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Role of Mood in Outcome of Biofeedback Assisted Relaxation Therapy in Insulin Dependent Diabetes Mellitus

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Stressful life events and negative mood have been associated with elevated blood glucose and poor self-care in individuals with diabetes. The purpose of this controlled study was to determine the effect of mood state, specifically depression, anxiety, and daily hassles on the outcome of biofeedback assisted relaxation in insulin dependent diabetes mellitus. Eighteen subjects completed the study, nine in biofeedback assisted relaxation and nine in the control group. There were no significant group differences in blood glucose between those receiving biofeedback assisted relaxation and the subjects continuing usual care. Five of the nine experimental subjects and one of the nine control subjects were identified as succeeders according to an arbitrary criterion. Treatment failures were more depressed, more anxious, and took longer to complete the protocol than succeeders. Statistically significant correlations were found between high scores on inventories measuring depression, anxiety, and hassles intensity and higher blood glucose levels and smaller changes in blood glucose as a result of treatment. It is suggested that mood has an important impact on the response to biofeedback assisted relaxation. Further research is necessary to determine whether assessment of anxiety and depression followed by appropriate treatment where necessary should precede biofeedback assisted relaxation in insulin dependent diabetes.

KEY WORDS: diabetes; biofeedback; relaxation; depression; anxiety.

INTRODUCTION

Diabetes mellitus is a chronic disorder of metabolism that affects about 6% of the adult population of the United States (Harris *et al.*, 1998). Individuals with insulin dependent diabetes (IDDM) require exogenous insulin to control the hyperglycemia induced by a lack of functioning pancreatic beta cells. Management usually consists of insulin, self-monitoring of blood glucose (SMBG), exercise, and a meal plan (American Diabetes Association, 1995). Physicians monitor glycemic control by reviewing patients' blood glucose data and with a biologic assay, glycohemoglobin, which represents the average blood glucose for the

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past 2 to 3 months (Krall & Beaser, 1989). The reliability of SMBG has been questioned, because patients may report erroneous values (Mazze, Shamoon, Pasmantier, Lucido, & Murphy, 1984). However correlations between biologic indicators of blood glucose and SMBG may alleviate some of the more serious concerns. The importance of an intensive medical regimen was emphasized by the results of the Diabetes Control and Complications Trial in which the incidence of complications was compared between persons receiving usual care and those receiving intensive care for their diabetes. Regular daily monitoring and multiple daily insulin injections led to a significant decrease in the number of complications of diabetes, particularly retinopathy, nephropathy, and neuropathy (Diabetes Control and Complications Trial Research Group, 1993).

In persons with IDDM, self-care and health maintenance behaviors can be disrupted by stressful events. An insulin dose may be delayed, exercise omitted, or the person may fail to monitor blood glucose due to the competing demands placed by family or occupation. Stressful life events have been correlated with increased variability in blood glucose, higher insulin dosage, and increased glycohemoglobin values (Cox & Gonder-Frederick, 1989). Negative mood or anxiety may precipitate poorer self-management, either for a short time or chronically (Goodall & Halford, 1991).

Although there are direct effects of stress on blood glucose via activation of the hypothalamic pituitary adrenal axis (Goodman, 1988), and psychological stress interferes with health promoting behaviors, the relationship between stress-induced anxiety and blood glucose has not been consistent. Stress may be associated with hyper- or hypoglycemia in different patients under various trigger situations (reviewed in Surwit & Schneider, 1993; and Surwit, Schnieder, & Feinglos, 1992). Niemcryk, Speers, Travis, & Gary (1990) found a significant correlation in young adults with IDDM between anxiety and current values of glycohemoglobin but no relationship between anxiety and follow-up values of the same variable. With regard to mood, clinical depression is strikingly more prevalent in individuals with diabetes than in the general adult population; and depressive symptoms are associated with poorer self-management and poorer glycemic control (Goodnick, Henry, & Buki, 1995; Gavard, Lustman, & Clouse, 1993; Rodin & Voshart, 1986).

Biofeedback assisted relaxation has been found to be useful in stress-related disorders, such as headaches and anxiety as sole therapy, or as an adjunct to pharmacotherapy in some chronic illnesses (Schwartz, 1995). The applicability of relaxation-based therapy to diabetes has produced equivocal results. In two studies of patients with noninsulin dependent diabetes mellitus (NIDDM), no group differences in blood glucose was observed between the group trained in relaxation and the usual care control group (Aikens, Kiolbasa, & Sobel, 1997; Jablon, Naliboff, Gilmore, & Rosenthal, 1997). In IDDM, no benefit was found for biofeedback and progressive relaxation in decreasing glycosylated hemoglobin (Feinglos, Hastedt, & Surwit, 1987).

However, two controlled studies from our laboratory assessed the effects of biofeedback assisted relaxation on blood glucose in IDDM (McGrady, Bailey, & Good, 1991; McGrady, Graham, & Bailey, 1996) and found encouraging results. Patients in the treatment groups received biofeedback and relaxation therapy, review of blood glucose records with the nurse, while the controls continued usual care and also reviewed their glucose records with the nurse. In both studies, the experimental group showed a significant advantage in lowering average blood glucose, percent of values above 200 mg/dl and percent of fasting values at target levels.

A possible explanation of the differences in outcomes of relaxation-based therapy in diabetes is the psychological or emotional factors in the patient participants. Therefore, the purpose of the present study was to explore the role of depressed mood, anxiety, and hassles on outcome of biofeedback assisted relaxation in IDDM. The hypothesis was that patients with negative mood, anxiety, and frequent and intense hassles would have a poorer response to biofeedback assisted relaxation.

METHODS

Subjects were recruited from the practice of James Horner, local physicians, and through advertisements in local newspapers. Subjects had IDDM for longer than one year, no other chronic nondiabetes-related illnesses, no severe complications from their diabetes, and no severe psychiatric disorders (psychosis or bipolar disorder). This information was determined by history. Subjects obtained written permission from their physicians to participate. At the first session, the study was explained to subjects and they signed the informed consent form previously approved by the Institutional Review Board. A brief history included length of illness, course of illness over time, and patient adherence to physician recommendations for self-management. Subjects were provided with a One Touch II Glucometer and blood glucose monitoring strips and were asked to measure blood glucose three times a day and keep the results in a log book. Psychological inventories, consisting of the State Trait Anxiety Inventory (Spielberger, Gorsush, & Lushene, 1970), the Zung Depression Inventory (Zung, 1965), and the Hassles Scale (Lazarus & Folkman, 1989), were administered. Blood samples were drawn for fructosamine, an indicator of average blood glucose for the preceding two to three weeks, and glycohemoglobin, an indicator of average blood glucose for the preceding two to three months (Springer, 1989). Normal ranges for our laboratory are 200–272 mmol/l for fructosamine and 3.3–5.6% for glycohemoglobin A1.

Data from the subjects' log books were averaged, using a minimum of 50 values obtained during a three- to four-week span. The data derived from these measurements are called Period 1: Baseline. During period 2, termed "Education," patients viewed a one-hour video entitled "Managing Your Diabetes" provided by Eli Lilly Company. The nurse met with each subject to discuss the video and the accompanying written information. The subjects continued to monitor and record their glucose values for an additional three weeks. At the end of this period, the psychological inventories and blood testing were repeated. Physiological measurements, consisting of heart rate, forehead muscle tension, finger temperature and blood pressure, were obtained. Forehead muscle tension was measured as an integral average in microvolts using an Autogen 1700 Electromyograph set at 100 hertz bandpass. Skin temperature measurements were made with a T808 Biologic Devices Instrument with the sensor placed on the anterior surface of the index finger.

At the end of period 2, the subjects were randomly assigned to one of two groups, experimental (E) or control (C). The C subjects were asked to continue to record their blood glucose values and insulin dosages daily with supplies provided by us. They returned every other week for review of log book data with the nurse. The E group performed SMBG and met with the nurse similarly to the controls, but also participated in twelve 45-minute sessions of biofeedback assisted relaxation. The relaxation therapy focused on autogenic phrases and diaphragmatic breathing (Davis, Eshleman, & McKay, 1995). Subjects were provided with

a 15-minute audio tape containing the autogenic relaxation phrases and were instructed to practice relaxation twice daily at home for 15 to 20 minutes. Adherence to home practice recommendations was not formally monitored. Muscle tension feedback from the forehead muscles and thermal feedback from the index finger were used to provide information about and to reinforce lowered muscle tension and increased temperature. No specific criteria were set; however, a decrease in tension of 50% and an increase in temperature to 95 degrees were suggested. Subjects were allowed to make up missed sessions so each E subject received 12 sessions, but length of treatment was variable.

Four weeks after the end of treatment (or an equivalent control period), subjects in both groups were retested by blood sample, psychological inventories, and physiological measurements. This is period 3, called One Month, after which the SMBG supplies were no longer provided for either group. The controls were offered the treatment so were no longer followed as controls. Three months subsequent to period 3, the experimental group was brought back to repeat the psychological, physiological and blood testing. This is period 4, called Three Months. There was no contact with patients between one and three months.

Data analysis consisted of analysis of variance (ANOVA) with repeated measures (periods 1, 2, 3), ANOVA, followed by post hoc tests (where appropriate), and Pearson correlation. Repeated measures ANOVA was conducted to determine whether the two groups differed across time on the dependent variables (group by time effect) and whether there were changes across time within each group (time effect). When a significant group by time interaction was identified, univariate ANOVAs were used to determine at which time point the groups differed. Significant time effects were explored within each group with post hoc *t* tests. SMBG change scores were calculated by subtracting period 3 values from period 2 values. An arbitrary criterion was set for success and failure. Subjects who decreased their average blood glucose values by at least 10% between periods 2 and 3 were termed succeeders, while those who did not were termed failures. This categorization was done in an attempt to define characteristics of patients associated with success or failure.

RESULTS

Twenty-five individuals agreed to participate in the study and signed the informed consent form. Seven of the 25 dropped out before randomization and eighteen completed the study. The dropouts were mainly concerned about the requirements of the study and the length of participation. Table I shows that the dropouts were all females, younger than those who completed the protocol and had poorer control of their diabetes, as indicated by higher blood glucose, fructosamine, and glycohemoglobin values.

During the initial interview, the nurse determined the extent and regularity of each subject's SMBG. Fourteen subjects were monitoring two to three times per day and four subjects were monitoring sporadically or rarely. Cost of supplies prior to study entry was identified as prohibitive by the nonadhering subjects. In comparison to the four nonadherers, the fourteen adherers were younger, had lower values of self-reported blood glucose and lower scores on all of the psychological inventories, indicating less depression, lower anxiety, and fewer and less intense hassles.

Table II illustrates the blood glucose data in the E group at periods 1, 2, 3, and 4 and the C group at periods 1, 2, and 3. There were no significant differences between groups in the baseline values of SMBG, insulin, fructosamine, or glycohemoglobin (MANOVA: $p = 0.58$). ANOVA with repeated measures (periods 1, 2, 3) in the E and C groups

Table I. Description of the Population

	Completers	Dropouts
Number	18	7
Gender	10 males 8 females	7 females
Age (years)		
Mean	41	29
Range	21–64	21–54
Race	16 Caucasian 2 African-American	7 Caucasian
Fructosamine (mmol/lit)	352	383
Glycohemoglobin (mg%)	7.1	8.8*
Range	4.5–9.2	3.7–13.6

*$n = 4$.

Table II. Indicators of Blood Glucose and Insulin Usage*—*Values are Mean (SD)*

	Groups	
	Experimental ($n = 9$)	Control ($n = 9$)
SMBG		
Baseline	178.6 (37.6)	160.1 (34.3)
Education	169.5 (33.7)	163.7 (39.5)
One Month	166.4 (40.9)	171.9 (33.4)
Three Months	173.8 (43.8)	—
Fructosamine		
Baseline	352.8 (48.5)	350.8 (58.0)
Education	320.6 (41.3)	362.7 (63.0)
One Month	319.4 (64.9)	351.3 (45.0)
Three Months	346.4 (35.9)	—
Glycohemoglobin		
Baseline	7.3 (1.2)	6.9 (1.5)
Education	7.2 (0.7)	6.9 (1.5)
One Month	6.9 (1.1)	7.1 (2.0)
Three Months	7.3 (1.1)	—
Insulin		
Baseline	51.1 (14.4)	60.1 (20.3)
Education	51.2 (14.0)	60.1 (20.6)
One Month	53.3 (15.9)	59.0 (18.2)
Three Months	48.8 (13.3)	—

*No significant effects in any variable.

showed no significant group by period interactions or main effects for blood glucose, insulin, fructosamine or glycohemoglobin. Blood glucose values from SMBG were correlated significantly ($p < .05$) with values of glycohemoglobin at period one ($r = .56$; $p = 0.04$) at period 2 ($r = .65$; $p = 0.01$) and period 3 ($r = .61$; $p = 0.02$)

Forehead muscle tension and finger temperature values in the E and C groups for Periods 2 and 3, are shown in Table III. These values were obtained before and after the series of biofeedback assisted relaxation sessions for the E group and a comparable time period for the C group (during which both groups met with the nurse for review of SMBG data). The treated subjects decreased muscle tension and increased temperature, reflecting the acquisition of the relaxation response by the E group. Statistical analysis showed a significant group by period interaction for temperature, and a main effect of time for temperature, with

Table III. Forehead Muscle Tension and Peripheral Temperature in the E and C Groups—*Values are Mean (SD)*

	Experimental	Control
Tension (uV)		
Period 2	2.2 (0.8)	2.0 (1.1)
Period 3	0.8 (0.4)	1.4 (0.7)
Temperature (°F)		
Period 2	85.7 (6.5)	92.0 (3.1)
Period 3	90.4 (1.4)	91.8 (3.3)

ANOVA with repeated measures
- Temperature
  - Group by Period: $F(1,15) = 5.7$; $p = .03$
  - Main Effect F: (1,15) = 11269; $p = .00001$
    - Univariate t-tests
      - Temperature E group $t = 2.04$; $p = .09$
- Tension
  - No significant effects.

Table IV. Psychological Measures—*Values are Mean (SD)*

	Experimental	Control
State Anxiety		
Baseline	36.0 (15.0)	35.0 (10.6)
One Month	31.6 (7.1)	37.2 (11.0)
Trait Anxiety		
Baseline	40.1 (11.9)	38.2 (10.7)
One Month	35.7 (9.9)	39.1 (13.2)
Depression		
Baseline	47.0 (13.0)	46.4 (11.6)
One Month	44.9 (9.0)	48.0 (12.8)
Hassles Intensity		
Baseline	1.5 (0.4)	1.5 (0.3)
One Month	1.3 (0.3)	1.4 (0.4)
Hassles Frequency		
Baseline	0.4 (0.09)	0.30 (0.22)
One Month	0.3 (0.15)	0.34 (0.16)

Analysis of Variance with repeated measures.
No group by period significant interactions.
Main effect: Trait anxiety $F(1,15) = 6.4$; $p = 0.02$.
t-test: E group $t = 2.1$; $p = .07$; C group n.s.

the E group increasing temperature. Table IV illustrates the comparison of the E and C groups on the psychological measures. There was no overall significant interaction but a significant main effect of time for trait anxiety. The E group decreased anxiety while the C group did not.

Table V illustrates the period 1 (baseline) values of the dependent measures for the succeeders and the failures. Because the numbers of patients are small, only descriptive statistics are reported. Succeeders were slightly younger and had diabetes a similar length of time; their baseline and end of education SMBG and insulin values were higher than failures. Eventual succeeders had lower scores on the anxiety, depression, and hassles inventories than failures. Furthermore, failures took almost twice as long (fifteen weeks) to complete the treatment compared to the succeeders (eight weeks).

Table V. Experimental Group Succeeders and Failures: Baseline Values—*Values are Mean (SD)*

	Succeeders	Failures
Age (Years)	39.0 (15.5)	44.5 (17.4)
Years of Diabetes	12.8 (9.5)	14.5 (4.4)
SMBG	163.0 (46.0)	198.1 (8.0)
Insulin	44.6 (11.2)	57.8 (17.2)
Fructosamine	341.8 (45.2)	366.5 (55.7)
Glycohemoglobin	7.3 (1.1)	7.3 (1.4)
Depression	40.8 (6.7)	54.8 (15.8)
Trait Anxiety	37.2 (14.6)	43.8 (7.9)
State Anxiety	34.8 (12.2)	37.5 (20.0)
Hassles Frequency	0.39 (.1)	0.42 (.09)
Hassles Intensity	1.2 (.15)	1.8 (.46)

Blood glucose values were then compared between subgroups of subjects in the E and C groups as follows. ANOVA with repeated measures was carried out on SMBG values from only patients whose depression scores were lower than 50 (values under 50 on the Zung Depression scale indicate the absence of depression). Using data from only the 12 nondepressed subjects, there was a significant interaction ($F = 4.2$; $p < .03$) between group and time in SMBG, with the E group lowering blood glucose to 148.5 mg% at one month from baseline of 163.6 mg% and the controls remaining essentially unchanged. A similar analysis was carried out in subjects whose trait anxiety scores were less than 40 (values of 40 or less on the anxiety instrument indicate low anxiety). Using data from the 9 nonanxious subjects, a decrease in SMBG from 161.4 mg% to 141.4 mg% was observed in the E while the C group remained at 165 mg%. However, there was no significant interaction between group and time ($F = 3.1$; $p = 0.12$).

Correlational analysis was carried out between the psychological variables and self-reported blood glucose (Table VI). Statistically significant correlations were observed between SMBG at period 1 and hassles frequency, between SMGB at period 2 and depression, between SMBG at period 3 and trait anxiety, depression score, and hassles intensity. A significant correlation was also observed between depression and blood glucose at period 4 (three months) for the E group. In addition, there were significant correlations between change in blood glucose and the indices of depression, anxiety, and hassles. SMBG change between periods 1 and 3 was negatively correlated with depression, state anxiety, trait anxiety, and hassles intensity.

DISCUSSION

The lack of significant differences between E and C groups in blood glucose as monitored by patients and as determined by biologic assay is contradictory to our previous studies, (McGrady *et al.*, 1991; McGrady *et al.*, 1996) where significant decreases in blood glucose were found in the patients treated with biofeedback assisted relaxation compared to usual care controls. Although data from SMBG was utilized for analysis in all of our studies, the SMBG values were well correlated with the biologic indicator, glycohemoglobin, which supports the validity of the patient's log books. The current sample of individuals with diabetes may have differed from those participating in our past studies in the psychological

Table VI. Correlations* Between Blood Glucose (SMBG) and Psychological Variables at Various Time Periods

Period	Psychological Variables	Correlation Coefficient
Baseline	Hassles Frequency	.54
Education	Depression	.53
One Month	Trait Anxiety	.58
	Depression	.61
	Hassles Intensity	.59
Three Months	Depression	.45

Correlations* Between Change in Blood Glucose as a Result of Treatment and the Psychological Variables at Various Time Periods

Period, Variable	Correlation Coefficient
Baseline	
Trait Anxiety	−.52
Hassles Intensity	−.54
One Month	
State Anxiety	−.62
Trait Anxiety	−.68
Depression	−.54
Hassles Intensity	−.62

*All significant at $p < .05$.

indicators of depression and anxiety. Unpublished data from our second study suggests that average scores on both the depression and trait anxiety instruments were lower than the values obtained from the current group of subjects. Furthermore, succeeders, (although judged by an arbitrary criterion) had lower scores on all of the psychological inventories than failures at baseline and were in poorer control of their diabetes. Perhaps most important are the significant correlations found between change in SMBG and depression, anxiety, and hassles.

We suggest, based on the current results, that psychological factors, particularly depression and anxiety impacted the outcome of the biofeedback assisted relaxation therapy in this sample of IDDM subjects. This view is strengthened by the results of the analysis of only nondepressed patients, which yielded the significant group by period interaction. Subjects characterized by relatively high depression and anxiety scores took longer to complete the treatment protocol, which may be reflective of poorer adherence. These participants did not derive benefit from a treatment where no specific psychotherapy or pharmacological therapy for the emotional symptoms was provided.

Depression has been suggested to have a major impact on diabetes from the standpoint of treatment, complications of the illness and glycemic control (Lustman, Griffith, & Clouse, 1988). Studies assessing treatment of depression with serotonin reuptake inhibitors suggest that antidepressants may improve glucose regulation and reduce hyperglycemia independent of the effects on mood (Goodnick *et al.*, 1995). Cognitive behavior therapy also was found to improve mood in subjects with NIDDM where decreases in glycosylated hemoglobin were observed at follow-up (Lustman, Griffith, Freedland, Kissel, & Flouse, 1998).

The findings from this study, taken with those of Aikens *et al.* (1997) and Lane, McCaskill, Ross, Feinglos, & Surwit (1993) suggest that specific subgroups of persons

with IDDM or NIDDM have the potential to benefit from relaxation based therapies. With respect to anxiety, there is disagreement on the characteristics of this subgroup, because Lane *et al.* (1993) suggest that the most anxious subjects may be the best candidates, while Aikens *et al.* (1997) found patients with less anxiety to be most responsive to relaxation therapy. In our study, patients with symptoms of depression and anxiety may have found the demands of the experimental protocol too arduous, and may have not adhered to recommendations for home practice of relaxation.

Further studies are needed in diabetic persons with mood and anxiety disorders and with subclinical levels of depression and anxiety to confirm the results of this pilot study. If confirmed, pretreatment with antidepressant medication or cognitive behavioral therapy may facilitate a positive response to biofeedback assisted relaxation.

LIMITATIONS TO THE STUDY

Interpretation of these results is limited by the small number of subjects, which increases the likelihood of type I error. Contact time differed between experimental and control subjects. The criterion for success was arbitrary, and should have been based on prior studies. We relied in part on subjects' self-reported SMBC values, which may have been somewhat unreliable. Finally, supplies were no longer provided to either group after period 3 and some of the relapse after one month in the E group may be attributed to less frequent monitoring.

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