZON is a reliable device with good accuracy and precision as seen from the Parke's Error grid model. Further, as the patients, majority of whom did not perform SMBG earlier were able to test their blood glucose themselves, the study also suggests that the meter

Table 1 : Demographic details of the study subjects

Demographic	Percentage (%)
n	100
Males	62%
Type 2: Type 1 diabetes	97:3
Therapy *	
Diet and exercise alone	47%
Oral hypoglycemic agents	78%
Insulin (%)	34%
Use of SMBG	
< 1 time / day	9 %
1 - 2 times / day	2 %
3 - 4 times / day	—
> 5 times / day	—
Does not test at all (%)	89 %

* Numbers do not add up as some patients have more than 1 type of treatment

Fig. 1 : Picture of One Touch HORIZON meter

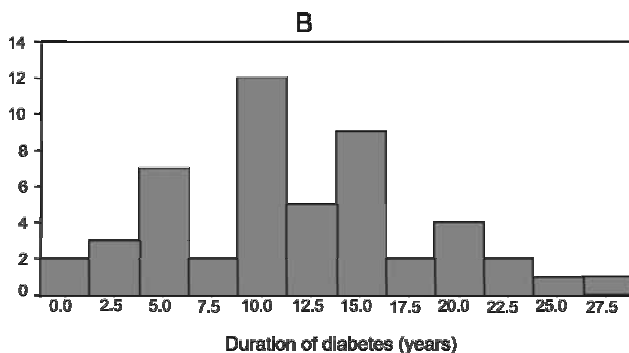


Fig. 2 : Age distribution (Fig 2A) and duration of diabetes (Fig 2B) distribution of the study population

is user friendly and has very minimal error rate.

As early as 1994, the American Diabetes Association emphasized the role of SMBG and suggested it to be an important component of diabetes treatment.⁶ However, awareness of diabetes per se seems to be very poor in developing countries like India and thus the awareness about benefits of SMBG is probably even less. This is very disturbing as India leads the world in the prevalence of diabetes with over 31 million diabetic subjects and these numbers are expected to increase to 79.4 by the year 2030.¹⁰ This places a large proportion of diabetic subjects at risk of developing micro and macro vascular complications. By regularly performing SMBG, it is likely that diabetes complications can be reduced considerably as better glucose control can be achieved.

In this study, only 11% of the participants at a primary diabetes centre in India performed SMBG as against 90% in the UK centres. This is similar to that reported in Italy in 2001 by Franciosi *et al.*¹¹ If this is the scenario among diabetic patients attending a tertiary care centre in India where diabetic patients are regularly educated about the importance of SMBG, the situation in the general population would be much worse. As already stated less than 0.2% of the diabetic population in Chennai perform SMBG and even these individuals do not perform SMBG on daily basis.

Since cost of the meter appears to be the major limiting factor, the One Touch HORIZON meter has been designed for developing countries like India by emphasizing efficiency in design and by limiting features to those that are most essential to the majority of patients. This allows the meter to

Fig. 3: Clinical accuracy of One Touch HORIZON - Parke's Error Grid
 A: Patients performed finger prick and loaded the blood samples on One Touch HORIZON test strip - 97% Zone A
 B: Patients performed finger prick and clinical staff loaded the blood samples on One Touch HORIZON test strip - 99% Zone A
 C: Clinical staff performed the finger prick and loaded the blood samples on One Touch HORIZON test strip - 100% Zone A

be made available at a lower cost than other meters and, as the machine is accurate and precise, it is indeed a boon for diabetic patients in India and other developing countries.

The cost of strips may also be a barrier to glucose testing. However the 10's pack that has been introduced for the first time in India means that the initial outlay can be much smaller. Also it is likely that there will be less wastage of strips as it is unlikely that the strips would cross the expiry date. The One Touch HORIZON meter is truly a tribute to a group of Asian diabetologists who got together and persuaded a multinational company to produce a meter to specifically cater to the needs of diabetic patients in developing countries.

Appendix : Background of the One Touch HORIZON blood glucose meter

The One Touch HORIZON meter is a unique contribution of key opinion leaders (diabetologists) of Asia who laid down the criteria for development of an affordable, user friendly and accurate meter for developing countries. Indian diabetologists who were part of the 'think - tank' for One Touch HORIZON were Dr. Shashank Joshi (Mumbai), Dr. Shishir Kumar (Mumbai), Dr. SK Wangnoo (New Delhi) and Dr. V Mohan (Chennai). Based on the specifications and conditions laid down by the key opinion leaders from Asia, the machine was developed by M/s. Lifescan Johnson and Johnson. The clinical trials were carried out at three centres (1) Madras Diabetes Research Foundation and MV Diabetes Specialities Centre, (Chennai, India) (2) New Royal Infirmary (Edinburgh, UK) (3) Birmingham Heartlands Hospital (Birmingham, UK). In this paper only the data from India is presented. However the data from the other centres in UK were virtually identical to that obtained at the Indian centre.

Johnson and Johnson Medical has commercial interest in the article with their product OneTouch Horizon™

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Announcement

Golden Jubilee Celebration - Year 2004

Prof. M Viswanathan DRC National Research Grant - 2004-2006

MV Hospital for Diabetes and Diabetes Research Centre



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