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Research Article

Role of autogenic relaxation in management of diabetic cardiovascular autonomic neuropathy in type II diabetes mellitus patients

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ABSTRACT

Background: Cardiac autonomic neuropathy (CAN) is a very common complication of Type II diabetes mellitus patients. Early detection and treatment of CAN is necessary for reduction of mortality and morbidity in type II diabetes patients.
Methods: The study included 120 diagnosed cases of type 2 diabetes mellitus with autonomic neuropathy both male & female, with more than 5 years duration of disease. Age group of the study subjects was between 30 – 70 years. All the 120 diabetic subjects were assessed for their heart rate variability. These 120 diabetic subjects were further divided in two groups by sealed envelope technique, with 60 subjects in each group. Subjects in Group I (Study group) were given relaxation therapy in the form of Rajyoga meditation, as guided by Rajyoga teachers. This group was asked to continue drug therapy for type 2 diabetes mellitus as prescribed by physician. On other hand, Group II (Control group) was given drug therapy as directed by physician but without relaxation therapy. At the end of 12 weeks HRV parameters, were re-evaluated and compared between the two groups.
Results: Post intervention, Heart Rate Variability results showed that mean RR interval was significantly increased, whereas mean HR was significantly decreased in group I than in group II. All Time Domain parameters (i.e SDNN, RMSSD, NN50, pNN50 & Variance) were significantly increased in group I than in group II. The Frequency Domain parameter i.e LF/HF ratio was significantly decreased in group I than in group II. Thus the results showed that Raj Yoga meditation had a beneficial effect by improving the HRV parameters in diabetic patients with autonomic neuropathy.
Conclusions: The study showed there is better improvement in all parameters of HRV in group I as compared to group II with the help of simple yet effective technique of Rajyoga meditation in type II diabetes mellitus patients with cardiac autonomic neuropathy.

Keywords: Diabetes mellitus, Heart rate variability, Cardiac autonomic neuropathy, Rajyoga meditation

INTRODUCTION

Diabetes mellitus is metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects of insulin secretion, insulin action or both.[1] The metabolic dysregulation associated with diabetes mellitus causes secondary pathophysiological changes in multiple organ systems that impose a tremendous burden on the individuals with diabetes and on the health care system. Diabetic neuropathy is the damage to the nerves and effects up to 50% of people with diabetes.[2] As many as 22% of people with type 2 diabetes mellitus (DM) suffer from cardiac autonomic neuropathy

(CAN) which leads to impaired regulation of blood pressure, heart rate and heart rate variability (HRV). Around 75% of people with diabetes die from cardiovascular disease such as heart attack and stroke. Silent ischemia is significantly more frequent in patients with than in those without CAN (38% vs 5%).[3] Measuring heart rate and its HRV is one of the principal methods for assessing cardiac autonomic tone. HRV is conventionally assessed by using Time-domain and frequency-domain techniques, which identify its coupling with a variety of phenomena, including respiration, baro-receptors, autonomic nervous system traffic, body temperature, metabolic rate, hormone levels, and diurnal variation.[4] Rajyoga is a method of autogenic relaxation with spiritual link, providing training in realization of the true self, contemplating on divine 'Supreme Being'. Rajyoga is one of the training courses of Rajyoga Education and Research foundation of Brahma Kumaris World Spiritual University (NGO body on consultative status with UNO, UNICEF and WHO). Rajyoga meditation of Brahmakumaris subsumes within itself the fundamentals of all methods of yoga and confers the achievement of all of them naturally and easily using one very simple method which anyone can learn.[5] Among all the Yogas, Rajyoga is best and very easy to practice, cost effective and helps in reducing economic burden due to diabetes complications. The objectives of this study was to assess the effect of Rajyoga meditation in patients of Type 2 diabetes mellitus

METHODS

The present study was conducted on 120 diagnosed patients of Type II diabetes mellitus, undergoing treatment in the Department of medicine in Jawaharlal Nehru Medical College, Sawangi (M), Wardha, Maharashtra. The protocol of study was approved by the ethical committee of our institute. The patients were briefed about the study protocol; they were motivated for compliance needed till the end of the study and informed consent was obtained from them. The subjects were both male and female between age group 30 - 70 years. The inclusion criterion was patients suffering from type II diabetes mellitus with more than 5 years duration. Patients with duration of type II diabetes mellitus less than 5 years were excluded. Patients with uncontrolled type II diabetes mellitus and with history of previous myocardial insufficiency and infarction were also excluded. All 120 patients assessed for the different time domain and frequency domain parameters with the help of heart rate variability in the neurophysiology lab of the department of Physiology, Jawaharlal Nehru medical college. They were randomly allocated into two groups by sealed envelope technique with 60 subjects in each group. Group 1 subjects underwent Rajyoga meditation (RM) training plus had their routine medication whereas group 2 subjects had routine medication only. The total duration of study was 12 weeks**.** Subjects in Group 1 (Study group) were given relaxation therapy in the form of Rajyoga meditation (RM) as guided by Rajyoga teachers. There are 3 steps in RM namely-

1. Initiation- in this stage, thoughts in the mind, comes in randomly.
2. Concentration- He now, converts all negative thoughts with positive thoughts of peace, happiness, love, bliss, purity, knowledge & power.
3. Realization-This final stage involves feeling the emotions of these positive thoughts.

RM was practiced in the following way-

First, the person is sited in a comfortable chair, with feet firmly planted on the floor in front of him. He is advised to stay conscious, which helps in controlling the duration of the technique. This procedure is done for only 3 to 5 minutes in the beginning. Once he is comfortable with the technique he is instructed to follow the procedure for 8-10 minutes. To start with, the person is asked to breathe deeply and evenly, feeling the cleansing power of oxygen permeating his body's cells as he breathes in, and the release of carbon dioxide waste as he breathes out.[6]

After this brief relaxation, he visualizes the soul as a point of white light shining like a diamond in between the eyebrows. Then, he focuses on the Supreme Soul, which is also a point of white light but ocean of energies. Eight sittings of 45 mins each on alternate days for two weeks were given followed by once a week interview during which the method followed by the patients and compliance to practice of meditation was checked. Also, any queries relating to the methodology were answered at the same sitting.[5] In addition they also continued drug therapy for type 2 diabetes mellitus as prescribed by physician from medicine department of Acharya Vinoba Bhave Rural Hospital (AVBRH)**.** On other hand, Group 2 (Control group) was given drug therapy as directed by physician only. Group 2 patients were called once a week and compliance about the treatment was noted. All the patients were followed for minimum of 12 weeks. After 12 weeks of intervention, all the parameters of HRV were again studied in both groups. For autonomic activity tests, ECG and respiration were recorded continuously on a computerized polyrite (data acquisition and analysis system). Resting heart rate variability analysis was done for studying cardiac autonomic modulation. For autonomic reactivity, deep breathing test was done. Autonomic activity was assessed by evaluating heart rate variability (HRV), which quantify autonomic drive to myocardium. Subjects were allowed to lie down on examination table for 15 minutes so that they were adjusted with the laboratory environment. ECG electrodes were applied and digital ECG recording was done in supine position at least for 15 minutes with the help of computerized polyrite (RMS, India). After recording digital ECG for 15 minutes the subjects were asked to take deep breaths (maximum possible deep inspiration followed by maximum possible deep expiration at the rate nearly 6 breaths per minute; that was approximately 5 seconds for each inspiration and 5 seconds for each expiration) and heart rate changes during these respiratory phases were recorded from the polyrite. The analogue to digital conversion of the ECG signal was done using A/D converter with the sampling frequency 256 Hz. Both frequency and time domain analysis of the data was done. For frequency domain analysis, Fast Fourier Transformation (FFT) was done using Welch's method with Hann Window. Entire spectrum of frequency was divided into three major bands, very low frequency (VLF, 0-0.04Hz), low frequency (LF, 0.04-0.15Hz), and high frequency (HF, 0.15-0.4Hz).[7] HF component denotes vagal activity and LF component denotes sympathetic tone of the individual.[8] By frequency domain analysis following parameters were obtained: VLF, LF, HF, Total power (TP), LF: HF ratio and normalized LF and HF (LF nu and HF nu).[7] From the same data, time domain measures of HRV were obtained. In the time domain, the standard deviation of normal to normal RR intervals (SDNN) was taken as an index of overall HRV. RMSSD, NN50, PNN50 were also calculated.

Statistical analysis

Results were analysed by Statistical Package for Social Sciences (SPSS) software, version 17.0. All the data was analysed group-wise by descriptive statistics using mean, standard deviation. For differences in sex-wise composition of two study groups, Chi-squared test was used. The data before and after the intervention for both Group 1 and Group 2 was tested by Wilcoxon Signed rank Test. Increase and decrease in value of different parameters with Group 1 and Group 2 was also compared using Mann-Whitney U test. The Statistical significance was considered at probability value less than 0.05.

RESULTS

120 patients entered the study, 60 in Group I (study group) and 60 in Group II (control group). Out of the 120 selected subjects 9 from the group 1 and 8 from the group 2 dropped out in due course of study. To maintain parity in two group sizes, data of 50 subjects from each group was analysed, thus, the total sample size of the study became 100. On comparing the demographic profile of the patients in two groups we found that they were comparable regarding age and sex. Table 1 showing age wise distribution of diabetic subjects in Group 1 and Group 2. The Mean age of Group 1 subjects was 49.16 yrs and in group 2 was 53.38 yrs which was statistically non-significant (p≥0.05). In Group 1 out of 50 subjects there were 41 (82%) males and 9 (18%) were females whereas in Group 2 out of 50 subjects there were 40 (80%) male and 10 (20%) were females, which was statistically non-significant (p≥0.05). For Group I, Average Mean RR, Average Variance increased significantly from 0.65 to 0.72 (z= 3.97, p≤0.05) and 766.83 to 1377.50 (z= 6.15, p≤0.05) respectively after 12 weeks of intervention. Average Mean HR in Group 1 decreased significantly from 84.56 to 76.02 after 12 weeks of intervention (z= 6.18, p≤0.05). Group II patients also showed increases in average Mean RR and average Variance and decrease in Average Mean HR but the change was non-significant (p≥0.05). The values of Average SDNN, RMSSD, NN50, and pNN50 increased significantly after 12 weeks of intervention in Group1 from 25.31 milliseconds (ms) to 37.95 ms (z= 6.15, p≤0.05), 13.93 ms to 24.78 ms (z= 6.15, p≤0.05), 4.52 to 21.57 (z= 5.27, p≤0.05), and 1.33% to 13.93% (z= 6.15, p≤0.05) as compared to Group 2 where increase was non-significant (p≥ 0.05). Average values of LF/HF ratio after 12 weeks of intervention in Group 1 significantly decreased from 4.22 to 2.03 (z= 6.15, p≤0.05) as compared to Group 2 where it decreased from 4.22 to 3.55 (p≥0.05). LF/HF ratio showed better improvement in Group 1 as compared to Group 2.

Table 1: Age wise distribution of patients in both the groups.

Age group (years)	Group 1	Group 2	ℵ2-value	p-value
31-40	10 (20%)	6 (12%)	4.50	0.21 NS, p>0.05
41-50	18 (36%)	13 (26%)		
51-60	14 (28%)	24 (48%)		
61-70	8 (16%)	7 (14%)		
Total	50 (100%)	50 (100%)		
Mean age	49.16	53.38		
SD	10.30	9.15		

Interpretation: There was no statistical significant difference in mean age between the group 1 and group 2.

Table 2: Gender wise distribution of patients in both the groups.

Gender	Group 1	Group 2	ℵ2-value	p-value
Male	41 (82%)	40 (80%)	0.06	0.79 NS, p>0.05
Female	9 (18%)	10 (20%)		
Total	50 (100%)	50 (100%)		

Interpretation: There was no statistical significant difference in sex wise distribution between the group 1 and group 2.

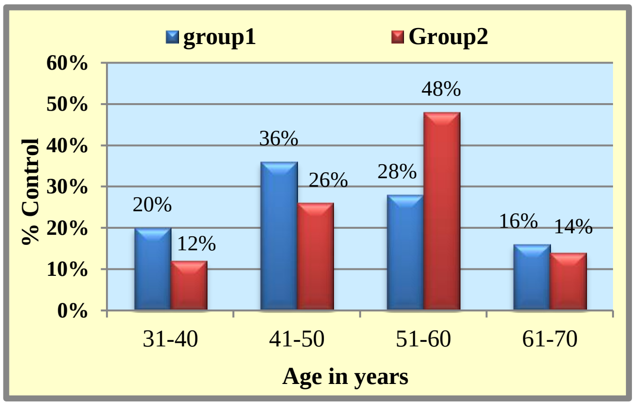

Figure 1: Age wise distribution of patients in both the groups.

Table 3: Comparison of mean RR, mean HR and variance (total power) of heart rate variability at baseline and after intervention in both the groups.

Parameters		Baseline	After 3 months	Wilcoxon signed rank test (z-value)	p-value
Mean RR	Group 1	0.65±0.11	0.72±0.07	3.97	0.000 S, p<0.05
	Group 2	0.64±0.13	0.65±0.11	0.58	0.55 NS, p>0.05
	Group 1 Vs Group 2 Mann-Whitney U test (Z-Value)	0.35 P=0.72 NS, p>0.05	3.27 P=0.001 S, p<0.05		
Mean HR	Group 1	84.56±6.77	76.02±5.96	6.18	0.000 S, p<0.05
	Group 2	85.14±7.02	84.56±6.77	0.66	0.50 NS, p>0.05
	Group 1 Vs Group 2 Mann-Whitney U test (Z-Value)	0.35 P=0.72 NS, p>0.05	3.27 P=0.001 S, p<0.05		
Variance	Group 1	766.83± 515.61	1377.50± 663.32	6.15	0.000 S, p<0.05
	Group 2	728.90± 652.62	768.83± 515.61	0.39	0.69 NS, p>0.05
	Group 1 Vs Group 2 Mann-Whitney U test (Z-Value)	0.75 P=0.45 NS, p>0.05	4.50 P=0.000 S, p<0.05		

Table 4: Comparison of different time domain and frequency domain parameters of heart rate variability at baseline and after intervention in both the groups.

Parameter		Baseline	After 3 mnths	z-value	p-value
SDNN	Group 1	25.31±11.4	37.95±10.05	6.15	0.000 S, p<0.05
	Group 2	23.63±13.69	25.31±11.44	1.04	0.29 NS, p>0.05
	Group 1 Vs Group 2 Z-Value	0.74 P=0.45 NS, p>0.05	4.90 P=0.000 S, p<0.05		
RMSSD	Group 1	13.93±7.94	24.78±7.17	6.15	0.000 S, p<0.05
	Group 2	12.43±8.10	13.93±7.94	0.61	0.167 NS, p>0.05
	Group 1 Vs Group 2 Z-Value	1.21 P=0.22 NS, p>0.05	6.03 P=0.001 S, p<0.05		
NN50	Group 1	4.52±6.64	21.57±22.05	5.27	0.000 S, p<0.05
	Group 2	2.98±4.23	4.52±6.64	0.91	0.360 NS, p>0.05
	Group 1 Vs Group 2 Z-Value	0.80 P=0.42 NS, p>0.05	6.32 P=0.000 S, p<0.05		
pNN50	Group 1	1.33±2.32	13.93±14.70	6.15	0.000 S, p<0.05
	Group 2	0.91±1.51	1.33±2.32	0.66	0.50 NS, p>0.05
	Group 1 Vs Group 2 Z-Value	0.81 P=0.41 NS, p>0.05	7.51 P=0.000 S, p<0.05		
LF/HF	Group 1	4.22±1.31	2.03±0.52	6.15	0.000 S, p<0.05
	Group 2	4.22±1.31	3.55±0.59	3.18	0.000 S, p<0.05
	Group 1 Vs Group 2 Z-Value	3.27 P=0.001 NS, p>0.05	10.89 P=0.000 S, p<0.05		

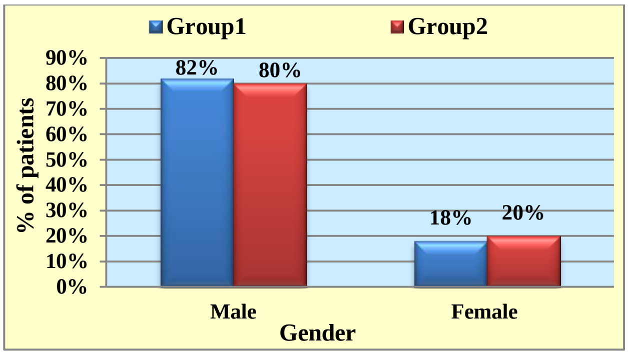

Figure 2: Gender wise distribution of patients in both the groups.

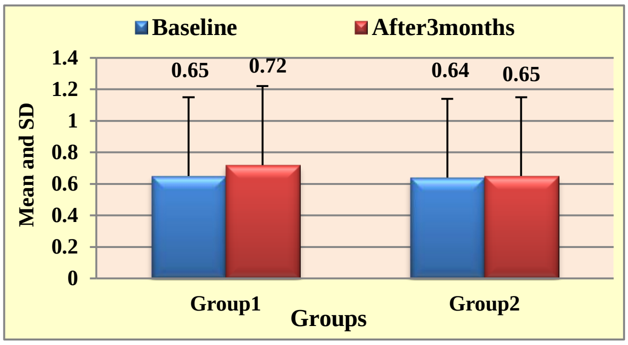

Figure 3: Comparison of mean RR at baseline and after intervention in both the groups.

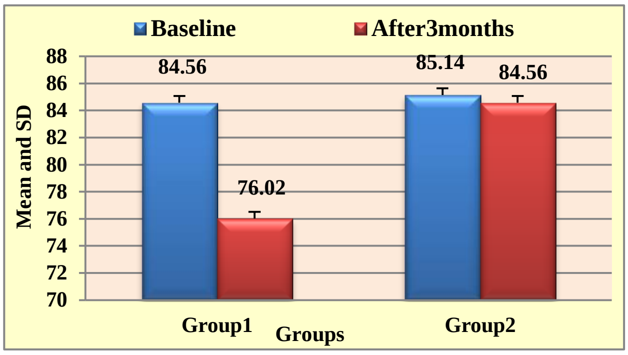

Figure 4: Comparison of mean HR at baseline and after intervention in both the groups.

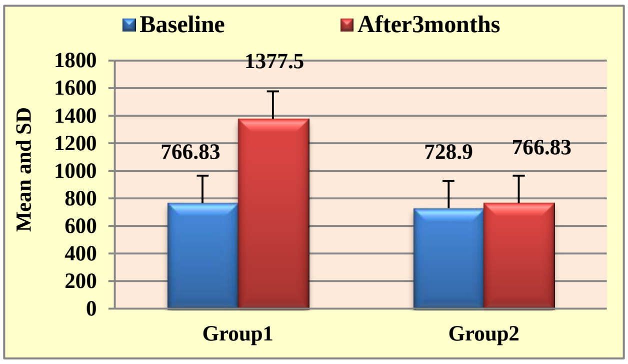

Figure 5: Comparison of variance at baseline and after intervention in both the groups.

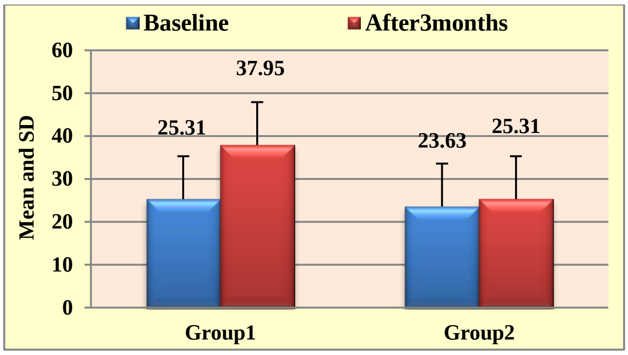

Figure 6: Comparison of SDNN at baseline and after intervention in both the groups.

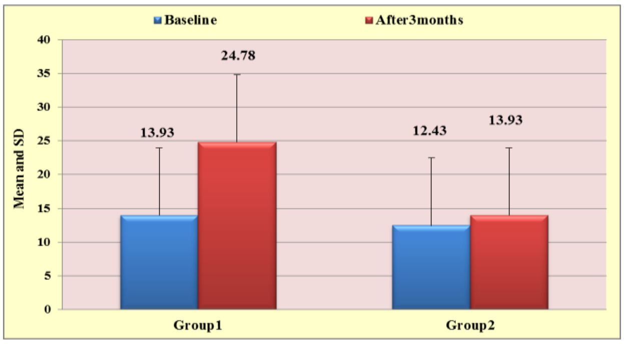

Figure 7: Comparison of RMSSD at baseline and after intervention in both the groups.

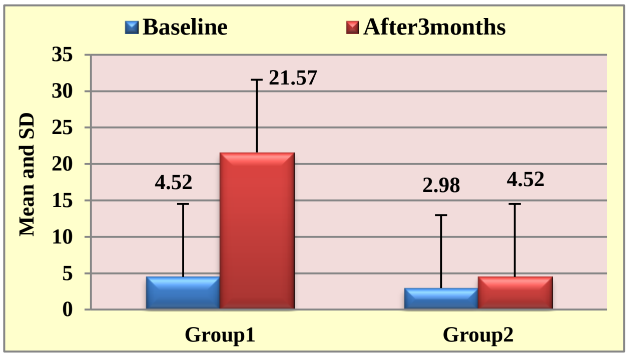

Figure 8: Comparison of NN50 at baseline and after intervention in both the groups.

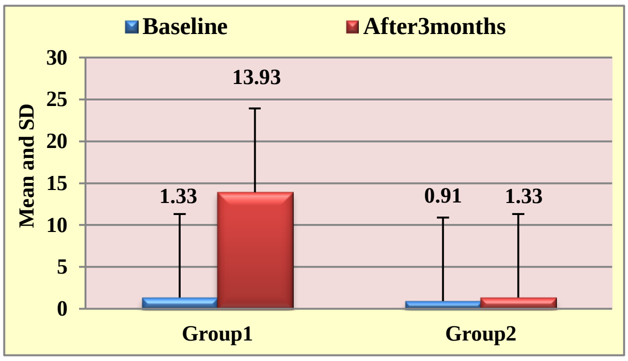

Figure 9: Comparison of pNN50 at baseline and after 3 Months in both the groups.

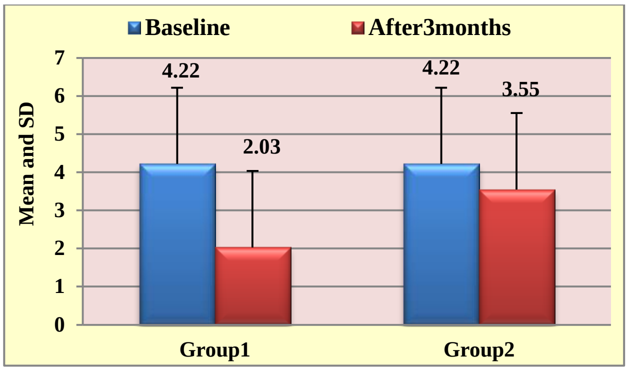

Figure 10: Comparison of LF/HF at baseline and after intervention in both the groups.

DISCUSSION

This study attempts to compare the influence of Rajyoga meditation on cardiac autonomic neuropathy in type 2 Diabetes Mellitus patients on regular medication. Meditation is believed to gradually reduce sympathetic dominance resulting in better balance between sympathetic and parasympathetic. Studies have proven that regular practice of Rajyoga meditation increase self-satisfaction by enhancing positive thinking, decrease heart rate and blood pressure and has cardio-protective effect.[9] Fluctuations of heart rate at frequency >0.15 Hz can be mediated almost entirely by the vagus and are usually directly associated with respiratory activity. Lower frequency fluctuation <0.15 Hz can be mediated by both vagus and cardiac sympathetic nerves and may be related to baroreflex activity, temperature regulation, and/ or maintenance of homeostasis during various cardiovascular stresses.[10]

Deep psycho-physiological relaxation causes the reversal of the 'flight or fight' response which results in maximum reduction of heart rate and blood pressure below the resting normal level. In such condition the parasympathetic predominance is established.[11,12] HRV is a known prime non-invasive measure for cardiovascular autonomic regulation. HRV also provides an opportunity to study and assess the association between psychological processes and physiological reactions. It expresses the balance between the regulation of sympathetic and parasympathetic nervous system.[13]

The association between reduced HRV and increased risk of morbidity and mortality is beyond dispute. A series of studies has shown this correlation with respect to myocardial infarction and chronic heart insufficiency: reduced HRV was associated with an increased cardiac mortality, and in particular an increase in fatal arrhythmias. The mortality rate in patients with a mean standard deviation of heart frequency (SDNN) of below 50 ms was more than five times higher than in patients with an SDNN of over 100 ms. In the context of CAN, a significant connection between HRV reduction and increased mortality risk was also shown for diabetics. Research has shown that increased activity of the sympathetic nervous system is associated with an increased risk of cardiovascular events, such as myocardial infarction or sudden cardiac death. Likewise, an increased heart rate, as arises in CAN by means of the early damage that occurs primarily to the parasympathetic nervous system, is identified as an unfavourable prognostic factor.[14]

In our study all the parameters of HRV (Time domain and Frequency domain) increased in Group I as compared to Group II after 12 weeks of Rajyoga Meditation. Similar increase in heart rate variability measures by Variance of RR intervals (also called as Total Power) has been reported by many workers. Increase in Parasympathetic activity as indicated by increase High Frequency (HF) has been demonstrated after endurance exercise and yogic exercises. Similar change in LF/HF ratio which changes the sympathovagal balance in favour of Parasympathetic component has been reported by many workers like Martenilli FS, et al; Tulppo M, et al; Atlaoui D, et al; Hautala AJ; Molgaard H, et al; Tulppo M, et al; Sharma R, et al; Vinit A, et al; Khattab K, et al.[15-23]

Satyapriya M, et al reported increased HRV in HF band and decrease in LF band and LF/HF ratio by integrated yoga practice and guided yogic relaxation in 122 healthy pregnant women.[24] Toivanen H, et al on his study on impact of regular relaxation training on the cardiac autonomic nervous system of hospital cleaners and bank employees reported improvement in cardiac autonomic functions on regular deep relaxation.[25] Vempati RP, et al reported during guided relaxation the power of the low frequency component of the heart-rate variability spectrum reduced, whereas the power of the high frequency component increased, suggesting reduced sympathetic activity in 35 male volunteers.[26]

CONCLUSION

In conclusion, Rajyoga meditation has stood the test of time and is relevant today in management of myriad illnesses as well as for research into states of consciousness. We suggest that physicians consider offering this meditation training as an alternative to suitable Diabetes patients. Once learnt, the practice involves no financial expense to the patient.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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