Capillary Blood Glucose Testing In The Elderly: Reliable and Accurate

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ABSTRACT

Reliability of home blood glucose monitoring in elderly subjects with diabetes mellitus has not been assessed. Therefore, this study determined the accuracy and precision of testing in the hands of newly trained elderly subjects with diabetes, after individual training, and compared their performance with that of younger subjects. Fifty-two elderly (>65 years) along with 49 younger subjects (< 50 years) were included in the study. Subjects were individually trained in the use of the capillary blood testing system. They performed ten practice control solution tests prior to two capillary blood glucose tests. Venous blood was collected within 15 minutes for comparative laboratory analysis. Comparisons were performed by both linear regression and total grid analysis.

The correlation between the first capillary blood glucose test results and the laboratory values were highly significant for all participants with no significant difference (p>0:05) between the elderly (r=0.956) and their younger counterparts (r= 0.925). Total Error Analysis also revealed that the Systematic Error (SE), Random Error (RE) and Total Error (TE) were all well within the acceptable norms at two glucose levels of 5.5 mmol/ (100 mg/dL) and 11.1 mmol/L (200 mg/dL); (SE < 10%, RE < 10% and TE < 15%) for all subjects with no significant differences among groups (p>0.05). This study demonstrates that with adequate individual teaching, elderly subjects are as capable as their younger counterparts in performing and achieving accuracy and precision in capillary blood glucose testing.

KEY WORDS: Elderly; Capillary blood glucose testing.

INTRODUCTION

In the past few years, many technological advances have been realized in the field of blood glucose monitoring. These advances have resulted in commercially available systems with test procedures so simple that the operator need only apply a drop of blood to the test strip. Moreover, the elimination of the complex timing and wiping steps may have made these systems easier for the initial training resulting in adequate proficiency in capillary blood glucose readings when compared with simultaneous venous blood glucose determinations performed by a clinical laboratory (1,2). Finally, with these advances in testing devices, further simplification of techniques and adequate individual training, capillary blood glucose testing has become reliable and accurate test in self blood glucose monitoring in the majority of subjects with type 2 diabetes mellitus (3-7). However, the data remains sparse regarding the capabilities of elderly subjects achieving precision, reliability and accuracy in capillary blood glucose testing. Therefore, this study was designed to assess the reliability and accuracy for capillary blood glucose testing in a newly trained population of elderly subjects with diabetes mellitus and compare their performance with that of their younger counterparts.

MATERIALS AND METHODS

101 subjects, previously diagnosed with diabetes mellitus were recruited to participate in this study from a diabetes clinic at the Veterans Affairs Medical Center, Phoenix, Arizona. They included 52 men with ages between 66-80 years and 49 men with ages between 35-50 years. The study was approved by the local Human Study Subcommittee and the Research and Development Committee. Every patient signed an informed consent prior to participation. Patients known to exhibit anemia (hematocrit < 35%) or polycythemia (hematocrit > 55%) were excluded from the study.

The same diabetes nurse educator conducted a one on one comprehensive training session with each participant in a standardized sequential format providing identical information. Each participant was trained in all aspects of the blood glucose testing meter (Companion 2, Medisense, Waltham, MA) operation, including calibration, error codes, control solution handling and testing, performing a fingerstick at an appropriate point of insertion in the lateral aspect of the fingertip and a capillary whole blood glucose test using the second drop of blood, the initial drop being wiped away. For hands-on practice with the glucose meter, each participant was required to perform five high control solution tests and five low control solution tests. Each participant then performed two capillary whole blood glucose tests with

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the meter. Time required for performance of these tests and the results were recorded. Immediately after the capillary tests, a venous whole blood sample was collected from each participant and then placed into an evacuated tube containing fluoride as an antiglycolytic agent (Becton Dickinson, Franklyn Lakes, NJ) and submitted for laboratory analysis. Glucose determination was performed with 15 minutes from the time of collection with the glucose oxidase method using a Parallel Analyzer (AM Diagnostics, Inc., Indianapolis, IN).

The means, standard deviations (SD) and coefficients of variation (CV) were calculated for both high and low control solution practice tests as well as capillary blood glucose readings individually for each patient. Then the means, SDs and ranges of the CVs were determined for these three tests in all subjects. Moreover, CVs were also calculated between the mean capillary blood glucose reading and the mean venous blood glucose value determined by the clinical laboratory, in all participants. Error grid analysis was calculated by comparing the first capillary Companion 2 glucose result to the laboratory result in order to assess accuracy and systematic error. A simple least squares linear regression analyses was performed using the first Companion 2 result as the dependent variable and the laboratory result as the independent variable. Systematic errors were calculated at 5.5 mmol/L (100 mg/dL) and 11.1 mmol/L (200 mg/dL) by comparing the predicted value from the regression equation with the target value. The second capillary Companion 2 glucose result was compared to the first in order to assess precision and random error. Random errors were calculated with a 95% confidence interval at 5.5 mmol/dL (100 mg/dL) and 11.1 mmol/L (200 mg/dL) by obtaining the mean CVs for the range encompassing that glucose level and multiplying by 1.96 (9). The total error was assessed at 5.5 mmol/L (100 mg/dL) and 11.1 mmol/L (200 mg/dL) by simply adding the systematic error and the random error. Correlation coefficients were also determined between mean of 2 capillary blood glucose readings and simultaneous determined venous blood glucose level in all subjects. Finally, comparisons for all the parameters between the elderly and the younger subjects were conducted by using student's 't' test and analysis of variance.

RESULTS

The demographics of the two groups of participants according to their ages are shown in Table 1. The mean time required for training, including 10 control solutions practice test was 57±8 minutes, not significantly different from the one noted (52±7 minutes) in their younger counterparts (Table 2). Highly significant correlations were noted between capillary blood glucose readings and simultaneously determined venous blood glucose concentrations in both groups. However, no significant differences were observed in correlation coefficients as well as the means and the ranges of glucose values amongst groups (Table2).

Table 1: Demographic Data of the Subjects.

	Elderly > 65 years	Young < 50 years
Age, years	69±2 (66-82)*	53±5 (33-64)*
Duration of Diabetes, years	15±4 (2-27)*	12±3 (0.5-22)*
Type 2/ Type 1	48/4	43/6
Insulin/Oral Agent/ Comb†	7/30/15	10/26/13

** Range † Combination of oral agents and insulin*

Table 2: Mean Venous Blood Glucose Levels [VBG], Correlation Coefficients [R] Between the Means of Two Capillary Blood Glucose Readings and Simultaneously Determined Venous Blood Glucose Levels as well as the Time Required for Training in the Procedure of Capillary Blood Glucose Testing in 52 Elderly [> 65 Years] and 49 Younger Subjects [≤50 Years].

Subjects	VBG mM/L	Coefficient 'r'	Time Min
Elderly	9.4±5.4 (2.0-26.5)*	0.956 †	57±8
Young	11.5±4.7 (2.5-24.7)*	0.925 †	52±7

**Range† p< 0.0001*

Moreover, the mean values and the ranges of the coefficients of variation for comparisons between control solutions tests, and two capillary blood glucose readings were almost identical in both groups (Table 3). Finally, error grid analysis conducted for two venous blood glucose concentrations, 5.5mM/l (100 mg/dl) and 11.1 mM/l (200 mg/dl) revealed that values for systematic, random and total errors, were all below the accepted norms of 10% and 15% respectively (4) and were not significantly different amongst groups (Tables 4 and 5).

Table 3: Coefficients of Variation* for the Practice Tests, 5 with Low Control Solution [LCS], 5 with High Control Solution [HCS] and 2 Capillary Blood Glucose Readings [CBG] in 52 Elderly [>65 Years] and 49 Young Subjects [≤ 50 Years].

	Coefficient of Variation (%)		
Subjects	**LCS**	**HCS**	**CBG**
Elderly	5.7±2.9 †	5.8±3.0 †	4.7±3.7 †
Young	5.9±2.8	5.7±2.8	4.7±3.6

**All values are reported as mean ± S.D. † p> 0.05 vs. young subjects*

Table 4: Systematic Error, Random Error and Total Error as Defined by Error Grid Analysis* at Venous Blood Glucose Level of 5.5 Mm/L [100mg/Dl] in 52 Elderly [>65 Years] and 49 Young Subjects [≤ 50 Years].

Subjects	Systematic Error	Random Error	Total Error
Elderly	7.3	7.4	11.2
Young	7.2	6.7	11.4

** All values for both groups are within the established norm [< 15%].*

Table 5: Systematic Error [SE], Random Error [RE] and Total Error [TE] as Defined by Error Grid Analysis* at A Venous Blood Glucose Level of 11.1 Mm/L [200mg/Dl] in 52 Elderly [< 65 Years] and 49 Young Subjects [≤50 Years].

Subjects		Systematic Error%	Random Error%	Total Error%
Elderly	7.0	7.9	11.7	
Young	7.7	7.1	11.7	

** All values are within the established norm [<15%].*

DISCUSSION

This study demonstrates that elderly subjects with type 2 diabetes mellitus are as receptive as their younger counterparts to the individual training in performance of capillary blood glucosetesting. Moreover, they do not require any additional extra time or effort on the part of the trainer, when compared with younger subjects (Table 1). The precision in the performance of the technique of capillary blood glucose testing attained by the elderly was equal to that in the hands of the younger subjects, as examined by the trainers. Therefore, it was not surprising to note that accuracy attained by the elderly in the capillary blood glucose readings was of the highest degree as reflected by the extremely high correlation (r= 0.956, p< 0.0001) noted between the capillary blood glucose readings and the simultaneous venous blood glucose concentrations. This degree of accuracy and reliability was further confirmed by previously established acceptable (<10%) coefficients of variation between several tests for control glucose solutions as well as two actual capillary blood glucose readings ranging between hypoglycemic (2 mm/L) and extreme hyperglycemic concentrations (25 mm/L). Finally, the high levels of accuracy and reliability were also evident by the established acceptable values of random, systematic, and total error calculated by the method of error grid analysis (4) at two different venous blood glucose levels (Table 3). Finally, the level of accuracy and reliability of capillary blood glucose testing was almost identical to their younger counterparts.

This high degree of accuracy, precision and reliability in performance of the capillary blood glucose testing by the elderly in this study may be attributed to the device, as well as adequate mental and physical abilities of the subjects. Alternatively, the simplification of technique attained by advancement in technology and therefore development of precision testing devices may have contributed to this noted accuracy.

Finally, several studies using self management techniques with education and training, including self blood glucose monitoring have documented improvement in glycemic control with reduction in complications and costs attributed to this disease. Therefore, with the continually rising prevalence, it is extremely important that all elderly with adequate mental and physical faculties be encouraged and trained in self management, including capillary blood glucose testing.

ACKNOWLEDGEMENTS: The authors are indebted to Linda Hayes, Charisse Reynolds, and Sue Kieffer for their secretarial assistance. Funding Sources: Suvarnam Foundation Inc., Urbandale, Iowa

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