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Impact of Integrated Amrita Meditation® technique on stress in type 2 diabetic patients

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***Background & objectives*: Several studies on mind-body relaxation techniques have demonstrated a reduction in psychological stress levels. Implementation of such cost-effective, persons suffering from chronic disorders would be beneficial for the diabetic population. This study was undertaken to understand the effect of Integrated Amrita Meditation® technique (IAM®) technique on stress and its benefit in attaining a better glycaemic control.**

***Methods*: Thirty type 2 diabetic patients aged between 30 and 65 yr were consecutively recruited for the study. They were randomly allocated to IAM® and control groups. Weight, body mass index (BMI), fasting blood glucose (FBG), glycated haemoglobin (HbA_{1c}) and perceived stress scale (PSS) were the variables assessed pre- and post-intervention during the three-month study period.**

***Results*: The mean changes between baseline and three months in the experimental group showed statistically significant decrease in HbA_{1c} (P=0.018) as well as psychological stress (P<0.001), whereas an increase in weight (P=0.046) and FBG (P=0.029) was observed in the control group. When the pre- and post-mean changes of the study variables were assessed between the two groups, the differences obtained were statistically significant for weight (P=0.048), BMI (P=0.055), HbA_{1c} (P=0.034) and PSS (P≤0.001).**

***Interpretation & conclusions*: The findings suggest that stress is an important risk factor hindering the glycaemic control of diabetic patients. Through reduction of psychological stress by IAM® practice, diabetic patients can attain a better glycaemic control along with the usual treatment regimens.**

Key words Diabetes - IAM® - meditation - stress - yoga

In India, prevalence of diabetes is suggestively approaching the status of a potential epidemic as is evident from the statistics projected by the International Diabetes Federation[1]. Normally, stress can elevate the blood glucose levels by stimulating the release of various hormones such as cortisol. Even though it appears to have an adaptive significance in normal healthy individuals, in people with diabetes, this stress-induced elevation in blood glucose cannot be metabolized effectively due to the relative or absolute lack of insulin[2]. Hence, exposure to chronic stress is menacing to diabetic population.

As type 2 diabetes mellitus (T2DM) is a psychosomatic illness, treating the somatic and symptomatic aspects of

the disease alone is insufficient. The psychiatric aspect of the disease, especially stress, must also be addressed. Although there are a number of medications to reduce the complications of diabetes and a few effective remedial measures are available to combat it. No effective pharmacological measures are developed either which can cure the psychological aspect of the disease *i.e*., stress, which ultimately ends up worsening the disease. Medications can only help treat the symptoms of the disease[3]. Maintaining the psychosocial well-being of diabetic patients is important clinically because diabetes being a chronic illness requires continuous support in terms of both medical care and patient education/self-care management. This combined effort from both the physician as well as the patient can ultimately taper the risk of long-term complications in diabetic patients and maintain a healthy life. Poor psychosocial health may impair biomedical health and can lead to suboptimal glycaemic control[4]. Hence, the only effective measure to deal with stress is lifestyle modification and behavioural therapy[3].

Focussing on effective stress-relieving strategies would be of paramount importance for attaining a healthy living for diabetic patients who are at risk of several diabetic complications. These complications can in turn impose financial burden over the individual and the nation[5]. In addition, living with diabetes and its complications and the burden of self-management can progressively cause considerable emotional distress among patients[6]. Relaxation exercises such as yoga and meditation can be easily learnt and practiced as these are safe, non-invasive and demand little in terms of equipment or professional training[7]. These lifestyle interventions not only minimize the risk of occurrence of diabetic complications, but also help in slowing the progression from pre-diabetes or metabolic syndrome to T2DM[8]. As stress and T2DM are important risk factors for coronary artery disease (CAD), incorporating meditation in the lifestyle of diabetic patients would pave way for reducing the risk of CAD by regulating the physiological response to stress through various neurohumoral mechanisms[9].

The Integrated Amrita Meditation® (IAM®) is a form of meditation whose core lies within Indian Tantric practices. It is well suited for people of the modern era surviving with various stress-related disorders as it encompasses yogic postures, breathing exercise and meditation, all the three components which can be practiced easily within 23 minutes[10]. Thus objective of the present study was to determine the effect of IAM® on stress and glycaemic control in type 2 diabetic patients.

Material & Methods

In our study, we used the Perceived Stress Scale (PSS) for assessing the psychological stress of the patient. PSS[11] is a self-reported questionnaire designed to measure 'the degree to which individuals appraise situations in their lives as stressful'. The items in the PSS assess the degree to which individuals believe that their life has been unforeseeable, uncontrollable and overloaded during the previous month. In our study, we have used the 10-item scale[11].

All the patients were from the department of Endocrinology, Amrita Institute of Medical Sciences and Research Centre, Kochi, India. The protocol received Institutional Human Research Ethical committee and Scientific Advisory committee clearance before the commencement, and the patients signed informed consent forms prior to participation in the study. A pilot study was conducted for calculation of minimum sample size as well as to standardize all the items and tools required for the main study[12]. Based on the results of the pilot study and with 99.9 per cent confidence and 90 per cent power, a minimum sample size reaches 10 in each group. Hence, we decided to include a total of thirty patients randomly assigned two groups (15 each), which would take care of the non-response rate if any.

Thirty eligible participants in the age group of 30-70 yr with diabetes of 1-10 yr duration and whose glycated haemoglobin (HbA_{1c}) level ranged between 7 and 10 per cent were recruited for the study. These patients had never undergone any specialized relaxation training and volunteered to participate in the study. Patients diagnosed with advanced diabetic complications – ongoing treatment for retinopathy/ renal impairment/symptomatic or unstable heart disease/uncontrolled blood pressure were excluded from the study.

Study design: The patients were randomly assigned to two groups – group 1/test group (IAM® group), consisting of Type 2 diabetic patients receiving standard medical care and undergoing IAM®, and group 2/control group (placebo group), consisting of type 2 diabetic patients receiving standard medical care alone and not undergoing meditation or any relaxation exercises. Randomization of the study participants was done through a computer-generated sequence. Both groups received advice from a physician, a dietician and

a social worker on maintaining a healthy lifestyle along with the conventional medications for hyperglycaemia. In addition, every three months, the participants had visits with the physician and social worker who reviewed their blood glucose levels to identify hypoglycaemic risk and to confirm the adherence to lifestyle modification. In addition to this, the test group participants received IAM® training under the guidance of certified IAM® teachers approved by Mata Amritanandamayi Math. Group 2/control group was be instructed on lifestyle modification by a trained social worker, including patient specific dietary modifications, exercises and psychological counselling but not IAM® technique. There was no change in medication during the three-month study period in either groups.

Intervention: IAM® is a simple combination of yoga, pranayama and meditation. It includes eight min of energizing exercises (yogic postures), a brief period of relaxation for two min and meditation for 13 min. Towards the end of the technique, the participants are asked to remain in silence for five min[10].

The test group patients were asked to report for the meditation class at 8 a.m. after an overnight fast of 8-12 h. Age and sex were noted, height and weight were measured and body mass index (BMI) was calculated. Fasting blood samples were collected for the analysis of fasting blood glucose (FBG) and HbA_{1c}. Two millilitres of blood was collected for FBG and 4 ml of blood was collected for HbA_{1c} analysis. Plasma glucose was analyzed by hexokinase method, and high-pressure liquid chromatography (HPLC) was used for the analysis of HbA_{1c}.

Before starting the meditation, the participants were given the psychological questionnaire for rating. The participants could clear their doubts with the master and feedback was taken after the meditation. There were periodic refresher courses under the guidance of a certified trainer to help patients adhere to the intervention. The patients practiced the technique once daily at home, and for a minimum of four times a week for standard of compliance. A self-maintained diary would assess their daily compliance on practice. Compliance was also assured telephonically. The second visit was after three months and the baseline variables were repeated. The control group participants were also followed up by a physician every three months and discussion with the social worker about their adherence to healthy lifestyle. Telephonic conversation with the dietician and social worker also motivated them to continue with their routine medication along with healthy diet and exercise.

Laboratory investigations: Biochemical investigations were carried out to determine the level of FBG and HbA_{1c}. FBG was analyzed through hexokinase method[13] and HbA_{1c} was estimated through HPLC[13].

Statistical analysis: Statistical analysis was performed using SPSS Software version 20.0 (IBM, Armonk, NY, USA). Categorical variables were expressed using frequency and percentage. Continuous variables were presented using mean and standard deviation. To test the statistical significance of the difference in the values of the variables (weight, BMI, FBG, HbA_{1c} and PSS) between baseline and three months, Wilcoxon signed-rank test was applied in each group. To test the statistical significance of the difference in the change from baseline to three months between the two groups, Mann-Whitney U-test was applied.

Results

Table I provides the sociodemographic characteristics of the study participants. The mean age of IAM® group participants was 54.87±10.27 yr and that of control group participants was 48.53±8.95 yr. Forty per cent of the participants were male and 60 per cent were female in both the groups. The groups were found to be comparable on the basis of age, sex, height, weight and BMI (P>0.05).

Comparison between baseline & three months within each group: Analysis within the IAM® group at the end of the third month showed a significant decrease in the mean values of perceived stress and HbA_{1c}. Continuous three months of IAM® practice within this

Table I. Sociodemographic characteristics of the study participants

Variables	Mean±SD	
	IAM® group (n=15)	Control group (n=15)
Age (yr)	54.87±10.27	48.53±8.95*
Height (cm)	157.53±5.71	158.60±10.01*
Weight (kg)	63.96±6.13	61.76±14.99*
BMI	25.56±2.21	24.26±4.48*
Gender, male:female (%)	6:9 (40:60)	6:9 (40:60)*

All differences were within sampling fluctuations (*P>0.05). BMI, body mass index; IAM®, Integrated Amrita Meditation; SD, standard deviation

group significantly brought down the psychological stress to a mean value of 16.80±3.34 from 21.13±3.72 (P<0.001). The mean change in stress within this group was 4.33±2.32 (P<0.001). The mean HbA_{1c} level dropped from 8.68±1.54 per cent to 8.19±1.29 per cent (P=0.018), both of which were statistically significant. However, weight, BMI and FBG did not show any significant changes post intervention in the IAM® group. On the other hand, in the control group, we could a statistically significant increase in weight (P=0.046) and FBG (P=0.029) after three months of follow up was observed. This difference in weight by three months was 0.62±1.10 kg and the change in FBG was by 11.40±16.58 mg/dl within the control group. A trend in increase of BMI was also observed in the control group, which was of borderline significant (P=0.061) (Table II).

Comparison of the difference in changes (baseline to three months) between the two groups: When the difference in the mean change obtained for each variable in both the groups was analysed (Table II), the difference in changes in weight, BMI, HbA_{1c} and PSS between the IAM® and control groups were all significant. After three months, the IAM® group showed a decrease in the mean weight by 0.29±2.01 kg and an increase of 0.62±1.10 kg in the control group. The difference in this change between the two groups was 0.91±1.62 kg, which was statistically significant (P=0.04). Similarly pre- and postchanges in BMI (0.38±0.65 kg/m^2, (P=0.055). HbA_{1c} (0.75 ± 0.97 per cent, P=0.034) were all found to be statistically significant. Of all the study variables, the psychological stress level assessed through the PSS showed a significance on between-group comparison. On comparing the mean changes in stress levels between the two groups, the difference obtained was 5.73±2.78 (P<0.001), and was statistically significant. The mean differences in FBG, however, showed a borderline significance on between-group comparison (P=0.063) (Table III).

During the study period, there was 20.23 per cent drop in the stress level of IAM® group, whereas the control group showed an increase of 7.45 per cent at the end of three months. This percentage difference in stress score was significant between the two groups (P<0.001). Similarly, the percentage drop of HbA_{1c} levels in the experimental group was 5.16±6.81 and the percentage increase of HbA_{1c} levels in the control group was 3.48±15.76, which was again statistically significant on between-group comparison (P=0.051).

Table II. Effect of three months of treatment on various parameters in the Integrated Amrita Meditation® (IAM®) and placebo groups

Parameter	IAM® group				Placebo group				Difference in change	
	0 (a)	Three months (b)	Change (a-b)=c	P^*	0 (d)	Three months (e)	Change (d-e)=f	P^*	(c-f)	P^{**}
Weight (kg)	63.96±6.13	63.67±7.14	−0.29±2.01	0.592	61.75±14.99	62.37±15.33	0.62±1.10	0.046	0.91±1.62	0.048
BMI (kg/m^2)	25.56±2.20	25.41±2.52	−0.15±0.81	0.493	24.26±4.47	24.49±4.56	0.23±0.44	0.061	0.38±0.65	0.055
FBG (mg/dl)	151.59±38.54	154.32±62.69	2.73±61.05	0.427	132.32±20.27	143.72±29.02	11.40±16.58	0.029	8.66±44.73	0.063
HbA_{1c} (%)	8.68±1.54	8.19±1.29	−0.49±0.70	0.018	7.86±1.17	8.12±1.55	0.26±1.19	0.41	0.75±0.97	0.034
PSS	21.13±3.71	16.80±3.34	−4.33±2.32	<0.001	20.26±4.66	21.66±5.16	1.40±3.18	0.110	5.73±2.78	<0.001

*The P value is for the change by three months within each group, **The P value is for the difference in change between the IAM® and placebo groups, −ve sign indicates a 'decrease' in change. BMI, body mass index; FBG, fasting blood glucose; HbA_{1c}, glycated haemoglobin; PSS, Perceived Stress Scale

Table III. Percentage change from baseline to three months between groups

Variable	Mean±SD (%)	
	IAM® group (n=15)	Control group (n=15)
Weight (kg)	−0.56±3.15	0.98±2.10
BMI (kg/m^2)	−0.65±3.16	0.97±2.04
FBG (mg/dl)	4.01±43.48	8.33±12.99
HbA1$_c$	−5.16±6.81	3.48±15.76*
PSS	−20.23±11.44	7.45±18.30***

*P**<0.05, ***<0.01, ****<0.001. −ve sign indicates a decrease in value

The percentage difference between the groups for all the other variables was of borderline significance in our study (Table III).

Discussion

Environmental factors, psychosocial factors and stress play an important role in the development and progression of T2DM in genetically susceptible individuals. Hence, in recent years, more research is being carried out on various non-medical measures to control DM and its complications[12,14]. The questions being addressed in this article include how IAM® technique is efficacious in alleviating stress and related hyperglycaemia in a group of diabetic patients practicing the technique as well as to compare it with a control group, and also to understand how stress affects the diabetes group not undergoing any relaxation exercise over a period of three months.

Reports on possible pathways that link psychological stress with diabetes are already available[15]. Various unhealthy lifestyle behaviours such as consumption of unhealthy food, sedentary lifestyle, smoking and alcohol abuse, all of which contribute to stress and in turn worsening the diabetic complications, are attributed as the first pathway or behavioural pathway that links stress with diabetes[15-17]. The second pathway suggested is via physiological mechanisms. Long-term activation of hypothalamic-pituitary-adrenal (HPA) axis and sympathetic nervous system occurs through chronic stress. This phenomenon in diabetic patients, in turn, strengthens the risk and complications of diabetes[18,19].

The results of the current study have found a significant reduction in perceived stress and HbA$_{1c}$ in the experimental group between baseline and three months of intervention. In addition, their mean changes between pre and post IAM® were of significance when analyzed between the two groups similar to findings of other reports in the literature[20-24]. It is evident that diabetic treatment consists of targeting not only the somatic aspect, but also the stressors, psychiatric and otherwise. Contradicting results showing no significant improvement in HbA$_{1c}$/FBG levels after yoga and pranayama interventions in diabetic patients were also noted in few studies[25,26].

The exact mechanism by which yoga and meditation reduces HbA$_{1c}$ and its related risk profiles is yet to be fully understood. However, two major pathways have been postulated which can bring forth a positive change through yoga. First, it can promote a feeling of well-being by lessening the activation of sympatho-adrenal system and HPA axis, thereby fostering positive beneficial effects on neuroendocrine, metabolic and inflammatory responses[27]. Second, yoga may strengthen parasympathetic activity by directly stimulating the vagus nerve, leading to decisive changes in cardiovagal function, emotional and energy level of patients. In addition, yoga can bring about healthy lifestyle changes in the individual by decreasing visceral adiposity and supplementing weight loss[28-30].

In the control group, an increase in weight and BMI was observed. The test group, however, did not show much difference over the study period. However, these variables showed significant differences when pre- and postchanges were compared between the two groups suggesting that IAM® meditation could be beneficial in maintaining the weight and BMI as proved by few meditation-based studies[8,24]. In addition, the control group showed a significant increase in FBG levels, whereas not much difference was observed in the test group, suggesting that the control group, who received medications alone had more chances of getting the blood glucose levels out of control.

Of all the variables in this study, changes in psychological stress score showed a significant between the two groups. The relationship between stress and T2DM has long since been established, and it was cited to be an important risk factor for the onset of T2DM[21,22]. The stress level in control group individuals was also significantly higher similar to a precious hatha yoga based study[31]. Similar findings were also reported in a randomized controlled trial[32].

This study brings light to the fact that mental health should always be a part of proper diabetic treatment regimen. Only when the stress issues of a patient are addressed will it be a comprehensive consultation.

Hence, along with medically prescribed regimens, diabetic patients can safely incorporate meditation into to their daily therapy as these relaxation exercises do not pose any side effects and thus help to significantly bring about a healthy and stress-free life.

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***Conflicts of Interest*:** None.

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