A community study of accuracy of blood glucose meter results

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ARTICLE POINTS

1 Capillary blood glucose monitoring (CBGM) is expensive and evidence is poor as to whether this cost is worthwhile.

2 There is a significant difference between laboratory and patient values.

3 Most patients obtained an adequate blood sample, however 66% did not wash their hands before doing so.

4 The difference between meter results and corresponding laboratory values were >15% of the for 43.2% of patients.

5 CBGM values should be reviewed with the knowledge of the expected accuracy (no more than 10% total error) of the meters.

KEY WORDS

- **Capillary blood glucose monitoring**
- **Glucose meter**
- **Readings**
- **Accuracy**

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Introduction

The evidence that capillary blood glucose monitoring improves diabetes control is weak. Despite this, the net cost of testing materials was £90 million in 2001 (Department of Health, 2002), and enthusiasm for their use continues to grow. One-hundred-and-two patients with type 1 and 2 diabetes were observed performing a capillary blood glucose test. Immediately afterwards, a venous sample was taken for glucose and the two values compared. Only 47% of patients' results were accurate to within 10% of their corresponding laboratory value (i.e. within the range deemed acceptable by the Medical Devices Agency). Healthcare professionals should review results from patients' glucose meters with caution.

This article summarises the current situation of self-monitoring, focused on the accuracy of the patients' blood glucose monitoring, and outlines some practical solutions for clinical practice.

Capillary blood glucose monitoring (CBGM) is established as an important tool in diabetes management for offering reassurance and warning of problems (Gallichan, 1993). Its importance has increased with the recognition that tight control of blood glucose levels are essential for risk reduction in developing micro- and macrovascular diabetic complications (Diabetes Control and Complications Trial, 1993; UKPDS, 1998). However, the evidence that CBGM improves diabetes control is weak (Worth et al, 1982; Burden, 1994; Gallichan, 1997; Miles et al, 1997). Despite this, the net cost of testing materials was £90 million in 2001 (Department of Health, 2001) and enthusiasm for CBGM is growing (Diabetes UK, 2002).

Current technology has stimulated a rapid growth in the number of different glucose meters available. Subsequently, meters are sold commercially, given as gifts (e.g. friends and relatives), or can be obtained from a diabetes educator. The training available to patients, therefore, ranges from comprehensive to inadequate, or even none at all.

Glucose meter reliability

The Medical Devices Agency (MDA) has produced evaluation reports (2002) on all available meter types. Others have researched glucose meter reliability (Poirier et al, 1998; Day et al, 1999; Parkes et al, 2000), concluding that each of the available testing methods has satisfactory analytical performance for precision and accuracy under ideal conditions in the hands of experienced personnel.

However, true performance depends heavily upon the ability of non-specialist staff and patients to use the equipment satisfactorily in 'every day' situations. When capillary blood assays are performed in the laboratory the variables are carefully controlled and a high degree of accuracy is achieved.

Regular, accurate monitoring has been shown to promote empowerment for the patient (Fleming, 1994; Hounsome, 1998) with decision-making about treatment based on these results. However, American studies (Parkes et al, 2000; Ryan and Nguyen, 2001; Alto et al, 2002) have shown that 47–55% patients are not accurate to within 10% of the corresponding

laboratory value despite national recommendations (American Diabetes Association, 1994).

Education

'Key' documents (Department of Health, 2002; National Institute for Clinical Excellence, 2002) are limited and lack detail for practical application as to which patients should be testing, guidance on training and how often tests should be performed.

Kabadi et al (1994) and Day et al (1999) evaluated training for both patients and nurses respectively, and discovered that incorrect results were the outcome of user error. They concluded that CBGM requires a robust system of training and review of performance, and that proficient use of glucose meters can be maintained with revision of CBGM skills at follow-up appointments.

Aim of the study

In the UK, background data are scarce for evaluation and formation of future benchmarks for CBGM. This needs to be addressed. Therefore, to establish how accurate patients' CBGM results are when compared to laboratory analysis would be a valid starting point.

Method

People with type 1 and type 2 diabetes who collected prescriptions for CBGM were randomly recruited from both primary and secondary care. The patients were observed performing CBGM 'how they usually do it'. It was noted whether adequate dosing of the meter strip and hand washing took place. The result from the meter was then recorded and immediately afterwards a venous blood sample for plasma glucose was taken. Some meters analyse plasma and some analyse whole blood so to allow for this because we analysed plasma in the laboratory before direct comparison, it had to be determined whether meters analysed plasma or whole blood. There was an allowance of +15% on meters that were calibrated to analyse whole blood.

The patients' own glucose meters were used. Venepuncture equipment was used and venous plasma assayed for glucose using glucose oxidase on a Roche 917 analyser. Ethical approval had been granted for this study.

Data analysis

An error grid devised by Parkes et al (2000) was used in this analysis. An error grid is a clinically orientated approach to blood glucose data. It displays the relative difference between the laboratory and meter values over the entire glucose range and provides the clinical significance of that difference. The error grid is based on three assumptions:

Table 1. Error grid definitions

Zones	Definition	Decision on treatment
A	Difference between the 2 measurements is <20%	Clinically correct
B	Difference between the 2 mesurements is >20%	Inappropriate but without any serious consequences
C	Difference leads to an over-correction of acceptable blood glucose levels	May cause the blood gluose level to drop below 3.9 mmol/l or above 10 mmol/l
D	Laboratory blood glucose levels are high or low but the meter gives values in the normal range	Dangerous failure to detect and treat
E	Laboratory values are opposite to the meter values	Erroneous treatment zone and treatment contradictory to that actually required

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1 The aim was to establish how accurate patients' CBGM results were in comparison to laboratory analysis of a blood sample.

2 Patients were observed performing CBGM. It was noted if they washed their hands first and whether there was adequate dosing of the meter strip.

3 An error grid was used for analysing the results (laboratory values plotted against meter reading values).

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1 Twenty-four different types of glucose meters were being used and patient technique was variable.

2 There were a wide range of differences between laboratory and meter readings.

Firstly that blood glucose readings <3.9 mmol/l should be raised. Secondly that blood glucose readings >10 mmol/l should be lowered and, finally, that acceptably accurate results are within 20% of the laboratory blood glucose (Clarke et al, 1987; Cox et al, 1997).

The grid defines the x-axis as the laboratory (actual) blood glucose and the y-axis as the value generated by the glucose meter. The data points obtained for each measurement fall into one of the different zones (A–E) described in *Table 1*. These zones were drawn on a grid and indicated how appropriate the therapeutic decision taken on the glucose meter result, would have been if the blood glucose result had been measured with the laboratory method.

Minitab (a statistical software package) was used to do a paired t-test and S-plus for linear regression. The results would be considered in pairs (i.e. laboratory and meter). A paired t-test was used to see if there was a significant difference between the pairs of values. Linear regression was used to predict the percentage difference between the laboratory and meter results.

Results

Patient sample

One-hundred-and-two patients were recruited, with an age range of 27–86 years. Eighty-nine patients were over 50 years old. Fifty-six (55%) of the patients were men; 45% were women. Venepuncture was unsuccessful in 10 patients. Two patients could not get their meter to work.

Treatment

Of the patients recruited, 51% were treated with insulin, 31% with oral hypoglycaemic agents, 14% were on insulin and oral hypoglycaemic agents, and 4% were managed using diet alone.

Glucose meters

Twenty-four different meter types were observed being used by the patients: four Medisense, six Lifescan, eight Roche, four Bayer and two 'others'.

Patient technique

Sixty-six per cent of patients did not wash their hands, whilst 12% did not obtain an adequate capillary sample.

Accuracy of the patients' results

A highly significant difference (P=0.001) was found between the laboratory and patient readings. Accuracy of meter readings was within 10% of their corresponding laboratory value in 46

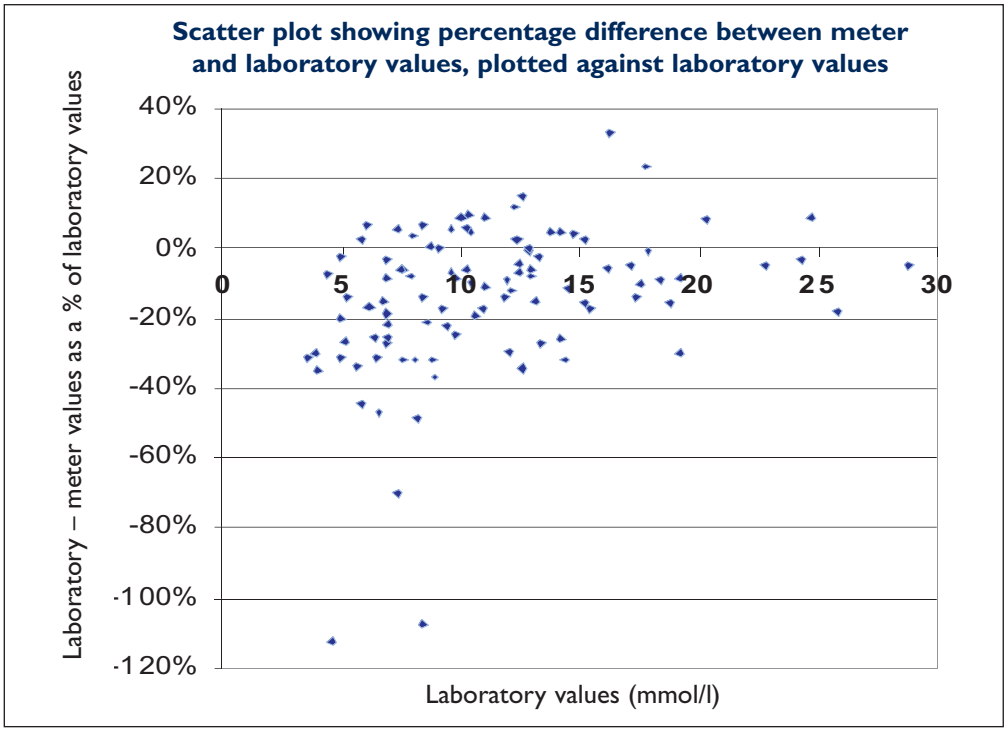

Figure 1: Scatter plot to demonstrate the variation between laboratory and meter readings.

patients (47%), and was within 15% in 56 (57%) patients.

Range of differences between the meter and laboratory values

The absolute differences between laboratory and patient readings were expressed as a percentage to obtain a range of differences. These were found to be -113.04% to +33.7%, with the mean of these differences being -13.67%. This suggested that the patient meters were over-reading by nearly 14%.

The differences between each pair of readings were then then plotted against the labtoratory values. This was to see if there was variation in the results as the laboratory readings increased (*Figure 1*). The outliers in the lower half of the reading scale were negative, confirming that the actual readings were overestimating the laboratory values.

Clinical significance of the errors

Error grid analysis classified 70 paired readings into zone A, 17 to zone B and one to zone C (*Figure 2*). The patient with a paired value in zone C had a meter reading of 9.9 mmol/l and a laboratory value of 4.8 mmol/l, which would create a risk of over-treating, leading to potential hypoglycaemia.

Discussion

Finding a statistically significant difference between the values of the patients' glucose meters and the laboratory would suggest that glucose meters have their limitations. This is particularly evident, when considering how wide the total error of variation was (-113.04 to +33.7%) from the laboratory values. This does not support the range of variation (+2.3% to +7%) that was seen by the MDA in their evaluation reports (MDA, 2002), neither does it support that their acceptable total error is no more than 10% for any meter design that is tested. Given that the mean of this variation was nearly 14%, these study results would also suggest that glucose meters are not performing to an acceptable standard and that glucose meters can only operate with satisfactory analytical performance in ideal conditions.

Inaccurate results did not appear to be related to hand washing, age or gender.

Although the majority of paired values appeared satisfactory on the error grid (i.e. within zones A and B), zone A is measuring an error of <20%, which is not comparable to the MDA who accept total error of <10%. This indicates a discrepancy over analytical precision and

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1 Patient meters were over-reading glucose levels by a mean average of nearly 14%.

2 A statistically significant difference was found between laboratory and meter readings in many cases, suggesting limitations in the use of glucose meters.

3 Inaccurate results did not appear to be related to hand washing, age or gender..

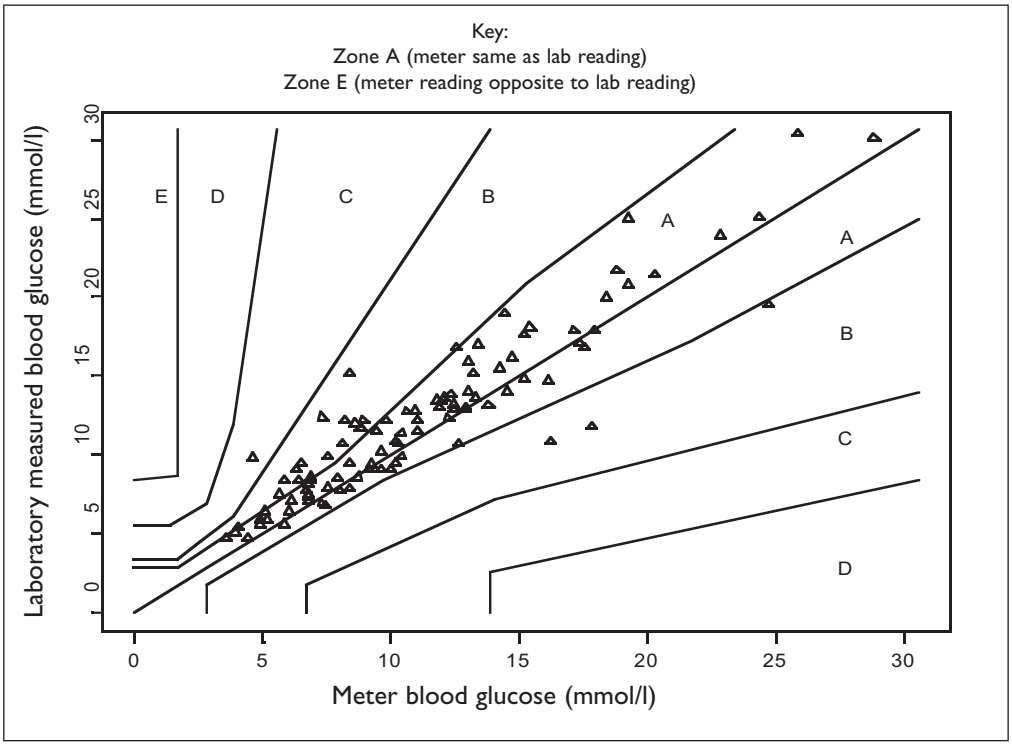

Figure 2. Error grid analysis of meter glucose readings against actual (laboratory) glucose levels.

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1 More consideration should have been given to confounding variables other than hand washing.

2 Results from paitents' glucose meters should be reviewed with caution and accuracy ascertained before treatment changes are made.

subsequent clinical acceptability. An agreement on the level that is clinically acceptable for meter inaccuracy would be worthwhile.

This study only allowed for a single measure of glucose comparison and consistent accuracy of CBGM values over time is a more important goal. The vast range of glucose meter types made analysis of reliability inconclusive.

Data analysis revealed that not enough consideration had been given to confounding variables. One had been included (hand washing) but not any others (e.g. dexterity, calibration, expiry date on glucose strips). This limited our conclusions.

Further work needs to be conducted to ascertain why patients get inaccurate results and a further study into these areas is nearing completion.

Conclusion

The results from patients' glucose meters should be reviewed with caution.

The accuracy of patients' blood glucose meters should be ascertained before treatment changes are made. This would provide an opportunity for revision of CBGM, possibly at annual review. Guidelines are needed for clinical acceptance of total error and analytical precision. ■

'The accuracy of patients' blood glucose meters should be ascertained before treatment changes are made'

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