BIOFEEDBACK-ASSISTED RELAXATION IN INSULIN-DEPENDENT DIABETES: A REPLICATION AND EXTENSION STUDY

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ABSTRACT

The effects of twelve sessions of biofeedback-assisted relaxation on blood glucose were tested in a controlled trial of 16 patients with insulin-dependent diabetes mellitus. Treatment consisted of electromyograph biofeedback, thermal biofeedback, relaxation therapy, and diabetes education. The controls received only diabetes education. All patients monitored blood glucose daily. The treated group improved on average blood glucose, percent of values above 200 mg/dl, and number of values at target. Two biologic indicators of blood glucose were used as correlates of self-reported blood glucose. Fructosamine and glycosylated hemoglobin were significantly correlated with values determined by self-monitoring of blood glucose at pretest. Fructosamine was a better index of short-term change than glycosylated hemoglobin. These results, though limited by size of population and reliance on self-reported blood glucose, support our earlier study and are promising for biofeedback-assisted relaxation as an adjunct to conventional therapy of insulin-dependent diabetes.


INTRODUCTION

Diabetes mellitus is a chronic disorder of metabolism that affects approximately 13 million persons or 5.2% of the population of the United States (1). The disease is characterized by hyperglycemia resulting from either relative or absolute deficiency of insulin. Management of insulin-dependent diabetes mellitus (IDDM) includes insulin, diet, physical activity, and self-monitoring of blood glucose (SMBG). Control of blood glucose is assessed by patients themselves with SMBG and by their physicians with biologic assays of glycohemoglobin (2).

Stressful life events and anxiety have been related to increased lability of blood glucose and to increased glycosylated hemoglobin (HbA1C) levels. Autonomic neural, adrenal medullary, and adrenocortical activation mediate the effects of stress on blood glucose. Health maintenance behaviors may also be disrupted by stressful events whether the latter are acute or chronic. Thus, psychosocial factors are relevant to all aspects of diabetes, including etiology and treatment. In fact, diabetes may be one of the most psychologically and behaviorally demanding of the chronic medical illnesses. Behavioral changes and maintenance of specific behavior patterns required after diagnosis must be continued throughout the lifetime of the person with diabetes (3–6).

Despite the evidence that psychological stress is associated with hyperglycemia, stress management has been largely overlooked in the traditional management of patients with diabetes. Stress management is often composed of relaxation therapy and biofeedback (biofeedback-assisted relaxation). Feedback of muscle tension or peripheral temperature provides reinforcement for lowered arousal levels (7). Biofeedback has been associated with lowered cortisol levels in hypertensive persons (8); relaxation has been shown to reduce sympathetic nervous system activity (9,10) and to decrease the release of glucose from storage, both of which would result in lowered blood glucose (11,12).

A previous controlled pilot study on 18 IDDM patients was reported from our laboratory (13). The individuals in the experimental group were treated with twelve sessions of biofeedback-assisted relaxation therapy. Both the experimental and control groups monitored blood glucose daily and met with a nurse biweekly to review blood glucose and insulin dosages. The experimental (treated) group decreased average blood glucose and the percent of values above 200 mg/dl while increasing the percentage of fasting blood glucose values at target (80–120 mg/dl). Average blood glucose decreased from 163 ± 48 mg/dl to 128 ± 22 mg/dl; the percent of values above 200 mg/dl decreased from 30% to 9.3% at the end of treatment. The percent of fasting blood glucose levels at target increased from 22% to 42%. There were no significant changes in insulin dosages in either group and no significant improvements in the control group.

Several limitations were identified in this early study. Patients used their own meters and supplies to monitor blood glucose. Meters may be calibrated differently, and the cost of the strips may have compromised compliance to the requested SMBG. Furthermore, no independent assays of blood glucose were used. The present study was designed to address these issues. The hypotheses were that the group treated with biofeedback-assisted relaxation would decrease blood glucose in comparison to the untreated control group and that the biological assays would correlate with average values derived from SMBG.
did not coincide with times of the day when hypoglycemia for home relaxation practice were recommended by the nurse were taught autogenic relaxation phrases (15,16) and were in-
tended monitoring. Treatment of the E group consisted of twelve 30-minute weekly sessions of biofeedback-assisted relaxation and biweekly meetings with the nurse for 30 minutes. Patients continued monitoring. Treatment of the E group consisted of twelve 30-minute weekly sessions of biofeedback-assisted relaxation and biweekly meetings with the nurse for 30 minutes. Patients were trained to relax the muscles of the face (EMG—six sessions) and to increase the temperature of their hands (thermal—six sessions).

After completion of treatment by the experimental patients and a similar time interval for the control group, all patients entered the three-week posttest period. Patients monitored blood glucose similar to pretest and were retested for fructo-
samine and glycosylated hemoglobin by blood sample. Patients were weighed again. The controls were offered the opportunity to receive the biofeedback-assisted relaxation at no charge.

Data Analysis

Data were analyzed using CSS Statistica. Comparison of pretest characteristics between the experimental group and the control group was accomplished using multivariate analysis of variance (MANOVA). Repeated measures MANOVA was used 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). Significant effects were explored with planned comparisons to determine which group changed over time.

RESULTS

Blood Glucose (Table 2)

Three indicators of blood glucose were compared between the experimental and control groups. There were no significant differences between the groups at pretest in average blood glucose, percent of values above 200 mg/dl, and percent of values at target (MANOVA p = .55). There was an overall significant interaction between group and time. The experimental group decreased average blood glucose and the percent of values above 200 mg/dl and increased percent of values at target. The
Biofeedback and Diabetes

TABLE 3
Biologic Assays of Blood Glucose
Values are Mean (SD)

<table>
<thead>
<tr>
<th>Group</th>
<th>Glycohemoglobin (percent)</th>
<th>Fructosamine (millimoles/liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>Pretest 8.5 (1.6)</td>
<td>377 (126)</td>
</tr>
<tr>
<td></td>
<td>Posttest 8.3 (1.6)</td>
<td>347 (80)</td>
</tr>
<tr>
<td>Control</td>
<td>Pretest 7.8 (1.1)</td>
<td>374 (60)</td>
</tr>
<tr>
<td></td>
<td>Posttest 7.7 (1.0)</td>
<td>370 (51)</td>
</tr>
</tbody>
</table>

MANOVA: overall interaction $F(1,14) = .7; p = .43$
Group X glycohemoglobin $F(1,14) = .7; p = .42$
Group X fructosamine $F(1,14) = .07; p = .80$

control group was unchanged. With regard to insulin dosage, all types of insulin (regular, long-acting) were counted and averaged. The E group’s insulin averaged 48 units at pretest and the same at posttest. The C group’s insulin was 43 at pretest and 44 at posttest. There were no significant differences in insulin between the groups nor were there any changes between pretest and posttest.

Biological Indicators of Blood Glucose (Table 3)

Table 3 shows fructosamine and glycohemoglobin values for both groups. There were no significant differences at pretest. There were no significant group by period interactions. Although the amount of fructosamine decreased in the experimental group from $377 \pm 126$ to $347 \pm 80$ millimoles per liter, these changes were not significant. The control group was essentially unchanged ($374 \pm 60$ to $370 \pm 51$ millimoles per liter). Fructosamine was correlated with average blood glucose; at pretest, the correlation was significant ($r = .66; p = .006$). At posttest, the correlation was $r = .42; p = .10$. Glycohemoglobin also was correlated with SMBG at pretest ($r = .75; p = .001$) but poorly correlated at posttest ($r = .36; NS$).

Body Weight (Table 4)

Table 4 illustrates the body weight data. There was a significant group by time interaction and an effect of time. The experimental group significantly increased body weight by four pounds, but the control group was unchanged.

Muscle Tension and Skin Temperature (Table 5)

Two indicators of patient’s level of physiological relaxation mediated by biofeedback-assisted relaxation were analyzed. Treatment was directed towards decreasing facial muscle tension and warming the hands. The E group lowered muscle tension and increased finger temperature, while the C group showed a small increase in tension and a decrease in temperature. The groups differed at pretest in temperature. The overall MANOVA interaction was marginally significant. The group by time interaction was significant for temperature.

DISCUSSION

The hypothesis that persons with IDDM who are treated with biofeedback-assisted relaxation would reduce blood glucose levels in comparison to an untreated control group is supported. Significant group differences in blood glucose were found despite the indication that the experimental group was in much poorer control than the patients randomized to the control group. The improvements in blood glucose in the E group were observed with very little change in insulin dosage and with an increase in body weight.

These results are similar to our previous report (13) where decreases were also observed in blood glucose in the treated group. Interestingly, in that study, the experimental group was under better control at entry than the control group. They also had lower forehead muscle tension levels and warmer hands, indicating less chronic skeletomotor and sympathetic activation. In the current study, the E patients not only had much higher blood glucose values but more striking indicators of physiological arousal than the control group. Nonetheless, regardless of entry levels, the group receiving the biofeedback-assisted relaxation acquired the relaxation response as well as achieved better control of blood glucose. In neither study was a change in insulin observed.

The validity of the self-report values is supported by the number of values produced by patients and by the correlation between fructosamine and self-reported blood glucose. Both pretest and posttest average blood glucose were derived from a minimum of 50 values. When strips and meters are provided, compliance to daily monitoring improves. Thus, the 50 values in almost all cases were gathered during a two- to three-week period. There are conflicting reports from other laboratories on much lower blood glucose values and better control than the patients randomized to the control group. The improvements in blood glucose in the E group were observed with very little change in insulin dosage and with an increase in body weight.

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the issue of reliability of self-reported values. Gonder-Frederick et al. (17) reported close approximation of self-reported values to independent measures, whereas Mazze (18) indicated distortions were common. Although bias cannot be completely eliminated, the number of values required and the frequent review by the nurses of both glucose and insulin usage decrease the likelihood that the E group reported distorted glucose and proportionately distorted insulin dosages.

The change in fructosamine in the experimental group was in the predicted direction but was not significant; the glycohemoglobin values did not show similar changes and were only poorly correlated with SMBG values at posttreatment. The HbA1C represents the previous two to three months average blood glucose, whereas fructosamine indicates the previous two to three weeks. The significant correlation observed pretreatment suggests that the patients’ blood glucose values were stable at entry and did not change during the three-week pretreatment period. However, the poor posttreatment correlation suggests that the change took place during the intervention. Glycohemoglobin is not a good indicator of short-term change.

A recently published large-scale clinical trial compared intensive and standard care of IDDM (19). Intensive therapy consisted of multiple daily doses of insulin and frequent SMBG; conventional therapy comprised one or two daily insulin injections. Complications of diabetes were significantly reduced with intensive treatment. In our study, the improvements in blood glucose in the treated group cannot be attributed to more consistent monitoring alone. Both groups had the benefit of test strips, reinforcement for SMBG, and review of blood glucose log books by the nurse. Commonality between groups was also enhanced by providing consistent diabetes education.

Weight gain in the treated group, also observed in the Diabetes Control and Complications Trial (19), may indicate better utilization of insulin. Insulin causes increased storage of carbohydrate, protein, and fat, so weight gain ensues if diet is not modified (20). Therefore, after treatment was completed, patients were advised to contact their physicians for adjustment in insulin or caloric intake. Weight, a key factor in Type II diabetes, also influences individuals with the insulin-dependent form of the disease (21).

Negative life events and daily hassles impact on the etiology, severity, and control of IDDM. Although the majority of researchers agree on the concept of stress effects on glucose control, many contributing factors can decrease or increase its impact. Stress is a general, though complex, term and affects intervention for these patients to the one in our previous study (13). Stress management may include several interventions. We attempted to provide a very similar intervention for these patients to the one in our previous study (13).

Several limitations to the current study must be identified. The population, though quite compliant, was small. Randomization to groups produced one group in adequate control (C) and one group in adequate control (C). Thus, the improvements in the E group could reflect a regression to the mean. With regard to the fructosamine data, large variations within the groups and low effect size produced low power. The lack of statistical significance in fructosamine increases the reliance on the self-reported glucose values, which are possibly biased. The nurses were not, nor could they have been, blinded to group participation since they recommended specific times of the day for relaxation practice. No data were gathered on compliance to diet or frequency of exercise. Finally, no long-term data are available to test the maintenance of improvements over time.

Further research is now needed to determine the stability of the changes in blood glucose over the long term and whether continued practice of relaxation is required to maintain the treatment effects. Also, some control of diet and exercise could be attempted. However, these results are encouraging and suggest that biofeedback-assisted relaxation be considered as part of the overall management of diabetes.

REFERENCES

(19) Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and

