

Effectiveness of Yoga-based Exercise Program Compared to Usual Care, in Improving HbA1c in Individuals with Type 2 Diabetes: A Randomized Control Trial

Abstract

Background: This study was designed to evaluate the effectiveness of a yoga-based exercise program (YBEP) in improving glycemic control in people with type 2 diabetes mellitus. **Materials and Methods:** Patients on stable oral glucose-lowering agents for at least 3 months and HbA1c 7.5%–10% were randomized in 1:1 ratio. The primary outcome measure was the difference of change in mean HbA1c between groups. **Results:** The participants ($n = 81$) had mean (\pm standard deviation) age of 50.6 (± 8.5) years and HbA1c of $8.5 \pm 0.7\%$ (68.97 ± 7.42 mmol/mol). The follow-up data were available in 96% (78/81) of participants. Of 40 participants, 25 (62.5%) attended $\geq 75\%$ (≥ 10 out of 13) of the sessions in YBEP. On the intention to treat analysis, a favorable reduction (0.21% 95% confidence interval $[-0.34, 0.75]$, $P = 0.454$) in HbA1c was seen in YBEP group as compared to usual care. The reduction in HbA1c by $\geq 0.5\%$ was observed in 44.7% of participants in YBEP as compared to 37.5% in usual care arm, respectively. Those who attended $\geq 75\%$ of the sessions had better HbA1c reduction of 0.3% in comparison to 0.1% reduction seen in those who attended $< 75\%$ of the sessions. **Conclusions:** YBEP demonstrated a clinically relevant HbA1c reduction compared to usual care in participants who had attended at least 75% of the yoga sessions. The reduction in HbA1c by $> 0.5\%$ in 44.7% in the yoga group, suggests, that it can be prescribed as an exercise to individuals who are unable to walk either due to limited joint mobility, adverse weather conditions, lack of space for walking, cultural or religious prohibitions for women for outdoor physical activity, and so on.

CTRI registration no: CTRI/2017/05/008564.

Keywords: Asia, diabetes, exercise, India, yoga

Introduction

Type 2 diabetes mellitus (T2DM) has become a major health burden, globally. India has nearly 73 million people affected with diabetes, and by 2045 the numbers are projected to increase to 134 million, which would make it a nation with the highest number globally.^[1] Medical nutrition therapy and physical exercise are essential pillars for the management of diabetes.^[2] However, adherence to these lifestyle measures has been sub-optimal in usual care for diabetes,^[3] resulting in poor glycemic control and a higher rate of diabetes-related morbidity and mortality.^[4]

To improve outcomes for individuals with diabetes, structured lifestyle intervention programs have been designed and evaluated in multiple regions, and shown to be effective

in improving glycemic and other metabolic parameters.^[5,6] However, in clinical practice, there are many people who are unable to incorporate physical activity (aerobic and resistance forms of exercise) regimen in their management plan for diabetes. The reasons may be due to limited joint mobility, adverse weather conditions, lack of space for walking, cultural or religious prohibitions for women for outdoor physical activity, and so on. Sohal *et al.*, systematically reviewed studies representing perspectives of South Asian people on the barriers and facilitators for diabetes management.^[7] South Asian individuals were concerned with the lack of gender-appropriate exercise facilities and fear of injury and the worsening of health with exercise. The key facilitator considered was the use of culturally appropriate exercises.

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For the above reasons, it becomes important to consider alternative forms of exercise (such as yoga), which can overcome some of the above-mentioned limitations, and are also culturally acceptable not only in South Asia but increasingly in other parts of the world. Yoga, an ancient discipline aimed at balancing and harmonizing the body, mind, and emotions,^[8] is recognized by the American Diabetes Association as one of the forms of exercise for people with diabetes.^[9] However, till date, yoga has been evaluated with rigorous training sections and supervision in most of the studies, which limits the potential of scalability. In this study, we evaluated the yoga program, designed and delivered in a manner that has the potential of scalability.

In our study, we aimed to evaluate the yoga-based exercise program (YBEP), in individuals with T2DM who had poor glycemic control. We also evaluated a video-based lifestyle education program as an additional arm in this randomized control trial (RCT). We used the same usual care group, against which each of the two-lifestyle intervention arms were compared. This design gave us benefit as a smaller number of participants (25% less) had to be recruited (using the same usual group) with potential savings in cost and time. In this manuscript, we present and discuss the results of Yoga-based lifestyle education program as compared to usual care. The results of video-based lifestyle education program have been published recently.^[10]

Materials and Methods

Settings and study design

This RCT was performed from June 2017 to October 2018 at the All India Institute of Medical Sciences (AIIMS), New Delhi, a tertiary care hospital in North India and was approved by the institutional ethics committee (IECPG-97/22.03.2017, RT-15/26.04.2017). Written informed consent was obtained from all participants. The trial registration number is CTRI/2017/05/008564.

Patient identification, recruitment, and procedure on the day of testing

Individuals with T2DM, diagnosed at ≥ 30 years of age, and those with HbA1c 7.5%–10% and on stable oral glucose-lowering agents for the past 3 months were eligible. Participants were advised to fast for at least 10 h and were evaluated for fasting plasma glucose, lipid profile, and HbA1c in the morning. Additional information such as demographics, relevant medical, and treatment history was collected. Weight, height, waist circumference, and blood pressure were recorded in the fasting state using standard methods.^[11,12]

Randomization, allocation concealment, and blinding

Patients were randomized in a 1:1 ratio using block randomization with varying block size, by computer generated random numbers. Allocation concealment was done by using sequentially numbered opaque sealed

envelopes. Since the intervention was apparent, the trial was open-labeled and nonblinded. However, an endpoint outcome assessment was done by a person who was unaware about the group of the patient to remove bias. The details of inclusion and exclusion criteria, biochemical measurements, and sample size calculations have been described in our previous publication.^[10]

Intervention and usual care details

Yoga based exercise program

An integrated module [details provided in Tables 1 and 2] was formulated using specific *asanas* (yoga postures), *kriyas* (cleansing practices), *pranayama* (breathing exercises), and meditation. Yoga sessions were conducted at the Centre for Integrative Medicine and Research, AIIMS. Yoga therapists in the Centre conducted the yoga sessions, which were supervised by yoga physician.

The participants in the usual care arm were prescribed dietary advice by a registered dietician and 30 min of walking at a speed of 5–6 km/h for at least 5 days a week.

Statistical analysis

Stata 12.0 (College Station, Texas, USA) was used for statistical analysis. Pearson Chi-square and student's *t*-test were used to comparing categorical and continuous baseline variables among the groups. The primary outcome measure was the difference of change in mean HbA1c between groups. Intention to treat analysis was done for the primary outcome. The difference of change in secondary outcomes in the two groups was assessed using per protocol analysis. The adjustment for baseline serum triglyceride and total cholesterol levels was made in the adjusted analysis as it was different at baseline between the two arms. The results are reported as a difference in changes between the two groups (95% confidence interval [CI]). Data are presented as number (%), mean \pm standard deviation (SD), or median (q_{25} – q_{75}) as appropriate. A value of $P < 0.025$ was considered statistically significant.

Results

Baseline characteristics

A total of 81 individuals were randomized, 41 participants in the usual care arm and 40 into YBEP arm. The participants ($n = 81$, women 44%) had mean (\pm SD) age of 50.6 (± 8.5) years, HbA1c $8.5 \pm 0.7\%$ (68.97 ± 7.42 mmol/mol), and BMI (\pm SD) 27.9 ± 4.7 kg/m². Family history of diabetes in first degree relatives was present in 69.1%, 42.0%, and 44.4% were on blood pressure and lipid-lowering medications, respectively. Twenty-seven individuals (33.3%) were taking > 2 oral glucose-lowering agents. The main difference among the two study groups was in serum triglycerides ($P = 0.041$) and cholesterol ($P = 0.025$), which was adjusted during the intention to treat and per protocol analysis [Table 3]. Among 81 participants, 1 from usual care arm and 2 from YBEP were

Table 1: Yoga teaching plan

Phase	Weeks/months	Training sessions in hospital
Training phase	First 2 weeks	3 classes/week
Supervision phase	Week 3 and 4	2 classes/week
		Supervisor has seen if the participants were doing yoga correctly or not
Query phase/re-supervision phase	Month 2, 3, 4 (First week of each month)	One class/month
		Supervisor has seen if the participants were doing yoga correctly or not and try to alleviate the queries

Table 2: Integrated yoga module

Step	Practice	Rounds	Duration (min)
1	Starting prayer		1
2	Breathing practices		
	Hands stretch breathing	10	2
	Hands in and out breathing	10	2
	Ankle stretch breathing	10	1
	Tiger breathing	5	1
	Straight leg raise breathing (both legs)	5	2
3	IRT		1
4	Loosening exercises		
	Slow jogging/drill walking	50	2
	Twisting	10	1
5	QRT		3
6	Yogasana standing		
	Ardhakati chakrasana		1
	Ardha chakrasana		1
	Vrikshasana		1
	Trikonasana		2
	Sitting		
	Vakrasana		1
	Ardha-matsyendrasana		1
7	DRT		7
8	Pranayama		
	Sectional breathing	12	3
	Nadisuddi pranayama	9	2
	Shitali/sitkari	9	2
	Bhramari		1
9	Meditation		
	Om meditation		7
	Total		45

IRT=Instant relaxation technique, QRT=Quick relaxation technique, DRT=Deep relaxation technique

lost to follow-up [Figure 1, consort diagram]. Adherence was defined as $\geq 75\%$ attendance to intervention (attending ≥ 10 out of 13 yoga sessions). Of 40 participants, 25 (62.5%) attended $\geq 75\%$ of the sessions in YBEP.

Effect on the primary outcome measure

On intention to treat analysis, there was favorable difference (0.21% 95% C. I. [-0.34, 0.75]; 2.24 mmol/mol 95% C. I. [-3.69, 8.18], $P = 0.454$) in HbA1c in YBEP as compared to usual care [Table 4]. On further analysis,

6 (15%) participants from usual care, 10 (26.3%) from YBEP had HbA1c reduction of $\geq 1\%$. The reduction in HbA1c by $\geq 0.5\%$ was observed in 44.7% participants in YBEP as compared to 37.5% in usual care arm. Those who were adherent had better HbA1c reduction of 0.3% in comparison to a 0.1% reduction in the nonadherent group.

Effect on secondary outcome parameters

There was no change in any of the secondary outcome parameters in YBEP as compared to usual care [Table 5].

Discussion

In this trial, we evaluated the effect of a YBEP delivered over 13 sessions in participants with T2DM having poor glycemic control. We found a favorable reduction in HbA1c in YBEP as compared to usual care.

Yoga-based exercise program led to a reduction (0.21% 95% C. I. [-0.34, 0.75]; 2.24 mmol/mol 95% C. I. [-3.69, 8.18], $P = 0.454$) in HbA1c as compared to usual care. The reduction in HbA1c by more than 0.5% was seen in 44.7% of participants which was 7% more than that observed in the usual care arm. Given that people had to learn a new form of exercise, which was a novel introduction to their lifestyle, this level of HbA1c reduction at 4 months can be taken as clinically relevant. Cui *et al.* (2016) in a meta-analysis of 12 RCTs showed a pooled weighted mean difference of -0.47% (95% CI -0.87 to -0.07; $P = 0.02$) for HbA1c in yoga participants.^[13] Subsequently, in a meta-analysis of 23 studies that evaluated different yoga components practiced over a median duration of 12 weeks, in comparison to the control group, yoga participants had a more favorable HbA1c reduction of 0.36% (95% CI = 0.16, 0.56; $P < 0.001$).^[14] Jayawardena *et al.* (2018), reported results of a meta-analysis on eight studies (40 days to 9 months), including 6 RCTs, evaluating benefits of yoga practice compared to physical exercise in the management of type 2 diabetes.^[15] Majority of studies had $>75\%$ attendance rate to yoga sessions. The HbA1c reduction observed was 0.39% (95% CI:-0.77, 0.00; $P = 0.05$) in yoga in comparison to control group. However, the results in their meta-analysis were driven by two trials, where yoga classes were nearly six times more as compared to yoga intervention in our study.^[16,17] In the RCT reported by Vaishali *et al.*, the average attendance rate was also

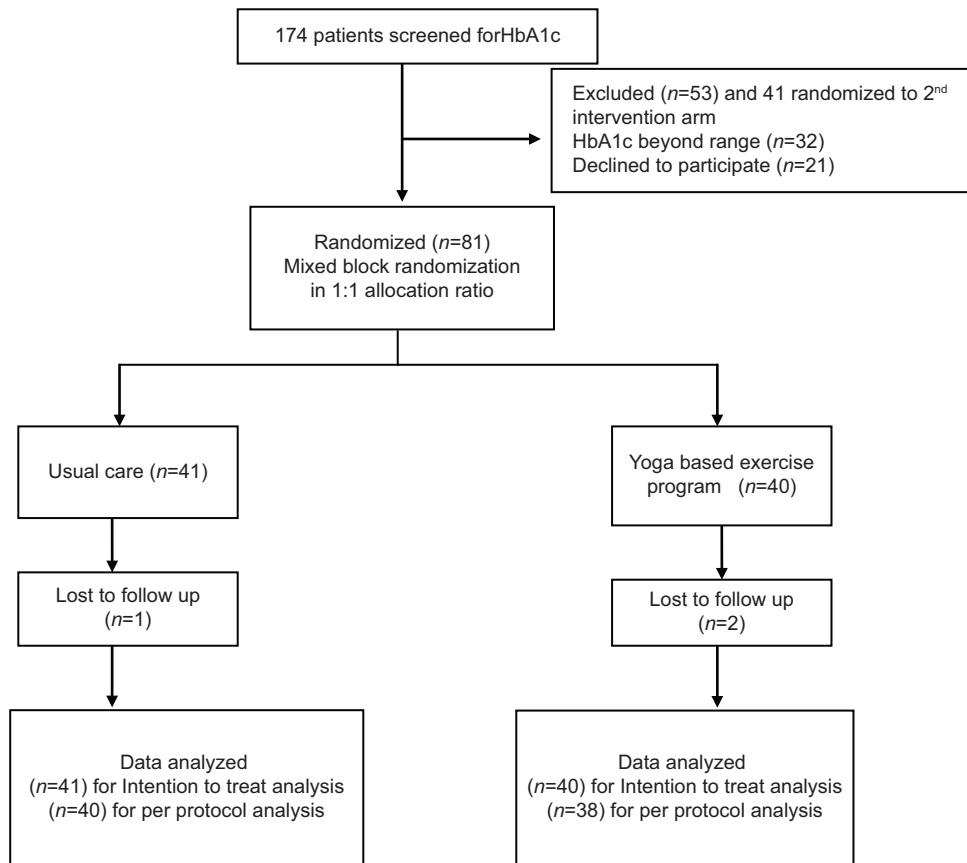


Figure 1: Flowchart showing patient recruitment and follow up

Table 3: Baseline characteristics of the participants

	Total (n=81)	Usual care (n=41)	YBEP (n=40)	P
Age (years)	50.6±8.5	50.2±8.6	51.1±8.6	0.636
Male (%)	45 (55.6)	24 (58.5)	21 (52.5)	0.585
Education, graduate and beyond (%)*	35 (43.2)	18 (43.9)	17 (42.5)	0.899
Employed (%)	40 (49.4)	21 (51.2)	19 (47.5)	0.738
Family h/o diabetes present (%)	56 (69.1)	26 (63.4)	30 (75.0)	0.259
Anti-hypertensive drug (s) (%)	34 (42.0)	15 (36.6)	19 (47.5)	0.320
Lipid lowering medication (%)	36 (44.4)	18 (43.9)	18 (45.0)	0.921
Number of participants with oral glucose lowering agents >2 (%)	27 (33.3)	11 (26.8)	16 (40.0)	0.209
Participants with diabetes related complication (s) (%)	25 (30.9)	12 (29.3)	13 (32.5)	0.753
HbA1c (%)	8.46±0.68	8.39±0.65	8.53±0.71	0.366
HbA1c (mmol/mol)	68.97±7.42	68.23±7.08	69.73±7.76	0.366
Weight (kg)	71.8±11.9	70.4±11.8	73.1±12.0	0.321
Body mass index (kg/m ²)	27.9±4.7	27.1±4.1	28.8±5.2	0.116
Waist circumference (cm)	98.9±9.1	98.2±8.7	99.5±9.7	0.548
Systolic blood pressure (mmHg)	130.7±18.0	130.5±18.7	130.9±17.4	0.914
Diastolic blood pressure (mmHg)	83.5±8.5	83.0±9.1	84.1±8.0	0.557
Fasting plasma glucose (mmol/L)	8.6±1.9	8.4±1.5	8.9±2.3	0.235
Total cholesterol (mmol/L)	4.5±1.0	4.3±1.0	4.8±1.0	0.025
Triglycerides (mmol/L)	1.6 (1.3-2.1)	1.5 (1.2-2.0)	1.8 (1.4-2.4)	0.041
LDL cholesterol (mmol/L)	2.5±0.8	2.4±0.7	2.7±0.8	0.171
HDL cholesterol (mmol/L)	1.1±0.3	1.1±0.3	1.1±0.2	0.544

*≥15 years of school/college/university education. Values expressed as n (%), mean±SD as appropriate. Triglycerides expressed as median (IQR). YBEP=Yoga based exercise program, LDL=Low density lipoprotein, HDL=High density lipoprotein, SD=Standard deviation, IQR=Interquartile range, HbA1c=Glycated haemoglobin

Table 4: Effect of intervention on HbA1c outcome (primary outcome) in YBEP vs usual care

	Usual care (n=41)	YBEP (n=40)	YBEP vs usual care Difference in difference (95% CI)	P
At baseline (%)	8.39±0.65	8.53±0.71		
After 4 months (%)	8.38 ± 1.37	8.31 ±1.32		
Difference (%)	0.01 ± 1.29	0.22 ±1.16	0.21 (-0.34,0.75) 0.23 (-0.34,0.81) ^a	0.454 0.424
At baseline (mmol/mol)	68.23±7.08	69.73±7.76		
After 4 months (mmol/mol)	68.10±14.96	67.36±14.41		
Difference (mmol/mol)	0.13±14.09	2.38±12.70	2.24 (-3.69,8.18) 2.55 (-3.76,8.86) ^a	0.454 0.424
PP analysis: (n=78) (n=40) (n=38)				
At baseline (%)	8.40±0.66	8.52±0.70		
After 4 months (%)	8.38 ± 1.39	8.29 ± 1.34		
Difference (%)	0.01±1.31	0.23±1.19	0.22 (-0.35,0.78) 0.24 (-0.36,0.84) ^a	0.448 0.427
At baseline (mmol/mol)	68.26±7.17	69.58±7.67		
After 4 months (mmol/mol)	68.12±15.15	67.08±14.60		
Difference (mmol/mol)	0.14±14.27	2.50±13.03	2.37 (-3.81,8.54) 2.63 (-3.92,9.17) ^a	0.448 0.427

YBEP: Yoga based exercise program, ^aAdjusted (for baseline triglyceride and cholesterol levels)

Table 5: Effect of intervention on secondary outcomes at 4 months

	Usual care (n=40)	YBEP (n=38)	YBEP versus usual care Difference in (95% CI)	P
HbA1c (%)	8.38±1.39	8.29±1.34	0.24 (-0.36-0.84)	0.427
Weight (kg)	70.0±11.7	72.4±12.2	-0.10 (-0.86-0.66)	0.795
Body mass index (kg/m ²)	27.0±4.0	28.6±5.4	0.01 (-0.32-0.33)	0.955
Waist circumference (cm)	97.9±8.4	98.7±9.4	0.30 (-1.57-2.18)	0.748
Systolic blood pressure (mmHg)	125.2±14.2	127.4±13.7	-1.21 (-9.05-6.63)	0.759
Diastolic blood pressure (mmHg)	80.6±7.6	84.2±8.8	-2.80 (-6.74-1.13)	0.160
FPG (mmol/L)	8.5±2.8	8.7±3.1	0.38 (-0.91-1.67)	0.557
Total cholesterol (mmol/L)	4.2±1.0	4.7±1.1	-0.11 (-0.47-0.25)	0.540
Triglycerides (mmol/L)	1.5 (1.1-2.0)	1.9 (1.3-2.5)		
LDL cholesterol (mmol/L)	2.4±0.8	2.7±0.9	-0.05 (-0.34-0.24)	0.713
HDL cholesterol (mmol/L)	1.0±0.3	1.1±0.3	-0.02 (-0.10-0.06)	0.577

Values adjusted for baseline triglyceride, total cholesterol levels observed at baseline. LDL=Low density lipoprotein, HDL=High density lipoprotein, CI=Confidence interval, YBEP=Yoga-based exercise program, HbA1c=Glycated haemoglobin, FPG=Fasting plasma glucose

81.3% to yoga sessions.^[17] Adherence to yoga sessions in our study was 62.5%. Those who were adherent had better HbA1c reduction of around 0.3% versus 0.1% reduction in nonadherent participants. It is possible that improving the attendance rate of training sessions, and supervision at home might increase the observed benefits of YBEP. However, this will also limit the potential for scalability. Furthermore, yoga, as such, is a broad area and includes components like yogic diet and instructions on other measures of life.^[8] Our yoga module predominantly focused on physical activity. The inclusion of diet education could have enhanced the benefits of yoga practice. There was no significant change in secondary outcomes, consistent with what has been reported in the above meta-analysis.^[15]

Yoga being an art needs mastery through practice; hence, additional benefits may accrue over time.

The study results suggest that even limited sessions have the potential to provide benefits to the patient. This study will help in laying the basis of future studies, in which training sessions can be minimized, especially when imparted by tertiary care hospitals. However, supervision may have to be enhanced, preferably on the phone or watching some sessions through video consultations.

Strengths and limitations

This study has provided preliminary insights on the magnitude of effect that can be seen with different methods

of education programs in people with diabetes and the scope of improvement in the formulation and delivery of the intervention. A key limitation of our study is the lack of long-term follow-up data as it is a pilot study of 4-months. Long follow-up periods may have different implications on outcomes and sustainability of benefits.

Conclusions

To conclude, YBEP is an effective strategy to achieve good glycemic control in people with type 2 diabetes in addition to usual care. The reduction in HbA1c by $>0.5\%$ in 44.7% in the yoga group, suggests, that it can be prescribed as an exercise to individuals who are unable to walk either due to limited joint mobility, adverse weather conditions, lack of space for walking, cultural or religious prohibitions for women for outdoor physical activity, and so on.

Future trials evaluating the combination of conventional forms of intervention and yoga, carried out over a longer period, in a larger population, can provide more insights into formulating effective means for improving outcomes of people with type 2 diabetes, especially in regions with a high burden and limited resources. It will also be important for future studies to evaluate which subset of patients gain maximum benefit from yoga and how. Similarly, it would be important to study the reasons why yoga does not show the desired benefits in some subgroups. It is equally important to understand the mechanism or physiological basis of benefit of yoga in diabetes. A holistic bedside to bench approach may help in the delineation of the biochemical effects and their clinical translation. This may set the stage of precision medicine for yoga in diabetes.

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Conflicts of interest

There are no conflicts of interest.

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