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Original Research Article

The effectiveness of HeartMath biofeedback intervention to improve blood glucose levels among type 2 diabetes mellitus patients

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ABSTRACT

Background: Biofeedback interventions are widely used among naturopathic practitioners to treat and manage various health conditions, such as mental health-related disorders, hypertension, and diabetes mellitus. The aim of the study was to evaluate the efficacy of the biofeedback HeartMath emWave Pro intervention in patients with type 2 diabetes mellitus (T2DM).
Methods: A total of 25 adults [male (n=14) and female (n=11)] participants (age: 51.32±4.13 years) were recruited in this quasi-experimental pilot study. Heart rate variability (HRV) and breathing analysis were trained and measured using HeartMath emWave Pro during biofeedback training. Blood glucose parameters [haemoglobin A1c (A1c)], fasting blood glucose, and post-prandial blood sugar) were measured pre- and post-intervention using a biochemistry auto-analyzer. Data were analyzed via the Wilcoxon Signed Rank test and Spearman correlation.
Results: Post-intervention findings revealed a significant difference in HbA1c, fasting blood sugar, post-prandial blood sugar, and cortisol (all, $p<0.05$). Post intervention, thyroid-stimulating hormone (TSH) (r=-0.408) and breathing (r=0.465) showed significant correlation with HRV (all, $p<0.05$).
Conclusions: These findings suggest that HeartMath biofeedback training may improve blood glucose control in individuals with T2DM.

Keywords: Type 2 diabetes mellitus, Biofeedback, Heart rate variability blood glucose, HeartMath

INTRODUCTION

The World Health Organization (WHO) defines diabetes mellitus (DM) as a chronic metabolic condition that results from insufficient insulin production by the pancreas or the body's impaired ability to effectively utilize insulin.[1] Insulin is an essential hormone for regulating blood glucose levels and plays a critical role in facilitating the absorption and use of glucose by cells, thereby supporting cellular energy metabolism.[2] Prolonged hyperglycaemia or increased blood sugar will cause significant damage to multiple human body systems, particularly the neurovascular system.[1] According to the International Diabetes Federation (IDF), DM as one of the fastest-growing global health emergencies of the 21st century.[3]

The global prevalence of DM has increased dramatically over time. According to the IDF, in 2019, it was estimated that approximately 9.3%, or about 463 million people globally, were living with diabetes.[4] In 2021, the number increased to about 536.6 million (10.5%) among individuals between ages 20 to 79.[5] Surprisingly, India presented as the fourth highest prevalence of DM in 2017, with about 24 million people suffering amongst the Indian population.[6] Moreover, in the following years, India presented as the second highest population of adults with diabetes of 77 million people and 74.2 million people in 2019 and 2021 respectively.[5,7] Furthermore, the DM prevalence in India is predicted to increase up to 125 million people in the year 2045.[5]

Research shows a significant association between DM with thyroid-stimulating hormone (TSH) and cortisol levels.[8,9] Fatigue presents as a primary symptom of the disease, even among individuals who do not have uncontrolled diabetes. Individuals suffering may have a range of symptoms in addition to fatigue, such as comorbid psychological, medical, metabolic, and endocrine issues, as well as acute or long-term consequences of the condition.[10] Also, fatigue impairs physical and mental functioning and reduces the quality of life of individuals.

Allopathic interventions, including pharmacotherapy and lifestyle modifications, are the cornerstone of diabetes management today. A recent comprehensive systematic review reported the efficacy of diabetes medications among individuals with diabetes. It demonstrates that they reduce the risk of complications, such as all-cause mortality and hospitalizations due to heart failure and end-stage kidney disease.[11] However, this group of researchers also found that certain diabetes drugs may cause harm to the individuals. For example, sulfonylureas that can cause all-cause mortality, thiazolidinediones may increase hospitalizations of heart failure, DPP-4 inhibitors likely increase the danger of severe hypoglycaemia, and SGLT-2 inhibitors increase the risk of genital infection, ketoacidosis and amputation.[11] Furthermore, a recent study suggested that metformin may be more beneficial than sulphonyl urea therapy, although the long-term detrimental effects of type 2 diabetes mellitus (T2DM) outweigh any short-term benefits.[12]

Measurement of heart rate variability (HRV) is one of the simplest and most reliable methods to assess cardiac autonomic neuropathy.[13] Heart rate variability is the difference in heart rate between two successive beats, and the greater the variation, the greater the parasympathetic activity.[14] Therefore, it is understood that an individual can adapt to micro-environmental changes constantly when the HRV is high. This mechanism is demonstrated in a recent study in which researchers found that an increase in blood glucose was associated with a significant decrease in HRV.[15] This observation was also observed among individuals with severe low blood glucose levels. Furthermore, Eckstein et al. (2022) reported that the cardio-autonomic response was also affected by the rate at which blood glucose rose and fell, which worsened HRV. The results indicate that the autonomic system responds rapidly to changes in blood glucose.[15]

On the other hand, there is a growing body of research on biofeedback therapy for various conditions, including chronic pain, stress and mental health symptoms, anxiety, stress, and depression, and diabetes management with various techniques of biofeedback application.[16-20] For instance, McGinnis et al. (2005) utilized electromyography (EMG), thermal and relaxation techniques for T2DM individuals for four weeks.[20] On the other hand, Aaraji et al. (2019) implemented a relaxation approach using electromyography, where a sensor was placed at the back of the participants' right shoulder, and they underwent biofeedback intervention for eight sessions.[18]

Another study conducted in India utilized galvanic skin resistance (GSR) biofeedback to assess blood glucose and anxiety among T2DM individuals for a 20-day period.[19] A group of researchers conducted a study on diabetic polyneuropathy using mobile HRV biofeedback.[21] However, there is limited research investigating the effectiveness of biofeedback training to control blood glucose levels using HeartMath emWave Pro.

Consequently, the current study aimed to assess the efficacy of HeartMath emWave Pro in relation to heart rate variability (HRV) and breathing on blood glucose parameters among adults with T2DM. The findings of this study may be beneficial for healthcare providers and patients in managing blood glucose levels in an accessible, practical, and safe manner.

METHODS

Participants and study design

This prospective quasi-experimental pilot study was conducted at Annai Theresa Centre for Elderly Care in Chennai, India, from April to June 2023. Participants were: (a) between ages 45-55 years old; (b) both men and women; (c) diagnosed with T2DM not more than five years prior; (d) non-smokers for the past five years; and (e) non-alcoholic for the past five years. Excluded participants were those: (a) diagnosed with T2DM more than 5 years prior; (b) who had undergone major surgeries or diabetic complications within the past six months; and (c) who were ages below 45 or above 55 years. The study protocol was approved by the Research Committee of Quantum University. All participants received comprehensive information regarding the study's objectives and methods and provided informed consent forms. The study was conducted at a designated office in Chennai. Screening procedures required participants to complete demographic data, including age, gender, smoking and drinking status, and medical history.

Blood glucose parameters

The blood glucose parameters that were tested in this study were haemoglobin A1c (HbA1c), fasting blood plasma glucose and post-prandial blood plasma glucose. All participants were required to fast overnight (8-12 hrs) for the fasting plasma glucose test. Upon completing this test, participants were allowed to eat a meal, and their blood samples were drawn again after post-2 hours of the meal. All these blood glucose parameters were taken, measured and recorded at pre-intervention and post-intervention, which was after 21 days. According to the Centers for Disease Control and Prevention (CDC), for HbA1c, the normal blood sugar is 5.7%, between 5.7 and 6.4% is pre-diabetes and 6.5% and higher is considered diabetic. For fasting blood sugar, normal values are between 99 mg/dl and lower, 100 to 125 mg/dl, and 126 mg/dl and higher are indications of pre-diabetes and diabetes, respectively (CDC, n.d.). Meanwhile, a 2-hr plasma glucose level is considered normal with values less than 140 mg/dl, 140 to 199 mg/dl and above 200 mg/dl are considered as pre-diabetes and diabetes, respectively.

HeartMath emWave Pro

The HeartMath emWave Pro-biofeedback system was used to assess the participants' coherence, breathing pattern and HRV. A pulse sensor was clipped to the fleshy part of an earlobe, while a lapel clip was attached on the participant's clothing. The pulse sensor collected recorded the participant's pulse data for each session. Following this, the client was assessed for their immediate breathing and heart rate for one or two minutes as a baseline measurement. Once this stage was completed, the client began the biofeedback training session for 20 minutes. All participants were instructed to focus their intention on the heart area, visualizing the breath flowing in and out from the chest or heart. They were required to breathe slower and deeper than usual at the count between 5 and 6 of inhaling and exhaling. Visual information on a screen was provided to each participant to create a smooth and ordered heart rhythm pattern, and to increase coherence. Participants were positioned comfortably in a chair next to the equipment; their forearm rested on a flat surface or their thighs. It is important for participants to remain steady, as movement can cause artifacts. The HeartMath emWave Pro-biofeedback system contains four levels of challenges: low, medium, high and highest. For this research, the medium level was used for all participants, as this level is effective for most people (HeartMath, n.d.).

Data analysis

Data was analyzed by using SPSS (Statistical software version 23.0 Windows). Descriptive statistics were used to analyze participants' anthropometric data, HbA1c, fasting plasma glucose, post-prandial glucose level, HRV, and coherence. The normality of the data was tested using the Shapiro-Wilk test. Spearman correlation was used to determine the association between HbA1c, fasting plasma glucose, post-prandial glucose level, HRV, and coherence among individuals with T2DM. The level of significance will be set at $p<0.05$.

RESULTS

Characteristics of participants

Table 1 illustrates the mean and standard deviation (mean±SD) of 25 research participants. The mean±SD of age of the participants in this study was 51.32±4.13 years, the height was 152.2±13.96 cm, and their weight was 55.84±16.29 kg. The BMI of this group of participants was 23.6±5.11 kg/m^2.

Comparisons of blood glucose levels, TSH, cortisol, and HRV between pre and post- intervention

Table 2 presents the summary of the statistical analysis of the blood glucose levels, TSH, and cortisol levels in male and female diabetic participants. Post-intervention, there were significant differences in HbA1c, fasting blood sugar, post-prandial blood sugar, and cortisol in all participants ($p<0.05$).

Spearman correlation between blood sugar parameters, TSH, cortisol, and HRV

Table 3 presents the correlation results of blood sugar parameters, fatigue, breathing and HRV of diabetic individuals. Pre-intervention, there was a positive association between TSH and breathing. In contrast, post-intervention, TSH and HRV were inversely correlated. Furthermore, HRV and breathing were significantly correlated (all, $p<0.05$).

Table 1: Characteristics of participants (n=25).

Characteristics	Mean±SD	Minimum	Maximum
Age (years)	51.32±4.13	45	57
Height (cm)	152.2±13.96	128	176
Weight (kg)	55.84±16.29	29	90
BMI (kg/m^2)	23.6±5.11	14.2	33.3

Note: Data was tested using descriptive analysis and presented as mean±SD. BMI- body mass index.

Table 2: Comparisons of blood glucose levels, TSH, cortisol, HRV and breathing between pre and post intervention.

Characteristics	Pre-test (n=25)	Post-test (n=25)	T value	P value
	Mean±SD	Mean±SD		
HbA1c (mmol/mol)	5.91±0.22	5.56±0.5	24	**0.001
Fasting plasma glucose (mg/dl)	122.4±6.07	93.48±13.02	0.00	**0.001
Post-prandial plasma glucose (mg/dl)	145.44±7.41	127.98±26.28	40	**0.003
TSH (mlU/l)	3.2±2.28	3±1.68	126	0.715
Cortisol (µg/dl)	11.89±2.52	10.65±1.65	60	**0.018

Continued.

Characteristics	Pre-test (n=25)	Post-test (n=25)	T value	P value
	Mean±SD	Mean±SD		
Breathing	34.55±18.51	33.75±15.23	143	0.6
HRV	30.64±14.65	38.57±12.72	233.5	0.056

Note: Comparisons were tested using the Wilcoxon Signed Rank Test. Data are presented as mean±SD. **The mean difference is significant at the level of $p<0.05$. HbA1c- haemoglobin A1C, TSH- thyroid-stimulating hormone, FAS- fatigue assessment scale, HRV- heart rate variability.

Table 3: Spearman correlation between the blood sugar level, fatigue and coherence in males and females.

Characteristics	Pre-intervention (n=25)				Post intervention (n=25)			
	Breathing		HRV		Breathing		HRV	
	r	P	r	P	r	P	r	P
HbA1c	0.219	0.292	0.199	0.341	0.032	0.878	-0.132	0.528
Fasting blood glucose	-0.238	0.252	-0.292	0.157	-0.012	0.952	0.069	0.744
Post-prandial blood glucose	0.011	0.96	0.161	0.441	-0.032	0.878	-0.064	0.76
TSH	0.413	**0.04	-0.186	0.374	0.079	0.707	-0.408	**0.043
Cortisol	-0.023	0.914	0.22	0.29	0.315	0.126	-0.007	0.975
Breathing	1	-	0.273	0.187	1	-	0.465	**0.019
HRV	0.273	0.187	1	-	0.465	0.019	1	-

Note: Comparisons were tested using Spearman correlation coefficient analysis. **Correlation is significant at the level of $p < 0.05$. HbA1c- haemoglobin A1C, TSH- thyroid stimulating hormone, FAS- Fatigue Assessment Scale, HRV- heart rate variability.

DISCUSSION

The results from the present study demonstrated significant differences blood glucose parameters, including HbA1c, fasting, and post-prandial blood sugar, between pre- and post-21 days of biofeedback training. Previous studies supported these findings, indicating that biofeedback training improves blood sugar levels.[18,19,22] Interestingly, an earlier study found that regular HRV training with deep breathing during exercise for a period of 12 months resulted in significant improvement in individuals with hyperglycaemia.[23] This group of researchers suggested that regular HRV training alters the cardiac sympathovagal balance in diabetic individuals, resulting in parasympathetic dominance. It is proposed that prolonged exercise may be beneficial in reversing the autonomic dysregulation. Meanwhile, Aaraji et al. (2019) stated that reducing the stress hormones and sympathetic activity helps decrease the arousal that results in a less severe blood sugar level.[18] This is supported by a previous study by Mccraty et al. (2000) where they found that regular HRV practices by using HeartMath reduced HbA1c that may be contributed by decreased stress and negative emotional arousal among T2DM individuals.[24] At the physiological level, emotional stresses stimulate the release of glucocorticoids and catecholamines into the serum, resulting in glycogenolysis, gluconeogenesis and impaired glucose tolerance in both types of diabetes.[25]

Current research suggests that emotional self-regulation strategies that modify autonomic nervous system activity can help manage diabetes physiologically in two main ways: by improving the patient's ability to secrete insulin and by reducing the amount of glucose and triglycerides produced and released from the liver and adipose tissues. Reduced autonomic activation and enhanced autonomic balance should lessen the liver's overproduction of glucose, as well as the mobilization of free fatty acids and the subsequent production of ketone and triglyceride molecules in Type 1 diabetic patients.[24]

This study also found that cortisol was significantly improved after 21 days of HeartMath emWave Pro biofeedback intervention. Similarly, previous studies found that there was a significant reduction in cortisol level after biofeedback training.[26,27] In their study, Kotozaki et al. (2014) found that biofeedback intervention affects regional gray matter volume, psychological test scores and salivary cortisol. It also states that biofeedback lowers salivary stress-marker levels, enhances the gray matter volume of the orbitofrontal cortex, subgenual anterior cingulate cortex, and hippocampus (associated with stress), and decreases daily stress. The gray matter areas are linked to the stress response and appear to be the most vulnerable to the negative consequences of stress overall.[26]

Besides, this study also found that there was a significant association between TSH and breathing. However, post-intervention, TSH and HRV were inversely correlated. In contrast, a previous study found that there was no significant association between TSH and HRV.[28] Interestingly, a recent study stated that a detrimental level of thyroid hormones and TSH may contribute indirectly to low HRV levels.[29] The inconsistent findings of present and previous studies could be attributed to several reasons, such as a small number of participants, short duration of intervention, and the design of the present study may influence the desired results. Furthermore, there was a significant correlation between breathing and HRV in this research. A study conducted by Chaitanya et al reported that after practicing resonance frequency breathing for 20 minutes each day for four weeks, there was an increase in parasympathetic and a decrease in sympathetic activity.[30] Similarly, another study found that individuals who were breathing at resonance frequency improved HRV, blood pressure, and mood.[31] Moreover, the research of these investigators on HRV demonstrated valuable findings by showing that breathing at resonance frequency encourages a more flexible emotional and physiological response. Generally, this study highlights the effectiveness of HeartMath emWave Pro biofeedback intervention, which demonstrated significant improvement in HbA1c, fasting blood glucose, post-prandial blood glucose, and cortisol after 21 days of treatment. The primary benefits of biofeedback technology as a conventional treatment for diabetes are the absence of side effects, its non-invasive application, and its holistic treatment.

The major limitation of the study is the small sample size of recruited participants. A small sample size may contribute to difficulty in determining the accuracy of the study's findings. Compared to other researchers, the study was conducted for a short duration of 21 days. To determine an appropriate change in HbA1c, a standard protocol of a duration of 3 months of intervention or follow-up should be considered in intervention research. The design of the present study may influence the findings, as a randomized controlled trial is the recommended research design for an intervention that will provide proper results.

CONCLUSION

In conclusion, this study has demonstrated significant differences in all blood glucose parameters, including HbA1c, fasting plasma glucose, post-prandial glucose, and cortisol, between the pre- and post-21-day biofeedback intervention duration. The findings suggest that biofeedback training may be utilized as a complementary treatment approach for individuals with diabetes, in supporting improved blood glucose levels and reducing their dependency on allopathic medicine. As noted earlier, this pilot study was designed to determine the feasibility of implementing various aspects of the proposed methodology for a larger, more rigorous, longer-duration, or confirmatory investigation.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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