AN EVALUATION OF THE ACCURACY AND COST-EFFECTIVENESS OF A REFLECTANCE PHOTOMETER FOR MONITORING BLOOD GLUCOSE CONCENTRATION IN THE HOSPITAL SETTING

by

Patrick James Cunningham

A project submitted to the faculty of the
University of Utah in partial fulfillment of the requirements
for the degree of

Doctor of Pharmacy

College of Pharmacy

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UNIVERSITY OF UTAH COLLEGE OF PHARMACY

FINAL READING APPROVAL

TO THE DOCTOR OF PHARMACY COMMITTEE OF THE UNIVERSITY OF UTAH COLLEGE OF PHARMACY:

I have read the clinical research project report of Patrick James Cunningham in its final form and have found that 1) its format, citations, and bibliographic style are consistent and acceptable; 2) its illustrative materials including figures, tables, and charts are in place; and 3) the final manuscript is satisfactory to the Supervisory Committee and is ready for submission to the Doctor of Pharmacy Committee.

5-25-85
Date

Chairman, Supervisory Committee

Approved for the Department of Pharmacy Practice

Chairman

Approved for the Doctor of Pharmacy Committee

Chairman, Doctor of Pharmacy Committee

3-4-86 9:15

UNIVERSITY OF UTAH COLLEGE OF PHARMACY

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5-28-85
Date

Chairman, Supervisory Committee

Approved for the Department of Pharmacy Practice

Chairman

Approved for the Doctor of Pharmacy Committee

Chairman, Doctor of Pharmacy Committee

UNIVERSITY OF UTAH COLLEGE OF PHARMACY

SUPERVISORY COMMITTEE APPROVAL

of a clinical research project report submitted by

Patrick James Cunningham

We, the undersigned, have read this clinical research project report and have found it to be of satisfactory quality for a Doctor of Pharmacy Degree.

5/20/85
Date

Chairman, Supervisory Committee

5-5-85
Date

Member, Supervisory Committee

5/20/85
Date

Member, Supervisory Committee

DEDICATION

To Linda Cunningham, my wife, Matthew and Bonnie Cunningham, my parents, for their support, wisdom, encouragement, and for being there when I needed them. Also, I dedicate this to the memory of a very special friend, Ryan Nitz. I miss him.

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INTRODUCTION AND BACKGROUND

Euglycemia is the goal of therapy for diabetic patients receiving insulin or oral hypoglycemic medications. Without proper control of blood glucose concentration serious complications may occur, such as, ketoacidosis or hypoglycemic shock. Historically, monitoring outpatient blood glucose has been accomplished by measuring the urine glucose content. Urine glucose indirectly reflects blood glucose concentration of 180 mg/dl or greater depending upon the glucose threshold of the patient's kidneys, and is inadequate in detecting hypoglycemia (1). Until recently, directly measuring a patient's blood glucose concentration was a process requiring a clinical laboratory and a trained phlebotomist to obtain blood for glucose analysis. With the advent of glucose reagent strips and reflectance photometers, home blood glucose monitoring has now become a possible alternative to urine glucose testing. Numerous reports and studies have defined the role of reagent strips and reflectance photometers in blood glucose monitoring procedures (2-25).

The role of glucose monitoring is not limited to diabetic patients: hyperglycemia and hypoglycemia are metabolic problems frequently encountered in critical care medicine. Hypoglycemia can accompany endotoxin

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A list of all registered trade names utilized in this paper are listed in Tables 1 and 2.

shock, hemorrhagic shock, sepsis, pancreatitis, renal failure, alcoholism, electrolyte and fluid therapy, hypothermia and the administration of numerous medications. Hyperglycemia, on the other hand, is frequently observed in patients receiving dextrose solutions or medications which antagonize the action of insulin such as corticosteroids, glucagon and catecholamines. Other critically ill patients have pre-existing diabetes mellitus or develop clinical conditions which may result in hyperglycemia (7,8). Also in critical care medicine, diabetic ketoacidosis is a clinical disorder requiring knowledge of serial blood glucose concentrations for the adjustment of intravenous (I.V.) and subcutaneous insulin therapy. The frequency of altered glucose homeostasis in critically ill patients makes rapid, accurate and cost-effective determination of blood glucose concentration important.

Another patient population which could benefit from such a blood glucose monitoring system are pregnant diabetics. The pregnant diabetic and her unborn child have an increased risk of morbidity from the effects of either hyperglycemia or hypoglycemia. The effect of hyperglycemia on fetal development includes excess fetal body fat, impaired pulmonary maturation, decreased serum potassium, muscle weakness, cardiac arrhythmias and death. Hypoglycemia has been associated with irreversible neurological damage (15). Maternal hyperglycemia had led to complications such as polyhydramnios, hypertension, urinary tract infection, candidal vaginitis, recurrent spontaneous abortions and infertility. The current recommendations for blood glucose monitoring in a pregnant diabetic requires seven daily blood glucose analyses (7,15,16).

In addition to the critically ill and the pregnant diabetic populations, all diabetic hospitalized patients could benefit from a system that would allow determination of blood glucose concentration prior to receiving their insulin dose, as opposed to an adjusted dose based upon laboratory information obtained several hours before dosing.

Studies

A number of studies have examined the accuracy of reflectance photometers and glucose reagent strips in comparison to hospital laboratory methods for blood glucose determination (2,3,6,8-14,16-20,22-25). Table 1 summarizes the brand name, manufacturer, chemical reagent system of the individual reagent strips and Table 2 presents a summary of the reflectance photometers used in the studies to be reviewed here. Table 3 presents a summary of these studies.

Stickland et al measured blood glucose concentrations in 171 patients attending a diabetic outpatient clinic with both the Glucometer and Eyetone (in duplicate) and by the usual clinic method (Glucose Analyzer Model 23 am, Clandon Scientific, Trenton, NY). The correlation coefficient between blood glucose concentration using either Glucometer or Eyetone and the glucose analyzer was found to be r=0.981 with the Glucometer compared to r=0.968 for the Eyetone (no statistical comparison was reported). The authors found the Glucometer easier to use than the Eyetone in an outpatient clinic and it produced accurate and reproducible results. Problems found with using the Glucometer by the medical staff included lengthy calibration procedures and a single occasion of malfunction (24).

Chernow et al compared two reagent strips (Chemstrip BG and Dextrostix) for the quantitative estimation of whole blood glucose concentra-

tions in 133 critically ill patients in an intensive care unit. Both strips were compared to the Roto Chem Parallel Fast Glucose Analyzer (Travenol Laboratories, Inc., Savage, MD) which served as the control. The authors found a significant correlation ($r=0.95$, $p < 0.001$) between both reagent strips and the measured values for the range of glucose concentration (10-600 mg/dl). In addition, the physicians found the Chemstrip BG easier to read and measured a wider range of glucose values than the Dextrostix method (8).

Shapiro et al studied venous blood glucose concentrations determined by a hospital laboratory glucose analyzer (from Technicon SMAC) compared with concentrations of capillary blood glucose determined by three reflectance photometers currently available in the United States (Eyetone, Dextrometer and Stat Tek) and by visual interpretation of reagent strips (Chemstrip BG). The authors found an acceptable correlation between laboratory serum glucose concentration and reflectance photometer blood glucose determination ($r=0.90-0.94$) or visual interpretation of Chemstrip BG ($r=0.85-0.92$) although statistical significance was not reported. The authors concluded that reagent strips not requiring the use of a reflectance photometer provide a technique of home blood glucose monitoring similar in performance to those using reflectance photometers. They also noted that although patients did not formally evaluate the three reflectance photometers, several patients expressed a preference for an instrument which provides an unequivocal reading of blood glucose concentration over a method requiring patient decision-making in the matching of reagent strips to a set of standard colors (19).

Schake et al examined the correlation between the blood glucose concentration estimated by diabetic patients at home using a Chemstrip BG reagent strip and blood glucose concentration subsequently measured by a Beckman Glucose Analyzer. The authors found a correlation ($r=0.85$, $p < 0.001$) between the blood glucose concentration as estimated by the Chemstrip BG and the blood glucose concentration as estimated by the Beckman Automated Glucose Analyzer (18).

The above studies indicate the utility of reflectance photometers and blood glucose reagent strips in monitoring blood glucose concentrations. The use of a reflectance photometer with a glucose reagent strip may reduce the variability of results seen with the reagent strip alone. The measurement of blood glucose concentration using a reflectance photometer may be as accurate as a more sophisticated laboratory method. The present study was designed to compare the Chemstrip BG interpreted by the Accu-Chek reflectance photometer with the Beckman Astra 8 Analyzer as a means of monitoring blood glucose concentrations in the hospital setting.

STUDY OBJECTIVES

1. To examine the correlation between Chemstrip BG reagent strips read by the Accu-Chek (reflectance photometer from Bio-Dynamics) as compared to the blood glucose concentration measured by the Beckman Astra 8 Analyzer as follows:
   a. Venous blood (Beckman) compared to venous blood (Accu-Chek)
   b. Venous blood (Beckman) compared to capillary blood (Accu-Chek)
   c. Venous blood (Accu-Chek) compared to capillary blood (Accu-Chek).

2. Compare the cost to the hospital of a laboratory blood glucose determination to the estimated cost of the Accu-Chek determination.

MATERIALS AND METHODS

Subjects

Eighteen subjects who were inpatients in the University Hospital were admitted to the study after informed consent was obtained. This study was previously approved by the University of Utah Institutional Review Board. The study group was composed of surgical and medical patients with the only exclusion criterion being hepatitis precautions or abnormal PTT, PT or bleeding time (normal limit as set by the clinical laboratory at the University of Utah Hospital). The study population consisted of ten female (ages 16-58 years) and eight male (ages 23-61 years) patients. Six of these patients were diabetic.

Blood Glucose Comparison

A total of 50 venous blood samples and 50 capillary blood samples (obtained by finger puncture) was collected. These samples were then analyzed for blood glucose concentration using the Accu-Chek (reflectance photometer) utilizing the Chemstrip BG reagent strip (both from Bio-Dynamics, Boehringer Mannhein Corporation, Indianapolis, IN 46250). The venous samples were also measured for plasma glucose concentration by the clinical laboratory associated with the University of Utah Hospital using the Beckman Astra 8 Analyzer, which was regarded as the reference (or true) value. The reported laboratory error of the Beckman Astra 8 analyzer at the University of Utah for plasma glucose concentration determinations is 0.1%.

Blood Glucose Collection

When the study patients were to have blood samples obtained for a laboratory blood glucose concentration determination, the phlebotomist obtained an additional small gray top tube (Vacutainer®, Bectin Dickinson, Rutherford, NJ) of blood (containing potassium oxalate and sodium fluoride), volume not exceeding one milliliter, for the Accu-Chek determination. Immediately following the venous blood collection (within five minutes) the patient underwent a finger (capillary) puncture accomplished by an automatic blood letting device (Autoclix®, Bio-Dynamics, Division of Boehringer Mannheim, Inc., Indianapolis, IN).

Blood Glucose Determination

The capillary blood sample (finger puncture) and the corresponding venous blood sample were measured for glucose concentration by the investigator using the Accu-Chek system. In all cases, the manufacturer's instructions pertaining to warm-up, calibration and operation of the reflectance photometer were adhered to strictly.

Cost Analysis

The second part of this study examined the cost difference of the two blood glucose monitoring systems. The cost of the hospital laboratory blood glucose concentration determination was compared with the estimated cost of the Accu-Chek determination. Included in the estimated cost of the Accu-Chek determination are:

1. The instrument cost distributed over one year.
2. Material cost to include the Chemstrip BG, lancets, cotton balls and alcohol wipes.

3. Personnel cost based upon seven minutes (manufacturer's suggested test time) of an average hospital pharmacist's salary in Utah (approximately $25,000/year).

The costs were taken as the retail selling price excluding discounts and rebates.

Data Analysis

The analysis of these types of data (predictions and reference or true values) has historically been linear regression analysis. In 1980 Sheiner and Beal (26) suggested that computing the correlation coefficient and/or the regression of predictions on reference (true) values is only a poor description of predictive performance. The reason is the correlation coefficient measures the degree of association along the "best" line relating the two variables. When comparing precision or accuracy of a new diagnostic test against a reference standard, the degree of association along the line of identity (with a slope of one and a y-intercept of zero) must be determined. The best line is not necessarily the line of identity. Therefore, the analysis of the data included the mean squared prediction error (a descriptive measure of precision) (26). The student's t-test (two-tailed) for paired samples was used for statistical analysis of the differences between the reference value and the capillary and venous Accu-Chek values and between the Accu-Chek capillary and venous values. Statistical significance for the three blood glucose determinations was set at ($p = 0.05$).

The mean, variance, range and standard deviation for both the error (difference in mg/dl from the true or reference value) and percent error

are reported. To coincide with the current medical literature, linear regression analysis comparing the laboratory blood glucose values vs the Accu-Chek capillary and venous values and comparing Accu-Chek venous vs Accu-Chek capillary values was performed and correlation coefficients (r) are reported.

RESULTS

The results of the 50 venous and capillary blood glucose determinations by the Accu-Chek and the 50 venous blood glucose determinations by the clinical laboratory are listed in Table 4, 5, 6, and 7. These tables also provide the mean, variance, range and standard deviation of the error and percent error. The overall mean venous blood glucose concentration determination from the clinical laboratory was 115.9 mg/dl with a range of 58-282 mg/dl. The Accu-Chek system blood glucose concentration determination from the venous blood samples ranged from 81-260 mg/dl with a mean value of 125.6 mg/dl, whereas the capillary blood samples ranged from 62-251 mg/dl with a mean value of 123.4 mg/dl. The Accu-Chek system reported a higher blood glucose concentration as compared to the clinical laboratory in 82% of the venous samples and in 84% of the capillary samples. The overall percent error (difference) from the reference value (clinical laboratory value) and the capillary values (measured by the Accu-Chek system) was 11.8% as compared to 17.2% for the venous values (measured by the Accu-Chek system). The mean squared prediction error (precision) for the Accu-Chek capillary versus the laboratory method was 182.9 compared to 312.4 for the Accu-Chek venous method versus the laboratory method.

A significant difference ($p < 0.001$) was found between the clinical laboratory and the Accu-Chek venous blood glucose concentration.

Likewise there was a statistically significant difference ($p < 0.001$) between the Accu-Chek capillary blood glucose concentration and the clinical laboratory venous blood glucose concentration. There was no statistically significant difference between the Accu-Chek capillary and venous blood glucose concentrations.

Linear regression analysis was applied to the data (Figures 1-3) which resulted in a correlation coefficient ($r=0.99$, $p < 0.001$) comparing the Accu-Chek capillary blood glucose concentration with the clinical laboratory venous blood glucose concentration. A correlation ($r=0.91$, $p < 0.001$) was calculated between the Accu-Chek venous blood glucose concentration and the clinical laboratory venous blood glucose concentration. Finally a correlation coefficient ($r=0.96$, $p < 0.001$) between the Accu-Chek venous and Accu-Chek capillary blood glucose concentration was performed.

The cost analysis of the two glucose monitoring systems are summarized in Table 8.

DISCUSSION

The study was undertaken to assess the feasibility of utilizing a reflectance photometer (Accu-Chek) as the primary instrument for blood glucose monitoring in the hospital setting. Blood glucose concentration assessment is a critical clinical analysis in the delivery of quality health care. Accuracy (performance) and cost are important factors that must be considered in the institution of a blood glucose monitoring system. However, at this time, there are no criteria for the degree of accuracy and precision of reflectance photometers. Without these criteria it is difficult to critically analyze the performance of the reflectance photometer. With the "normal" range of blood glucose

varying between 80-120 mg/dl, an acceptable degree of error will be difficult to determine. An error of 15% or less would likely not alter clinical decision-making. As the percent error increases so does the likelihood of an erroneous reading causing an unnecessary or detrimental change in therapy. In the present study, patients with plasma glucose concentrations exceeding 80 mg/dl had Accu-Chek capillary blood glucose readings within an acceptable deviation from the laboratory reading.

As can be seen in Tables 4, 5, and 6 the mean, variance, range and standard deviation of the percent error and error increase as the reported blood glucose concentrations decrease. The explanation for this phenomenon is not readily apparent. It is possibly an artifact of the sample size or perhaps an error in methodology.

This study varied from the published literature in that the majority of the Accu-Chek capillary blood glucose concentrations were found to be higher than those measured by the clinical laboratory. Arterial blood is generally higher in glucose content than venous blood (5,27, 28). The literature suggests that the finger pad or ear lobe (capillary) blood glucose concentration approximates the glucose concentration of the arterial blood, and after eating, the arterial blood glucose concentrations usually range 20% to 30% higher than the venous blood (5,27,28). This study found that neither the venous nor capillary Accu-Chek blood glucose concentration was predominantly higher than the other.

The analytical method employed by the clinical laboratory utilizes plasma rather than whole blood for glucose assay. It has been reported that the concentration of glucose in the plasma is 15% to 20% higher than the glucose concentration in whole blood. The present study found

a consistently higher glucose concentration in whole blood as measured by the Accu-Chek reflectance photometer. (5,27,28) This finding could result from a consistent error in methodology by the investigator or an error in the instrumentation. A measure of the inter-instrument reliability of the Accu-Chek reflectance photometer should be determined to rule out instrument error.

There was a lower mean squared error for the Accu-Chek capillary versus laboratory methods for measuring blood glucose compared to that for the Accu-Chek venous versus laboratory methods (182.9 and 312.4, respectively). These values indicate a greater precision and therefore a preference for using capillary blood rather than venous blood for the Accu-Chek method.

In the cost analysis (Table 8) it was demonstrated that there is a potential for cost savings. At the University Hospital in 1984, 94 diabetic patients were admitted for a variety of medical reasons with an average length of stay of 6.1 days. Assuming an average of three to four blood glucose determinations per day, the cost savings to the hospital would have been $135 to $185 per patient. With the implementation of prospective reimbursement programs for patient care the use of reflectance photometers for monitoring blood glucose concentrations may allow close patient monitoring while minimizing hospital costs.

CONCLUSION

This study demonstrates that the Accu-Chek reflectance photometer is a clinically acceptable method for monitoring blood glucose concentrations in most hospitalized patients. Patients with blood glucose concentration readings below 80 mg/dl, however, may need to have their blood glucose concentration confirmed by a more precise method. Many

hospitals and clinics throughout the country are currently using a reflectance photometer for their routine monitoring of blood glucose. The Accu-Chek was found to be a rapid, accurate and cost-effective method of blood glucose monitoring as compared to the hospital laboratory.

TABLES

Table 1. Blood Glucose Reagent Strips

Product	Manufacturer	Range (mg/dl)	Chemical Reaction
Chemstrip BG	Bio-Dynamics*	40-800	Glucose oxidase/peroxidase
Stat-Tek	Bio-Dynamics*	-	Glucose oxidase/peroxidase
Dextrostix	Ames**	0-250	Glucose oxidase/peroxidase
Visidex	Ames**	20-800	Glucose oxidase/peroxidase

* Bio-Dynamics, Division of Boehringer Mannheim, Inc., Indianapolis, IN.

** Ames, Division of Miles Laboratories, Inc., Elkhart, IN.

Table 2. Blood Glucose Reflectance Photometers

Product	Manufacturer	Reagent Strip Used
Dextrometer	Ames	Dextrostix
Glucometer	Ames	Dextrostix
Glucoscan	Lifescan*	Dextrostix
Accu-Chek	Bio-Dynamics	Chemstrip BG
Eyetone	Ames	Dextrostix
Stat Tek	Bio-Dynamics	Stat Tek

* Lifescan, Sun Valley, CA.

Table 3. Literature Analysis

Authors	Method vs. Laboratory	Samples	Correlation Coefficient	Mean Deviation	Mean % Error
Reeves(17)	Chemstrip BG®	200	0.98	228	13.7
Schake(18)	Chemstrip BG®	22	0.95	NR*	NR
Clements(9)	Dextrostix®	41	0.952	NR	10.7**
	Eye Tone®	41	0.966	NR	10.7**
Alexander(2)	Chemstrip BG®	143	0.942	NR	NR
Shapiro(19)	Chemstrip BG®	125	0.935	NR	17.8
Chernow(8)	Chemstrip BG®	133	0.96	NR	NR
Strickland(24)	Glucometer®	171	0.981	NR	NR
	Eye Tone®	171	0.968	NR	NR
Vanden(4)	Chemstrip BG®	23	NR	20	NR
	Stat Tek®	23	NR	15	NR
Fairclough(11)	Chemstrip BG®	33	0.96	NR	10.7
Perelman(16)	Chemstrip BG®	90	0.798	26.2	NR
Frindik(12)	Chemstrip BG®	99	0.84	12.4	
Silverstein(20)	Chemstrip BG®	159	0.976	NR	26**
Aziz(3)	Accu-Chek®	115	0.842		
Godine(6)	Accu-Chek®	163	0.96	NR	7.9
Cunningham	Accu-Chek® (cap)	50	0.99	11.5	12.3
Cunningham	Accu-Chek® (ven)	50	0.91	15.6	17.1

* Not reported

** Percentage of determinations that varied by greater than 20% from the true or reference value

Table 4. Patient Data with Glucose Concentration Greater Than 125 mg/dl

Sample Number	Laboratory Value*	Accu-Chek® Venous Value*	Accu-Chek® Capillary Value*	Lab vs. Accu-Chek® Ven.% Diff	Lab vs. Accu-Chek® Cap.% Diff	Accu-Chek® Venous vs Cap.% Diff
1	282	260	251	7.8	11.0	3.5
2	252	240	234	4.8	7.1	2.5
3	248	241	236	2.8	4.8	2.1
4	242	230	224	5.0	7.4	2.6
5	242	230	241	5.0	0.4	4.8
6	238	231	226	2.9	5.0	2.2
7	236	224	234	5.1	0.8	4.5
8	166	158	175	4.8	5.4	10.8
9	160	150	165	6.3	3.1	10.0
10	156	146	161	6.4	3.2	10.3
11	156	148	165	5.1	5.8	11.5
12	141	131	146	7.1	3.5	11.5

Error mg/dl	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	10.8	10.6	10.8
Variance	16.2	72.3	22.4
Standard Deviation	4.0	8.5	4.7
Range	15.0	30.0	12.0

(continued)

Table 4. (continued)

Percent Error	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	5.3	4.8	6.4
Variance	2.2	8.6	16.4
Standard Deviation	1.5	2.9	4.0
Range	5.0	10.1	9.4

* Glucose concentration (mg/dl)

Table 5. Patient Data with Glucose Concentrations Between 125 mg/dl and 80 mg/dl

Sample Number	Laboratory Value*	Accu-Chek® Venous Value*	Accu-Chek® Capillary Value*	Lab vs. Accu-Chek® Ven.% Diff	Lab vs. Accu-Chek® Cap.% Diff	Accu-Chek® Venous vs Cap.% Diff
13	122	149	131	22.1	7.4	12.1
14	119	132	131	10.9	10.1	1.0
15	110	102	124	7.3	12.7	21.6
16	106	116	111	9.4	4.7	4.3
17	104	141	101	35.6	2.9	28.4
18	103	130	112	26.2	8.7	13.8
19	102	112	122	9.8	19.6	8.9
20	102	112	110	9.8	7.8	1.8
21	100	113	118	13.0	18.0	4.4
22	100	113	112	13.0	12.0	1.0
23	96	99	97	3.1	1.0	2.0
24	96	109	110	13.5	14.6	1.0
25	91	83	105	8.8	15.4	26.5
26	87	97	92	11.5	5.7	5.2
27	87	97	95	11.5	9.2	2.1
28	87	94	105	8.0	20.7	11.7
29	86	111	93	29.1	8.1	16.2
30	85	93	100	9.4	17.6	7.5
31	85	97	99	14.1	16.5	2.1
32	83	93	103	12.0	24.1	10.8
33	81	103	92	27.2	13.6	10.7
34	81	94	99	16.0	22.2	5.3
35	81	101	98	24.7	21.0	2.9
36	80	93	94	16.3	17.5	1.1

(continued)

Table 5. (continued)

Error mg/dl	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	14.3	11.9	9.3
Variance	63.9	28.9	91.6
Standard Deviation	7.9	5.4	9.6
Range	34.0	19.0	39.0

Percent Error	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	15.1	13.0	8.3
Variance	65.7	41.5	66.7
Standard Deviation	8.1	6.4	8.2
Range	32.5	23.1	28.3

* Glucose concentration (mg/dl)

Table 6. Patient Data with Glucose Concentrations Less Than 80 mg/dl

Sample Number	Laboratory Value*	Accu-Chek® Venous Value*	Accu-Chek® Capillary Value*	Lab vs. Accu-Chek® Ven.% Diff	Lab vs. Accu-Chek® Cap.% Diff	Accu-Chek® Venous vs Cap.% Diff
37	79	100	84	26.6	6.3	16.0
38	87	104	96	19.5	10.3	7.7
39	77	90	91	16.9	18.2	1.1
40	75	82	93	9.3	24.0	13.4
41	75	91	85	21.3	13.3	6.6
42	75	81	78	8.0	4.0	3.7
43	74	99	81	33.8	9.4	18.2
44	72	100	74	38.8	2.8	26.0
45	72	105	100	45.8	38.9	4.8
46	72	94	85	30.6	18.1	9.6
47	70	94	72	34.3	2.9	23.4
48	65	95	91	46.2	40.0	4.2
49	60	88	62	46.7	3.3	29.5
50	58	86	67	48.3	15.5	22.1

Error mg/dl	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	21.3	10.6	12.4
Variance	71.0	72.4	74.4
Standard Deviation	8.4	8.5	8.6
Range	27.0	26.0	25.0

(continued)

Table 6. (continued)

Percent Error	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	30.4	14.8	13.3
Variance	193.6	152.4	86.2
Standard Deviation	13.9	12.3	9.3
Range	40.3	37.2	28.4

* Glucose concentration (mg/dl)

Table 7. Combined Patient Data

Error mg/dl	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	15.4	11.5	10.5
Variance	51.4	58.7	66.5
Standard Deviation	7.2	3.6	8.2
Range	34.0	30.0	39.0

Percent Error	Accu-Chek® Venous vs. Lab	Accu-Chek® Capillary vs. Lab	Accu-Chek® Venous vs. Accu-Chek® Capillary
Average	17.0	11.5	9.0
Variance	81.1	37.9	56.9
Standard Deviation	9.0	6.2	7.5
Range	43.5	39.6	29.4

Table 8. Cost Analysis

A. Clinical Laboratory	Patient Charges
Blood Glucose	$ 9.00-12.00
Stat Fee	7.00- 9.00
Research Fee (blood glucose)	5.00

B. Accu-Chek® Capital Items[a]	Costs Distributed Over One Year
Instrument	$ 0.42/day
Auto clix®	0.02/day

1. One Time Charges

Item	Charge
Lancets	$ 0.07/each
Alcohol Wipes	0.02/each
Cotton Balls	0.01/each
Chemstrip BG	0.45/each

2. Employee Charge[b]

Pharmacist	$ 1.52/seven minutes

3. Calculated Costs for Accu-Chek® System

Draws per Day	Cost
One daily draw	$ 2.51/draw
Five daily draws	2.16/draw
After one year	2.07/draw

[a] Based on retail price of $150 for the Accu-Chek® and $7 for the Auto-clix®

[b] Based on an average pharmacist salary of $25,000 annually

FIGURES

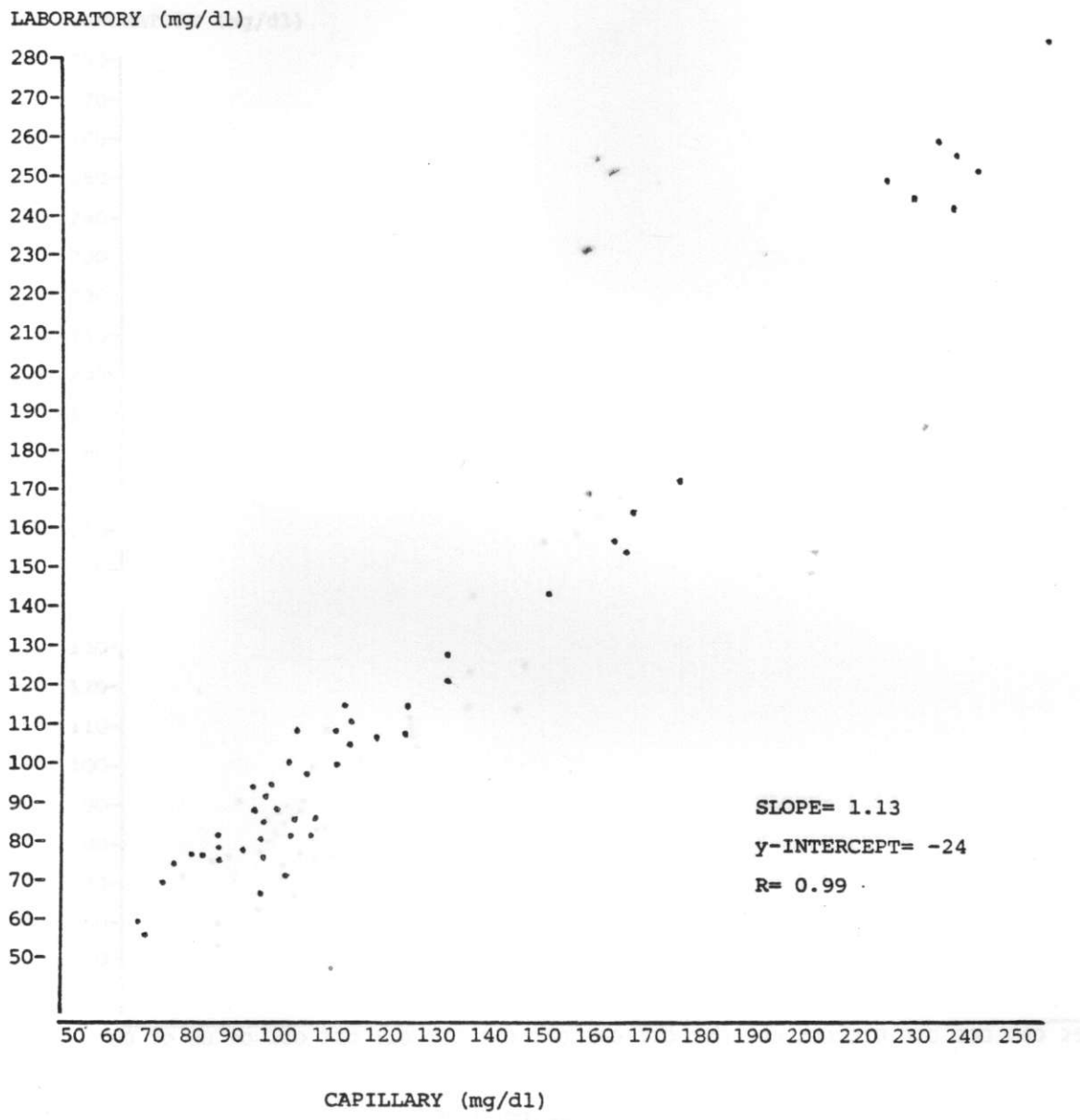

Figure 1. Blood Glucose Concentrations - Laboratory vs Capillary (Accu-Chek)

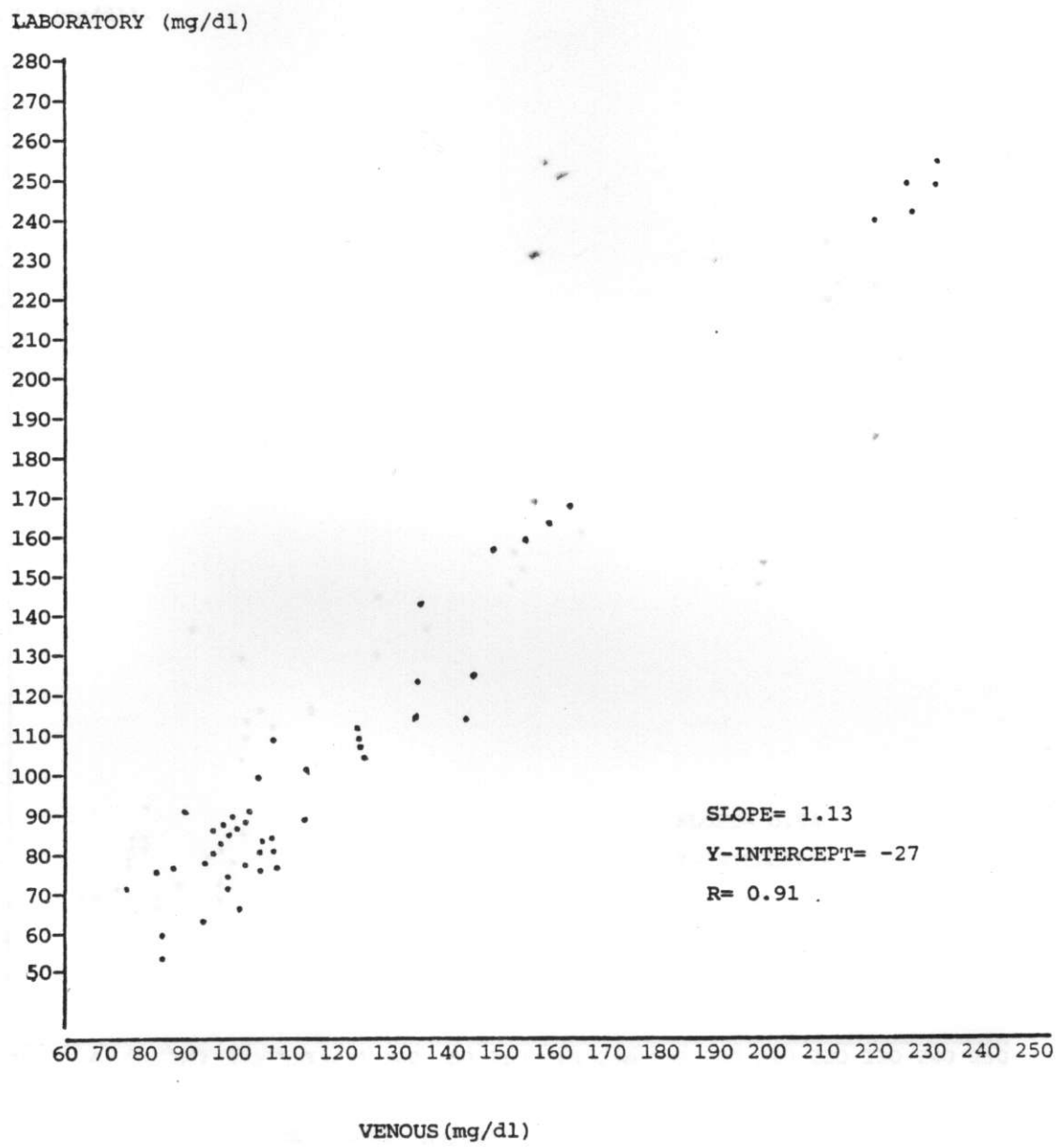

Figure 2. Blood Glucose Concentrations - Laboratory vs Venous (Accu-Chek)

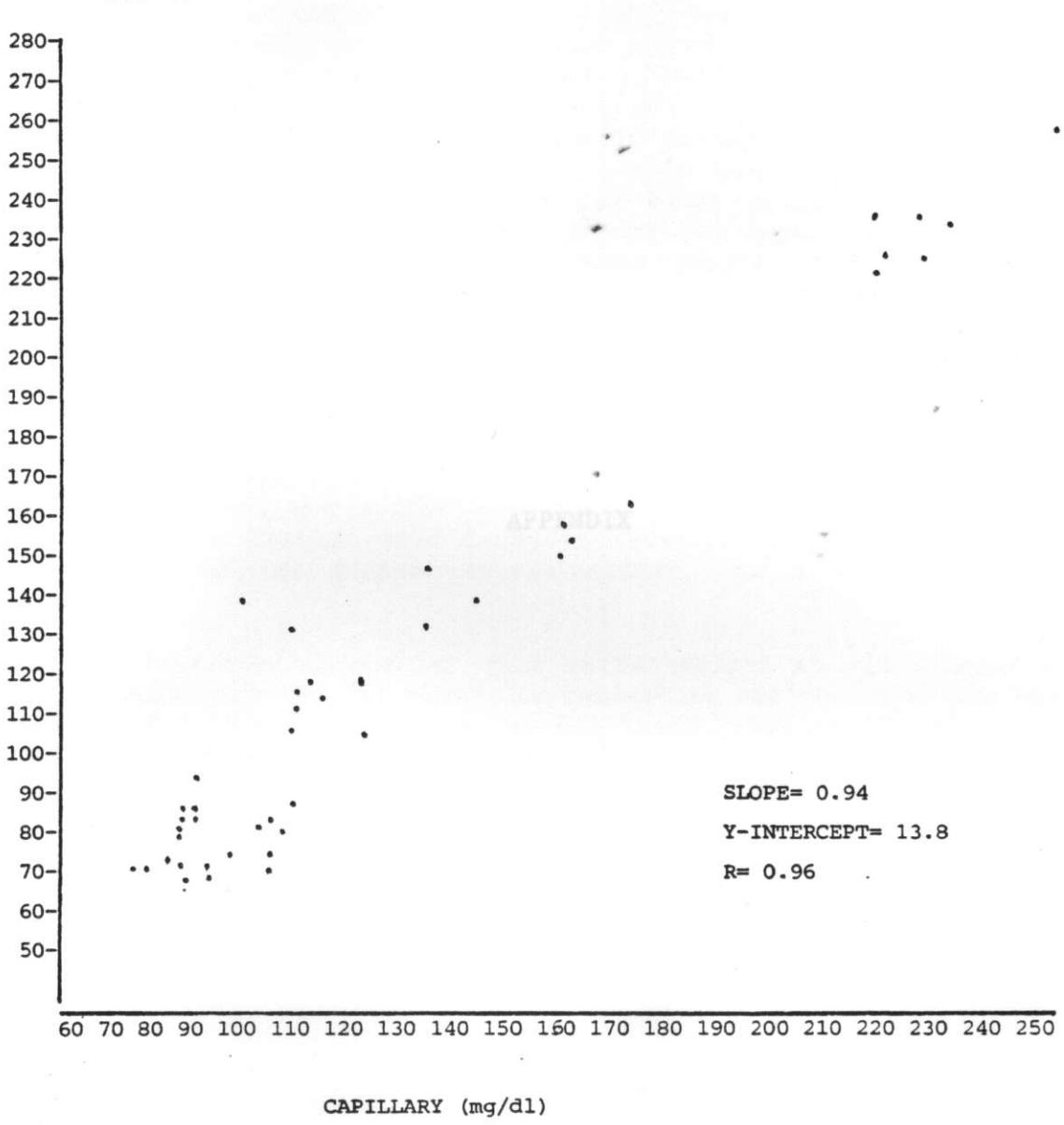

Figure 3. Accu-Chek Blood Glucose Concentrations - Venous vs Capillary

APPENDIX

A COMPARISON OF TWO BLOOD GLUCOSE MONITORING METHODS FOR ACCURACY AND COST-EFFECTIVENESS IN THE HOSPITAL SETTING

Informed Consent Form

You are invited to participate in a study to determine whether a small portable instrument (Accu-Chek) that measures the amount of sugar in the blood is an accurate and cost-effective alternative to measuring blood sugar by the hospital laboratory. Monitoring blood sugar is important in the ill, diabetic, and in patients receiving intravenous fluids. This study will examine venous blood, one milliliter (15 drops), obtained at the same time as blood obtained by the hospital laboratory. Therefore, no extra venous punctures will be necessary. Immediately after obtaining the venous sample, the participant will undergo a finger puncture, accomplished by a automatic device that punctures the end of the finger. Two to four drops of blood will be collected for the Accu-Chek glucose determination. These two blood samples (venous and finger puncture) will be compared to the blood sugar concentration measured by the hospital laboratory.

The possible risks of the finger puncture includes mild localized pain, infection, and slight bleeding. The possible future benefits of the Accu-Chek system would include; decrease in the number of venous punctures, quicker glucose determinations, and a decrease in patient cost.

Patient confidentiality will be maintained at all times. If the participant ever has any questions concerning the study, he/she may call Patrick Cunningham at 485-8875 or Dr. Frank Tyler at 581-2121. Patient participation in this study is voluntary and the participant at any time may decline to continue the study without any consequences.

_____

Participant Signature Date

_____

Guardian Signature (if patient is under 18 years of age)

REFERENCES

1. Hayford JT, Weydert JA, Thompson RB, et al. Validity of urine glucose measurements for estimating plasma glucose concentration. Diabetes Care 1983; 6:40-44.

2. Alexander IJ. Blood glucose testing. J Am Opt Assn 1982; 53(5): 387-390.

3. Aziz S, Hsiang Y-H. Comparitive study of home blood glucose monitoring devices: Visidex, Chemstrip BG, Glucometer, and Accu-Chek BG. Diabetes Care 1983; 6(6):529-532

4. Bell PM, Walshe K. Benefits of self-monitoring of blood glucose. Br Med J 1983; 206:1230-1231.

5. Bernsteins RK. Diabetes - The Glucograf Method for Normalizing Blood Sugar, Crown Publishing Co., New York, 1981, pp. 105-109.

6. Brouhard BH. Control and monitoring for the child with insulin-dependent diabetes mellitus. Am J Dis Child 1983; 134:787-794.

7. Burghen G. Therapy in childhood diabetes. JAMA 1983; 249(21): 2938-2939.

8. Chernow B, Diaz M, Cruess D, et al. Bedside blood glucose determination in critical care medicine: A comparitive analysis of two techniques. Crit Care Med 1982; 10(7):463-465.

9. Clements RS, Keane NA, Kirk KA, et al. Comparison of various methods for rapid glucose estimation. Diabetes Care 1981; 4(3): 392-394.

10. Drucker RF, Williams DR, Price CP, et al. Quality assessment of blood glucose monitors in use outside the hospital laboratory. J Clin Pathol 1983; 36:948-953.

11. Fairclough PK, Clements RS, Filer DV, et al. An evaluation of patient performance of and their satisfaction with various rapid blood glucose measurement systems. Diabetes Care 1983; 6(1):45-49.

12. Frindik PJ, Neeley WE, Zettner A, et al. Comparison of Visidex and Chemstrip BG with Beckman Glucose Analyzer determination of blood glucose. Diabetes Care 1983; 6(6):536-539.

13. Giampietrol O, Pilo A, Buzzigoli G, et al. Four methods for glucose assay compared for various glucose concentration and under different clinical conditions. Clin Chem 1982; 28(12):2405-2407.

14. Godine JE. Capillary blood glucose monitoring in a general hospital. Unpublished data abstracts from the 1984 National American Diabetes Association Convention, Las Vegas, Nevada, June 6, 1984.

15. Irsigler K. Self-monitoring improves pregnancy outcome in diabetic women. Symposia Reporter 1981; 5(1):1-16.

16. Perelman R, Gutcher GR, Engle MJ, et al. Comparative analysis of four methods of rapid glucose determination in neonates. Am J Dis Child 1982; 136:1051-1053.

17. Reeves ML. Comparison of methods for blood glucose monitoring. Diabetes Care 1981; 4(3):404-406.

18. Schake B, Paulshock BZ, Snyder M, et al. A comparison of methods for blood glucose monitoring. Diabetes Care 1981; 4(3):420-421.

19. Shapiro B, Savage PJ, Lomatch D, et al. A comparison of accuracy and estimated cost of methods for home blood glucose monitoring. Diabetes Care 1981; 4(3):396-403.

20. Silverstein JH, Rosenbloom AL, Clark DW, et al. Accuracy of two systems for blood glucose monitoring without a meter (Chemstrip/Visidex). Diabetes Care 1983; 6(6):533-535.

21. Skyler JS, Golde SH, Dorey S, et al. Blood glucose control during pregnancy. Diabetes Care 1980; 3:69-76.

22. Steinbeck K, Kidson W, Kidson L, et al. Home blood glucose analysis. Med J Aust 1981; 2:128-135.

23. Stewart TC, Kleyle RM. Statistical comparison of blood glucose as determined by several test-strip procedures and by a hexokinase procedure. Clin Chem 1983; 29(1):132-135.

24. Stickland MH, Wales JK: Blood glucose determinations, the use of a new reflectance photometer. Practitioner 1982; 226:271-272.

25. Vanden MA, Hyneck ML. Accuracy of four methods of home blood glucose monitoring in hemodialysis patients. Clin Pharm 1984; 3:291.

26. Scheiner LB, Beal SL. Some suggestions for measuring predictive performance. J Pharmacokin and Biopharm 1981; 9(4):503-513.

27. Krall L. Joslin Diabetes Manual, 11th edition, Larger Print Books, Inc., New York, 1978.

28. Lewis JE, Caryl D. The ABC's of Diabetes, American Diabetes Association, New York, 1979, pp. 102-104.

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