

ORIGINAL ARTICLE

Forearm blood glucose testing in diabetes mellitus

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Aims: To compare the accuracy and acceptability of capillary blood glucose testing from the forearm with finger prick testing in diabetic children.**Methods:** Blood glucose measurements from samples taken from the forearm and the finger were compared in an outpatient setting from 52 children and adolescents with diabetes mellitus aged 6–17 years. Opinions on forearm sampling were collected by questionnaire.**Results:** Blood glucose results obtained from forearm sampling correlated well with results from the finger measured by the Yellow Springs Instrument analyser. Error grid analysis showed that 100% of measurements were clinically acceptable; 61% of children reported that forearm testing was painless and 19% that it was less painful than finger prick testing.**Conclusion:** Forearm testing is an acceptable alternative to finger prick testing for blood glucose measurement in children and adolescents.

Self monitoring of blood glucose plays a vital role in the treatment plan of children with diabetes mellitus. Regular self blood glucose monitoring enables the appropriate changes to be made in the treatment and management of the child's diabetes to meet individual goals and needs. Barriers to frequent self monitoring include the pain and trauma associated with the finger prick necessary to obtain blood for the test. Non-compliance with blood glucose monitoring is common, especially in adolescents.¹ Although modern blood glucose meters only require a small sample of blood, monitoring remains a problem. Using an alternate site for sampling, namely the forearm, may be beneficial to the patient and reduce the level of pain they experience. The main objective of the study was to assess the accuracy of a forearm testing device (SoftSense) in a paediatric population, in comparison to a standard reference laboratory method. The secondary aim was to determine the opinion of children and parents on the desirability of forearm testing. Although the accuracy of the system had previously been assessed in an adult population, the opinions of patients had not been determined² and its potential use in children had not been explored.

METHODS

Fifty two patients were enrolled (age 6–17 years, mean 13 years). Ethical approval had been given. Results for six children were excluded from analysis (one child opted out of the study after enrolment, three subjects deviated significantly from the protocol in that completion of all tests exceeded 20 minutes, and three had "high" glucose levels that could not be allocated numerical values, being outside the range of the method).

Age, gender, height, weight, type of diabetes, duration of self blood glucose monitoring, and other medications were recorded. The time and nature of the last food and sugary drink intake, time, dose and type of last insulin, and time and nature of last exercise prior to testing were detailed.

The SoftSense instrument, which combines a lancing device, application of a small vacuum, and direct measurement of blood glucose on an electrochemical strip, was used. The glucose range measured by the device was 1.7–25.0 mmol/l. There is a second port in the device to enable finger prick testing if required. SoftSense blood glucose test strips are calibrated against the Yellow Springs Instrument (YSI) whole blood glucose analyser (YSI Inc., Yellow Springs, Ohio, USA).

Two devices were assigned to each patient and two capillary forearm tests and two capillary finger prick tests, using the second port, were performed. These tests were performed within a five minute time frame. Capillary blood glucose measurements were performed using a YSI 2300 whole blood glucose analyser. Either forearm was used and the finger prick sample was taken from the same arm. The maximum circumference of the forearm was measured. The child and parent were asked to rate the pain of the forearm test compared to the child's current finger prick method used at home. Participants were asked for any other opinions on the forearm device.

In discussion with both child and parent a questionnaire was completed documenting current blood glucose measurement practice. Opinions from child and parent on finger prick and forearm testing in general terms were recorded prior to testing, and opinions relating to pain and convenience of use were recorded after testing.

Statistical analysis

Weighted regression analysis was used to compensate for the increase in spread of glucose values with increasing levels of glucose. The weights applied were derived from historical data, based on the relation between the residual SD and the mean response; they were standardised so that the sy_x represents the residual SD at the mean glucose level. Results were plotted on the Clarke error grid³ (figs 1 and 3). Zones A and B represent clinical acceptability and zones C, D, and E represent areas in which the result would be potentially clinically dangerous. They were also plotted by Bland-Altman analysis (figs 2 and 4). The YSI reference results were multiplied by 1.12 to reflect the plasma calibration position of the test strips.

RESULTS

Patient characteristics

Forty six subjects (20 boys, 26 girls) had a mean age of 13 years (range 6–17); 45 had type 1 diabetes mellitus and one had type 2 diabetes mellitus. Their mean BMI was 20.8 (range 15.2–36.1). The mean time from the last food or sugary drink intake to testing was 1.8 hours and the mean time from the last insulin injection to testing was 5.3 hours (n = 46).

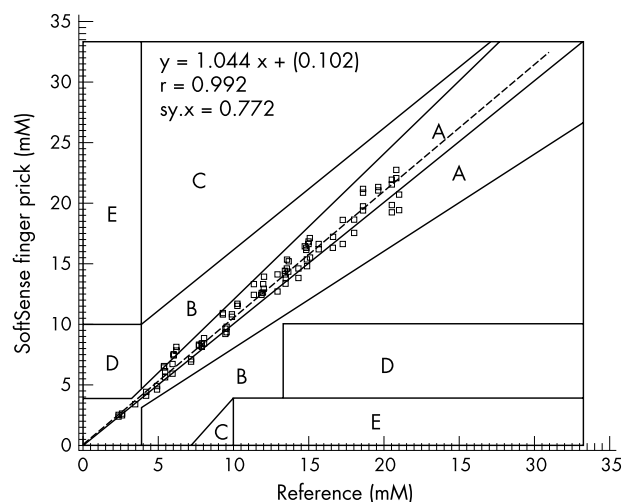


Figure 1 Comparison of SoftSense finger prick blood glucose measurements with the reference method (finger prick sampling) ($n = 90$) using the Clarke error grid.³

The mean duration of self blood glucose monitoring was 5.0 years (range 0.1–15.5).

Comparison of finger prick blood glucose measurements using SoftSense and the reference method

Plotting SoftSense against YSI reference method values of blood glucose from finger prick samples (fig 1), the slope was 1.04 (standard error 0.77), the intercept 0.10, the correlation coefficient 0.99, and the residual SD ($sy.x$) at the mean glucose level 0.77. Using the Clark error grid 100% of measurements were within zones A and B (94% within A) (fig 1). The mean difference by Bland-Altman analysis was +5.9% (fig 2). The mean paired replicate coefficient of variation for SoftSense finger prick results was 3.0%.

Comparison of forearm blood glucose measurements with finger prick method

Forearm testing yielded sufficient blood on the first attempt in 92% and in the remaining 8% on the second attempt.

Plotting the forearm values of blood glucose against the YSI reference method values from finger prick samples (fig 2),

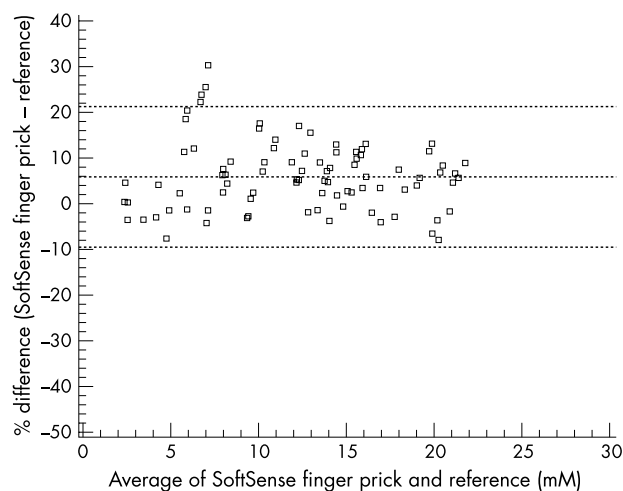


Figure 2 Bland-Altman analysis of SoftSense finger prick blood glucose measurements with reference method ($n = 90$) with lines representing the mean difference and ± 2 SDs.

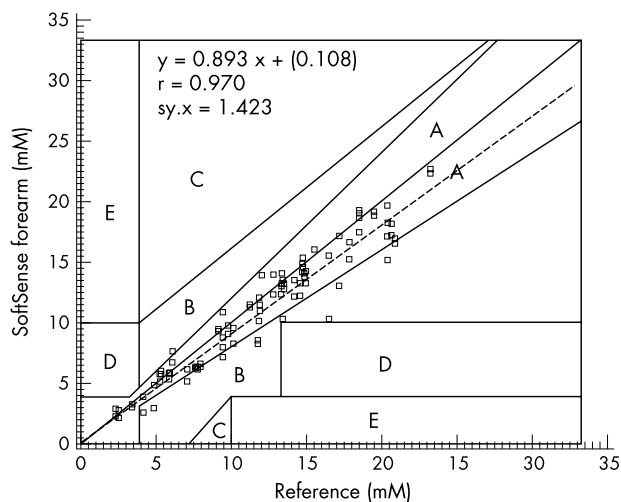


Figure 3 Comparison of forearm blood glucose measurements with the reference method (finger prick sampling) ($n = 92$) using the Clarke error grid.³

the slope was 0.89 (standard error 1.42), the intercept 0.11, the correlation coefficient 0.97, and the residual standard deviation ($sy.x$) at the mean glucose level was 1.42. Using the Clark error grid, 100% of measurements were within zones A and B (85% within A) (fig 3). The mean difference by Bland-Altman analysis was -7.7% (fig 4). The mean paired replicate coefficient of variation of forearm results was 7.8%.

Questionnaire prior to forearm testing

Children stated that the frequency of blood glucose testing was less than daily in 12%, one or two times per day in 45%, two or three times per day in 37%, and more than three times per day in 6%. Sixty five per cent of children stated that none of these tests were performed away from home; 43% of children said that finger prick testing was not a problem and didn't stop them testing when they should, while the remainder felt it was a problem.

Children gave a variety of reasons for disliking finger prick testing: 37% said that it hurt, 18% said that it was inconvenient, 2% felt they lacked motivation, and 26% had other adverse comments; 25% said that there was nothing they did not like about finger prick testing (table 1).

Parents had differing perceptions of the reasons for disliking finger prick testing: 30% said that it hurt, 4% that it was inconvenient, 28% felt that their child lacked motivation, and 25% had other adverse comments; 13% said there was nothing they did not like about finger prick testing. One parent commented that finger prick testing was barbaric.

Questionnaire after forearm testing

Sixty one per cent of children reported that forearm sampling was painless, 19% reported it was only slightly less painful than their usual finger prick method, 14% felt it was similar, and 6% said it was slightly more painful (table 2). Seventy six per cent of children and 76% of parents thought the forearm testing device was convenient to use; 49% of children and 85% of parents reported that the device was too large. However, 86% of children and 85% of parents said they would like to use the device for forearm testing. Fifty five per cent of children thought that forearm testing would improve their regularity of blood glucose monitoring (of whom three-quarters had felt that finger prick testing had an adverse effect on their frequency of monitoring). Of the 45% who thought that forearm testing would not improve monitoring frequency or were unsure, almost half were already testing

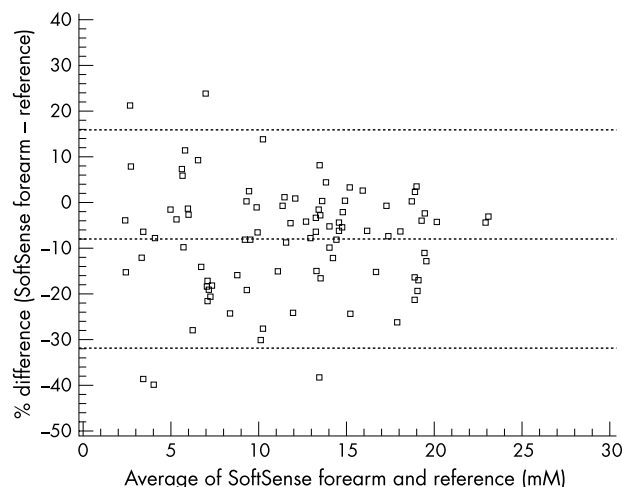


Figure 4 Bland-Altman analysis of SoftSense forearm blood glucose measurements with reference method (n=92) with lines representing the mean difference and ± 2 SDs.

2–3 times a day. Parents and children expressed opinions as to when and where they would use the forearm device. These views are summarised in fig 5.

DISCUSSION

Regular blood glucose self monitoring is highly desirable in children and adolescents so that appropriate adjustments to insulin and diet can be made to achieve good glycaemic control. However there is often a reluctance to perform this task, based in part on the discomfort and pain of finger prick sampling. There was evidence that the pain of finger prick sampling was an important factor for some children in this study. It was encouraging to find that 61% of children found the forearm sampling to be painless and that a further 19% found it less painful than pricking their fingers. However, parents felt the SoftSense device was too large and heavy. Nevertheless the majority of children and parents clearly preferred forearm sampling and felt that it would improve the frequency of blood glucose monitoring and would be prepared to use it outside the home.

The performance characteristics of the SoftSense device were satisfactory for safe clinical use. There was a tendency for the blood glucose measure to be lower (fig 4) when sampling from the forearm, but no value fell into clinically unacceptable areas on the Clark error grid (fig 3). It has been shown that rapid changes in postprandial blood glucose levels are detected later in the forearm or thigh than at the finger tip.⁴ However, the general advice for routine blood glucose monitoring is that sampling is more useful in making insulin adjustments when it is performed half an hour before a meal.

The precision of measurement was poorer using forearm sampling than when using finger prick sampling (mean paired replicate coefficients of variation were 7.8% and 3.0%

	% of children
Painful	37
Inconvenient	18
Lacked motivation	2
Other adverse comments	20
No problems reported	25

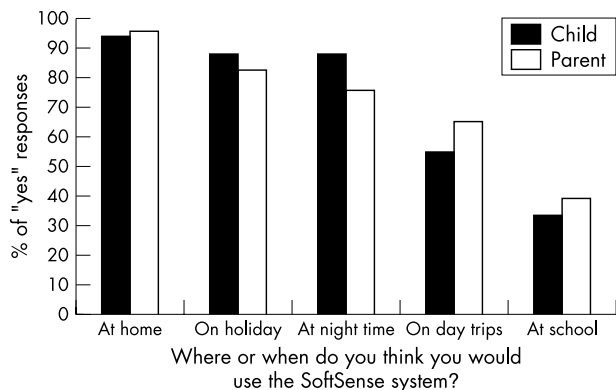


Figure 5 The answers given by children and adolescents or their parents when asked “where or when do you think you would use the SoftSense system?”.

Comment	% of children
Painless	61
Slightly less painful	19
Similar degree of pain	14
Slightly more painful	6

respectively) but was still acceptable considering that the two values measured for forearm testing were from two separate samples and thus strictly did not constitute a true test of precision.

The expressed preference for forearm sampling by children and adolescents within this study may improve adherence to more regular and frequent blood glucose monitoring, but whether this results in improved glycaemic control needs to be tested. In a crossover study in adults,⁵ although a preference for alternate site testing was reported, no increase in frequency of testing or improvement of glycaemic control was measured. The authors⁵ commented that their population tended to be well controlled and compliant with testing and thus perhaps had little room for improvement.

This study has shown that forearm sampling for blood glucose testing is acceptable to children and adolescents and seems to be preferred. Also the forearm testing device has been shown to have acceptable performance characteristics. However, new devices and methods are often met with initial enthusiasm that is short lived, and we intend to perform a crossover trial of finger and forearm sampling to show the effect on glycaemic control.

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