

A Prospective Study on Type-2 Diabetic Complications and Efficacy of Integrated Yoga: A Pan India 2017

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Abstract

Background: Type 2 diabetes (T2DM) contributes to high mortality and morbidity because of its major complications related to kidney, heart, brain, and eyes. It also poses a high risk for mortality because of COVID-19. Studies suggest the possible implications of Yoga in delaying or attenuating such complications.

Methodology: This was a pan-India multi centered cluster-randomized (4 level) two-armed trial in the rural and urban population of all populous states of India. Data were obtained using mobile app in all adults in the household of the selected clusters.

Results: We report the diabetes related complications in 16623 adults (48% males, 52% females) from 65 districts (1 in 10 districts, 2011 census) of 29 (out of 35) states and Union Territories of India; mean age was 48.2 ± 12.46 years. Out of this 40% lived in rural and 62% in urban locations. In high risk diabetes individuals (scored ≥ 60 points on Indian diabetes risk score key), 18.0% had self-reported history of (peripheral neuropathy, 6.1% had h/o major strokes, 5.5% had minor strokes (transient ischemic episodes), 18.1% had lower limb claudication, 20.5% leg ulcers, 4.4% had h/o cardiac surgery, 4.8% angioplasty, and 15.1% had diabetes retinopathy. Complications were higher in rural than in urban areas, higher in people with extended duration of diabetes. Integrated yoga module for three months (one hour daily) showed significantly better reduction in symptoms related to complications as compared to control group ($P < .001$)

Conclusion: The alarming high prevalence of complications in diabetes population calls for urgent action, where yoga may show the benefits in reduction of symptoms of complications.

Keywords

High-risk diabetes, Complications, Yoga, Prevalence of known and newly diagnosed diabetes

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Introduction

In the recently estimated worldwide prevalence of diabetes, it has been appraised that 20% of world diabetes population belongs to South Asia. Many studies on the prevalence of diabetes have demonstrated that India will become the diabetes capital of the world by 2030, with a global increase of type 2 diabetes by 48% (186 million).^{1,2,3,4}

Type 2 Diabetes is known for its complications culminating in mortality and morbidity because of micro-vascular and macro-vascular changes. The association between socio-economic status and the prevalence of diabetes with propensity of for macro-vascular disease has been reported. Mortality in diabetes is chiefly because of the effect of metabolic imbalances affecting the vital organs of the body (including heart, brain, and kidney).⁵

Neuropathy in DM

Approximately 50% of adults with diabetes will be affected by peripheral neuropathy in their lifetime.⁶ A study in UK on 6487 diabetes patients reported an overall prevalence of neuropathy of 28.5%. When it was compared between type 1 and type 2 diabetes, neuropathy was observed in 22.7% in type 1 and 32% in type 2 diabetes. An association between

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peripheral neuropathy and increasing age (5% in 20–29 year age group and 44% in 70–79 year age group) has also been observed.⁷

Retinopathy in DM

A pooled analysis of data from eight population-based eye surveys in the United States has shown that the estimated crude prevalence rates for retinopathy and vision-threatening retinopathy were 40.3% and 8.2%, respectively, in patients with diabetes, whereas the prevalence rates in the US general population were only 3.4% and 0.75%, respectively.⁸

Looking at the Indian scenario, Chennai urban rural epidemiology study established the overall prevalence of diabetes Retinopathy as 17.6% which included 21% in patients with known diabetes and 5% in newly detected diabetes cases.⁹ Another Chennai study showed similar results with a diabetes retinopathy prevalence of 18%. Retinopathy was significantly associated with higher risk in men, in those with longer than 15 years duration of diabetes and use of insulin.¹⁰

Heart Disease in DM

The age and sex-adjusted cardiovascular disease incidence rate was 286 per 10000 person-years in the patients who attended examination during 1955–1966, whereas it had increased to 147 per 10000 in the patients who attended examination during 1997–1995.¹¹

Two systemic reviews and meta analyses have shown that integrated yoga lifestyle that included yogic diet, physical postures, pranayama, relaxation techniques, meditation, and yogic concepts for stress management is a safe and effective intervention that improves not only the glycemic outcomes but reduces the associated risk factors for complications in adults with type 2 diabetes.^{12,13,14} Yoga resulted in significant reduction of BMI, improved glycemic control, and melon aldehyde besides increase in glutathione and vitamin C when compared to standard care groups with micro vascular and macro vascular complications.¹⁵ Other yoga studies have shown improvement in balance and improvement in nerve function in cases with sub-clinical neuropathy.¹⁶ Yoga asana resulted in increase of median nerve conduction velocity.¹⁷

Sahay et al reported lowering of drug requirement and the incidence of acute complications like infection and ketosis, decrease in free fatty acids, increase in lean body mass and decrease in body fat percentage and decline in insulin resistance.¹⁸ Thus, yoga appears to be a vital adjuvant in the management of risk factors, disease progression, and complications of type 2 diabetes.¹⁹

In this study, we plan to report the prevalence of complications of diabetes in a high-diabetes risk (score more than 60 on Indian diabetes risk score [IDRS] key) in the Indian population in 2017 and the effect of a short-term yoga lifestyle intervention on the complications of type 2 diabetes.

Methodology

The study methodology relating to the formation of research advisory committee, ethical clearance, registration of the trial, sample size calculation, four-level randomization in rural and urban locations for selection of the survey clusters, training of personnel, are reported in detail in our earlier publications.^{20,21} In brief *Niyantrita Madhumeha Bharata* (Control of Diabetes in India) 2017, or NMB 2017, was a two-phased nationwide study with the twin objectives of estimating the prevalence of diabetes and prediabetes and its complications in a high-risk population followed by an randomized control trial (RCT) using a validated yoga lifestyle protocol.

Phase 1 was a cross-sectional door-to-door survey using a multilevel stratified cluster sampling technique in randomly selected clusters of urban and rural populations, covering 65 (10%) districts of the most populous states/union territories (29/35) of India. This captured the data on IDRS and self-reported diabetes individuals. This was followed by detailed assessments of the presence of complications, the status of diabetes control, laboratory, and other investigations only in the high diabetes risk (≥ 60 on IDRS) individuals (17852).

Phase 2 was a two-armed RCT for three months on a subsample of 4822 (Yoga: 3,130, control –1692) to test the efficacy of a validated common yoga-based lifestyle protocol.

Intervention

In the current study, the intervention of a validated integrated yoga lifestyle protocol was taught by trained certified yoga therapists at all locations daily for 9 days (2 hours/day) in camps followed by weekly supervised group classes and daily one hour home practice using the help of a video and/or booklet. The yoga module included specific practices that would help in lifestyle change through stress management and long-term behavioral change. This included practices that would correct deep-seated imbalances at (a) physical level: Yogic, simple wholesome nutritionally balanced diet, cleansing techniques (yogic nasal wash—*neti*, stomach wash—*dhoti*, and neuro-respiratory detox kriya—*kapalabhati*), and asanas designed for offering deep rest to the sick tissues; (b) pranayama designed to slow down the rate of breathing to improve parasympathetic tone; (c) meditation and relaxation techniques for autonomic stability; and (d) notional correction and devotional sessions for stress management.

Ethical Clearance

Ethical clearance was obtained by the Institutional Ethical Committee of the Indian Yoga Association. Registration was obtained at the central trial registry of India. Funding was given by the Ministry of Health and Family Welfare and the Ministry of AYUSH Government of India, New Delhi.

Data Acquisition

Details of the methodology of the four-level randomization (clustered 29 populous states into seven zones; randomly selected 1:10 districts in each state; one census enumeration block in one randomly selected ward in one randomly selected urban town, and four villages with 250–300 households in rural areas, covering 4,000 population per district) using randomizer.com, of the urban and rural clusters to collect representative samples from all seven zones of India, is published in earlier.²² Briefly, in the first phase, the data was collected at two levels, using a screening questionnaire to estimate the frequency of self-reported diabetes and comorbidities, select the population at risk for diabetes on IDRS. In the second level, only those in high risk (> 60 on IDRS) and self-reported diabetes were invited for detailed assessments.

Collection of Data of Complications

Table 1 shows the questions pertaining to complications.

The mobile app that was used for detailed data collection included the questions with binary answers (Table 1) to document the complications and associated conditions related to the nervous system, cardiovascular, musculoskeletal, renal, and ophthalmic complications with 3–4 items under each heading.

Table 1. Complications - Questions Used for Factor Analysis.

Code	Medical History Stroke	Answer
MHS	Have you ever been told by a health care provider that you have had any of the following problems?	
MHS1	Stroke	No 0 Yes 1
MHS2	Transient ischemic attacks (TIA or "mini-strokes")	No 0 Yes 1
	Heart	Answer
HEA	Have you ever had any of the following operations or procedures related to your heart? (circle one answer on each line)	
HEA1	Coronary artery bypass surgery (open heart surgery)	No 0 Yes 1
HEA2	Coronary angioplasty ("balloon" heart procedure)	No 0 Yes 1
HEA3	Heart catheterization (angiogram)	
Code	Pain/lesions in body or feet or legs	
BFL	Have you ever been told by a health care provider that you have any of the following problems with your shoulder, feet or legs?	

(Table 1 continued)

(Table 1 continued)

Code	Medical History Stroke	Answer
BFL1	Peripheral vascular disease (poor circulation in the legs) Any infected wound or ulcer which is not healing	No 0 Yes 1
BFL2	Do you have stiffness and pain in your shoulder since last three month or more	No 0 Yes 1
BFL3	Intermittent claudication (cramping in the calves after exercise)	No 0 Yes 1
BFL4	Peripheral neuropathy (nerve problems causing numbness, tingling, or burning)	No 0 Yes 1
KD	Kidney disease	
KD1	Have you ever been told by a health care provider that you have kidney disease?	No 0 (skip to next section) Yes 1
KD2	Do you now take medication for your kidney disease?	No 0 (skip to next section) Yes 1
KD3	How many tabs/doses and how many times a day do you have to take your medication for kidney disease?	1. Once a day 2. Twice a day 3. Three times a day 99 Don't know/Not sure
Code	High blood pressure	
HBPI	Have you ever been told by a health care provider that you have High blood pressure?	No 0 (skip to next section) Yes 1
HBP2	Do you now take medication for your high blood pressure?	No 0 (skip to next section) Yes 1
HBP3	How many tablets a day do you have to consume for high blood pressure?	1. Once a day 2. Twice a day 3. Three times a day don't know/Not sure
Code	High cholesterol	
HC1	Have you ever been told by a health care provider that you have high cholesterol?	No 0 (skip to next section) Yes 1
HC2	Do you now take medication for your high cholesterol?	No 0 (skip to next section) Yes 1
HC3	How many tablets a day do you have to consume for high cholesterol?	1. One tablet at each intake 2. Two tablets at each intake 3. Three tablets at each intake 4. More than four tablets at each intake Don't know/Not sure

(Table 1 continued)

(Table 1 continued)

Code	Medical History Stroke	Answer
Code	Any other disease or complications	
CO1	Have you ever been told by a health care provider that you have any other disease or complications at present?	No 0 (skip to next section) Yes 1
EYE1	Have you ever been diagnosed with any of the following ocular conditions: e.g.: glaucoma, cataracts, macular degeneration, eye injury, retinal disease, blindness, dry eyes	No 0 Yes 1
CO2	Other complications	
CO3	Do you now take medication for your other disease or complications?	No 0 (skip to question xx) Yes 1
CO4	How many tabs/dose and how many times a day do you have to take your medication for any other disease or complications?	1. Once a day 2. Twice a day 3. Three times a day Don't know/Not Sure

Reliability and validity of the factors checked by Cronbach's α for subscales. Results: 0.762 with a factor loading of 0.7 in different factors

Statistical Analysis

Data were uploaded via mobile apps by trained field personnel under the supervision of senior research fellows. Uploaded data from screening forms (about 4 < 0.001/district), registration forms, and laboratory data (about 50, < 0.001) were checked for perfect matching of coding. The data set was analyzed using Statistical Package for Social Sciences (SPSS) (23.0) and R software for bio-statistical analyses. Chi-square test was adopted for checking the significance of distribution.

Results

Figure 1 shows the consort diagram. Of the 17852 adults screened, data of 16,623 at high risk for diabetes (> 60 on IDRS) were available for analysis after removing missing values. The mean age was 48.2 ± 12.46 years, 48% were males; 39% rural, and 41% urban clusters. The mean duration of diabetes was 7.6 ± 8.3 years. Of these, data on 4,822 respondents (yoga group 3130, control group 1692) for the intervention were available for analysis.

Table 2 shows the percentage of individuals in different categories who reported a history of different complications.

Neurological Complications

Major stroke was reported in 6.1% of patients with diabetes with higher percentages in self-reported known diabetes

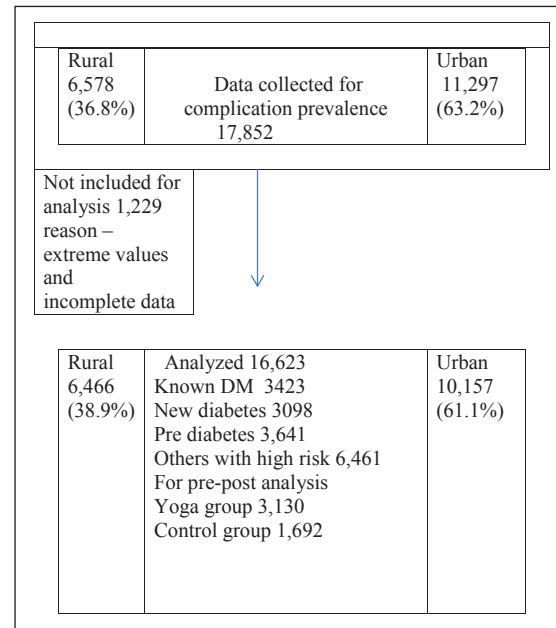


Figure 1. Study Profile

patients which increased from 4.7% to 8%, as the duration of diabetes increased from 1st to 20th year. Similar trends were found in minor strokes (transient ischemic attacks [TIA]) with an overall prevalence of 5.5%, higher in self-reported (8.1%) known diabetes individuals. Two percent of those who were not aware of their diabetes (newly diagnosed, A1c > 6.5%) already had experienced these minor episodes of TIA.

Peripheral neuropathy was reported in 18.0% of patients with diabetes, higher (22.7%) in the self-reported known diabetes group than newly diagnosed (12.6%) or the prediabetes group (14.4%). In the newly detected and prediabetes adults, leg-related complications (claudication and foot ulcer) were higher when compared to other neurological or cardiac complications. (Table 2)

Cardiovascular Complications

Reports of history of coronary artery bypass graft surgery and angioplasty were higher in self-reported diabetes (5%, 7%) than the newly diagnosed diabetes (3.7%, 2.2%) and prediabetes (2.2%, 1.8%). Peripheral vascular problems with intermittent claudication of lower limbs (18.1%) and leg ulcers (20.5%) showed high prevalence. Retinopathy was found in 15.1% of diabetes adults.

Subgroup Analyses

Looking at the gender differences, most of the major complications such as strokes, claudication, neuropathies, retinopathy, and foot ulcers were higher in females than males. (Table 3), whereas the history of cardiac bypass surgery and angioplasties was higher in males.

Table 2. Prevalence of Complications in Diabetes Group

Groups	Neuro			Cardiac			Limb		Eyes
	Major stroke (in %)	Minor stroke (in %)	Peripheral neuropathy (in %)	Bypass (in %)	Balloon angioplasty (in %)	Kidney Disease	Claudication (in %)	Foot ulcer (in %)	Patients with diabetes-related eye problems (in %)
Total DM	6.1	5.5	18.0	4.4	4.8	3.2	18.1	20.5	19.9
Self-reported DM	8.5	8.1	22.7	5.0	7.0	4.4	22.9	25.8	25.1
New DM	3.4	2.4	12.6	3.7	2.2	1.5	12.4	14.1	13.8
Pre DM	3.0	2.2	14.4	2.2	1.8	1.3	14.0	14.8	14.6

Table 3. Prevalence of Complications in The Study Population

Groups		Neuro			Cardiac			Limb		Eyes
		Major stroke (in %)	Minor stroke (in %)	Peripheral neuropathy (in %)	Bypass (in %)	Balloon angioplasty (in %)	Kidney Disease	Claudication (in %)	Foot ulcer (in %)	Patients with diabetes eye (in %)
Gender	M	8.1	6.7	23.0	4.4	3.2	5.3	19.7	23.1	25.2
	F	8.9	9.4	33.1	2.0	2.7	3.7	26.1	28.9	25.1
Area	Urban	7.9	7.4	25.8	5.3	2.8	5.0	23.1	25.5	26.2
	Rural	9.0	8.7	35.2	4.6	3.1	4.0	22.6	26.2	23.5
Age	20-35	7.0	6.5	25.8	2.8	2.2	7.5	17.2	24.3	11.2
	35-50	7.6	6.7	27.4	4.0	2.5	4.5	22.2	26.2	21.8
	50-70	7.6	6.9	28.1	5.7	3.5	4.3	22.5	27.4	28.7
Zones	NW	2.6	1.3	25.8	2.6	1.2	0.9	23.1	14.4	31.0
	N	3.6	2.7	31.8	2.2	0.9	1.3	26.0	19.7	32.1
	NE	3.3	8.1	22.5	0.5	0.4	4.3	21.4	19.0	30.0
	W	5.3	3.5	24.6	5.3	1.9	2.5	24.1	27.0	24.3
	C	10.1	7.6	33.2	6.1	2.1	6.9	38.6	32.5	26.0
	E	11.2	6.0	35.4	5.8	10.1	7.2	21.2	42.9	23.4
	S	5.9	3.6	24.7	5.8	2.4	4.9	16.3	20.3	23.3

Age and Complications

Foot ulcer, shoulder pain, neuropathies, and eye problems were higher in older age (50–60 years) than younger ones; history of intermittent limb claudication was high in the younger (20–35 group) diabetes population.

Complications in Rural and Urban Population

The number of diabetes patients who reported a history of foot ulcer, shoulder pain, strokes, and or eye-related complaints was higher in the rural regions than urban areas; the prevalence of claudication and nerve problems was high in urban than rural localities.

Complications in Different Zones of India

Number of individuals with foot ulcer, shoulder pain, claudication, and history of stroke was highest in the East

zone; nerve problem was highest in the central zone and eye problems were highest in the North zone (Table 3).

The proportion of all complications increased with the increasing duration of diabetes. The percentage of individuals with foot ulcers, shoulder pain, nerve problems, claudication, and eye problems was highest in those with a duration of diabetes of 15–20 years (Table 4).

The following changes were noticed in prepost changes in complications: after yoga, 10% reported reduction in foot ulcers, whereas in the control group it increased by 2%. About 5.1% reported a reduction in symptoms related to the eyes. There was 5.1% reduction in diabetes retinopathy in yoga and 7% increase in Control group. Shoulder pain reduced by 9.5%, while in control it increased by 4%; peripheral neuropathy related symptoms reduced by 10.6%, while it increased in the control group by 1%. (Table 5)

Table 4. Duration of Diabetes and Complications.

Complications	1–5 years (in %)	5–10 years(in %)	10–15 years(in %)	15–20 years(in %)	SignificanceP (Independent Samples t-test)
Stroke	4.7	5.7	8.2	8.0	.029
Minor stroke	3.2	3.5	7.2	6.2	.022
neuropathy	22.7	22.3	27.8	31.5	.052
Claudication	19.9	19.2	22.7	25.3	.266
Foot ulcer	22.6	23.1	29.9	25.3	.122
Kidney disease	3.2	3.3	5.2	3.2	.002
Bypass surgery	3.4	3.4	9.3	9.2	.002
Balloon surgery	2.5	3.4	5.0	6.8	.002
Patients with diabetes retinopathy	23.4	27.7	32.1	35.8	.000
Shoulder pain	24.0	25.2	31.4	32.7	.011

Table 5. Symptoms Related to Complications Before and After Intervention

Complications	Yoga Pre(in %)	Yoga Post (in %)	Control Pre(in %)	Control Post(in %)	Significance
Foot ulcer	17.3	7.2	17.9	19.5	$P < .001$
Shoulder pain	18.5	9.0	20.1	24.1	$P < .001$
Claudication	15.9	6.8	15.7	17.3	$P < .001$
Neuropathy	16.4	5.8	16.0	17.0	$P < .001$
Diabetic eye	15.6	10.5	16.8	23.8	$P < .001$
Patients with diabetes retinopathy	15.6	10.5	16.8	23.8	$P < .001$

Discussion

The current pan India community-based cluster-randomized trial of 2017 describes the prevalence of self-reported complications in 16623 adults with high diabetes risk (score > 60 on IDRS) and also the effect of yoga intervention of three months duration.

Comparisons

Overall, the neurological complications were reported in 29.6%, cardiac (bypass surgery + angioplasty) in 9.2% of diabetes individuals. An earlier study in Goa²³ in 2010 had reported the prevalence of diabetes complications as follows: neuropathy 60%, coronary heart disease -32.3%, cataract 20%, retinopathy 15.4%, peripheral vascular disease 11.5%, and cerebrovascular accidents (CVAs) 6.9%. They also had reported the rising trend in the prevalence of diabetes complications with advancing duration of diabetes which is also seen in our study.

In the present study, we found the prevalence of self-reported known diabetes was higher in females than males, and the prevalence of complications corresponded to the

overall prevalence of diabetes in females. This observation of higher prevalence of self-reported diabetes in high-risk females could be because of obesity which is a major risk factor in Indians and is known to be higher in women.^{24,25}

The prevalence of diabetes complications was higher in rural than urban regions. The awareness about health was found to be much lower in rural areas when compared to urban areas. Studies have discussed that knowledge about diabetes and health awareness is negligible in rural areas²⁶. This may be the explanation for the high prevalence of complications in rural areas. As expected, the prevalence was higher among people with a longer duration of diabetes.

A study on the prevalence of neuropathy in 6487 diabetes individuals in the UK in the year 1993 was 32.1% in type 2 diabetes patients.⁷ The researchers observed that the prevalence of diabetic peripheral neuropathy increased with age, from 5% in the 20–29 year age group to 44.2% in the 70–79 year age group. But in our study, it was 25.8% in the age group 20–35, in the age group 50–70 it was 28.1%.

Prevalence of neuropathy increases with the duration of diabetes, and earlier studies have reported neuropathy in 20.8% in patients with diabetes duration of fewer than five years and 36.8% in those with greater than ten years duration.⁷

The prevalence in our study seems to be similar; it increased from 22.7% in those with 1–5 years duration of diabetes to 31.5% in those who had diabetes for 15–20 years.^{6,7}

We observed a prevalence (25.1%) of retinopathy in our sample. Ghodasra et al observed an 18.0% prevalence of diabetic retinopathy in patients with diabetes in 2006. In their study, the variables that were significantly associated with increased risk of patients with diabetic retinopathy included gender (men at greater risk), use of insulin, and longer duration of diabetes.¹⁰ Similar was our observations in our subjects with known diabetes as we noted an association of retinopathy with increased age, female gender, and duration of diabetes.

Studies have shown strong association between hypertension and hyperlipidemia with diabetic nephropathy.²⁷ Patients with diabetes complications and/or coronary artery disease had higher prevalence of stroke.³¹

In the current study, three months of intervention of a validated integrated yoga lifestyle protocol has shown significant ($P < .001$) reduction in all self-reported complications. We hypothesize that the observed results of reduction of self-reported complications in the present study could be because of stress reduction. It is evident by the earlier studies that patients with diabetes complications have increased oxidative stress levels.²⁸ It is also known that chronic stress leads to poor control of diabetes with increased risk of micro and macro-vascular complications through activation of the hypothalamic-pituitary-adrenal axis, resulting in increased levels of cortisol, epinephrine, norepinephrine, glucagon, prolactin, leptin, and neuropeptides.²² Chronic activation of the HPA axis is also associated with increased level of inflammatory cytokines that contribute to insulin resistance in type 2 diabetes. Chronic psychological stress can result in insulin resistance, hypertension, and an increased risk of cardiovascular events.²⁹ A systematic review on yoga practices on oxidative stress in different populations reported that diabetes patients showed increased glutathione, vitamin C content, and superoxide dismutase activity and decreased malondialdehyde content following yogic practices; prediabetes and hypertensive patients showed reduced malondialdehyde content following yogic practices, and renal disease patients showed decreased protein oxidation and increased superoxide dismutase activity following yogic practices. The review concluded that regular yogic practices can improve antioxidants and reduce oxidative stress in healthy, diabetes, prediabetes, hypertensive, and renal disease patients.³⁰

Strengths of the Study

It is the first parallel survey covering 29 states/union territories of India on the prevalence of complications and the effect of yoga on all self-reported complications. The self-administered questionnaire used is found to be reliable and valid. This is

also the first report that offers evidence to the beneficial effect of yoga in reducing the symptoms (self-reported) related to complications of diabetes.

Limitations of the Study

The limitation of the study was that there were no objective measures of the status of the complications as it was self-reported data.

Conclusions

The prevalence of complications is high in known diabetes individuals. Integrated yoga module can play a significant role in reduction in symptoms related to diabetes complications as self-reported symptoms are reduced. But this should be studied further with bio markers. This study offers important evidence to implement urgent action by policy makers to prevent complications and also offer protection to diabetes community during the present COVID-19 pandemic.

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Ethical Statement

Ethical clearance was obtained by the Ethics Committee of the Indian Yoga Association. The study was registered on central trial registry of India (Registration Number – Trial REF/2018/02/017724). This article complies with the International Committee of Medical Journal editor's (ICMJE) uniform requirements for the manuscript.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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