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Effectiveness Of Yoga Versus Exercise on Lipid Profile, BMI, And Blood Pressure Among Patients with Type II Diabetes Mellitus – A Community Based Randomised Control Trial

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ABSTRACT

Context/Background: Lifestyle interventions have proven to reduce the incidence of type 2 diabetes mellitus and prevent the complications. Yoga is considered safe, simple to learn, and can be practiced even by ill, obese, elderly, or disabled persons at home. The present study was conducted to assess the effect of one year of yoga therapy on lipid profile, BMI, and blood pressure in subjects with type 2 diabetes mellitus.

Methodology: This randomized controlled trial was conducted in an Urban Health center, Belagavi from July 2018 to December 2019. Around 120 participants diagnosed with type 2 diabetes mellitus were randomized into "Yoga" and "Exercise" groups. Fasting lipid profile, BMI, and blood pressure were examined at baseline, six months, and after one year of intervention.

Results: GEE model analysis showed that there were significant effects of Intervention × Time on Cholesterol (p=0.001), LDL (p=0.006) and VLDL (p=0.000). It was identified that the exercise intervention was found to decrease cholesterol and TG significantly more than the yoga group. Also, there was a significant reduction in BMI in both the exercise and yoga groups at the end of six months and one year (p=0.247).

Conclusions: Yoga can be a complementary therapy for type 2 diabetes, along with medications and exercise.

Keywords: Diabetes mellitus, yoga, lipid profile, exercise, randomised control trial

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic progressive metabolic disease characterized by persistent hyperglycemia. The key risk factors for the development of T2DM include increasing rates of urbanization, sedentary lifestyle, psychological stress, and unhealthy diet.[1, 2] World Health Organization estimated that 425 million adults have diabetes in 2014, accounting for a global prevalence of 8.5% in the adult population.[3] According to International Diabetes Federation (IDF), the prevalence of diabetes may reach 700 million by 2045[4]. As per 2019 estimates, 77 million individuals (8.9%) had diabetes in India.[5] T2DM is the leading cause of death and disability, and it significantly increases the risk of microvascular and macrovascular complications.[6]

Apart from medications, lifestyle modifications like dietary changes and regular physical activity are required for the proper management of the disease. Adults with diabetes should involve themselves with at least 150 minutes of moderate to vigorous physical activity weekly, spread over three days/week,

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with not more than two consecutive days without activity.[7] However, most people fail to engage in physical activity due to time constraints, lack of exercise venues, and lack of awareness and knowledge.[8]

Yoga originated in India 4000 years ago and has improved emotional, physical, and spiritual wellbeing.[9-13]Asanas, pranayama, and meditation are the important components of yoga. Though the effect of yoga on long-term endpoints like HbA1c and prevention of diabetes-related complications are unclear and inconclusive, several studies have shown that yoga improves glycemic outcome, cholesterol, oxidative stress, blood pressure, BMI, and waist to hip ratio.[14] Thind et al.[15] in a meta-analysis, reported that participants with type 2 DM practicing yoga had significant improvement in lipid profile, blood pressure, and BMI. In a recent study[16] conducted in South India on 300 individuals with type 2 DM, it was identified that there was a significant reduction in BMI and lipid levels in the yoga group compared to the non-yoga group. Though there are adequate studies conducted in India to evaluate the effect of yoga on lipid parameters, BMI, and blood pressure, most of the studies have limited sample size and have not followed proper randomization methods. Hence, the present study was randomized to compare the effectiveness of yoga versus exercise therapy on lipid parameters, BMI, and blood pressure in patients with T2DM in the Indian settings. The results drawn from the study may likely have implications in the better management of T2DM and can provide new avenues in complementary therapies.

METHODOLOGY

The present study was a randomized controlled trial conducted in an Urban Health Centre in Belagavi. Study participants were recruited from the diabetic register maintained at the Urban Health Center, Belagavi. All potentially eligible participants were informed about the study and screened for eligibility.

The patients eligible as per the inclusion criteria were enrolled at the time of data collection from the OPD of Urban Health centre. The sample size was calculated by the below mentioned formula

$$N = \{(Z_{1-\beta} + Z_{1-\alpha})^2 (SD_1^2 + SD_1^2)\}/(\bar{x}_1 - \bar{x}_2)^2$$

Where, Z_1-α = at 95%, Confidence Interval = 1.96, $Z_{1-\beta}$ = at 80 %, Power of the test = 0.84, Mean and SD for exercise and yoga intervention groups were taken as: 0.59 and 3.34[12-13], X1-X2 = Expected impact size, $n = (0.84 + 1.96)^2 (0.59^2 + 3.34^2) / (9.0 - 7.29)^2 = 57$. Accounting for drop out cases as 10%, then the calculated sample size was = 63 in each group. Participants were randomly divided into exercise and yoga Intervention Groups by computer generated, randomized number sequence method. Inclusion criteria were age between 30- and 60-years old adults with T2DM diagnosed as diabetic for over a year with HbA1c concentrations of 6.5% or greater who were permanent residents of urban field practice area. Diabetic patients with cardiovascular complications, stroke, and cellulitis were excluded from the study as this can interfere with the physical activities of the patients. Participants who had impairment of speech, hearing, vision, or cognition and patients on insulin & pregnant women were also excluded. The details of the recruitment and workflow are depicted in CONSORT flow diagram (Figure 1).

Data Collection: During the first visit, socio- demographic details, medication, medical history, any associated health problem and duration of diabetes were obtained by interviewing the participants. All study subjects were given health education regarding diet and the importance of treatment adherence. Baseline investigations like fasting lipid profile, BMI, and blood pressure were done at the beginning of the study, after six months, and at the end of one year. The patients were divided randomly into two groups by computer generated, randomized number sequence method.

Yoga Interventional Group: Sixty study participants were there in this group. Participants were on dietary control, an anti-diabetic drug, and yoga therapy. For the first two months, intensive yoga teaching sessions were conducted by the yoga teacher. Yoga classes composed of asanas (physical poses), pranayama (breathing exercises), relaxation, and meditation Exercises. Classes were taught by a qualified registered yoga teacher (RYT) and were in the Urban health centre area. The duration and frequency of classes were approximately 50-60 minutes, three days per week. For the next four months, participants continued yoga under the observation of a recognized family member. After six months and at the end of one year, baseline investigations were repeated. Yoga was taught by qualified research yoga teacher thrice a week for first two months later study participants were encouraged to repeat the same yoga asanas at their home. One person in the family was identified and was given a checklist to monitor whether participant is regularly doing asanas. Research staff Nurse was hired to coordinate and do the follow up of study participants. Health education and counselling on nutritional aspects was given by the dietician and the importance of adherence to proper diet and treatment was monitored. Glucose tablets (Glucoenergy, Gluconorm) was kept available during yoga classes as a preventive measure for the unlikely occurrence of a hypoglycemic event. Four of these glucose tablets provide 15 grams of carbohydrate as suggested by the ADA to offset a sudden drop in circulating plasma glucose**.**

Exercise Interventional Group: Sixty study participants were there in this group. Participants were on dietary control, anti-diabetic drug, and exercise. The unstructured activity was defined as an intervention in which participants were not engaged in supervised exercise training but received advice to increase the "physical activity" which refers to any bodily movement produced by skeletal muscles that

results in an expenditure of energy and includes a walk for 45 min/day. One person in the family was identified and was given a checklist to monitor whether the participant is regularly doing exercise. Research Medico social workers coordinated and followed up the study participants. Although hypoglycemia is uncommon during exercise in individuals who are not treated with insulin, such as the participants of this study, caution was always implemented.

Biochemical Analysis: For the estimation of biochemical parameters like fasting lipid profile about 5 ml of blood was drawn and analyzed by phlebotomist of Sisco Research Laboratories (SRL) of Belagavi at Urban health centre. Serum total cholesterol was determined by an enzymatic (CHOD-PAP) colorimetric method and Triglycerides were determined by an enzymatic (GPO-PAP) method. HDL-Cholesterol was estimated by a precipitant method and LDL-Cholesterol and VLDL- Cholesterol will be calculated by using Friedewald's formula as has been shown below: LDL-C = TC - HDL-C – (TG/5), VLDL= TG/5.[17] Anthropometric measurements were also obtained (i.e., height, weight, waist circumference) by trained researcher. The waist circumference (WC) was reported in centimetres. The BMI was obtained by using the formula (weight in kg/height (meter)^2. Baseline investigations like fasting lipid profile, BMI, and blood pressure were done at the beginning of the study, after six months, and at the end of one year.

Ethical consideration: Prior approval was taken from the institutional ethics committee (ref no. KLEU/EC/17-18/D-102; Dated 5/6/2017.). Informed written consent was obtained from the participants before initiating the data collection process. Anonymity and confidentiality of information were maintained and informed about their freedom of choice.

Statistical analysis: As the data violated the normality and homogeneity of variance assumptions, Generalized Estimating Equations (GEE) models were performed instead of mixed-model ANOVA. GEE models were performed on dependent variables (lipid profile variables, BMI, and blood pressure) to assess the differences between the two interventions groups over time. SPSS version 25.0 was used for calculations.

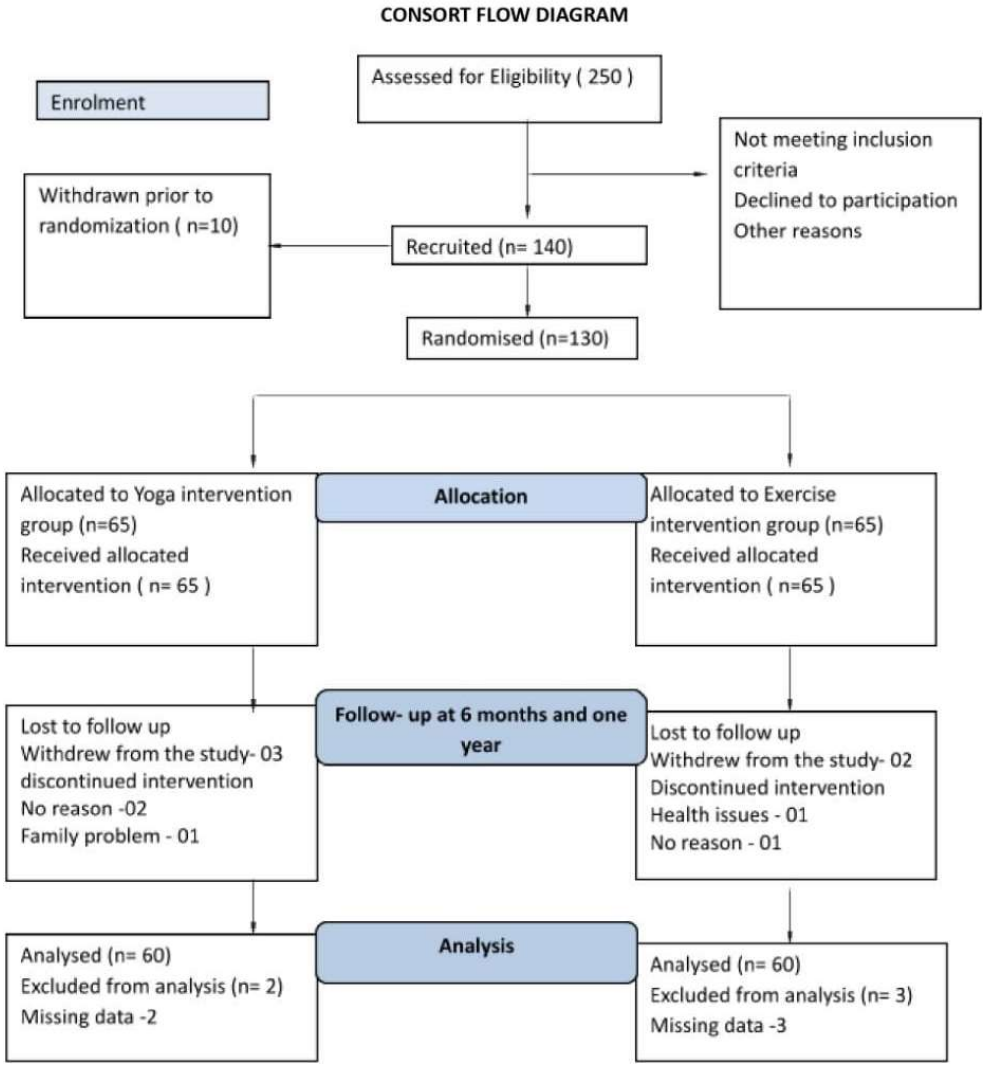

Figure 1: CONSORT flow diagram of participants' allocation, intervention, dropouts, follow-up, and analysis

RESULTS

The background characteristics of study participants between the exercise group and yoga group were compared. There was no statistically significant association between the intervention group and any of the given socio-demographic variables (p>0.05) suggesting a good randomization. Female participants were slightly more than the male participants in the exercise group (57.3%) compared to yoga intervention group (42.7%). Hindus were marginally more than Muslims in this study as participants. In our study, most of the study participants had 5-9 years of duration as diabetics (45.5% in the exercise intervention and 54.5% in the yoga intervention). Most study participants belonged to class III socioeconomic status according to Modified B.G. Prasad classification (Table1).[18]

GEE model analysis showed that there were significant effects of Intervention × Time on Cholesterol (p=0.001), LDL (p=0.006) and VLDL (p=0.000). Although Cholesterol and LDL were significantly reduced in both groups over time, exercise intervention was found to decrease cholesterol and TG significantly more than the yoga group. The exercise intervention was found to decrease VLDL over the time significantly, but there was no significant difference in VLDL over time in the yoga intervention group.

There were no significant effects of Intervention × Time on TG (p=0.682) and HDL (p=0.252). However, there was a significant increase of HDL in both the groups after 6 months and 12 months compared to baseline. There was a significant decrease of TG in the exercise group after six months and 12 months as compared to baseline, and in yoga group, there was a significant decrease in TG only after six months compared to baseline (Table 2).

Table 1: Age and gender of the study population (N=120)

Background characteristics	Study Groups		P-value
	Exercise (N=60)(%)	Yoga (N=60) (%)	
Age group			
28 to 56	32 (53.3)	28 (46.7)	0.584
57 to 83	28 (46.7)	32 (53.3)	
Sex			
Female	43 (57.3)	32 (42.7)	0.06
Male	17 (37.8)	28 (62.2)	
Socioeconomic Status			
I	3 (75)	1 (25)	0.527
II	15 (41.7)	21 (58.3)	
III	38 (52.8)	34 (47.2)	
IV	4 (50)	4 (50)	
Duration of DM			
1 to 4 years	35 (53.8)	30 (46.2)	0.464
5 or more years	25 (45.5)	30 (54.5)	
No of days practiced			
142 -159 days	29 (61.7)	18 (38.3)	0.061
160-171 days	31 (42.5)	42 (57.5)	

Table 2: Comparison of lipid profile between exercise group and yoga group at different point of time

Variable	Intervention		P-value* for Interaction	P-value* for Baseline characters
	Exercise (Mean ± SD)	Yoga (Mean ± SD)		
Cholesterol				
Baseline	206.07±32	192.6±47.88	0.001*	0.073
6 months	176.97±21.6**	178.37±30.69**		
12 months	166.33±18.76**	169.72±22.88**		
TG				
Baseline	192.23±65.24	189.2±101.54	0.682	0.459
6 months	154.43±27.04**	150.8±44.85**		
12 months	150.98±23.53**	161.87±131.49		
HDL				
Baseline	59.17±15.35	46.03±12.96	0.252	<0.001 ***
6 months	63.85±15.65**	53.05±12.26**		
12 months	65.78±18.1**	55.3±13.18**		
LDL				
Baseline	116.78±34.46	111.28±27.05	0.006*	0.333
6 months	97.12±30.25**	100.33±25.69**		
12 months	93.07±28.32**	98.87±24.17**		
VLDL				
Baseline	39.82±14.91	34.49±15.17	0.000*	0.055
6 months	34.22±11.84**	34.17±12.76		
12 months	33.89±10.71**	33.84±12.07		

P-value* is for interaction effect between Intervention and Time
**Denotes significant difference between baseline and follow-up time (6 months & 12 months)

Table 3: Comparison of BMI between exercise group and yoga group at different point of time

BMI	Intervention		P-value* for Interaction	P-value* For Baseline characters
	Exercise (Mean ± SD)	Yoga (Mean ± SD)		
Baseline	25.87±3.03	26.94±4.96	0.247	0.155
6 months	24.93±2.8**	26.24±4.34**		
12 months	24.59±2.78**	25.79±4.05**		

Table 4: Comparison of blood pressure between exercise group and yoga group at different point of time

Variable	Intervention		P-value* for Interaction	P-value* For Baseline characters
	Exercise	Yoga		
Systolic blood pressure (SBP)				
Baseline	146.47±14.59	131.95±17.57	**0.001***	**0.001*****
6 months	143±9.97*	134.43±12.53**		
12 months	143.57±10.66	138±11.92**		
Diastolic blood pressure (DBP)				
Baseline	80.33±15.1	77.8±12.49	0.671	**0.002****
6 months	81.6±2.82	80.3±4.13		
12 months	82.23±3.74	81.47±4.55**		

P-value* is for interaction effect between Intervention and Time
** denotes significant difference between baseline and follow-up time (6 months & 12 months)

There was no significant effect of Intervention × Time on BMI (p=0.247). However, there was a significant decrease in BMI in both the groups after 6 months and 12 months compared to baseline (Table 3). There was a significant effect of Intervention × Time on Systolic blood pressure (p=0.001). SBP significantly increased over time in the yoga group, whereas in the exercise group, SBP significantly decreased only after six months compared to baseline. There was no significant effect of Intervention × Time on Diastolic blood pressure (p=0.671). However, there was a significant increase in DBP in the yoga group after 12 months as compared to baseline (Table 4). To summarise the post-hoc analysis of 120 Type II DM patient's data inferred that Yoga and exercise have shown statistically significant (p-value <0.05) effect on reducing lipid profile variables (except VLDL), Blood pressure and BMI values from baseline to 6 months and 12 months duration. No statistically significant difference (*p-value*>0.05) was observed when the yoga group was compared with the exercise group on the above parameters. When GEE test was carried out, the simple effects for difference in baseline Biochemical parameters both groups statistically significant difference was found for HDL, SBP and DBP with P <0.001 ***, P < 0.001*** and P=0.002** respectively and these values were mentioned in the respective tables.

DISCUSSION

According to the International Diabetes Federation (IDF), the top five countries with the highest number of diabetic patients include China, India, United States, Russia, and Brazil.[19] Diabetes caused 4.2 million deaths, and 374 million people are at increased risk of developing T2DM.[4]

Lifestyle modifications are vital for the prevention and management of T2DM. Most adults find it difficult to adhere to the recommended levels of physical activity.[20] Yoga is an ancient psychological, physical, and spiritual exercise regimen that can be practiced even by an ill, elderly groups of patients. [11-13] Several studies documented that yoga significantly reduced the glycaemic outcome, lipid parameters, BMI, and blood pressure.[15]

In the current study, 120 patients were randomised into exercise and yoga groups. The exercise intervention was found to significantly reduce the levels of cholesterol, TG, and VLDL. There was a significant increase in the levels of HDL in both the exercise and yoga intervention groups. There was a significant decrease in BMI in both the groups after 6 and 12 months of intervention. This significant decrease in BMI as seen in this study were in line with the study done by Telles S et al, wherein, yoga intervention led to decreased body mass index (BMI), waist and hip circumference, fat- free mass, total cholesterol, high-density lipoprotein and fasting serum leptin levels.[21]

There was a significant decrease in systolic and diastolic blood pressure after 6 and 12 months of yoga intervention, respectively. Similar to our study, Sreedevi et al.[22], in an open-label randomized controlled trial involving 124 women with diabetes, identified a significant decrease in 3 mmHg diastolic blood pressure and a decline in 6 mmHg systolic blood pressure in the yoga group. Dutta et al.[23], in a meta-analysis involving 13 studies, identified that individuals doing yoga had significantly lower triglycerides and LDL-C and higher levels of HDL-C. Also, in a recent study, HDL cholesterol was significantly higher in the "yoga training" group than the "resistant training" group. People practicing the highest levels of vigorous physical activity had the lowest levels of LDL cholesterol.[24] The improvement in the lipid profile after practice of yoga could be due to increased hepatic lipase and lipoprotein lipase at cellular level, which influence the metabolism of lipoprotein and thus increases uptake of TG by adipose tissues.

Further studies are warranted to clarify the role of yoga in reducing the lipid profile, BMI, and blood pressure in patients with T2DM. The present study has few limitations. Since this study is for one year and most of the yoga practice and exercise was unsupervised and adherence was mainly based on study participants reporting. The longer time follow-up of patients and the close monitoring of the patients during the study remained as the challenges of this community-based RCT. Large multicentre trials with improved methodology are needed for further research

CONCLUSION

Yoga is as effective as exercise, hence people with morbidities or who are unable to go for exercise can practice yoga at home which will help them for proper control of their lipid profile, BMI, and Blood pressure.

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APPENDIX

First two months intensive Yoga teaching sessions was conducted by research yoga teacher. For the next four months the participants were told to continue yoga under the observation of a recognized family member. After six months and at the end of one year baseline investigations were repeated.

Every month when patient used to come to urban health centre for collection of his anti-diabetic drugs, random blood sugar level was checked. Cross verification of participant family member checklist was done and health education and counselling on nutritional aspects was given on the importance of adherence to proper diet and treatment.

The yoga intervention consisted of hatha yoga classes composed of asanas (physical poses), pranayama (breathing exercises), relaxation, and meditation exercises. Classes were taught by a qualified registered yoga teacher (RYT) and were held in the Urban health centre. The duration and frequency of classes were approximately 50-60 minutes, three days per

week. Because all participants may be previously sedentary, overweight, and above the age of 50 years, all poses were modified to accommodate limited levels of flexibility, balance, and strength. Props such as chairs, belts or blankets will be used for such modifications to allow for appropriate alignment, technique, and balance and specially to provide participants the opportunity to obtain full benefit from the asanas within their limitations. During each class, participants was instructed to center their attention on their breathing throughout the practice session and to increase the awareness of their body position in each pose. The closure of each session consists of a relaxation exercise in which participants was asked to scan their entire body to locate any tension still present in their muscles and to relax those specific muscles with every exhalation emphasizing focus on the natural pattern of breathing and its sound.

Yoga was taught by qualified research yoga teacher thrice a week for first two months and later study participants were encouraged to repeat the same yoga asanas at their home. One person in the family is identified and was given a checklist to monitor whether participant is regularly doing asanas. Research staff Nurse use to coordinate and had done the follow up of study participants.

Handouts with yoga poses and meditation exercises was provided approximately every 2 weeks so that participants will continue practice at home and even after the end of the intervention.

Finally, although hypoglycaemia is uncommon during exercise in individuals who are not treated with insulin (ADA, 2016), such as the participants of this study, caution was always implemented. In addition, glucose tablets (Glucoenergy, Gluconorm) were kept available during yoga classes as a preventive measure for the unlikely occurrence of a hypoglycaemic event. Four of these glucose tablets provide 15 grams of carbohydrate as suggested by the ADA to offset a sudden drop in circulating plasma glucose (ADA, 2016).