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Original Article

The Impact of Biofeedback on Diabetic Patients' Glycemia



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Abstract

HPR

Background: Complementary medicine claims that biofeedback affects the reduction of blood glycemia.

Objective: The current study aimed to determine the effects of biofeedback on decreasing blood glucose levels and tension and increasing the quality of life in diabetic patients.

Methods: The current retrospective evidence-based study used pretest-posttest accidental sampling to select a group of 30 diabetic patients admitted to Glenview Clinic in the Aghdasiyeh region, Tehran, Iran, as the sample. Participants were divided into two 15-membered groups, the experiment and the control groups, matched by age and gender. Data gathering tools included the Quality of Life questionnaire in diabetic patients by Thomas et al, the Perceived Tension Index by Cohen et al, a glucometer, and the fasting blood glucose test. Data was analyzed using analysis of covariance (ANCOVA).

Results: The results showed that biofeedback training was effective in decreasing blood glucose levels in diabetic patients. **Conclusion:** Biofeedback can reduce tension and improve the quality of life of diabetic patients; thus, it could be used as a complementary service in healthcare centers.

Keywords: Neurofeedback, Biofeedback, Blood Glucose, Health Status, Quality of Life, Diabetes

1. Background

Due to its chronicity and implications, diabetes mellitus is one of the most prevalent diseases worldwide, leading to about 4 million deaths per year. Due to the growing trend of diabetes in the world, the World Health Organization (WHO) has described this disease as a hidden epidemic. The global prevalence of diabetes among adults in 2010 showed an increase of about 6.4%. At this rate, the afflicted population will be equivalent to 285 million people by the year 2030. The increase will be about 69% in developing countries, while it will be around 20% in developed ones.¹

Some researchers have defined the fasting plasma glucose concentration under normal conditions.² Accordingly, when a person has consumed no calories for a minimum of 8 hours, the plasma glucose concentration is greater than or equal to 126 mg/dL (7 m.mol/L). The measure for the 2-hour plasma glucose concentration is greater than or equal to 200 mg/dl (11.1 m.mol/L) during an oral glucose tolerance test, while the random plasma glucose concentration (any time of day with no regard to the latest meal) is lower than or equal to 200 mg/dL (11.1 m.mol/L) together with the signs and symptoms of diabetes, which

is in conformity with the diagnosis criteria for diabetes.^{3,4} Two laboratory measures should be given to confirm the diagnosis if there no signs or symptoms.⁵ The classical symptoms of diabetes include excessive polydipsia (thirst), excessive urination, and considerable weight loss.^{6,7}

Glycated hemoglobin (hemoglobin A1C) reflects the estimated average blood glucose level within the past 2-3 months.^{8,9} This factor is the gold standard for the diagnosis of diabetes, and measuring hemoglobin A1C is an approved method for diagnosing diabetes in most people.¹⁰ The hemoglobin A1C test is more convenient for patients, because it does not require fasting,¹¹ and a result greater than or equal to 6.5% indicates diabetes.^{12,13} People with hemoglobin A1C test results in the range of 5.7%-6.4% are at high risk for diabetes and should receive effective interventions such as weight reduction and physical exercise.^{14,15} Over time, high glucose levels can destroy the very small capillaries in the body, possibly involving different organs such as the kidneys, eyes, and nerves.15 High glucose levels also have a direct correlation with increased risks of cardiovascular diseases and other health problems such as high blood pressure and

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high cholesterol. Diabetic patients may even have such conditions for months or years before symptoms begin. In addition to physical complications, this disease can also have emotional and psychological effects on patients.¹⁶

Diabetes mellitus is one of the most important health issues in Iran. Its treatment costs are very high, and chronic disease can lead to extensive disabilities. Thus, various strategies, including diet therapy, physical activities, and the use of oral and intravenous drugs, are suggested for a healthy lifestyle.¹⁷⁻²⁰ and the rates of glycated hemoglobin (glycohemoglobin) are higher in people with anxiety or mood disorders (in diabetes types 1 and 2).²¹⁻²³ Briefly speaking, behavioral and psychosomatic factors are constantly interacting. Stress can cause unhealthy variations in behavior, mood, and physiological responses, which will subsequently increase blood glucose. It can also affect a patient's self-medication.²⁴ Generally, it can be said that about 20%-40% of people with diabetes experience some degree of emotional distress and general symptoms of anxiety and depression ²⁵⁻²⁷

Some studies have indicated that people who react to stress indicate a significant correlation between confrontation with feelings and blood glucose levels,²⁸ while others do not respond to increases in blood glucose on the same or next day. Low levels of emotional health also lead to other adverse outcomes in patients, such as poor quality of life, poor self-care, undesirable metabolic control, increased risk of side effects, and increased mortality rates. Stress related to diabetes is also a problem. Hence, many psychological interventions are used simultaneously with medical interventions to control the disease and its related complications.^{29,30}

Various studies have shown that group stress management in diabetic patients reduces the rate of hemoglobin A1C in a one-year period.³¹ Cognitive behavioral therapy, admission and commitment to therapy, yoga, etc. can be cited as required psychological interventions.^{32,33} Some researchers also believe that mindfulness can be effective in controlling blood glucose levels.^{34,35} Cognitive behavior therapy (CBT) has also been useful in improving mood and in facilitating self-care in people afflicted with diabetes mellitus.³⁶

One psychological intervention for diabetic patients is the use of biofeedback.37 Studies have shown that relaxation and biofeedback can help patients better control their psychological and physiological responses to stress and, in general, their diabetes.³⁸ Some studies mention the every process such as diagnoses, practice, and treatment can increase the stress level in diabetic patients and affect to the quality of life significantly.39 Moreover, reducing the amount of stress hormones and sympathetic activities causes less arousal, thereby leading to lowered blood glucose levels.40,41 This technique is part of an ancient and traditional approach to health.⁴⁰ The term "biofeedback" is comprised of two parts, "bio" and "feedback", the combination of which indicates the process of gaining greater awareness of many physiological functions.^{40,42} Some researchers define biofeedback as the process by

which a person learns to constantly affect his physiological responses, which are of two different types, i.e. those not normally subject to voluntary control and those to which one usually adjusts easily, although these responses are not set due to the emergence of injuries or disease.⁴²

Biofeedback includes the use of biological and electronic sensors which supervise human physiological reactions such that people can observe their own body functions. The aim of biofeedback is to understand these habitual patterns, so that steps can be taken to change them in order to reduce the symptoms associated with various disorders and diseases. Biofeedback is a type of active conditioning, enabling the organism to control the physiological processes which are usually involuntary (such as heartbeat) by voluntarily utilizing various feedbacks. In biofeedback systems, notification is done through feedback; however, learning how to reduce a control variable, such as blood glucose in the body, is a time-consuming task that requires extensive and sometimes complicated exercises, which are known as biofeedback exercises. The need for a relatively high number of training sessions and a great deal of patience explains the relatively high expense of this healthy treatment and the poor welcome it receives from patients. Biofeedback can be useful for any type of diabetes, such as diabetes mellitus types I and II and gestational diabetes. Different forms of biofeedback can reduce blood glucose and blood pressure. With this method, diabetic patients with peripheral nerve damage (which causes weakness, pain, and numbness mainly in the hands and feet) could have increased blood circulation to their hands and feet, and thus experience less pain and nerve damage. Researchers also found that people using bio- and neurofeedback treatment reported improvement in their mood, quality of sleep, and quality of life. Coherent treatment, knowledge, attitude, and practice can increase the metabolic control of diabetes mellitus and significantly promote quality of life.

One of the various types of biofeedback is electromyography, in which the electrical activity that is generated by muscles is used as an indicator of muscular tension; by reducing the tension, the patient receives stimulation. The effectiveness of biofeedback treatment and relaxation sessions in patients with diabetes and depression were considered simultaneously.⁴³ Inactive and progressive relaxation were used in addition to electromyography and thermal biofeedback.⁴³ Patients with depression wanted to cease their participation due to the research requests, i.e. repeated blood sampling and daily relaxation exercises.⁴⁴ This intervention was associated with significant reductions in glycosylated hemoglobin in the non-depressed group, although no changes were seen for 3 months.⁴⁵

2. Methods

This research was a retrospective evidence-based study which used pretest-posttest sampling with the involvement of a control group. In this study, the effects of biofeedback were assessed based on reductions in blood pressure and tension and increases in quality of life. The statistical population in this study included all patients with diabetes who referred to the Glenview Clinic in the city of Tehran in 2017. The sample size was determined according to the minimum requirements for pilot projects in similar studies. The inclusion criterion was introduction by the diabetes clinic as a patient affected with diabetes, and the exclusion criteria included patient's incompatibility with adapting the variables of age and gender between the intervention and control groups. The sample size of the present study included 30 diabetic patients, who were selected as available volunteers for the experiment. Among the participants, 15 were considered for the intervention group, and the remaining 15 were considered for the control group using the alignment method. The intervention group received biofeedback, but the control group did not in order for the effect of the experimental function on the dependent variable, i.e. the reduction of blood glucose, to be investigated. The patients were given the required advice in the first session, and biofeedback was described to them. Then, they were asked to sign a consent letter and complete the quality of life questionnaire for diabetic patients as well as the Cohen perceived stress scale as the pretest.⁴⁶ Patients were encouraged to eat a regular and fixed diet. Instructions on performing the relaxation method at home before sleeping or at stressful times were given to the patients.

Relaxation biofeedback based on electromyography was done by installing the required sensor at the back of the right shoulder. For the posttest, the fasting blood glucose level of each participant was measured and recorded. The participants then completed the quality of life questionnaire and the Cohen perceived stress scale again. Covariance analysis was used to analyze the statistical methods.

3.1. Quality of Life Questionnaire

The quality of life questionnaire used in this study was created by Patterson et al. It comprised 15 questions regarding the quality of life of diabetic patients, and the response spectra on a 5-point Likert scale were 1-totally dissatisfied, 2-dissatisfied, 3-at times, 4-satisfied, and 5-fully satisfied (1,2,3,4,5). Overall scores on this questionnaire will range from 15 to 75. Moreover, the content validity and validity of internal consistency of this questionnaire were verified and confirmed using Spearman's correlation coefficient.⁴⁷ Cronbach's alpha coefficient was 0.77, which indicates the good reliability of this questionnaire.⁴⁸

3.2. Cohen Perceived Stress Scale

The perceived stress scale constructed by Cohen et al is formed by 4 items: 2 positive factors (2 questions) and 2 negative ones (2 questions) and is used to measure the degree to which the conditions in a person's life are affected by stress. A score between 0 and 4 indicates that the perceived stress level is low, whereas a score between 4 and 8 shows that the perceived stress is moderate. Any score above 8 demonstrates a high level of perceived stress.⁴⁶ The reliability of the scale has been analyzed in various studies using Cronbach's alpha coefficient and the testretest. In a study conducted in a sample of 2387 people in the United States reported the Cronbach's alpha coefficients related to SPSS 14, 10, and 4 versions of this scale as 0.75, 0.78, and 0.60, respectively. Some studies have shown that, the convergent validity of this scale is appropriate, in such a way the scores of this scale have significant positive relationship with the scores of tools such as Beck Anxiety Inventory, Beck Depression Inventory-2, 12-question General Health Questionnaire, and short form of Depression, Anxiety and Stress Scale. In addition, a significant negative correlation between positive and negative factors of different versions of this scale has also been reported.

The Cronbach's alpha coefficients of the positive and negative factors of the SPSS version 14 of this scale were 0.86 and 0.85; for SPSS version 10, 0.83 and 0.86 were reported; and SPSS version 14 showed 0.44 and 0.70 numbers. The Cronbach's alpha coefficient for the total scale of SPSS versions 14, 10, and 4 were 0.90, 0.90, and 0.77, respectively, which were acceptable and indicated the internal consistency of the scale phrases.⁴⁹

To measure fasting blood glucose by glucometer, samples were taken as the pretest from the subjects under fasting conditions. By the end of each of the 8 sessions, blood glucose levels were also measured and recorded using a glucometer. By the last biofeedback session, blood glucose was measured by glucometer, and fasting blood glucose tests were repeated on the subjects as the posttest criterion. A 4-channel biofeedback device (Medicom, Russia) was used in this study, and the relaxation biofeedback based on electromyography was done by installing a sensor on the back of the right shoulder of the subjects. Pretest and posttest scores for blood glucose variables (including tension and quality of life) were divided into the intervention and control groups as shown in Table 1. In the current study, it was hypothesized that biofeedback is effective in reducing blood glucose, reducing tension, and increasing quality of life in diabetic patients. Covariance analysis was used to analyze the hypotheses. Observing 7 common assumptions was considered in the covariance analysis. Moreover, observing the homogeneity assumptions of variances was also examined using SPSS software (version 20), this scale, and homogeneity of regression slopes.

4. Results

To become more familiar with the nature of the current findings in the framework of research variables, a description of the statistical data is given in Table 1.

Based on the data shown in Table 2, whereas the significance level of the within-group variance is equal to 0.001 (which is smaller than the benchmark significance level of 0.01), and since the value of the obtained F (12.91) is greater than the critical value with the degree of freedom (1.27), the first hypothesis of the research, based on the effect of the instruction of biofeedback on reducing blood

Pretest Posttest **Group Variable** Group No. SD Mean SD Mean Intervention 15 186.20 24.71 138.87 24.01 Blood glucose Control 15 208.87 62.92 213.67 72.55 Total 197.53 48.36 176.27 65.32 30 Intervention 15 7.07 3.56 5.13 1.96 Stress Control 15 5.20 1.93 5.47 2.56 Total 30 6.13 2 97 5.30 2.25 Intervention 15 44.53 9.13 53.13 8.13 Quality of life 15 45.73 6.42 7.10 Control 45.87 Total 30 45.13 7.78 49.50 8.36

Table 1. Descriptive Indices of the Research Variables in the Intervention and Control Groups

glucose in diabetic patients, is approved. It can, therefore, be concluded that there is a significant difference in the average scores of blood glucose between the intervention and control groups. Also, comparing the mean values in the posttest scores show that the intervention group (with 138.86) obtained lower scores in the rate of blood glucose than the control group (213.66).

According to the data in Table 3, whereas the significance level for the within-group variance is equal to 0.0001, and since the value of the obtained F (38.40) is greater than the critical value with the degree of freedom (1.27), the second hypothesis of the research, based on the effect of the instruction of biofeedback on improving the quality of life in diabetic patients, is approved. It can, therefore, be concluded that there is a significant difference in the average scores of quality of life between the intervention and control groups. Moreover, comparing the mean values in the posttest scores showed that the intervention group

(with 53.13) reported higher scores regarding quality of life than the control group (45.86).

Based on the data shown in Table 4, since the significance level in the within-group variance is equal to 0.002, which is smaller than the benchmark significance level (0.01), and since the value of the obtained F (11.49) is greater than the critical value with the degree of freedom (1.27), the third hypothesis of the research, based on the effect of the instruction of biofeedback on reducing stress in diabetic patients, is approved. It can, therefore, be concluded that there is a significant difference in the average scores of stress between the intervention and control groups. Moreover, comparing the mean values in the posttest scores indicates the intervention group (with 5.1) has a lower rate of stress than the control group (5.46).

The present study aimed to investigate the effects of biofeedback on reducing blood glucose, quality of life, and tension in diabetic patients. The results obtained from

Statistical Index of the Variation Source	Sum of Squares	Degree of Freedom	Average Squares	Coefficient (F)	P Value
Pretest (intervening)	29628.828	1	29628.828	15.347	0.001
Control	24937.311	1	24937.311	12.917	0.001
Error	52126.239	27	1930.601		
Total	1055816	30			

Table 3. Results of Covariance Analy	sis of Intervention and Control (Groups After Controlling	g the Intervening Variables	s (Pretest) in Hypothesis 2

Statistical Index of the Variation Source	Sum of Squares	Degree of Freedom	Average Squares	Coefficient (F)	P Value
Pretest (intervening)	1271.233	1	1271.233	95.28	0.0001
Control	512.451	1	512.451	38.409	0.0001
Error	360.234	27	13.342		
Total	75535	30			

Table 4. Results of Covariance Analysis of Intervention and Control Groups After Controlling the Intervening Variables (Pretest) in Hypothesis 3

Statistical Index of the Variation Source	Sum of Squares	Degree of Freedom	Average Squares	Coefficient (F)	P Value
Pretest (intervening)	127.703	1	127.703	194.106	0.0001
Control	7.559	1	7.559	11.49	0.002
Error	17.763	27	0.658		
Total	989	30			

variance analysis showed that biofeedback was effective in reducing blood glucose in patients afflicted with diabetes.

5. Discussion

The following indications can be considered to explain the obtained⁵⁰:

- Emotional distress or events that are perceived by individuals as challenges can activate several psychological pathways that may lead to excessive glucose release into the bloodstream or increased insulin resistance;
- Stimulating the sympathetic nervous system causes glucagon to be released from the pancreas and decreases insulin secretion;
- Reducing the activity of the parasympathetic nerve also results in lower available insulin levels;
- The imbalance related to the autonomic nervous system (ANS) leads to lower insulin levels, reduced glucose entry, and increased glucose levels in blood. Moreover, sympathetic stimulation releases epinephrine and norepinephrine from the center of the adrenal gland;
- There is a relationship between insulin resistance and sympathetic nerve activity in diabetes mellitus type 2;
- Psychosocial stress increases blood glucose through the central pathways of the adrenal gland and sympathetic tubes;
- An imbalance in the performance of the hypothalamicpituitary-adrenal route increases the likelihood of fat accumulation in the viscera, which increases insulin resistance.50

The results of the current study showed that biofeedback improves quality of life in diabetic patients, which is consistent with the results of Bogusch and O'Brien.36 In explaining this result, it can be said that biofeedback transforms into the mainstream, it is often recommended to patients with diabetes because of its ability to maximize control of blood glucose and blood pressure levels, increase blood flow, and reduce the effects of peripheral neuropathy and retinal damage. As mentioned earlier, diabetes is a progressive chronic disease which may be associated with potentially harmful effects. By controlling blood glucose, biofeedback eliminates one of the greatest concerns and feelings of disability, which, in itself, is a stressor for diabetic patients. Meanwhile, biofeedback can help regulate blood pressure which, in addition to fixing an acute problem, can eliminate other concerns of diabetic patients. By increasing and improving the blood flow to different organs, biofeedback can reduce the effects of peripheral neurological damage and retinal damage. Also, biofeedback is recommended for reducing stress, improving the quality of sleep, and improving mood. In such case, the outlook for the disease is more prominent, and an improved quality of life is provided for the patients.

When, through biofeedback, patients reduced their stress, experienced relaxation, and realized the effect of biofeedback on reducing blood glucose (i.e. when they

notice the effect of stress on their disease), they discovered that stress and anxiety had extensive negative effects on their lives and increased their efforts to alter their stressful living conditions. Moreover, counseling with these patients provided solutions for reducing or eliminating some of the stressful problems. When these patients took the time for such a treatment, they sensed a greater value for themselves, which furnished them with good feelings. All of these factors led to the hope of controlling the disease and its complications. By decreasing the patients' sense of frustration, their quality of life was improved. All of the findings of this study confirmed the proposed hypothesis.

The results of the present study showed that biofeedback leads to reduced stress and tension in diabetic patients, which is consistent with the findings of McGinnis et al³⁷ and many other researchers.⁵¹⁻⁵³ By relating with the biofeedback device, the patient goes into relaxation mode, and the beautiful and natural images and soft music initiates the highest contraction and relaxation actions, and the patient immediately enters the relaxation stage. By forcing the person to the highest muscular contraction and complete muscular relaxation, which is done a number of times, the average potential for the contraction and relaxation of the patient is obtained. The patient will notice the rise in muscular tension caused by the device and realize he is in relaxation mode during the playing stage. Stress will be reduced, and therefore the patient will be successful in playing. When the least stress is created, there will be an interruption or a problem in the game. When the person sees or hears her body in the form of images or sound and perceives what conditions create the feeling of relaxation and calm, how she reacts to stress, and how she can return to relaxed mode, and the patient can use the information to reach calm conditions. Since biofeedback is a learning and conditioning process, the exercise should be continued for at least 8 sessions before expecting to see signs of the development of this skill in the patient.

6. Conclusion

Biofeedback provides information about specific biological activities that are available to the brain. When the brain receives information about itself and the body (such as how it reacts to stress and how it can return to calm conditions), it can use the information to restore the body to equilibrium and reduce the effects of stress.53 The main aim of using biofeedback is for the subject to gradually learn to pay attention to his mental and intrinsic biological states without relying on biofeedback notifications given by the advanced devices and to use them as instructions to achieve the desired scenarios and actions.52

A study has shown that relaxation and biofeedback can help patients feel more in control of their psychological responses and physiology, stress and, in general, diabetes. Furthermore, decreasing the number of stress hormones and amount of sympathetic activity in the blood causes less arousal, thus leading to less severe blood glucose levels. In general, the current results show that biofeedback reduces

Research Highlights

What Is Already Known?

Nowadays, Diabetes is a global public health hazard and concern. Patients with diabetes have no significant symptoms which is also known as the silent killer.

What This Study Adds?

Biofeedback might be a good choice for not only the patients with chronic conditions but also the other persons who have any symptoms, as a way for healthy lifestyle. Therefore, The results from this study suggest that, the biofeedback may be able be the best way to promote the quality of life by minimum cost and the maximum health rate of most the people who demand from healthcare service providers.

blood glucose, improves quality of life, and reduces stress in diabetic patients. Because of the effective role of biofeedback, specialists active in the field of diabetes are highly encouraged to benefit from biofeedback as a subordinate treatment together with medicinal methods, diet therapy, and therapeutic exercises.⁵²

In this research, variables such as the level of individual and family education, family income, and affective family environments, which can affect the dependent variables along with the experimental ones were not controlled, and this can be considered a limitation of the study.

Authors' Contributions

All authors contributed equally to this research.

Conflict of Interest Disclosures

The authors declare that they have no conflicts of interest.

Ethical Approval

This study was approved by Ethics Committee of Islamic Azad University, South Tehran Branch. Also the informed consent was filled out by patients.

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