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Original Article

Physiology Section

Effect of Six Months Yoga Intervention on Metabolic Profile and Carotid Intima Media Thickness in Prediabetes

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ABSTRACT

Introduction: Diabetes, the most common endocrine disorder, is projected to show a worldwide increase from 366 million people in the year 2011 to 552 million in the year 2030, out of which around 101 million is expected to be contributed by India. Moreover, the disease manifestations start in the early stages of diabetes and before it gets established as a full blown condition in the pre-stage called prediabetes.

Aim: To highlight the importance of yoga intervention on metabolic profile and Carotid Intima Media Thickness (CIMT) in prediabetic subjects and implement it as a therapy for primary prevention of diabetes.

Materials and Methods: This interventional study was done among adults aged 31-50 years in RUHS College of Medical Sciences and Associated Rukmani Devi Beni Prasad Jaipuria Hospital in Jaipur City, Rajasthan, India. A total of 250 prediabetic subjects were recruited from Jaipuria Hospital. These were divided into two groups, Study group (Group A, n=125) were engaged in yoga session and Control group (Group B, n=125) did not perform any yoga session. Written informed consent was taken from the participants in the local language. Study was conducted over a period of six months from July to December 2018. Statistical analysis was done by student's paired t-test for intragroup comparison before applying this test the Smirnov-Kolmogorov test was conducted to confirm the normality of each parameter.

Results: Yoga intervention resulted in a significant decline in blood glucose ($p<0.0001$), Glycated haemoglobin ($p<0.01$), lipid profile Cholesterol ($p<0.01$), Triglyceride ($p<0.01$), Low Density Lipoprotein (LDL) ($p<0.01$), High Density Lipoprotein (HDL) (p-value >0.05) and Very Low Density Lipoprotein (VLDL) (p-value >0.05), CIMT (p-value <0.05) relative to the control group.

Conclusion: Yoga intervention was found to be helpful in control of metabolic profile and CIMT in prediabetes subjects. This preliminary study indicates that a yoga intervention would be a possible risk reduction option for adults at high risk for type 2 diabetes. In addition, yoga holds promise as an approach in reducing cardiometabolic risk factors, atherosclerosis and Cardiovascular (CV) events.

Keywords: Blood glucose, Glycated haemoglobin, Lifestyle intervention, Lipid profile

INTRODUCTION

Diabetes, the most common endocrine disorder, shows a worldwide increase from 366 million people in the year 2011 to 552 million in the year 2030, out of which around 101 million is expected to be achieved by India [1]. Prediabetes do not only have an increased risk of type 2 diabetes, but also of CV events and recurrent stroke [2,3]. Prediabetes represents the initial stage of diabetes development, progression to overt type 2 diabetes occurs when pancreatic beta cells are not able to produce insulin to overcome insulin resistance, resulting in further hyperglycaemia [4]. According to the American Diabetes Association, the diagnostic criteria for prediabetes is an elevated fasting plasma glucose level (100 mg/dL-125 mg/dL), a glycated haemoglobin (HbA1c) value of 5.7% to 6.4%, or an elevated plasma glucose level after an oral glucose tolerance test (140-199 mg/dL) [5].

Carotid Intima Media Thickness (CIMT) is a well known surrogate marker for CV risk. Several studies have reported that thickened CIMT correlates with the presence of CV events and strokes [6-8]. CIMT is significantly higher in diabetic [9-11] and an increased CIMT is associated with coronary artery disease and predicts future events of silent brain infarction in type 2 diabetic subjects [12]. CIMT is increased even from the prediabetic stage, i.e., persons with Impaired Glucose Tolerance (IGT) have elevated levels of CIMT [13].

Lifestyle interventions that include a healthy diet, regular physical activity, yoga, weight maintenance/reduction, smoking and alcohol cessation, and stress management have been shown to reduce Cardiovascular Disease (CVD) risk factors [14,15]. Use of surrogate markers that predict the likelihood of CVD events is becoming more accepted as an approach to improve clinical trial efficiency, duration and cost. Measurement of CIMT by B-mode ultrasonography is among the imaging tools for non-invasive assessment of atherosclerosis and has been validated as a predictor of CV events in several studies [16-20].

The prevention of type 2 diabetes in prediabetics is an area of concern. Lifestyle intervention programmes such as yoga can prove to be a beneficial, easily accessible, non-pharmacologic intervention in preventing progression of prediabetes to type 2 diabetes. The science of yoga is an ancient one and benefits all components of health. The effects of yoga on the endocrine system, nervous system, and physical health are documented. Yoga, a complex intervention includes components with varying degrees of physical movement, muscle stretching, activates neuroendocrine system, mind body exercises and in-depth philosophical teachings [21]. In yoga breathing techniques include the practice of *prāṇāyāma,* which regulates respiration through variety of exercises, and *āsana,* which includes various physical exercises, stretching and postures in a highly coordinated manner integrated with systematic breathing [22]. These exercises have been found to bring about positive biochemical and hormonal changes by elevating mood, eliminating stress and instilling a sense of discipline [11]. The yogic therapeutics helps in restoring the neuroendocrine, internal secretions to their normal value by securing the health of all the endocrine organs [23]. The effect of yogic practices on the management of prediabetes has not been investigated well. However, there are few studies assessing the effect of lifestyle interventions on metabolic profile and progression of CIMT and atherosclerosis. So, the aim of

this well designed short term study was to assess the effect of integrated approach of yoga therapy on metabolic profile and CIMT which assessed the impact of yoga intervention on atherosclerosis progression over six months.

MATERIALS AND METHODS

A prospective comparative interventional study was conducted among prediabetic adults aged 31-50 years in a tertiary health care centre, Jaipur, Rajasthan, India. Written informed consent was taken from the participants in the local language and the study was approved by Ethics Committee (Registration No.ECR/762) of the RUHS College of Medical Sciences. A total of 2000 participants were screened out of RDBP Jaipuria hospital and different yoga centers from which 250 were found to be prediabetic. Study was carried out over a period of six months from July to December 2018. Details about the age, sex, family history, socio-demographic, lifestyle, physical activity, Body Mass Index (BMI), dietary habits, medical factors were recorded in the information collection proforma. Prediabetes was defined as per American Diabetes Association criteria [5].

Inclusion criteria: No history of CVD in subject or in first-degree relatives, and should not be on drugs which affect blood sugar levels.

Exclusion criteria: Fasting blood glucose <100 mg/dL and >126 mg/dL and oral glucose tolerance test <140 mg/dL and >200 mg/dL, Glycated haemoglobin <5.5% and >6.5% subjects that have systolic blood pressure >160 mmHg and diastolic blood pressure >100 mmHg, abnormal liver function test Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) >2.5-fold the upper normal limit, alcoholic individuals, renal dysfunction, diabetic retinopathy, neuropathy and further major complications were excluded.

Sample size calculation: As the prevalence of prediabetes in India is 8% [2] taking it as a reference the sample size is estimated using the appropriate size formula $n=z^2pq/d^2$, where, n denotes the sample size, z represents the statistic corresponding to level of confidence, p is anticipated prevalence, q is (1-p), where p and q were taken as 0.08 and 0.92 to get the maximum sample size with 5% permissible error (precision) and 10% non-response rate, the desired sample size was 125 with 95% confidence interval.

A total of 250 prediabetics were recruited in the study. These were divided into two groups viz., study group (group A: n=125) i.e., prediabetic with yoga intervention and control group (group B: n=125) i.e., prediabetic without yoga intervention. Baseline parameters like anthropometic, blood pressure, pulse rate were recorded and biochemical parameters like blood glucose and lipid profile were measured using enzymatic colorimetric kits on a biochemistry analyser. Evaluation was done before yoga intervention and after six months postintervention.

Measurement of CIMT was performed in the posterior wall of both carotid arteries by mode B ultrasound with an Acuson Sequoia ultrasonography device equipped with a liner probe operating 8 mHz. The scanning session lasted for an average of 30 minutes. The Intima Media Thickness (IMT), as defined by Pignoli P and Tremoli E was measured as the distance from the leading edge of the first echogenic line to the leading edge of the second echogenic line [24]. The CIMT will be calculated as the mean of eight measurements. IMT values below 0.8 mm will be considered as normal. The presence of plaques and degree of stenosis will be noted and analysed. Plaque is defined as a localised lesion of thickness ≥1.0 mm; stenosis is defined as >50% occlusion with systolic frequency peak ≥4.0 KHz and spectral broadening. All scans to be conducted by sonologist as shown in [Table/Fig-1].

Yoga was used as an interventional therapy in this study. Yoga training was given by certified yoga instructor. These sessions were approximately 46 minutes six day in a week over a period of six months. The Integrated Approach of Yoga Therapy included Prayer,

[Table/Fig-1]: Assessment of right and left Carotid Intima Media Thickness (CIMT).

Omkar recitation, yoga postures (*asanas*), breathing (*pranayama*) techniques, Shavasana, Counseling and diet was also be part of the programme. To facilitate and guide home practice, participants were given an video recording (CD) of the yoga sessions recorded under direction of the certified yoga instructor in RUHS College of Medical Sciences and compliance of patients were checked by message daily and weekly telephonic conversions. The components of intervention using integrated approach of yoga therapy are detailed in [Table/Fig-2].

S. No.	Yogic practices	Duration
1	Prayer	3 minutes
2	Omkar recitation	3 minutes
3	Pranayama	5 minutes
4	• Asanas (SuryaNamaskar, Sukhasana, Bhujangasana, Pashimottanasana, Padmasana, Tadasana, Trikonasana, Sarvangasana, Ardhmatsyendrasana, Pawanmuktasana, Vajrasana, Dhanurasana)	30 minutes
	• Shavasana	5 minutes

[Table/Fig-2]: Schedule of yoga practices.

The subjects were encouraged to perform all exercises as accurately as possible. Each asana lasted 30-60 seconds and some of them were repeated multiple times during a session. Subjects relaxed at the end of each yoga session, with 5 minutes of Shavasana.

STATISTICAL ANALYSIS

Mean and standard deviations were calculated for each parameter. The appropriate tool for comparison for the change in the level of a variable was student's paired t-test for intragroup comparison before applying this test the Smirnov-Kolmogorov test was conducted to confirm the normality of each parameter. For all the variables normality was confirmed. The level of significance was taken at 5%. Tables were constructed to show mean and standard deviation for the various parameters. Inference of significance was drawn on the value of p. Apart from comparing the various parameters of the data with respect to before and after yoga, comparison was made with respect to a control group. There are 125 persons in both group. To show that initially the two groups are on the same platform for each parameter, student's unpaired t-test was conducted for intergroup comparison. If the value of 'p' was

more than 5%, for any parameter, that shows there is no significant difference between the two groups.

RESULTS

All the parameters of the data were quantitative variables. The main purpose of the study was to compare the levels of these parameters before initiating integrated approach of yoga therapy and after six months of practicing International Association of Yoga Therapists (IAYT). Apart from comparing the various parameters of the data with respect to before and after yoga, comparison were made with respect to a control group. There were 51 prediabetics subjects in both the groups.

The [Table/Fig-3] shows the age and gender distribution in different age groups. Majority of subjects between age group 41-50 years and females.

Age group	Male	Female	Total
31-40 years	35	65	100
41-50 years	50	100	150
Total	85	165	250

[Table/Fig-3]: Age and gender distribution of the study population.

The [Table/Fig-4] shows the baseline parameter BMI, waist hip ratio, systolic and diastolic blood pressure and pulse rate were statistically significant in yoga group as compared to control group.

S. No.	Baseline parameters	Control pre	Control post	p-value	Study baseline	Study six months	p-value
1.	BMI (kg/m^2)	28.6±3	28.7±4	NS	27.8±7	26.8±3	<0.01
2.	Waist hip ratio	90±6	92±7	NS	91±7	85±4	<0.001
3.	Blood pressure SBP (mmHg)	152±8.3	151±7.4	NS	154±8.4	130.7±10.1	<0.002
	DBP (mmHg)	90.8±4.2	90.5±4.3	NS	92.8±4.2	86.3±3.9	<0.001
4.	Pulse rate (beats per minute)	90.2±9.8	90.1±8.8	NS	89.2±9.7	82±8.6	<0.001

[Table/Fig-4]: Baseline parameters in control and study groups.
Paired t-test; p-value <0.05 considered significant

[Table/Fig-5] shows mean values of blood glucose, lipid profile, glycated haemoglobin for control and study groups. Results of blood glucose was highly significant (p-value <0.0001), Glycated haemoglobin (p-value <0.01) and lipid profile Cholesterol (p-value <0.01) and Triglyceride (p-value <0.01), LDL (p-value <0.01), HDL and VLDL and CIMT are significant (p-value <0.05) in study groups as compared to control group.

Yoga intervention resulted in a significant decline in blood glucose (p<0.001), Glycated haemoglobin (p<0.01), lipid profile Cholesterol (p<0.01), Triglyceride (p<0.01), LDL (p<0.01), HDL (p-value >0.05) and VLDL (p-value >0.05), CIMT (p-value <0.05) relative to the control group.

DISCUSSION

The effect of yogic practices on the management of prediabetes has not been investigated well. The aim of this study was to assess the effect of integrated approach of yoga therapy on metabolic profile and CIMT progression over six months. Yoga intervention resulted in a significant decline in blood glucose, glycated haemoglobin, lipid profile Cholesterol, Triglyceride, CIMT, LDL but HDL and VLDL showed non-significant relative to the control groups.

The Diabetes Prevention Program Research Group has published several studies showing that Type 2 diabetes may be preventable by diet and Lifestyle Modification (LSM) [25-27]. LSM is the most effective, low cost and safer approach. LSM is from a pragmatic perspective, considered to be the primary line of intervention prior

S. No.	Parameters	Groups	Biochemical parameters		p-value
			Mean±SD (before yoga)	Mean±SD (after yoga)	
1.	Blood glucose (mg/dL)	Control	116.67±4.37	117.8±4.87	0.844
		Study	116.87±4.57	108.75±5.51	<0.0001
2.	Glycated haemoglobin (Percentage)	Control	6.41±.86	6.47±.90	0.325
		Study	6.42±.86	5.67±.40	<0.01
3.	**Lipid profile**				
	TG (mg/dL)	Control	132.35±7.39	133.36±8.20	0.875
		Study	133.36±7.52	126.78±8.10	<0.01
	Cholesterol (mg/dL)	Control	187.92±26.47	188.94±26.98	0.896
		Study	186.92±26.42	179.78±24.98	<0.01
	HDL (mg/dL)	Control	44.86±3.22	43.28±2.45	0.136
		Study	44.88±3.22	45.28±2.35	0.08
	LDL (mg/dL)	Control	116.59±4.51	118.99±4.6	0.744
		Study	115.36±4.52	108.14±4.2	<0.01
	VLDL (mg/dL)	Control	26.47±1.478	26.67±1.64	0.145
		Study	26.67±1.504	26.3±1.62	0.06
	CIMT (mm)	Control	0.70±.07	0.70±.05	0.22
		Study	0.71±.05	0.69±.073	<0.05

[Table/Fig-5]: Intragroup comparison of results of biochemical parameters and Carotid Intima Media Thickness (CIMT).
*p-value<0.05 significant; Unpaired t-test applied; TG: Triglyceride; HDL: High density lipoprotein; LDL: Low density lipoprotein; VLDL: Very low density lipoprotein; CIMT: Carotid intima media thickness

to any pharmacological therapy for preventing the progression of diabetes in high risk individuals [28-30].

In present study postintervention decrease in blood glucose levels were observed in the study group (116.87±4.57 mg/dL to 108.75±5.51 mg/dL; p-value <0.0001) when compared to control group (116.67 mg/dL ±4.37 to 117.8±4.87 mg/dL; p-value 0.844) [Table/Fig-5]. Sinha AK et al., reported in a yoga intervention study conducted on coronary artery disease subjects, over a period of six months observed that post yoga their was significant reduction in fasting blood glucose levels in study group (97.2±11.0 g/dL to 91.9±5.5 g/dL, p-value <0.001), results were similar to present study [31].

Hegde SV et al., studied effect of three months yoga intervention on type 2 diabetic subjects and observed that post yoga there was significant reduction in plasma glucose levels in yoga group (8.1±2.6 to 7.3±2.3, p-value <0.001) mmol/L when compared to control group (8.6±3.1 to 9±3; p-value <0.001), similar to present study [32].

Malhotra V et al., observed a study on non-insulin dependent diabetic subjects in which diabetic subjects enrolled in study practised 40 days yoga asanas protocol under the direction of a yoga instructor [33]. In this yoga protocol 13 specific yoga asanas were included i.e., surya namaskar, padmasana bhujangasana, vajrasana, dhanurasana and trikonasana, tadasana, sukhasana, pashimottanasana, ardhmatsyendrasana, pawanmuktasana shavasana and breathing practices (*pranayam*). Fasting blood glucose levels were observed at baseline and after 40 days of yoga practice. Post significant lessen was observed in fasting blood glucose levels from (208±20.0 to 172±19.5; p-value <0.001) mg/dL, similar to present study [33].

Vaishali K et al., reported in a yoga intervention study conducted on type 2 diabetes subjects conducted over a period of three months and observed that post yoga there was significant reduction in blood glucose levels in study "group" (163.45±14.8 to 115.62±13.7; p-value<0.001) when compared to control group (154.86±16.40 to 144.06±22.58; p-value <0.05) [34].

A significant decrease in the glycated haemoglobin (p≤0.01) has been observed in the present study in study as compared to the control group. Decrease in glycosylated haemoglobin in the yoga group was

in accordance with the earlier study reported by Malhotra V et al., [33]. A significant improvement in glycosylated haemoglobin level, fasting glucose level, and serum lipid profile in yoga group compared to educational group has been reported by Vaishali K et al., [34].

The decrease in lipid profile observed in this study was in agreement with the previous studies [35,36]. The improvement in the lipid profile after yoga could be due to increased hepatic lipase and lipoprotein lipase at cellular level, which affects the metabolism of lipoprotein and thus increase uptake of triglycerides by adipose tissues [37,38]. An 8-week, randomised controlled trial of yoga for prediabetes reported that yoga group had significant improvements in weight and waist circumference, cholesterol and blood pressure improved glucose control on the Oral Glucose Tolerance Test (OGTT) and decreased insulin resistance [39].

Manjunatha S et al., studied the effect of four sets of asanas in random order for five consecutive days and observed that the performance of asanas led to increased sensitivity of B-cells of the pancreas to the glucose signal [40]. They proposed that this increased sensitivity is likely to be a sustained change resulting from a progressive long term effect of asanas. The mechanism of the anti-glycaemic activity of yoga exercise has yet to be described. A mechanism of neurohormonal modulation involving insulin and glucagon activity remains a possibility.

In this present study, CIMT significantly decreased after six months yoga intervention which was similar with previous studies [41,42]. Lipid improvement is an important factor, as the extent of CIMT change has been significantly related to atherosclerotic changes in pharmacologic studies [43]. There is potential for LSM to have a favourable impact on Cardiovascular (CV) morbidity and mortality. A recent review suggests that about a 40% reduction in CV mortality is expected in CAD patients who practice a healthy lifestyle [44]. In the health professional's follow-up study, men who adopted ≥2 lifestyle practices over 16 years had a 27% lower risk of CAD and 62% of their CV events might have been prevented with the best adherence to recommended lifestyle practices [45]. The Rotterdam study, cardiovascular health study and the atherosclerosis risk in communities study demonstrated 1.3-1.7 fold higher risk of myocardial infarction for approximately each 0.2-mm CIMT increase [44]. Large scale epidemiologic studies have found a significant association between CIMT progression and CV events [19,45]. In carotid atherosclerosis progression study, each 0.16-mm CIMT increase was significantly predictive of a 1.45-fold higher incidence of myocardial infarction, stroke, or death [46]. Thus, the reduction of CIMT among subjects achieving the greatest number of CV health measures in present study supports the potential of lifestyle intervention to reduce future CV morbidity and mortality.

In present study, among prediabetics with elevated fasting blood glucose, participation in a 24 week yoga intervention was feasible and resulted in greater weight loss and reduction in waist circumference, metabolic profile and CIMT when compared to a control. Yoga offers a promising lifestyle intervention for decreasing type 2 diabetes risk factors and potentially increasing psychological well-being. The feedback of most of the participants enrolled in present study and performing yoga asanas reported a feeling of well-being, more relaxed and satisfied, and a sense of relief from anxiety and stress. They were more alert and active which could be due to release of opiods and altered neuroendocrine adrenocortical activity. Yoga-asanas with its change in posture and controlled breathing in pranayama influences mental status of an individual allaying apprehension, stress and brings about feelings of well-being, and neuroendocrine balance [47].

Limitation(s)

The findings of this study need to be explored in larger sample size involving prediabetics. Larger clinical trials of lifestyle interventions that assess metabolic profile and CIMT as an endpoint are needed to provide convincing evidence in this regard.

CONCLUSION(S)

The study clearly indicates that yoga is a potential intervention strategically targeting prediabetics, prevent progression of prediabetes to diabetes and diabetic complications like retinopathy, neuropathy, nephropathy, microangiopathy. It is a low-cost, easily accessible lifestyle management program which holds promise as an approach to reducing cardiometabolic risk factors and increasing exercise self-efficacy for prediabetics performing yoga. A six months intensive LSM intervention in prediabetics improved glycaemic control, lipid profile and decreased progression of CIMT.

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