EFFECTIVENESS OF YOGA WITH EXERCISE ON GLYCEMIC CONTROL AMONG PATIENTS WITH TYPE II DIABETES MELLITUS: A COMMUNITY BASED RANDOMISED CONTROL TRIAL

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Doctor of Philosophy in the Faculty of

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By

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September-2023

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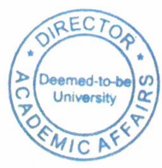

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Dr. Rajesh R. Kulkarni

Date:

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LIST OF ABBREVIATIONS USED (IN ALPHABETICAL ORDER)

2-h PG	-	2-h plasma glucose
A1C	-	Glycosylated haemoglobin
ADA	-	American Diabetes Association
ANOVA	-	Analysis of variance
BG	-	Blood glucose
BMI	-	Body mass index
BP	-	Blood pressure
CAD	-	Coronary artery disease
CCTs	-	Controlled clinical trials
CHD	-	Coronary heart disease
CI	-	Confidence interval
CKD	-	Chronic kidney disease
cms	-	Centimeter
CNS	-	Central nervous system
CVD	-	Cardiovascular disease
CVS	-	Cardiovascular system
DBP	-	Diastolic blood pressure
DC	-	Data collection
DCCT	-	Diabetes Control and Complications Trial
DKA	-	Diabetic ketoacidosis
DM	-	Diabetes mellitus
DPP4	-	Dipeptidyl peptidase 4 inhibitors
DYP	-	Diabetic yoga protocol

eg,	-	Examplia gratia
ESE	-	Exercise self-efficacy
ESRD	-	End-stage renal disease
FBG	-	Fasting blood glucose
FBS	-	Fasting blood sugar
FGT	-	Fasting glucose test
FPG	-	Fasting plasma glucose
g	-	Gram
GABA	-	Gamma-aminobutyric acid
GDM	-	Gestational diabetes mellitus
GEE	-	Generalized Estimating Equations
GIT	-	Gastrointestinal tract
GLDs	-	Glucose lowering drugs
GLP-1	-	Glucagon-like peptide-1
GUT	-	Gastrointestinal tract
HbA1c	-	Glycosylated hemoglobin
HDL	-	High density lipoprotein
HDL-C	-	High-density lipoprotein-cholesterol
HPA	-	Hypothalamic–pituitary–adrenal
HPG	-	Hourly plasma glucose
HR	-	Heart rate
HTN	-	Hypertension
i.e.	-	That is,
IDF	-	International diabetes federation
IFG	-	Impaired fasting glucose

IGT	-	Impaired glucose tolerance
IR	-	Insulin resistance
Kg	-	Kilogram
kg/m^2	-	Kilograms per square meter
LDL	-	Low-density lipoprotein
LDL-C	-	Low-density lipoprotein-cholesterol
Lt	-	Left
M.F	-	Multiplication Factor
MD	-	Mean difference
METS	-	Metabolic equivalents
mg/dL	-	Milligrams per deciliter
MHR	-	Maximal Heart Rate
min	-	Minutes
mmHg	-	Millimeters of mercury
mmol/L	-	Millimole per litre
mmol/mol	-	Millimole per mole
MODY	-	Maturity-onset diabetes of the young
mol/L	-	Moles per liter
MSS	-	Musculoskeletal system
n	-	Total number
N\AbN	-	Normal/Abnormal
NGSP	-	National Glycohemoglobin Standardization Program
NHANES	-	National Health and Nutrition Examination Survey
NIDDM	-	Non insulin dependent diabetes mellitus
OGTT	-	Oral glucose tolerance test

OHA	-	Oral hypoglycaemic agent
p	-	Probability
PAI-1	-	Type-1 plasminogen activator inhibitor
PCOS	-	Polycystic ovarian syndrome
PG	-	Plasma glucose
PPBG	-	Post prandial blood glucose
PPBS	-	Post prandial blood sugar
Pr \ Ab	-	Present/Absent
PRISMA	-	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PVD	-	Peripheral vascular diseases
QoL	-	Quality of life
r	-	Pearson's correlation coefficient
RBCs	-	Red blood cells
RBS	-	Random blood sugar
RCTs	-	Randomized controlled trial
RIYP	-	Residential Integrated Yoga Program
rpm	-	Revolutions per minute
RS	-	Respiratory system
Rt	-	Right
RYT	-	Registered yoga teacher
SBP	-	Systolic blood pressure
SEA	-	South East Asia
SGLT2	-	Sodium glucose linked transporter 2 inhibitors
SMD	-	standardized mean difference
SOC	-	Standard of care

STD	-	Sexually transmitted diseases
T1DM	-	Type 1 diabetes mellitus
T2DM	-	Type 2 diabetes mellitus
TC	-	Total cholesterol
TG	-	Triglyceride
U.S.	-	United States
UK	-	United Kingdom
USA	-	United States of America
UTI	-	Urinary tract infection
VLDL	-	Very low density lipoprotein
VO_2	-	Maximum rate of volume of oxygen consumption
vs	-	Versus
WHO	-	World Health Organization
YG	-	Yoga group

ABSTRACT

Background

Lifestyle interventions have proven to reduce the incidence of T2DM and prevent the complications. Yoga is safe, simple to learn, and can be practiced even by anyone.

Objectives

To assess the effectiveness of yoga with exercise on glycemic control, BMI and lipid parameters among patients with type II diabetes mellitus.

Methodology

This single center randomized controlled trial was conducted in under the department of Community Medicine Jawaharlal Nehru Medical College, KAHER, Belagavi for the period of 14 months from June 2017. A total of 126 eligible participants diagnosed to have T2DM and registered in the study area were enrolled. Based on computer generated, randomized number sequence method, participants were divided into two groups of 63 each as Yoga Group(dietary control, anti-diabetic drug with Yoga therapy) and exercise group (dietary control, anti-diabetic drug with exercise).

Results

Most of the participants (53.30%) in yoga group were aged between 28 to 56 years compared to 46.07% in exercise group (p=0.584). Majority of the participants (62.20%) in yoga group were males compared to 37.80% in exercise group (p=0.054).The duration of T2DM among 54.50% of the participants in yoga group was ≥5 years compared to 45.50% in exercise group (p=0.464).Most of the participants

(57.50%) in yoga group practiced the intervention for 160 to171 days compared to 42.50% in exercise group ($p=0.061$).The yoga brought about maximum change in RBS (MD:25.76) followed by Cholesterol (MD:22.88).There was significant decrease of HbA1c and RBS in both the groups after 6 months and 12 months as compared to baseline ($p<0.001$).There was significant decrease of total cholesterol, triglycerides, LDL, and VLDL in both the groups ($p<0.001$) while there was significant increase in HDL in both the groups after six and 12 months as compared to baseline ($p<0.001$).Also, there was significant decrease of BMI in both the groups after six months and 12 months as compared to baseline ($p<0.001$).

Conclusion

Overall, both the interventions that is, yoga and exercise are equally effective and offer excellent glycaemic control with prevention of lipid derangement and obesity thereby further morbidity and mortality associated with T2DM. Given the equal effect of yoga and exercise, people with morbidities or who are unable to go for exercise can practice yoga at home which will help them in glycaemic control and prevent lipid abnormalities and obesity.

Keywords

Body mass index; Exercise; Glycaemic control; Lifestyle intervention; Type 2 diabetes mellitus; Yoga; Lipid profile;

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INTRODUCTION

Diabetes mellitus (DM) is a term used to describe a set of common metabolic illnesses that share the hyperglycemia phenotype. It is caused by deficiencies in insulin secretion and action. Such significant effects seen in DM include long-lasting damage to various organs like the heart and blood vessels. A series of complex interactions between hereditary and physical factors leads development of numerous unique kinds of DM. Reduced insulin secretion, decreased glucose consumption, and increased glucose generation leads to hyperglycemia depending on the etiology of the DM.[1]

Diabetes has two types, with type 1 and type 2, maturity-onset diabetes of the young (MODY), gestational, neonatal diabetes, as well as diabetes caused by endocrinopathies, drugs, and other factors. The two distinct types of DM are type 1 DM (T1DM) and type 2 DM (T2DM), both of which are caused by defective insulin secretion or action. Type 2 DM, is common among middle-aged persons who have persistent hyperglycemia as a result of lifestyle and dietary choices, whereas T1DM is common among children or teenagers. The pathophysiology of T1DM and T2DM differs so greatly that each type has a distinct origin, presentation, and course of management.[2] However the present study is aimed to ascertain the effect of yoga and exercise on glycemic control among patients with T2DM, the content in this research is limited to T2DM only.

About 90–95% of DM cases are T2DM.[3] A metabolic and endocrine disorder termed T2DM is characterized by hyperglycemia linked to IR and/or improper insulin production.[4]

The prevalence of DM is increasing across the world at a shocking rate.[4] Significant to note that all six of the world's inhabited continents are experiencing an increase in prevalence.[5] Over the past 30 years, DM has evolved from a minor geriatric condition to one of the leading causes of morbidity and mortality among young and middle-aged adults. Type 2 DM, which makes up the highest of 90% of all instances of DM, is the main cause of diabetes, even though T1DM prevalence is also rising.[6]

In 2000, globally there were an estimated 171 million patients with DM; this number is likely to increase to 366 million by 2030, and the proportion of patients with DM residing in developing nations is predicted to rise from 74% in 2000 to 81% in 2030.[7,8] There is a sizable spread of Asian Indian people living in countries like Europe, Africa and in the middle east. These regions have a considerably higher prevalence of DM than the native populations of those countries.[8-10] Diabetes mellitus affects a considerable number of people in South Asian countries such as Bangladesh, Pakistan, Sri Lanka, and Nepal.[11-14]

Asian Indians have a particular phenotype marked by higher intra-abdominal fat and IR (IR) despite having a low body mass index (BMI), predisposing them to a risk of T2DM and early coronary heart disease (CHD). Asian Indians account for more than 17% of the global population.[14,15]

India has the world's second-highest number of diabetics (69 million in 2015), making it one of the epicenters of the global epidemic.[14,16]

The metabolism of carbohydrates, proteins, lipids, water, and electrolytes is hampered by DM. Persisting with these metabolic disruptions creates persistent,

irreversible changes in the functional and structural makeup of the body's cells, resulting in the appearance of "diabetic complications" that predominantly impact the cardiovascular system, eye, kidney, and nerve system.[17]

Glycosylated hemoglobin (HbA1c), shows glucose directive in diabetes and is a marker formed by sluggish and non-enzymatic glycosylation of hemoglobin. Additionally, it demonstrates glycemic control in diabetics and is strongly linked to the possibility of acquiring DM problems.[18,19] Higher glucose levels, as assessed by HbA1c, are related to an increased chance of health complications[18,20] according to epidemiologic research on type-2 diabetes. For patients with a brief history of DM, a longer life expectancy, and a low risk of hypoglycemia, the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists recommend a target HbA1c of 6.5% or 7.0%, respectively.[18,21,22]

Need for the study

Despite of several benefits of Yoga on not only glycaemic control but even the overall wellbeing, to date, there has been minimal research on whether yoga can improve quality of life by alleviating stress, anxiety, and depression, as well as motivating people to pursue an active lifestyle. Previous research has emphasized the significance of future research to better understand the possible impact of yoga on glucose levels. Considering these facts, the present study was undertaken to determine the effectiveness of yoga with exercise on the glycaemic control, lipid profile and BMI in patients with T2DM.

BACKGROUND

Diabetes mellitus is a complicated disease, and its therapy necessitates tackling complications prevention, early detection, Hyperglycemia, hypertension, dyslipidemia, obesity, and other CVD risk factors must be effectively controlled. Diabetes mellitus and its related problems, as well as their risk factors, are managed by prescribing various pharmacological and non-pharmacological methods, as well as regular screening to prevent long-term sequelae. Essentially the focus for implementing such measures is patient education in addition to the care system offered by a multidisciplinary clinical team.[23] Several studies have also found a dose response relationship between the rate of physical activity and the degree of the protective effect. These studies suggest that physical inactivity contributes to T2DM.[24] Dose-response association between the physical strength of the defensive result remained also reported in several studies. These investigations suggest that physical inactivity plays a causal effect on T2DM.[25,26]

There is a link between the pathophysiology of T2DM and stress, as well as associated disorders including anxiety and depression. The modern lifestyle, which encourages a sedentary way of life and less physical activity, is strongly linked to T2DM. High levels of stress can cause the blood to become overloaded with sugar as a reaction to stress. Since stress and DM have a common pathophysiology, it is impossible to say with certainty which condition causes the other. But from the perspective of a clinician, it's critical to manage both the disease and its effects. Yoga appears promising in this circumstance.[26-28]

According to yoga philosophy, the majority of illnesses are caused by a lack of daily activity that lowers immunity and increases susceptibility to infections.[29] Yoga

emphasizes treating the underlying issue rather than only the symptoms. Yoga's capacity to improve the quality of life and glucose management in DM patients may be advantageous.[26,30,31] The prevention and treatment of T2DM have certain inherent issues. Patients with T2DM exhibit higher medication compliance and poorer exercise and lifestyle change compliance. Additionally, more people abandon a fitness program as the intensity of the exercise increases. Previous research has suggested that yoga might be more beneficial than exercise.

The hypothalamic-pituitary-adrenal (HPA), which becomes overactive in response to aberrant physical and mental stress, is downregulated by yoga. Yoga prevents this stress cascade by inhibiting how stressful things seem to be. Through a decrease in heart rate (HR), blood pressure (BP), and respiration rate, yoga lessens physiologic symptoms. Successful diabetes management includes lowering cardiovascular risk factors in diabetes patients. Yoga's potential mechanisms of action can be divided into two categories: vagus stimulation and parasympathetic activation thereby modulation of the hypothalamic-pituitary-adrenal (HPA) axis. The first mechanism that describes how yoga works is, it increases baroreflex sensitivity and decreases inflammatory cytokines, which stimulate the vagus nerve thereby enhancing endothelial performance and lowering CVD risks in T2DM. The stimulation of the parasympathetic nervous system and related antistress mechanisms is the second hypothesized route of action for yoga. It improves overall metabolic and psychological profiles by lowering perceived stress and HPA axis activation.[26]

LITERATURE REVIEW

Since this study is aimed to compare the effect of yoga and exercise on glycemic control among patients with T2DM, literature pertaining to T2DM including epidemiology, pathophysiology, diagnosis, management, glycemia control and finally studies comparing the effect of yoga compared to exercise on glycemic control have been reviewed.

Diabetes mellitus

Diabetes mellitus is a common metabolic disorder that shares the phenotype of hyperglycemia. The several types of DM are caused through multiple interactions between an individual's genetics, environment, and lifestyle. Diabetes is caused by the reduced use and secretion of insulin. As a result of metabolic dysregulation associated with DM, numerous organ systems suffer secondary pathophysiologic alterations. Diabetes mellitus is the common cause of end stage renal disease (ESRD), lower extremity amputation, and adult blindness. With an increasing incidence, DM will be a leading cause of morbidity and mortality.[1]

Diabetes mellitus is one of the oldest diseases known to mankind. The first description was stated in an Egyptian document about 3000 years ago.[32]

Diabetes is a chronic, metabolic disease with elevated levels of blood glucose (BG) (or blood sugar), which results in serious damage to the heart, blood vessels, eyes, kidneys and nerves over a period of time. However, the common type that is T2DM is diagnosed among adults usually, which is when the body becomes resistant to insulin or doesn't make enough insulin. In the past 30 years, the prevalence of T2DM has ascended dramatically in countries with different income levels. Type 1

DM, also known as juvenile DM or insulin-dependent DM, is a chronic condition due to which the pancreas produces little or no insulin by itself.[33]

According to recent estimates by WHO, worldwide about 422 million people are having DM with a majority of them living in low and middle income countries. The number of patients and prevalence of DM have been increasing in recent decades. The cases of DM rose from 108 million in 1980 to 422 million in 2014. Globally occurrence of DM among adults over 18 years of age rose from 4.7% in 1980 to 8.5% in 2014. DM has been rising more rapidly in low and middle income countries than in high income countries.[34,35]

In 2016, 1.6 million deaths were attributed to DM. Another 2.2 million deaths occurred due to high BG in 2012.[35] Almost 50% of all deaths are attributable to hyperglycemia before the age of 70 years. It is estimated by WHO that DM was the seventh leading cause of death in 2016.[36]

Spectrum of glucose homeostasis and DM[1]

Type of diabetes	Normal glucose tolerance	Hyperglycemia			
		Impaired fasting glucose or impaired glucose tolerance	Diabetes mellitus		
			Not insulin required	Insulin required for control	Insulin required for survival
Type 1					
Type 2					
Other Specific types					
Gestational diabetes					
Time (years)					
FPG (mg/dL)	< 110	110-125	≥ 126		
2-HPG (mg/dL)	< 140	140 – 199	≥ 200		

Broadly DM is split into two types T1DM and T2DM with significant differences in clinical manifestations and disease development. Although DM organization is vital for effective pharmacological treatment, At the time of treatment, some people cannot be classified as having T1DM or T2DM. Traditional paradigms of T2DM being seen only in adults and T1DM in children or young appear to be incorrect, as DM occurs in both age ranges. However, T1DM particularly in children, is characterized by polyuria, and approximately one-third of the population has diabetic ketoacidosis (DKA).[1]

The onset of T1DM can be different in adults, and may not present with the classic symptoms like in children. Occasionally, patients with T2DM may present with DKA, particularly in minor ethnicities. Although difficulties in distinguishing

DM types can occur at any age, the true diagnosis becomes apparent over a period of time. Various factors including hereditary and environmental factors can lead to progressive damage to b-cell function in both types, resulting in hyperglycemia clinically. Once hyperglycemia develops, various types of chronic problems are experienced by the patient, with varying frequency of progression. Early diagnosis of DM is required for future therapeutics. The underlying pathophysiology of T1DM is well understood than that of T2DM.[1]

According to investigations on the degree relatives of T1DM patients, the presence of increased autoantibodies is usually a clear sign of clinical hyperglycemia and DM. The rate of progress is controlled by the age at which the antibody was found, the number of antibodies, specificity, and titer. Significant rises in glucose and A1C levels before the onset of DM enable identification. Three main stages of T1DM can be identified and used to guide future research and regulatory decisions. The processes driving b-cell death and malfunction in T2DM are less well understood, though a lack of b-cell insulin production, generally in the setting of insulin resistance (IR), appears to be the common denominator. Subtypes of this complex illness have been identified and confirmed among Scandinavian and Northern European populations, but not in other ethnicities and racial groups.[1]

The detailed evaluation of T1DM is outside the scope of this review as the current research is limited to the comparison of the effect of yoga versus exercise on glycemic control in T2DM patients.

Type 2 DM is primarily associated with insulin secretory defects related to inflammation and metabolic stress among other contributors, including genetic factors. Further classification schemes for DM are likely to focus on the underlying

pathophysiology of b-cell dysfunction and the stage of disease indicated by glucose status (normal, impaired, or diabetes).[37]

Type 2 diabetes mellitus

This type of DM affects approximately 90-95% of patients comprised of persons who have IR and hence have relative insulin deficiency but not absolute.[1]

There are different causes of T2DM. Particular etiologies are not identified. Generally, patients with T2DM are obese and obesity itself causes some degree of IR. This form of DM frequently goes undiagnosed for many days to years, as the hyperglycemia develops slowly. These patients are at high risk of developing macrovascular and microvascular complications. The risk of developing T2DM increases with age, obesity, and lack of physical activity and occurs frequently in women with history of gestational diabetes mellitus (GDM),[38] individuals with hypertension (HTN), or dyslipidemia. It is also associated with a strong genetic predisposition, more so than T1DM.[39]

Epidemiology

<u>Worldwide</u>

The global epidemic of T2DM is high on the public health agenda as a danger to human health and global economies.[40]

In the previous 20 years, patients with T2DM are doubled.[40,41] According to the IDF, 415 million people were diagnosed with T2DM in 2015, which is expected to increase to 642 million by 2040.[16,40] These findings correspond to a global incidence of 8.8% in 2015 and a projected global prevalence of 10.4% in 2040.[16,40]

According to the WHO first global diabetes report, the number of adults living with DM has nearly multiplied since 1980, reaching 422 million adults.[35,42]

In 2008, the global age standardized adult DM prevalence was 9.80% for men and 9.20% for women, up from 8.30% and 7.50%, respectively, in 1980.[35,42]

Diabetes mellitus has become one of the important causes of early illness and death in several countries, owing to a higher risk of CVD, which accounts for more than half of all diabetic patients.[42,43]

Although DM is sometimes regarded as a big cause of concern in wealthy countries, the loss of life due to early death among DM is utmost in underdeveloped countries. A majority of adult diabetics (almost 80%) reside in countries with low or middle income.[42,43]

Diabetes mellitus is postulated to affect 643 million persons by 2030, and 783 million by 2045. Three out of every four diabetics live in countries with low and middle income. Almost 50% of all diabetics (240 million) remain undiagnosed. Diabetes mellitus caused the death of 6.7 million people. Type 2 DM is more likely to affect 541 million people.[44]

The prevalence of DM for all age groups was predicted to reach 4.4% in 2030. Furthermore, the prevalence of DM in adults (aged 20-79 years) was anticipated 300 million in 2025, and 439 million in 2030.[7,45,46]

<u>Sex predilection</u>

Diabetes affects men more than women.[45-51]

Mortality

Diabetes mellitus caused 1.5 million fatalities worldwide in 2012, making it the eighth most common cause of death, with low and middle income nations accounting for more than 80% of deaths in patients with DM. Diabetes during pregnancy affected over 21 million live births in 2013, and over 79,000 children were diagnosed with T1DM.[45-51]

Indian scenario

Now there is sufficient data to support the "Asian phenotype" in DM. The age of onset for DM is earlier among Asians with higher risk even at a lower BMI, more abdominal obesity, and higher CVD.[52] These common traits must impact the therapeutic options available to and chosen for our patients.[53,54] The "Asian Indian phenotype" is a strange group of irregularities in South Asians, in which they have the higher total body and visceral fat, IR contributing to a higher prevalence of DM for any given BMI level than white Caucasians.[55]

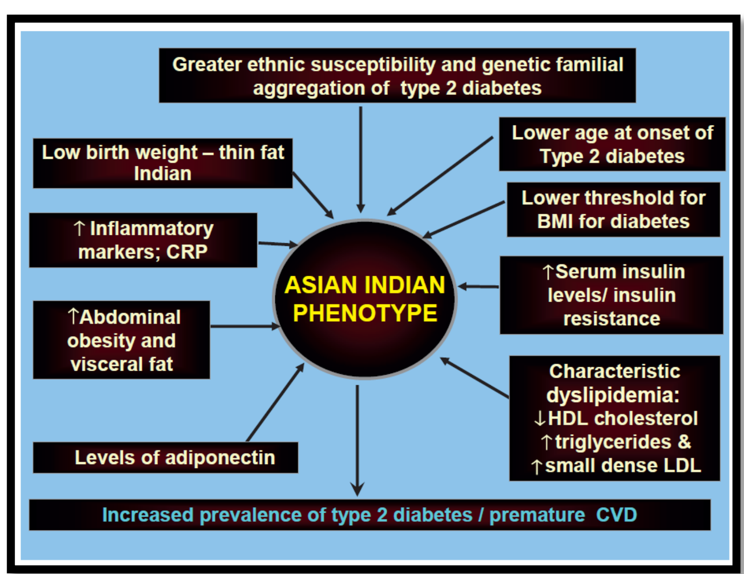


Figure 1. The "Asian Indian phenotype"[55]

According to recent estimates by IDF, India is one of six countries in the IDF South East Asia (SEA) region with more than 74.20 million DM cases in 2021 and is in first place.[56] Furthermore, one in every seven adults has DM. it is expected that 152 million people are likely to have DM by 2045, an increase of 69% from now. Over half of all diabetic individuals (51.2%) are undiagnosed and DM was responsible for 747,000 fatalities in 2021, with an 8.3% prevalence.[56]

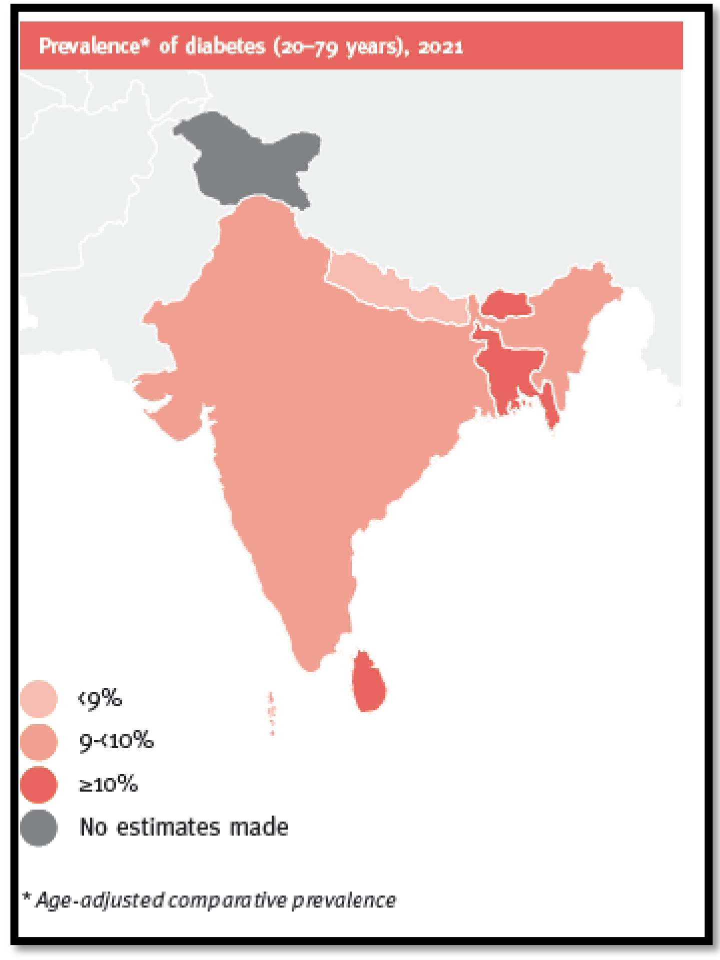


Figure 2. Prevalence of diabetes in India[56]

Within the study area, a community-based cross-sectional study conducted in 2013 by Bhalerao SD et al.[57] found an overall prevalence of T2DM as 17.7%, ranging from 15.3 to 18.7%, with prevalence being higher in rural populations compared to previously data in the study area.[57]

Risk factors for Type 2 DM[44,58]

- Diabetes in the family (parents or siblings with T2DM)
- Overweight
- Unnatural diet
- Usual physical inactivity
- Cumulative age
- Increase in BP
- Race
- Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT)
- History of DM during pregnancy or delivery of a baby with a weight of more than four kg.
- A triglyceride level of more than or equal to 250 mg/dL (2.82 mol/L) and/or an HDL cholesterol level of less than or equal to 35 mg/dL (0.90mmol/L).
- Polycystic ovarian syndrome (PCOS), also known as Acanthosis nigricans.
- History of vascular disease.

Symptoms

The symptoms of both types of diabetes are similar, although their severity varies. Type 1 diabetes causes symptoms to appear more quickly. Diabetes symptoms include polyuria, polydipsia, polyphagia, weight loss, weariness, slow-healing wounds, recurring skin infections, blurred eyesight, and tingling or numbness in the hands and feet. Diabetes patients are at a higher risk of acquiring a variety of major health issues.[55,56,58]

Pathophysiology

A shortage of endogenous insulin, which can be absolute (as in T1DM) or partial (as in T2DM), causes hyperglycemia. Insulin resistance in muscle, fat, and the liver, as well as insufficient pancreatic beta cell responsiveness, are important causes of relative insulin deficit. Increased plasma free fatty acid levels that have been related to IR.[59] As a result, muscular glucose transport is reduced, hepatic gluconeogenesis is increased, and fat breakdown is accelerated. A sedentary lifestyle paired with a vulnerable genotype is most likely to blame for T2DM complications. BMI at which the risk of diabetes increases varies by race. People of Asian descent, for example, are more likely to develop diabetes while being less overweight than people of European ancestry.[60] The diagram below represents a simplified way to understand the biology of poor glucose metabolism in T2DM.

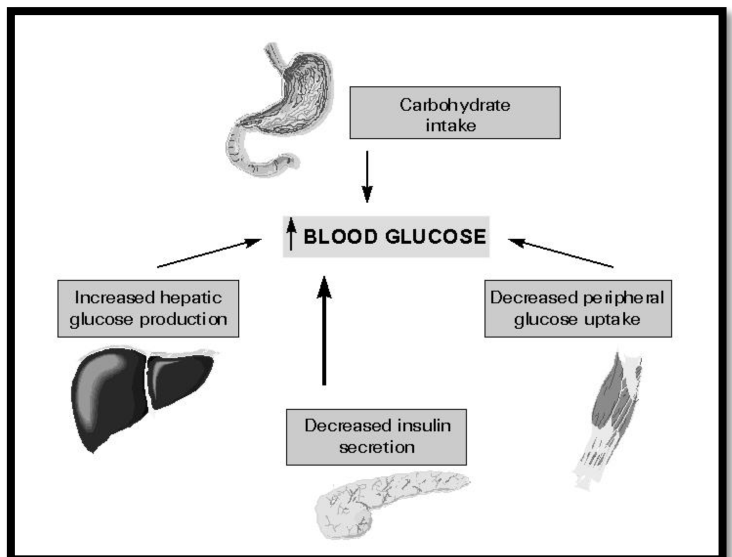


Figure 3. Pathophysiology of T2DM[61]

Increased blood sugar levels are an established risk factor for microvascular and metabolic problems.

Glycemia, on the other hand, has less impact on macrovascular issues. Insulin resistance is associated with lipid metabolism abnormalities (e.g., small dense low-density lipoprotein [LDL] particles, low HDL-C levels, elevated triglyceride rich remnant lipoproteins) and prothrombotic states, as well as traditional atherosclerotic risk.[61]

Diagnosis

Diabetes is diagnosed with a random plasma glucose of more than or equal to 200 mg/dL [11.1 mmol/L] in a patient with characteristic symptoms (hyperglycemia or hyperglycemic crises + signs of hyperglycemia). Meaningful plasma glucose level is critical in these situations since it will inform therapy options as well as establish that the symptoms are due to diabetes. Some doctors may also want to know the A1C to determine the severity of the hyperglycemia. Diabetes is diagnosed using the criteria listed below.[62]

Diabetes can be diagnosed using plasma glucose criteria, such as fasting plasma glucose (FPG) or 2 hour plasma glucose (2h PG) measurements derived from a 75 g oral glucose tolerance test (OGTT), or A1C criteria, as mentioned below.[61]

Criteria for the diagnosis of diabetes.[62]

- FPG concentration: 126 mg/dL (7.0 mmol/L). Fasting is described as not eating or drinking anything for at least 8 hours.

OR

- PG 200 mg/dL (11.1 mmol/L) was given for 2 hours during the OGTT. According to WHO guidelines, the test should be performed with a glucose load containing the equivalent of 75 g of anhydrous glucose dissolved in water.

OR

- A1C 6.5% (48 mmol/mol). The test should be carried out in a laboratory and the method that has been accredited by the National Glycohemoglobin Standardization Program (NGSP) and is standardized to the Diabetes Control and Complications Trial (DCCT) assay is to be used.

OR

- In a random plasma glucose level of more than 200 mg/dL (11.1 mmol/L) in a patient with normal hyperglycemia or hyperglycemic crises is deemed abnormal.

**In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.*

Normally, FPG, OGTT, and A1C are all appropriate for diagnostic testing. The tests do not always detect SM in the same person. The efficacy of interventions for T2DM primary prevention has been demonstrated primarily in people with impaired glucose tolerance (IGT) with or without elevated fasting glucose, not in people with isolated impaired fasting glucose (IFG) or in people with prediabetes defined by A1C criteria.[62]

Further tests were used to screen and detect prediabetes in adults. Diabetes can be discovered at any point along the clinical spectrum: in those who appear to be at low risk yet have glucose testing, in people who are evaluated based on diabetes risk assessment, and in symptomatic patients.[62]

Diabetes can be diagnosed using abstaining and 2 h glucose levels. The FPG and 2 h PG tests have a poor concordance. Numerous studies have proven that the 2 h

Post Glucose value when compared to FPG and A1C cut points, identifies more persons with diabetes.[62]

Glycosylated Hemoglobin (HbA1c)

Since the half-life of red blood cells is believed to be two to three months, glycated hemoglobin (HbA1c) offers information on BG levels averaged during this period. So, HbA1c level is widely regarded as a standard of care (SOC) to diagnose and monitor diabetes – T2DM in particular.[63]

Huisman et al.[64] isolated HbA1c in 1958 and Bookchin and Gallop[65] identified it as a glycoprotein in 1968. Rahbar et al.[66] reported increased HbA1c values in diabetic patients in 1969. Bunn et al.[67] discovered the mechanism that leads to HbA1c production in 1975. In 1976, HbA1c was proposed, by Koenig et al.[68], to be a biomarker for monitoring glucose levels in diabetic patients.

Recent guidelines by ADA recommend HbA1c with a cut-point of 6.50% as an alternative to FPG level based on criteria for diagnosing DM. HbA1c values of [69] remain strongly linked to FPG.[70]

HbA1c testing may not be possible for various reasons (such as pregnancy or unavailability of the assay) or may not be useful due to patient issues that prevent its interpretation. It is only in these situations that FPG, 2 hour post-glucose load BG levels, and OGTT should be used to diagnose T2DM.[19,71]

The standard test for diabetes monitoring and treatment is HbA1c because it is an important measure of hyperglycaemia that corresponds well with the risk of long term diabetic complications. However, the HbA1c cut-point remains questionable from a diagnostic standpoint.

In diabetics, BG levels increase and glucose bonds to a haemoglobin molecule in a concentration-dependent manner. HbA1c, or glucose-bound (glycated) hemoglobin, measures the average level of blood glucose as it becomes glycated with hemoglobin. It should be noted that HbA1c levels are closely related to BG levels. A fast glucose test (FGT) is a simple blood sugar test that evaluates how much glucose is in a person's blood at a given time.[72]

Although the FGT is an effective test for glucose levels but, does not provide detailed information about the trend of glucose levels. In contrast, the HbA1c test measures average glucose levels over the past two to three months. Contrary to common opinion, the HbA1c level is used to diagnose, control, and monitor both T1DM and T2DM.[73]

Khan et al.[74] postulated that an HbA1c cut-point of 6.5% was associated with 3.78% false negative predictions in a series of 12,785 male DM cases, while the majority of the false negative cases had borderline FPG (7.00-8.00 mmol/L) and HbA1c (6.00%-6.50%), and thus belonged to the at-risk category based on HbA1c alone criteria. Among those with HbA1c between 6.00% and 6.50% should have their status validated using a combination of FPG and HbA1c criteria. Recently, in another study[70] by the same author, they constructed regression equations to predict the interconversions of FGT and HbA1c levels in DM individuals.

Diabetic individuals' HbA1c levels fluctuate depending on their diabetes history, medication use, time, and/or short-term insulin treatment. Hyperglycemia is caused by T2DM because insulin synthesis is hindered (no production or unavailability). The HbA1c test is useful for diabetes diagnosis and prognosis because it offers a thorough picture of insulin and IR. HbA1c and IR are inextricably linked,

with HbA1c being more strongly linked to healthy persons with normal glucose tolerance and insulin sensitivity is measured. When assessing the glycemic spectrum for IR, the HbA1c test revealed a low overlap in values between normal glucose tolerance in those with T2DM. As a consequence, HbA1c is a trustworthy biomarker and an effective indication of IR when screening for DM and prediabetes.[63]

Kwon et al.[75] observed that HbA1c was a potential indicator of postnatal diabetes, although, it was found to have a high sensitivity but a low specificity for diagnosing gestational diabetes in pregnant women. Based on receiver operating characteristic curve analysis, HbA1c showed a sensitivity of 78.60% and a specificity of 72.50% with a cut-off value of 5.55% in predicting postpartum DM.

HbA1c is not only a good prognosticator of lipid profile, but it is also an active biomarker of long term BG control; hence, monitoring BG control with HbA1c may have the additional benefit of recognizing DM patients at a higher risk of CVD problems.[63] As a result, HbA1c as a single test provides important information for dealing with chronic conditions.[60]

In a study of 1,011 persons with T2DM, [67] HbA1c levels were found to be directly linked with triglycerides (TG), cholesterol, and LDL cholesterol, as well as inversely related to high-density lipoprotein (HDL) cholesterol. HbA1c and dyslipidemia had a linear association, Patients with higher BG levels had significantly higher blood TC and TG levels and significantly lower HDL levels than patients with optimal BG levels.[67]

Recommendations by ADA 2023 for HbA1c[62]

- An NGSP-certified method that is standardized to the DCCT assay should be used to perform the A1C test, to avoid wrong diagnosis.
- Significant differences between recorded A1C and plasma glucose levels raise the possibility of A1C test interference due to hemoglobin abnormalities (hemoglobinopathies), as well as the use of an interference-free assay or plasma BG criteria to diagnose diabetes.
- During the pregnancy especially in the second and third trimesters, recent blood loss or transfusion, erythropoietin therapy, sickle cell disease, etc. when the red blood cell turnover is high, only plasma BG criteria is to be used for the diagnosis of DM.

Although point-of-care A1C assays may be NGSP certified, proficiency testing is not mandated for performing the test. So, point-of-care assays are not recommended for diagnostic purposes as of now. However, this may change in the future if proficiency testing is performed, documented, and found adequate.

The HbA1C has various advantages over FPG and OGTT, including convenience (fasting not necessary), greater preanalytical constancy, and fewer day to day variations during anxiety and disease. However, the lesser sensitivity of A1C at the planned cut point, higher pricing, restricted availability of A1C testing in certain developing nations locations, and the unclear link between A1C and average glucose in some people may limit these benefits.[62]

The A1C cut-off of 6.50% (48 mmol/mol) recommended by the National Health and Nutrition Examination Survey (NHANES) corresponds to a prevalence of

undiagnosed diabetes that is only a third of that identified by glucose criteria. It is important to recognize, when using A1C to diagnose diabetes, that A1C is only an indirect proxy for average BG levels. One also has to consider other factors, such as age, race/ethnicity, and anemia/hemoglobinopathies, that can affect hemoglobin glycation independently of glycemia.[62]

Age

The studies which form the basis for proposing A1C to diagnose diabetes have only considered the adult populations. Hence, it is not certain whether A1C and the same A1C cut off point may be implied to diagnose DM in children and adolescents.[62]

Race/Ethnicity/Hemoglobinopathies

Although hemoglobin polymorphisms can impede A1C detection, the vast majority of tests used in the United States are unaffected by the most common variants. For individuals showing significant discrepancies in A1C and plasma glucose levels, the A1C assay should be considered unreliable. For the person with a hemoglobin variant (sickle cell trait) but normal red blood cell turnover, an A1C assay should be used which is not susceptible to interfering from hemoglobin variants. When examined with continuous glucose monitoring for a particular mean glucose concentration, glucose levels and A1C levels may be higher. A1C levels are also known to vary with race/ethnicity in the absence of hemoglobin variants and independently of glycemia e.g., A1C levels in non-Hispanic whites may be lower than those in African Americans with similar fasting and post-glucose load glucose levels. African Americans may also have lower 1,5-anhydroglucitol and higher fructosamine and glycated albumin levels, indicating a heavier (especially postprandially) glycemic burden.[62]

Red Blood Cell Turnover

Only plasma BG criteria can be used to diagnose DM in situations requiring rapid RBC turnover, such as sickle cell disease, pregnancy (second and third trimesters), hemodialysis, the recent history of blood loss or transfusion, and erythropoietin therapy.[62]

Confirmation of the Diagnosis

A second test is a must for confirmation if, there is no clear clinical diagnosis such as random plasma glucose more than or equal to 200 mg/dL (11.1 mmol/L) and other clinical manifestations of high BG levels. For confirmation, a second test (same or different) should be performed as soon as feasible using a new blood sample. As an example, diabetes is confirmed if the A1C is 6.70% and the repeat test results in A1C of 6.9%. Similarly, the diagnosis is also confirmed if, say, FPG and A1C, are above the standard cut-off. However, if the two tests performed yield opposite results, then the test whose result was positive should be repeated, taking into account the possibility of A1C assay interference. Finally, the diagnosis is based on the results of the confirmed test e.g., a patient who fulfills the A1C diabetes criterion on two tests (above 6.50% [48 mmol/mol] each) but not the FPG cut off (126 mg/dL [7.0 mmol/L]), should be diagnosed as diabetic.[62]

Because all tests contain pre-analytic and analytic variability, it is feasible that an abnormal result (i.e., over the diagnostic cut point) will generate a value below the diagnostic cut point when repeated. This scenario is achievable for FPG and 2-h PG if the glucose samples are allowed to sit at room temperature and are not centrifuged properly. Plasma glucose samples must be spun and separated as soon as possible

after being drawn. If the results are uncertain, the patient should be followed up and the test should be repeated over 3-6 months.[62]

Management of T2DM

A healthy lifestyle, which includes eating nutritious foods, exercising regularly, not smoking, and maintaining healthy body weight, is the cornerstone of treating T2DM. A healthy lifestyle may not be adequate to keep BG levels under control over time, and persons with T2DM may need to take oral medication. If a single medicine is insufficient, combined therapy may be prescribed. When oral medication fails to keep BG levels under control, persons with T2DM may need insulin injections.[58]

While dietary and lifestyle changes are important in T2DM treatment, the majority of patients but not all, eventually require pharmacological medications to control BG and prevent further complications. While BG control (FBS/PPBS or HbA1c) is crucial in the care of DM, it should not be the primary determinant of therapy.[54] On the one hand, the ADA/European Association for the Study of Diabetes recommendations advocate for an "individualized approach" to match the patient's needs and status to a range of alternatives.[62] The American Association of Clinical Endocrinology guidelines are more detailed and present possibilities in desirable order and are more explicit in their recommendations.[76] Because of their glycemic and extra glycemic benefits, newer drugs such as glucagon-like peptide-1 agonists (GLP-1), sodium glucose linked transporter 2 inhibitors (SGLT2), and dipeptidyl peptidase 4 inhibitors (DPP4) (in that order) should be preferred over older options.[54]

In the last two to three years SGLT2 inhibitors, have been shown to considerably reduce CVD events in secondary prevention settings (EMPA-REG

study).[77] Primary and secondary prevention settings (CANVAS study)[78], both in clinical trials and real-world settings (CVD-Real).[79] The majority of persons with T2DM who are overweight or obese are advised to attain and maintain a 5% weight loss through nutrition, physical exercise, and behavioral therapy. Further reductions in body weight typically lead to enhancements in the control of diabetes and cardiovascular risk. Furthermore, where available, long-term (almost one year) weight maintenance programs are recommended for persons who successfully lose weight. At the very least, such programs should provide support and contact once a month, recommend ongoing body weight monitoring (weekly or more frequently) and other self-monitoring approaches, and promote regular physical activity (200-300 minutes a week).[62]

Monitoring glycaemic control, optimal BMI and prevention of dyslipidemia are essential goals of diabetes management.

Monitoring glucose control

HbA1c-equivalent BG targets are suggested by guidelines.[55] An HbA1c target between 7.50% and 8.00% (58 to 64 mmol/mol) may be more acceptable in patients subject to medications such as glucose lowering drugs (GLDs), and having cognitive impairment, Chronid kidney disease (CKD), or severe CVD coupled with other comorbidities. Referrals for specialized care should be made for patients with those conditions. Patients using insulin must monitor their blood sugar levels constantly. During treatment modifications, acute illnesses, or as a self-care education tool, glucose monitoring is helpful.[55,62] The lowest risk of microvascular and macrovascular problems was related to the ideal A1C. A1C and microvascular/macrovascular complications are inversely correlated. There is clear evidence that reducing A1C

with appropriate treatment can lessen the complication rates. Studies, however, hardly ever discussed what a low A1C should be. According to this study, an A1C between 6.5% and 7.0% was ideal for the general population with T2DM to reduce the risk of microvascular and macrovascular problems. Furthermore, there is no universal A1C goal. Another important result is that patients' long-term clinical outcomes may suffer if their glycemic management is excessively strict (5.8%).[62]

In the ADVANCE[80] and STENO-2[81] investigations, intensive glycemic management dramatically reduced the microvascular consequence. With an A1C achievement of reducing from 7.5% to 6.5%, ADVANCE study[80] established the impact of tight A1C control on microvascular complication reduction, which is compatible with some of our findings. Only 20% of patients with strict glycemic control met the target of A1C 6.5%, according to the STENO-2[81] study. It implied that a high A1C level may not have a substantial link with a better clinical outcome of vascular problems. In epidemiological research, the link between A1C and microvascular problems was curved. Lowering A1C from 7% to 6% was related to a further reduction in the risk of microvascular problems, with the absolute risk reductions being significantly less. Furthermore, reducing A1C even after it had reached 6.8% was found to be inversely related to a higher risk of microvascular problems. Furthermore, the UKPDS trial discovered that strict glycemic management is related to lower microvascular risk, primarily retinopathy. Because the UKPDS trial intended to lower fasting BG, the A1C of the intensive treatment group (7%) was lower than the control group (7.9%).[82]

Glycemic management is still significant in macrovascular problems, even though A1C is the key predictor in microvascular issues. However, to reduce the risk

of microvascular and macrovascular consequences, strict A1C control is less appropriate for black patients with T2DM than for white individuals.[82]

Weight control for optimal BMI

Controlling and losing weight is critical for persons with T2DM who are overweight or obese. To reduce excess body weight and improve clinical markers, lifestyle intervention programs must be sufficiently intensive and have frequent follow ups. This will aid in weight loss and improve A1C, cardiovascular risk factors with overall well being in persons with overweight/obesity and DM. Strong and reliable evidence supports the idea that sustained, modest weight loss is good for the management of T2DM. Additionally becoming more common in diabetic patients, obesity and overweight provide clinical difficulties for managing diabetes and CVD risk factors. Maintaining weight loss over five years is connected to sustained improvements in lipid and A1C levels, despite the difficulty of doing so.

Dyslipidemia

Dyslipidemia manifested as high triglyceride and low HDL cholesterol levels, is frequent in T2DM patients. In diabetic patients, statin medication has been demonstrated to be helpful in both primary and secondary prevention of coronary heart disease (CHD) events.[83] The target for LDL cholesterol was set at less than 70 mg/dL in the ADA's Standards of Care in Diabetes—2023[62] for those with diabetes aged 40 to 75 who have a higher risk of cardiovascular disease, such as those who had least one atherosclerotic cardiovascular disease risk factor.[62] An LDL cholesterol level under 55 mg/dL was recommended for diabetics who had atherosclerotic cardiovascular disease.[83]

Complications

An increased risk of heart disease, hypertension, stroke, neuropathy, renal failure, gum disease, blindness, infections of the feet and legs, sexual dysfunction, and pregnancy difficulties can result from uncontrolled diabetes. Acute metabolic abnormalities that result in life-threatening consequences such as diabetic ketoacidosis and hyperosmolar coma can also be caused by it.[45,84,85]

Acute complications[1]

- Diabetic ketoacidosis
- Hyperglycemic Hyperosmolar state
- Hypoglycemia

Chronic Complications [86-92]

The majority of morbidity and/or mortality related to the disease may be caused by the chronic complications of DM, which have an impact on multiple organ systems.

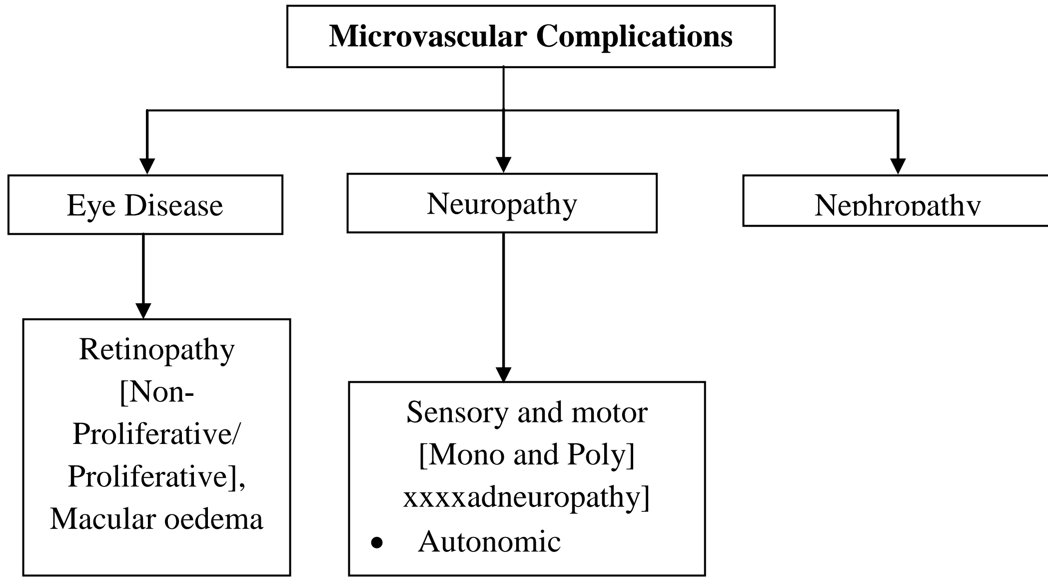


Figure 4. Microvascular complications seen in DM

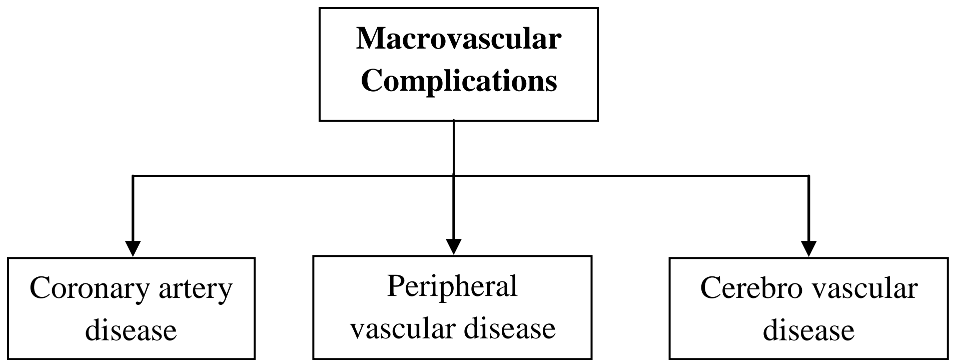


Figure 5. Macrovascular complications seen in DM

Other complications seen in DM:[86-92]

- Gastro-intestinal (GI) problems for example gastroparesis.
- Genitor-urinary (GU) problems for example uropathy.
- Skin irritation.
- Infections.
    - Urinary tract infection (UTI)
    - Tuberculosis
    - Candidiasis – oral / vulvovaginal
    - Mucormycosis
    - Necrotizing fasciitis
    - Periodontitis
- Cataracts and Glaucomas.
- Dupuytren's contracture, Pseudogout

Lifestyle Modifications and Management of T2DM

Physical Activity

Physical activity is the movement of the body persuaded by skeletal muscles that require the expenditure of energy. Daily lifestyle activities such as school and

afterschool, weekend activities wherein kids play are active, and expend energy are examples of physical exercise. There is evidence that physical activity behavioral patterns developed in childhood are maintained into adulthood. Even though regular exercise and physical fitness are distinct concepts, this phrase is commonly employed interchangeably in studies.[93]

Exercise has been defined as any sort of bodily activity that increases metabolic demand to build physical fitness. The well planned, structured, and systematic steady exercise plan encourages physical fitness.[93]

The effect of exercise on BG levels varies depending on the patient's carbohydrate consumption and insulin dose, both of which suffer from metabolic disruptions. The most typical challenges include determining the patient's pre-exercise blood glucose level, determining the intensity and length of the planned activity, and considering the time of day when the patient exercises. Exercise operates similarly to insulin, so if the daily exercise routine and exercise parameters are constant, the balance between insulin therapy and diet may be aided; nevertheless, for teenagers, this aim is nearly difficult to achieve in real life. Exercise training studies support the notion that moderate intensity aerobic activity increases the risk of hypoglycemia during and after exercise. Due to the production of adrenaline and noradrenaline in the blood, which stimulates the liver to release glucose more quickly than usual, high-intensity exercise with anaerobic use may boost BG levels. Exercise-induced glucose increase is followed by hypoglycemia several hours later as counterregulatory hormone levels decline. Both aerobic and anaerobic training programs enhance glucose absorption and insulin sensitivity. School-aged children participate in a variety of moderate- and high-intensity sports activities regularly. Their workouts are

usually spontaneous and impromptu. Each sort of activity needs a specific approach to maximize BG levels, although management difficulties are well understood. Patients' tolerance to exercise and insulin requirements vary, and it is hard to offer proper instructions that are suited for everyone with T1DM; hence, regular BG monitoring experiences are inevitable. Continuous glucose monitoring may help active diabetics track changes in their blood glucose levels and provide information about their responses to exercise. There are several guidelines for discussing safe sports engagement in type 1 diabetes children and adolescents. These suggestions can be tailored to personal measurements and an understanding of common reactions to a particular form of exercise.[94]

Physical activity is linked to improved glucose management in T2DM patients. Moderate, everyday physical activity is a useful method for managing the long-term symptoms of diabetes. Walking, gardening, and other routine household tasks are examples. Walking is the most helpful physical activity in T2DM because it provides significant glucose control while requiring little physical effort in physically weak patients. Furthermore, changes in sedentary behaviors are a much-needed lifestyle adjustment in T2DM patients. Sedentary behavior results in much lower energy use. Sedentary behavior is also associated with uncontrolled glucose levels in T2DM patients. Reduced sedentary time is therefore crucial in diabetic patients, which can be addressed by increasing physical activity. Furthermore, regular aerobic exercise has been shown to lower HbA1c levels in diabetics. Aerobic exercise improves patient health outcomes via several pathways, including increased mitochondrial density, insulin sensitivity, blood vessel compliance, and lung functions with higher cardiac output. Regular physical activity paired with supervised exercise is an important part of T2DM therapy. A comprehensive examination should be

performed before suggesting an exercise regimen to diabetics. The exercise program should be adapted to each individual's skill and capability. Exercise improves insulin sensitivity, decreases the risk of heart disease, high blood pressure, bone disorders, and unhealthy weight gain, boosts strength and stamina, promotes restful sleep, boosts metabolic rate and digestion, lowers lipids, and slows the aging process.[95]

Yoga

Yoga, which originated over 5,000 years ago in India, seeks to assimilate and merge the body, mind, and emotions. Evidence suggests that it not only addresses the pathophysiologic mechanisms of DM but also aids in the treatment and its consequences as well.[96]

Yoga, despite being performed since ancient times, remains a relatively young and increasing trend in the domain of healthcare. Significant research has linked yoga practice to biochemical, electrophysiological, cellular, genetic, neuromuscular, and behavioral changes. As a result, yoga, which originated as a mind-body practice aimed at spiritual enlightenment, is now acknowledged globally as a clinically useful treatment for several ailments, although it is a health management discipline and not a medicine for the treatment of specific conditions.[96]

Yoga is known to have the potential to regulate eating habits. As a result, it is proposed to have applications in the treatment of eating disorders. Yoga is also intended to increase self-awareness, introspection, and development by encouraging a mind-body connection. Yoga, pranayama, and sudarshan kriya have all been shown to improve eating habits and medication compliance.[96]

Yoga participation is shown to correlate positively with vegetable and fruit consumption. It is known to improve eating behaviours by helping one to eat in moderation, enhance mindfulness through meditation, and prevent oneself from binge eating. In diabetics, mindful eating has been found to enhance nutrient intake, mild weight loss, and glycemic management.[96]

Various kinds of yoga have been proven useful in managing T2DM; nevertheless, a comprehensive assessment of a patient's general health, unique needs, contraindications, associated risk factors, etc. is necessary before their prescription. The aforementioned assessment should consider the individual as a whole, and Yoga practices of varying intensity should be recommended depending on the amount of physical inactivity and/or other living patterns.[96]

However, the recommendations for frequency and duration of yoga practice are not precisely defined, and studies have analyzed with vide variation of frequencies and durations. Yoga practice lengths of 10 min, 25 to 35 minutes, and 60 minutes per day, 45 minutes one hour six days every week, 75 minutes thrice a week, and 90 minutes sessions twice weekly, all have yielded significant benefits. Many research reported improvements after an intervention of three months, while a few also analyzed 15 days, 40 days, and 6 months of therapies. Yoga practice has been shown to have an impact on its therapeutic advantages.[96]

Diabetes is a chronic metabolic disease that adversely affects one's quality of life. Psychological and emotional stress comes in the way of controlling diabetes bidirectionally. Stress stimulates the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic axis as well as parasympathetic withdrawal. This raises the severity and risk of DM owing to increased cortisol, glucagon, epinephrine, norepinephrine,

growth hormone, prolactin, catecholamines, leptin and neuropeptide Y levels. HPA axis activation is known to be associated with worse diabetes control and complications like diabetic neuropathy. In T2DM patients, elevated inflammatory cytokines promote IR, which, along with hypertension and the risk of cardiovascular events, is known to be worsened by chronic mental stress. This is what Yoga targets – it aims to reduce stress, thereby helping with the management of diabetes. In healthy volunteers, yoga practice resulted in better physical wellbeing, lower levels of stress and anxiety, an improved psychological, social and physical state, an overall improvement in their perspective on life. Yoga practice boosts performance on a variety of psychological assessments, including satisfaction impact and concern. It also increases physical activity, causes positive behavioural changes and improves eating habits, apart from its contribution to managing stress.[96]

It is believed that abdominal stretching during yoga moves results in pancreatic cell regeneration. The numerous postures employed in yoga practice serve to improve β-cell sensitivity to glucose, hence increasing insulin secretion, as well as increasing blood flow to the muscle and muscular relaxation, both of which benefit glucose absorption. Improved hormonal balance improves glycemic control in T2DM patients. Yoga therapy also has an immunomodulatory effect by improving immune function and lowering proinflammatory responses.[96]

Changes in neurotransmitter and hormonal levels are responsible for the benefits of yoga therapy. Increased dopamine, serotonin and β-endorphin levels lead to the euphoria of yoga. Increased levels of arginine-vasopressin reduce gamma-aminobutyric acid (GABA)-ergic inhibition of the supraoptic area of the hypothalamus, leading to improvements in arousal. Stimulation of the lateral

hypothalamus is responsible for the feelings of blissfulness and ecstasy. Melatonin leads to the calming effect of yoga. Raised 5-methoxydimethyl tryptamine and N-acetylaspartylglutamate levels together with lowered GABA levels are responsible for decreased spatial orientation during meditation and the associated out-of-body experience.[96]

Yoga is also believed to have a "beyond the drug action" by possibly helping in the regeneration of tissues by replenishment and recruitment of stem cell-derived cells. This is due to a potential increment (the mechanism for which remains to be better understood) in the trafficking of stem cells to the peripheral blood.[96]

Yoga asanas increase flexibility, endurance, strength and muscle activity, and also modulate gene expression with a desirable impact on IR, dyslipidemia, body weight and adiposity.[96]

Yoga reduces leptin, interleukin 6 and malondialdehyde levels in the serum while improving the levels of adiponectin, leading to decreased oxidative stress. Yoga therapy not only increases the number of insulin receptors but also improves receptor binding. It lowers the levels of fasting insulin, decreases peak insulin levels, and regularises the insulin-to-glucose ratio, thereby improving insulin kinetics. It also decreases IR while increasing insulin sensitivity as indicated indirectly by lowered free fatty acid levels. The functioning of the lungs is also shown to have been improved by yoga, especially, breathing exercises. Yoga is also known to improve lymphocyte migration in T2DM patients, indicating improved cell-mediated immunity.[96]

People who are susceptible to diabetes can also benefit from yoga. It was observed to reduce diabetes symptom scores. It improves glycemic control by

lowering blood sugar levels, both fasting and postprandial, as well as HbA1c levels, and the need for medication against diabetes. Yoga therapy also increases lean body weight by reducing skin fold thickness, BMI, body fat percentage by mass, overall weight and waist to hip ratio.[96]

Free fatty acid, LDL and TG levels are found to reduce by yoga, while HDL levels are likely to see an improvement. Practicing yoga regularly leads to better exercise and dietary habits. Yoga was also found to benefit exercise tolerance that is, an improvement in the treadmill test performance from eight to twelve metabolic equivalents (METS), resulting in a postponement of the anaerobic threshold. Studies also show that people who practice yoga had lower systolic and diastolic BP.[96]

Diabetes related problems are reduced by regular yoga practice. Clinical studies show that practicing yoga regularly improves cardiac autonomic function (independent of diabetic management), thereby reducing the risk of cardiovascular autonomic dysfunction, which is considered to be a cause of sudden death in diabetic patients. Yoga practice also improves cognitive function and nerve conduction in patients with DM by stabilizing their coagulation profile.[96]

Weight gain occurs in patients with T2DM when glycemic control is improved with anti-diabetic medication or insulin up-titration without exercise and moderated eating habits. Yoga, on the other hand, is found to help maintain glycemic control without an increase in body weight, in fact, certain studies have reported a decrease in body weight due to yoga.[96]

Yoga's ease of use, safety and numerous mental advantages have led to its increased acceptance in the culture, It is now considered a low-cost intervention to address a variety of lifestyle illnesses, including diabetes.[96]

Yoga treatment is generally good for both wellness and disease. Recent scientific evidence suggests that yoga helps manage T2DM and its risk factors holistically through its immunological and psychoneuroendocrine effects. The anti-stress actions of yoga together with the parasympathetic activation it stimulates improve not only the metabolic and psychological profiles of patients but also their lipid metabolism and glucose tolerance The various aforementioned yoga practices viz., asanas, pranayama, bandha, meditation, mudras, mindfulness and relaxation, have all been found to lower BG levels and facilitate the management of T2DM and the comorbid conditions associated with it.[96]

Recent studies on the effect of yoga with exercise on glucose levels among patients with T2DM.

Boule NG et al.[97] (2001) published a review to look into the impact of exercise on glycosylated hemoglobin (HbA1c) and BMI in patients with T2DM. Fourteen controlled clinical trials (CCTs) with a total of 504 individuals were considered, with 11 RCTs (412 patients) and three non-RCTs (92 patients). The authors stated that exercise should be considered helpful in and of itself for persons with T2DM, regardless of any effect on weight, and that future trials should be well-designed, longer in duration, and assess changes in body composition.

Sharma M. and Knowlden AP.[98] (2012) evaluated studies on the therapy of yoga in prevention. Nine out of eleven studies that evaluated changes in fasting BG found a substantial decrease. The authors cited a lack of a theory-based approach, small sample numbers, and the inability to assess adherence as significant shortcomings of the studies examined.

In western Odisha, a study by Dash S and Thakur AK.[99] (2014) investigated the efficacy of yogic asana and pranayama on a variety of biochemical indicators in T2DM patients. Sixty people with T2DM (NIDDM) were separated into two groups. Yoga patients in Group I (n1 = 30) were subjected to various Yogic asanas for 40 days., in addition to meals and diabetic drugs. Group II (n2 = 30) patients were kept on a diet in addition to normal medical care. The biochemical tests include baseline measurements such as FBG, PPBG, HbA1C, and lipid levels. Based on the statistical investigation of the study's results and their comparison with other published data, it is feasible to conclude this yoga helps to reduce BG levels under control. Similarly, reducing HbA1C protects patients from the onset of several complications associated with DM. The improvement in lipid profile delays the emergence of associated diseases such as hypertension and CAD. Yogasana and pranayama were found to be beneficial as an adjunct to medical therapy for optimizing metabolic parameters. Yoga treatment also aids diabetics by lowering medication doses, enhancing physical and mental alertness, and preventing complications.

Chimkode SM. et al.[100] (2015) conducted a prospective case-control study and discovered a highly statistically significant ($p<0.001$) reduction in mean PPBS and FBS values at the end of six months compared to those before and during (i.e., at the three-month mark) the yoga practice. When compared to pre-yoga mean levels, this drop in FBS and PPBS values at three months was highly significant in the T2DM group ($p<0.001$), but not statistically significant ($p>0.05$) in controls. The authors concluded that yoga effectively reduces BG levels in patients with T2DM.

Park JH et al.[101] (2015) observed the effect of exercise on glucose levels and provided suitable exercise guidelines for Korean patients with T2DM. They studied a

sample of 1,328 T2DM patients aged between 30 and 90 years. They observed a lowered risk of glycemic control failure when the participants were subject to the aerobic exercise of low and moderate intensity with adjustments for resistance exercise. In conclusion, the authors claimed that physical activity is likely to minimize the chronic and acute complications of DM by improving glycemic control.

Cui J. et al.[102] (2017) conducted a meta-analysis, involving a total of 864 patients across 12 randomized controlled trials, to assess the effectiveness of yoga in adults with T2DM. They found weighted mean differences in FBS, HbA1c and PPBS to be -23.72 mg/dL (p=0.001), -0.47% (p=0.02; I 2 = 82%) and -17.38 mg/dL (p=0.001) respectively. Authors also noted a difference of -18.50 mg/dL (p=0.001), 4.30 mg/ dL ($p<0.001$), -12.95 mg/dL ($P<0.001$) and -12.57 mg/dL (p=0.16) in total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides respectively. Owing to these findings, the authors concluded that yoga indeed benefits adults with T2DM; but, considering the heterogeneous nature of their sample and limited methodologies, they also emphasized the need for future studies that may support these findings and examine the long-term impact of yoga on T2DM

Najafipour F. et al.[103] (2017) conducted a quasi-experimental trial with pretest posttest design. The study featured a sample of with 65 T2DM patients, of which 30 were controls, with ages ranging from 33 to 69 years. They investigated the effects of their long-term exercise training program on HbA1C, BMI and VO_2max levels in their study population and found a statistically significant ($p<0.05$) improvement in all three aforementioned biological indicators. The said long-term exercise training not only improved glycemic control but also improved cardiovascular fitness and body composition in patients with T2DM. With this conclusion that long-term

physical exercise offsets the imbalanced levels of the mentioned indicators, the authors also expressed a need for further studies focusing on real-life implementation of long-term exercise programs and their effect on the health of participants.

In a retrospective study, Singh A et al.[104] (2017) examined the impact of the Residential Integrated Yoga Program (RIYP) on the BG levels of 598 T2DM patients in Bengaluru, India. A significant decrease, relative to baseline, was noted in FBS and PPBS ($p<0.001$ each) after 15 days of RIYP. Also noted were significantly reduced symptom scores and need for medication The authors concluded that in patients with T2DM, two weeks of a residential yoga program improved not only BG levels but also BP and medications.

Raveendran AV. et al.[96] (2018) In their study from Mumbai, India, they determined that yoga helps to improve health and wellness. The most recent scientific evidence suggests that yoga-based lifestyle adjustments may have a role in the treatment of T2DM and risk factors. It was been postulated that psychoneuroendocrine and immunological pathways have a broad impact on diabetes regulation. The stimulation of the parasympathetic nervous system improves patients' overall metabolic and psychological profiles, as well as glucose tolerance and lipid metabolism. Yoga practices such as asanas, pranayama, mudras, bandha, meditation, mindfulness, and relaxation have been found to lower BG levels and aid in the management of T2DM-related concomitant illness conditions, with notable good clinical effects.

Kurniawati Y et al.[105] (2019) We out a data evaluation on the effect of physical movement on glucose level management in T2DM. Out of 1145 publications retrieved, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-

Analyses) approach generated 14 papers. Aerobic exercise improved glycemic control in people with T2DM widely used and significant for glycemic control. The three-times-a-week, 60-minute sessions over two months plan was extensively used and effective in lowering BG and hemoglobin A1c (HbA1c).

Das J. et al.[106] (2020) enlisted 40 patients for their study to ascertain the benefit of exercise in the treatment of T2DM. The patients were separated into two groups: study and control with 20 patients in each group. The study found that exercising in T2DM according to the program is safe, acceptable, and beneficial in lowering BG levels. It was not surprising that lowering BG levels were correlated with functional development, as evidenced by statistically significant differences in BG levels on the majority of the scales. According to the authors, exercise in patients with T2DM under limited conditions appears safe and effective.

Shah SZA et al.[107] (2021) in their systematic review and meta-analysis of the literature on the therapeutic benefits of exercise on BG control among individuals with T2DM), found a total of 21,559 articles from various databases. Of them, only 32 randomized controlled studies, were considered appropriate for inclusion. The average exercise session lasted 45.15 minutes, and the average follow-up period was 21.94 weeks. According to data, the average exercise frequency was 3.25 days per week. Almost all of the studies found that exercise significantly reduced HbA1c ($p=0.001$), FBG ($p=0.03$), BMI ($p=0.04$), and waist circumference ($p=0.007$). It was concluded that exercise plays an important role in optimizing glycemic control and improving quality of life (QoL), BMI, and waist circumference in T2DM patients.

Singh VP, et al.[26] (2021) A randomized controlled study was done to demonstrate the effect of yoga and exercise for control on BG levels, anxiety,

depression, exercise self-efficacy, and QoL. A total of 227 people were randomly assigned to either the yoga group or the exercise group. The yoga group did yoga for two weeks under supervision before continuing her practice at home for three months. The exercise group walked for 30 minutes five days a week. The mean change in glycated haemoglobin in the yoga group was 0.47 with a p value of less than 0.050, which was larger than the mean reduction of 0.28 in the exercise group. In three months, the yoga group decreased state anxiety by 7.80 and trait anxiety by 4.40 ($p<0.050$), compared to nonsignificant declines of three and one in the exercise group ($p>0.050$). Both groups saw a statistically significant drop in depression score, 8.6 in yoga and 4.00 in exercise, with the yoga group reporting a higher decrease (P 0.050), but only by 2.20 in the exercise group ($p>0.05$). Quality of life improved by 23.70 points in the yoga group and when compared to the YG. When compared to the YG, quality of life improved by 23.70 in the yoga group and 3.0 in the exercise group which was nonsignificant in the exercise group as compared to the yoga group. The study concluded that Yoga is superior to exercise alone as a lifestyle modification program in improving glycemic control, anxiety, depression, and quality of life QoL as well as ESE.

A North Indian randomized controlled trial by Kaur N. et al.[108] (2021) evaluated the usefulness of the diabetic yoga protocol (DYP) against the risk profile of the cardiovascular disease in a community from Chandigarh having a high risk for diabetes. The authors found that DYP could improve lipid levels and glucose tolerance of the high-diabetes-risk participants, as explained, in part, by their reduced abdominal obesity. The authors emphasized the real-time benefits of yoga on cardiovascular risk profile in their sample of high-diabetes-risk participants.

Yuniartika W et al.[109] (2021) A study has been published to evaluate how yoga and walking treatment affected diabetes individuals in the community. Before (217.00) post (187.72) ($p<0.050$) fasting sugar levels in the yoga group, before (209.89) post (193.83) ($p<0.050$) in the walking group, and before (221.50) post (225.17) ($p=0.067$) in the control group. Yoga and walking therapy have been shown to reduce fasting glucose levels.

Chen S. et al.[110] (2022) investigated the efficacy of yoga instruction on diabetes-related markers against standard therapy. The standardized mean difference (SMD) for the effects of yoga was significant on HbA1c (SMD = −0.47 percent; p=0.003), FBG (SMD =−0.92; p=0.004), PPBG (SMD = −0.53; p=0.001), and TG (SMD = −0.32;p=0.004). Yoga did not affect TC (SMD = 0.84; p=0.06) or BMI (MD = 0.63; p=0.120). According to the study, yoga can enhance T2DM patients' biochemical markers of elevated BG and lipid profile. As a result, authors recommended yoga as an active and successful supplement to T2DM treatment. However, yoga was only evaluated on the short-term basis in this study.

Recently, Verma MR et al.[111] (2022) reported a drop in BG levels in patients with DM compared to non DM individuals in their observational study on the effect of yoga and sudarshan kriya among T2DM patients, which included 137 participants. However, the drop in SBP and DBP in diabetics and non-diabetics was similar ($p>0.05$). However, the percentage reduction in pulse rate was larger ($p<0.05$) in patients with DM than non-DM. The study concluded that thorough yogic breathing practices may be advantageous in T2DM patients.

JUSTIFICATION

Diabetes control relies heavily on medication, diet, and physical activity/exercise.[62] However, many complementary and alternative therapies, including yoga, have been employed in diabetes prevention and treatment. Yoga began as a type of ancient mind-body training in India some 5000 years ago. Yoga has been studied for its potential to help with many chronic diseases, including hypertension, asthma, chronic obstructive pulmonary disease, and diabetes.[112] There is a scarcity of data from randomized blinded studies with an adequate sample size in the literature. There is a dire need to examine the efficacy of other therapies such as yoga due to their holistic nature, cost-effectiveness, and lack of side effects.[26] The use of adjuvant drugs, according to the ADA, should be based on clinical study findings.[62] According to [96,110-112] reports, there is a change and certain studies[102]. reveal that there is no change in HbA1c following yoga practice. Yoga is also generally safe, simple to learn, and may be performed by anybody, even the sick, elderly, and disabled. Many writers have stated that extra research is required to define the potential effect of yoga, on glucose levels, as well as to explain the likely mechanism underlying the improvement in glycemic control that yoga may bestow on T2DM patients. Finally, no similar study on the effect of yoga compared with exercise on glycemic control in T2DM patients in this region of the country has been published. Given these facts, the current study sought to investigate the effects of yoga and exercise on glycemic control, lipid profile, and BMI in T2DM patients.

Objectives

The objectives of this study were;

Primary

To compare the effect of yoga with exercise on glycemic control among patients with T2DM.

Secondary

To compare the effects of yoga and exercise therapy on lipid profile and BMI among patients diagnosed with T2DM.

Hypothesis

Null hypothesis

Yoga compared to exercise has no beneficial effect in terms of glycemic control, lipid profile and BMI among patients with T2DM.

Alternative hypothesis

Yoga compared to exercise has beneficial in terms of better glycemic control, improves lipid profile and prevents obesity among patients with T2DM.

MATERIAL AND METHODS

The current study was carried out at Jawaharlal Nehru Medical College, KAHER, Belagavi, under the Department of Community Medicine.

Study design

The study design was single center randomized controlled trial.

Duration

This study began in June 2017 and continued until the sample size for participant enrollment was reached, which was in December 2017. The trial lasted 18 months, including the follow-up period.

Study area

The current study was carried out at the Urban Health Centre, Ashok Nagar, Belagavi, which is part of the Department of Community Medicine, Jawaharlal Nehru Medical College, KAHER, Belagavi. Participants in the study were taken from the diabetic register at the Urban Health Centre in Ashok Nagar, Belagavi.

Participants

All potentially eligible participants diagnosed to have T2DM and registered in the study area.

Sample Size

The sample size was calculated by using below mentioned formula;

$$\frac{(Z_{1-\beta} + Z_{1-\alpha})^2\ (SD_1^{\,2} + SD_2^{\,2})}{(\bar{X}_1 - \bar{X}_2)^2}$$

Where,

- Z_1-α = at 95%, Confidence Interval = 1.96
- Z_{1-}b = at 80 %, Power of the test = 0.84
- Difference in Mean and SD for exercise and yoga intervention groups which were considered as 0.59 and 3.34 based on the study by Sanghani NB et al.[113] (2013).
- X1-X2 = Expected impact size
- $n = (0.84 + 1.96)^2 (0.59^2 + 3.34^2) / (9.0 - 7.29)^2 = 57$
- Considering the attrition rate to be 10%, the calculated sample size was amended to 63 in each group.

Hence a total of 126 participants divided into two groups of 63 each were planned for the study.

Selection criteria

Inclusion

- Participants with a history of T2DM for more than a year with an HbA1c level of more than 6.5 and residing in the study area.
- Participants aged between 40 to 85 years.
- Participants with a history of T2DM were treated with oral hypoglycaemic agents.

Exclusion

- Participants with known vascular problems such as coronary artery disease (CAD), stroke, or cellulitis that, in the investigator's opinion, may have jeopardized the patient's physical integrity.
- Participants with other chronic conditions that limit physical activity, such as peripheral vascular disease (PVD).
- Participants who have lost their ability to speak, hear, see, or think.
- Participants with T2DM on Insulin and women participants with pregnancy.

Randomization

Based on computer generated randomized number sequence method, participants were subdivided into two groups as below.

- Yoga Group: This group was on a dietary control, anti-diabetic medication, and Yoga treatment.
- Exercise Group: This group's participants were on a dietary control, anti-diabetes medication, and exercise.
- **Ethical clearance**

The work was authorized by the Institutional Ethics Committee for Human Subjects Research at JNMC, KLE University, Belgaum (Annexure I).

Written informed consent

Eligible participants were informed about the study's purpose and potential health benefits. Participants who stated a self willingly taking part in the study were enrolled after providing written informed permission.

Data collection (DC)

Participants were interviewed, then sociodemographic information such as age, gender, socioeconomic status, diabetic history such as duration of diabetes, dietary history and diabetic medication were collected. The investigator also performed a complete general medical examination to record anthropometric data and blood pressure readings. All of these answers were recorded on a predesigned and pretested proforma that was standardized before the study began.

Investigations

All investigations for blood chemistry analyses were completed by an offsite laboratory. Under aseptic precautions, venous blood was drawn by using sterile disposable syringes and needles for the biochemical examination which include random blood sugar, HbA1c and fasting lipid profile. Participants underwent the following investigations.

Blood sugar levels

- Random blood sugar
- HbA1c

Lipid profile

- Total cholesterol (TC)
- HDL
- LDL
- TG
- Very low-density lipoprotein (VLDL)

Intervention

Participants were recruited over a period of six months. The intervention program was initiated when a batch of 20 participants was completed.

After the collection of baseline data and recruitment of study participants in the first two months of starting the study, all study participants in both groups were given health education regarding diet and the importance of treatment adherence. The first two months of intensive Yoga teaching sessions were conducted by the research yoga teacher. For the next four months, yoga was done under the observation of family members who were identified prior. Then for the next six months, participants were asked to continue yoga sessions on their own at home and follow up by a research staff nurse.

Yoga Group:

The 24-week intervention was 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). First two months training was provided under qualified yoga teacher. The yoga classes were held in the study area. The duration and frequency of classes was approximately 50-60 minutes, three days per week. As all the participants may be previously sedentary, overweight, and above the age of 50 years, the yoga poses were modified to accommodate limited levels of flexibility, balance, and strength. Props such as chairs, belts, or blankets were used for such modifications to allow for appropriate alignment, technique, and balance, and especially to provide participants the opportunity to obtain full benefit from the asanas within their particular limitations. During each

class, participants were 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 was consisted of a relaxation exercise in which participants were 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.

Handouts with yoga poses and meditation exercises were provided approximately every two weeks so that participants continued to practice at home and even after the end of the intervention. One person in the family was identified as a key person and was given a compliance sheet to monitor whether the participant is regularly doing yoga or not. Research staff Nurses coordinated and did the follow up of study participants to monitor compliance and provided individualized feedback.

Exercise Group:

Unstructured activity was defined as an intervention in which patients 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.

Research Medico social worker coordinated and did the follow up of study participants. One person in the family was identified and was given a checklist to monitor whether the participant was regularly doing exercise.

Management of hypoglycaemic events during intervention

Although uncommon, to manage hypoglycaemic events during yoga and during exercise in individuals who are not treated with insulin, such as the participants of this study, caution was implemented at all times. In addition, glucose tablets (Gluco energy, Gluconorm) were 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 carbohydrates as suggested by the ADA to offset a sudden drop in circulating plasma glucose.[114]

Compliance/adherence to the intervention

The family member of the participant was provided with a checklist to ensure compliance/adherence to the intervention. Every month when the patient visited the Urban Health Centre for collection of anti-diabetic drugs, random blood sugar levels were checked and cross verification of the checklist provided to the participant's family member was done.

Study variables

Socioeconomic status

The entire monthly income of the family in Rupees, as well as the family size, were acquired. The monthly income per capita in rupees was computed, and the family was categorized using a modified version of B. G. Prasad's classification.[115]

Modified B. G. Prasad's Classification

Socioeconomic class	Prasad's classification (1961) per capita income in Rs./ month[115]	Modified Prasad's classification in the study period (2017)[116] Per capita income in Rs/month
I	100 & above	6254 & above
II	50 – 99	3127 & 6253
III	30 –49	1876 & 3126
IV	15 – 29	938 & 1875
V	below 15	below 938

Average Consumer Price Index for the year 2017 = 727[116]

The Multiplication Factor (M.F) was used to make the modifications, which are listed below:

$$\text{M. F.} = \frac{\text{Average Consumer Price Index for study period}}{100} \times 4.93$$

$$\text{M. F.} = \frac{727}{100} \times 4.93$$

$$= 35.8 \approx 36$$

Body mass index

Height

The standing body height (cms) was measured. Body height was measured to the closest 0.5 cm using a commercial stadiometer. The participants were told to stand erect, with their bare feet on the stadiometer's floorboard and their backs on the stadiometer's vertical backboard. Both heels were positioned together, with both heels

contacting the vertical board's base. The vertical backboard makes contact with the buttocks, scapulae, and head.

Weight

For body weight measurement, weight (kg) was recorded using a digital scale with an accuracy of 100 grams. Participants were requested to wear light clothing and to stand barefoot on the center of the weight scale platform. Each participant's BMI was calculated by dividing his or her body weight in kilograms by his or her height in meters square. The BMI was determined using the Indian population's BMI guidelines. The subjects were categorized following the BMI categorization provided by the WHO Steering Committee, the International Association for the Study of Obesity, and the International OBESITY Task Force.[117], as shown below.

Classification of Obesity

BMI kg/m^2	Classification
≤18.49	Underweight
18.5–22.99	Normal weight
23 – 24.9	Overweight at risk
25 – 29.9	Pre-Obese
30- 34.9	Obese I
35 – 39.9	Obese II
≥40	Obese III

Glycaemic control

Following a 12-hour overnight fast, a venous sample of 2 mL was collected at 8:30 a.m. for random blood sugar testing. The blood was taken and placed in centrifuge tubes. After allowing it to clot, it was centrifuged at 3000 rpm for 15 minutes at room temperature. The serum was pipetted into a clean blood sample bottle and examined for biochemical tests on the day of collection. The Ion Exchange Resin Method was used to calculate HbA1C. ADA recommended HbA1C of 6.5% for diabetes diagnosis and 5.7-6.4% for those at high risk of developing diabetes.[114]

Interpretation of HbA1c for glycaemic control[114]

HbA1c	Interpretation for Diabetic Patient
Less than 6%	Normal
6 to 7.5%	Good control of DM
7.6 to 9%	Unsatisfactory control
More than 9%	Very poor control

Lipid profile

An enzymatic (CHOD-PAP) colorimetric approach was used to assess serum total cholesterol, and an enzymatic (GPO-PAP) method was used to determine TG. The precipitant method was used to estimate HDL cholesterol and Friedewald's formula was used to compute LDL and VLDL cholesterol:

LDL-C = TC - HDL-C – (TG/5)

VLDL= TG/5

Further individuals' serum lipid profiles were assessed using readily available reagent kits. The values were interpreted using the National Cholesterol Educational Program's Adult Treatment Panel III model and the ADA's 2016 glycemic management guidelines.[114,118]

Interpretation of Lipid Profile[114,118]

Lipid parameter	Normal range
TC	130-200 mg/dL
TG	80-170 mg/dL
HDL	30-60 mg/dL
LDL	66-178 mg/dL
VLDL	2 to 30 mg/dL

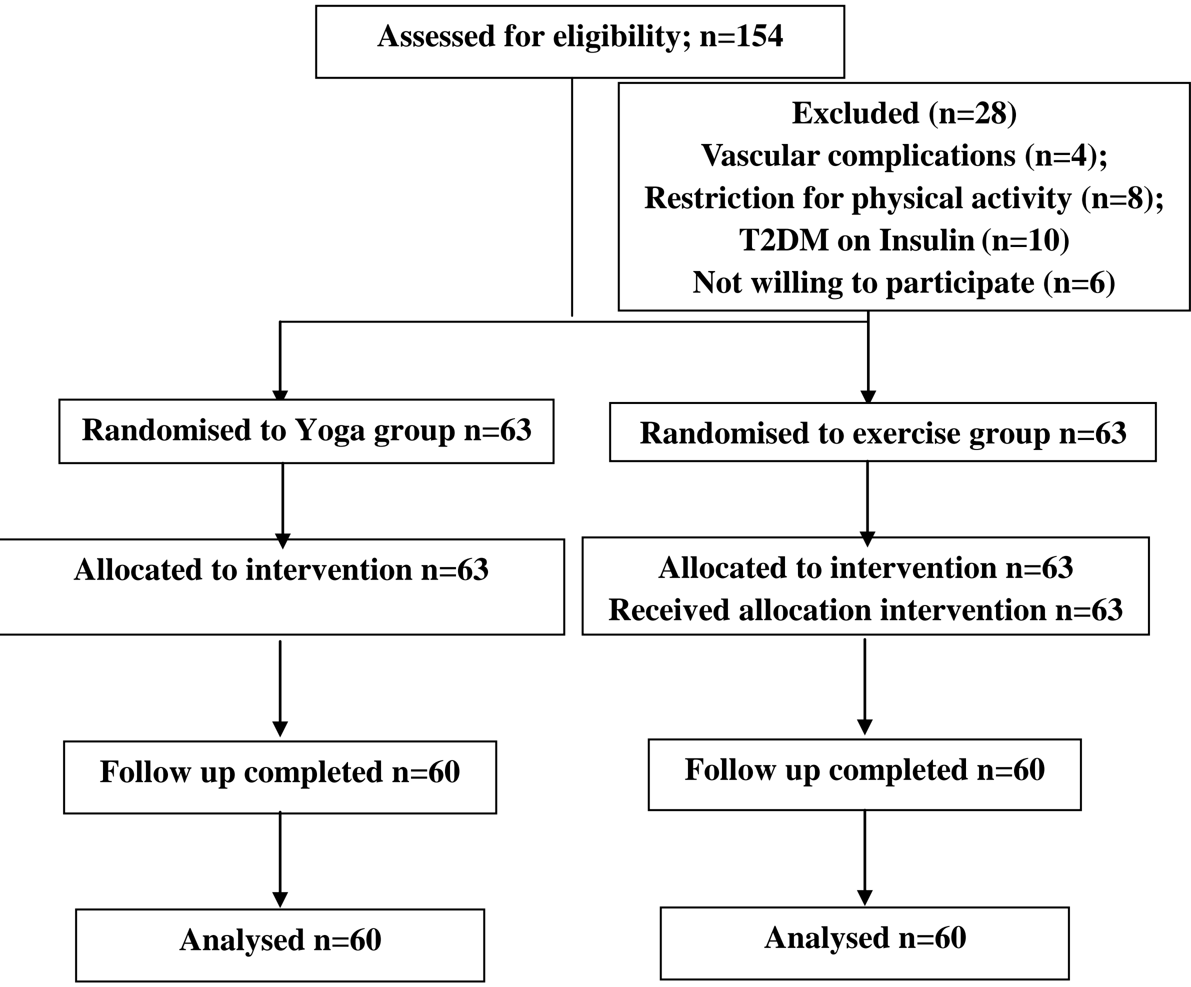
DATA ANALYSIS PLAN

The information was plotted on a excel sheet and master chart was prepared (Annexure IV). Percentages, rates, and ratios were used in the analysis. As an alternative to using mixed-model ANOVA, Generalized Estimating Equations (GEE) models were used. GEE models were run on dependent variables (glycemic control variables, lipid profile variables, BMI, and blood pressure) to compare two intervention groups over time.

RESULTS

This 14-month single-center randomized controlled experiment was undertaken at Jawaharlal Nehru Medical College, KAHER, Belagavi, under the Department of Community Medicine. A total of 126 eligible people with T2DM who were registered in the research region were enrolled. Patients are separated into two groups, each with 60 patients. The Yoga Group (Yoga treatment) and Exercise Group (Exercise therapy) both use a computer-generated, randomized number sequence approach. The picture below depicts the process of selecting and enrolling people.

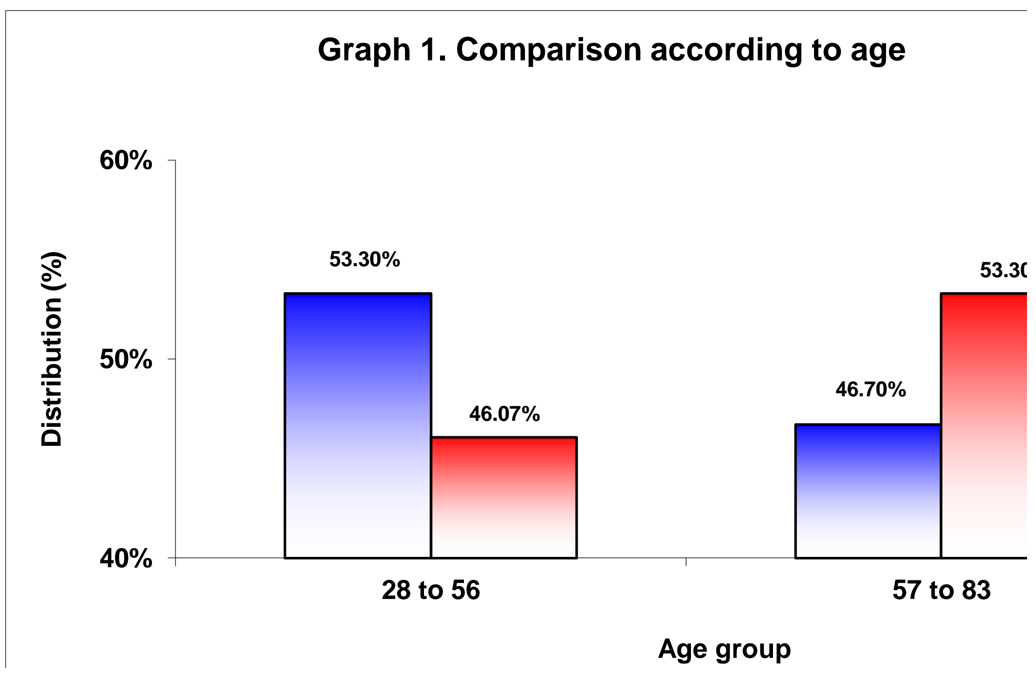
Figure 6. STROBE flow chart for screening and selection of patients



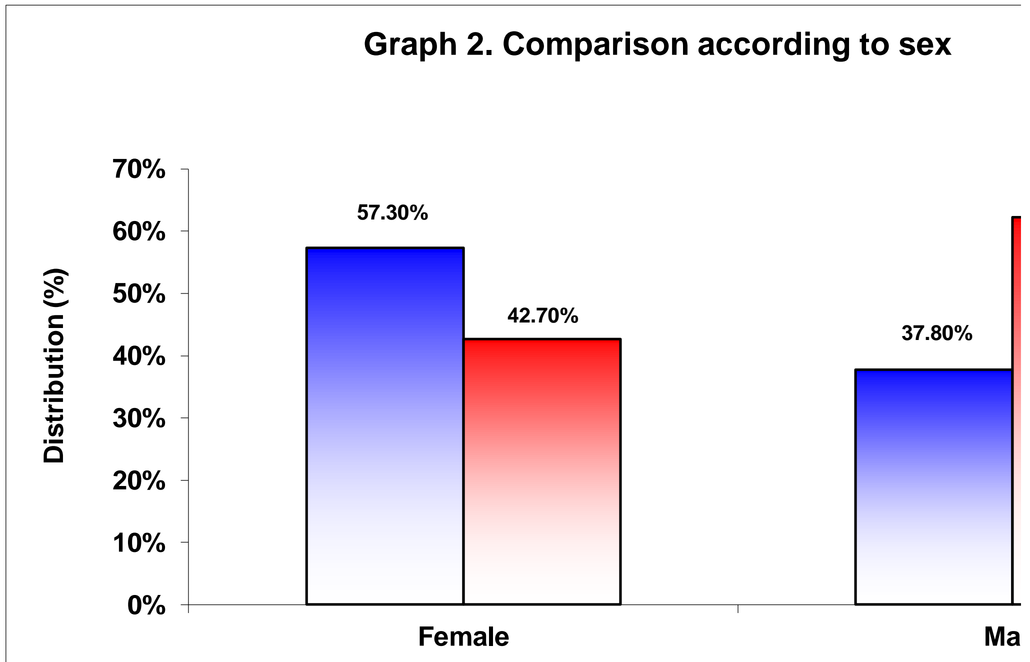
The data obtained was analyzed and the final results were tabulated and interpreted as below.

Table 1. Comparison of background characteristics between exercise group and yoga group

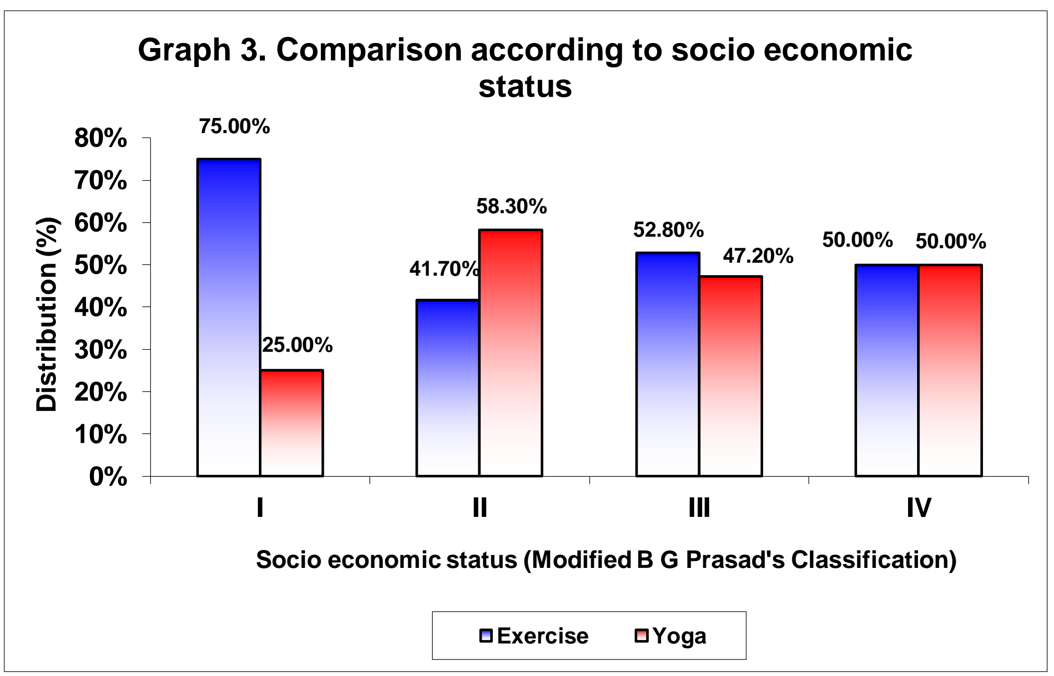
Background characteristics		Exercise (N=60)		Yoga (N=60)		P-value
		Number	%	Number	%	
Age group (Years)	28 to 56	32	53.3	28	46.7	0.584
	57 to 83	28	46.7	32	53.3	
Sex	Female	43	57.3	32	42.7	0.054
	Male	17	37.8	28	62.2	
Socioeconomic Status (Modified B G Prasad's Classification)	I	3	75.0	1	25.0	0.527
	II	15	41.7	21	58.3	
	III	38	52.8	34	47.2	
	IV	4	50.0	4	50.0	
Duration of DM (Years)	1 to 4	35	53.8	30	46.2	0.464
	≥5	25	45.5	30	54.5	
No of days practiced (days)	142 -159	29	61.7	18	38.3	0.061
	160-171	31	42.5	42	57.5	



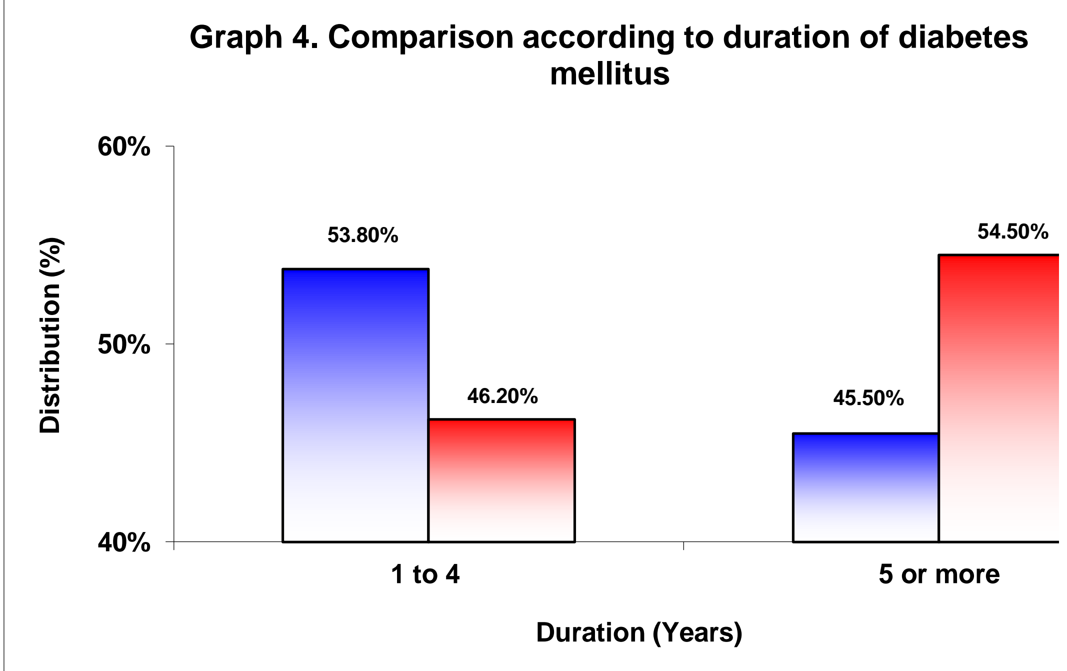
In the present study 53.30% of the participants in the yoga group were aged between 28 to 56 years compared to 46.07% in the exercise group This difference, however, was not statistically significant (p=0.584).



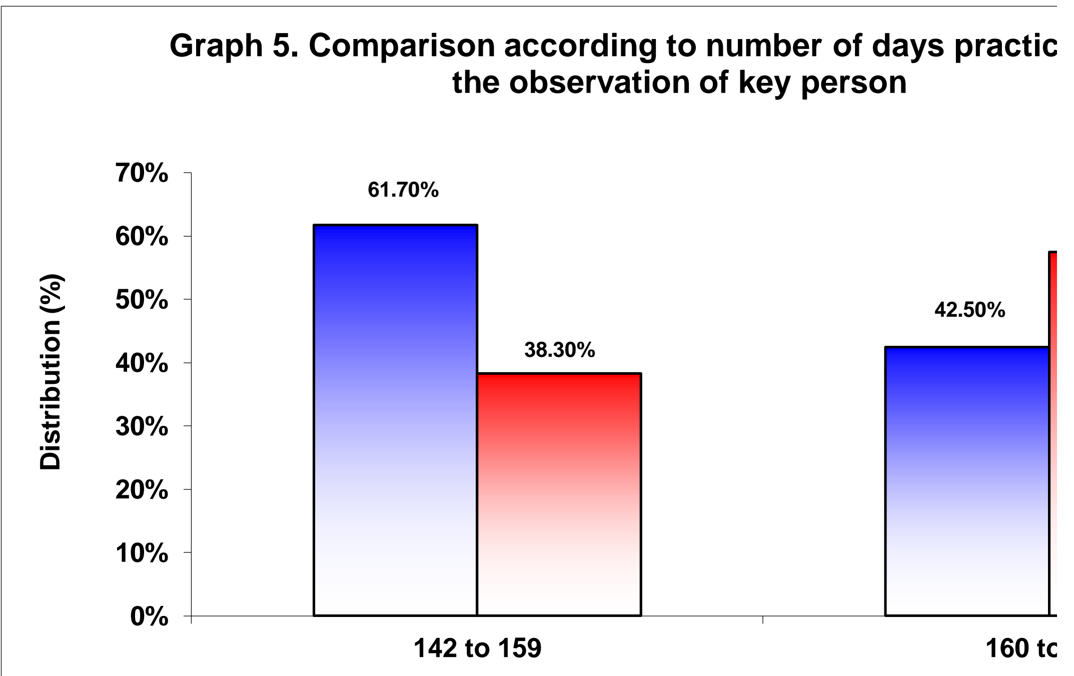
In this study, 62.20% of the participants in the yoga group were males compared to 37.80% in the exercise group. This distinction was not statistically significant (p=0.054).



In the present study, 58.30% of the participants in the yoga group belonged to Class II socio economic status compared to 41.70% in the exercise group. This difference, however, was not statistically significant (p=0.527).



In this study, the duration of T2DM among 54.50% of the participants in the yoga group was ≥5 years compared to 45.50% in the exercise group. This difference was statistically not significant (p=0.464).



In the present study, 57.50% of the participants in the yoga group practiced under the observation of key person the intervention for 160 to 171 days compared to 42.50% in the exercise group. This difference was statistically not significant (p=0.061).

Table 2. Comparison of glycemic control between the exercise group and yoga group at different points in time

Variable	Time	Intervention Exercise (Mean±SD)	Yoga (Mean±SD)	p-value*
HbA1c	Baseline	8.54±1.26	8.73±1.54	
	6 months	7.8±1.02**	8.01±1.17**	0.318
	12 months	7.65±0.93**	7.77±0.98**	
RBS	Baseline	190.66±45.28	194.63±53.55	
	6 months	165.37±32.57**	174.9±32.74**	0.431
	12 months	156.68±27.67**	168.87±29.06**	

P-value is for the interaction effect between Intervention and Time*

*** denotes significant difference between baseline and follow-up time (6 months & 12 months)*

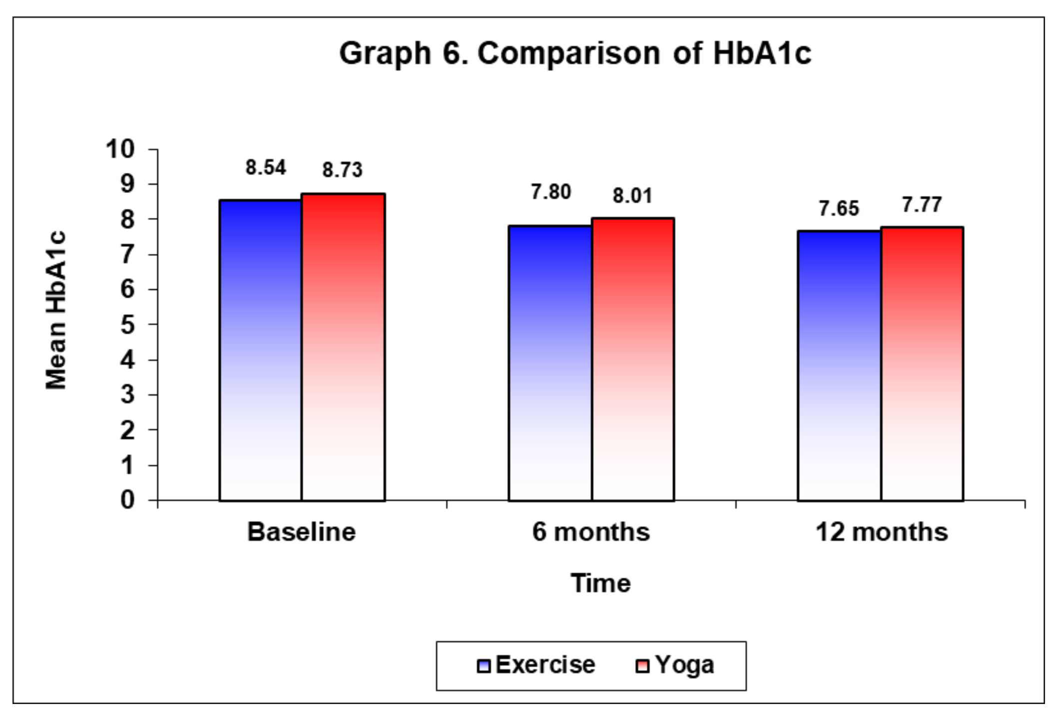


Table 2 and Graph 6 demonstrate a comparison of HbA1c levels at the beginning, six, and twelve months. The GEE model analysis revealed that the Intervention Time had no significant influence on HbA1c (p=0.318). In both groups, however, there was a significant drop in HbA1c at 6 and 12 months compared to baseline.

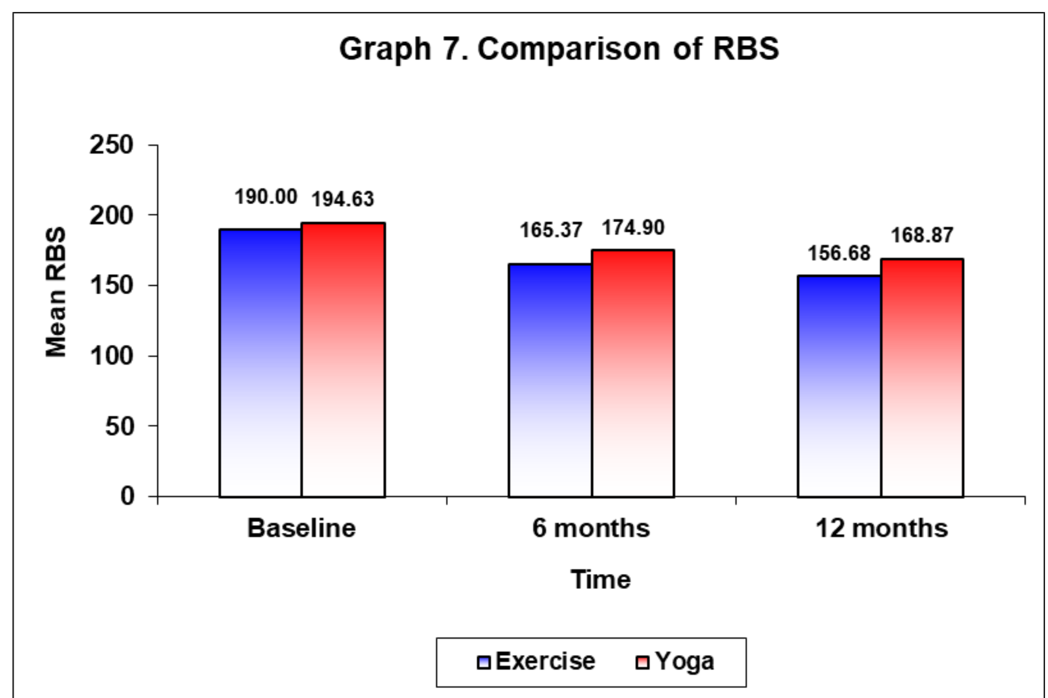


Table 2 and Graph 7 provide a comparison of RBS at the beginning, six, and twelve months. The GEE model analysis revealed no important impacts of follow up Time on RBS (p=0.431). However, when compared to baseline, RBS dropped significantly in both groups at 6 and 12 months.

Table 3. Comparison of lipid profile between exercise group and yoga group at different points of time.

Variable	Time	Intervention Exercise (Mean±SD)	Yoga (Mean±SD)	P-value*
Cholesterol	Baseline	206.07±32	192.6±47.88	
	6 months	176.97±21.6**	178.37±30.69**	**0.001***
	12 months	166.33±18.76**	169.72±22.88**	
TG	Baseline	192.23±65.24	189.2±101.54	
	6 months	154.43±27.04**	150.8±44.85**	0.682
	12 months	150.98±23.53**	144.92±101.54	
HDL	Baseline	59.17±15.35	46.03±12.96	
	6 months	63.85±15.65**	53.05±12.26**	0.252
	12 months	65.78±18.1**	55.3±13.18**	
LDL	Baseline	116.78±34.46	111.28±27.05	
	6 months	97.12±30.25**	100.33±25.69**	**0.006***
	12 months	93.07±28.32**	98.87±24.17**	
VLDL	Baseline	39.82±14.91	34.49±15.17	
	6 months	34.22±11.84**	34.17±12.76	**0.000***
	12 months	33.89±10.71**	33.84±12.07	

P-value is for the interaction effect between Intervention and Time*

*** denotes significant difference between baseline and follow-up time (6 months & 12 months)*

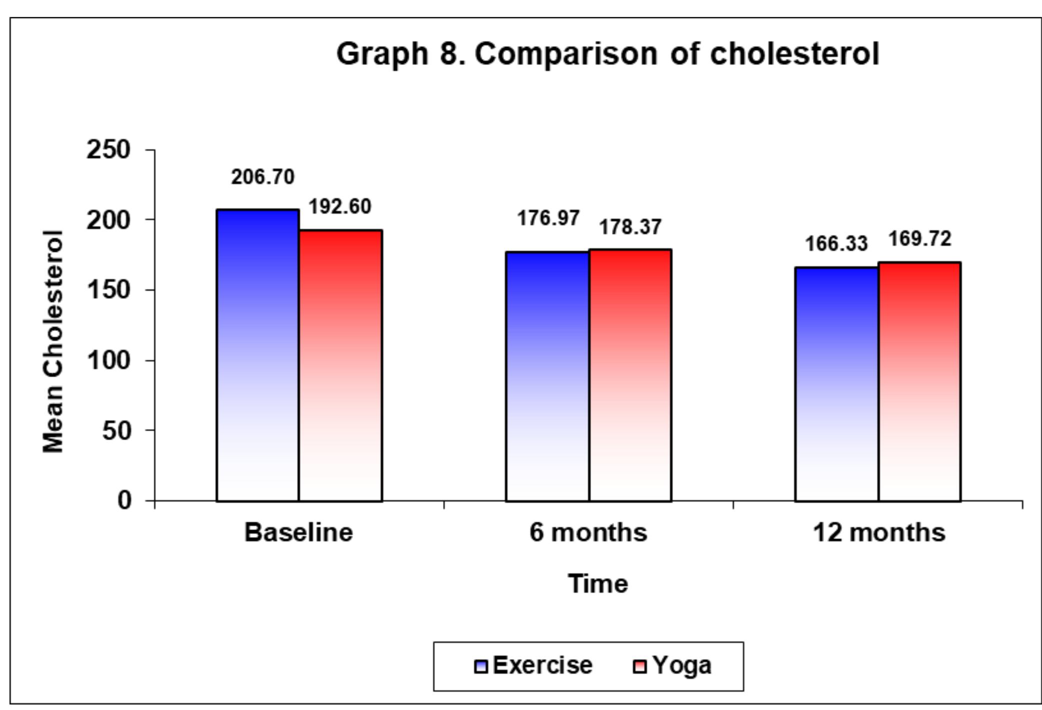


Table 3 and Graph 8 provide a comparison of mean cholesterol levels at the beginning, six, and twelve months. The GEE model analysis revealed that the intervention duration had a significant effect on Cholesterol (p=0.001). Cholesterol was significantly lower in both groups over time, the exercise intervention significantly reduced cholesterol and TG more than the yoga group.

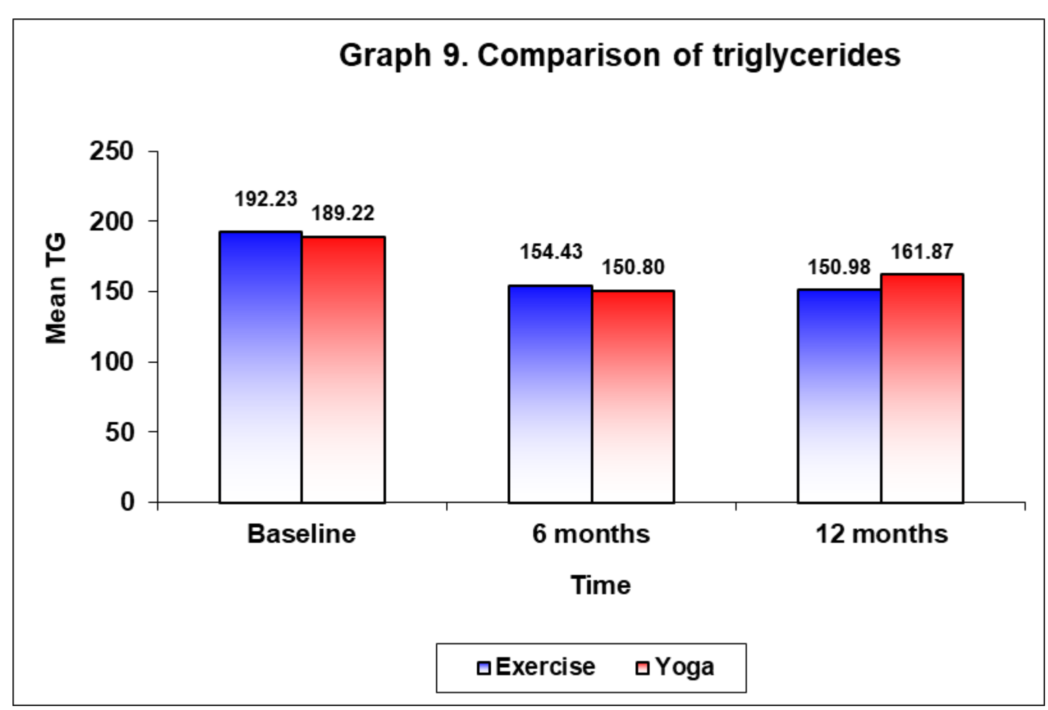


Table 3 and Graph 9 demonstrate a comparison of mean TG at the beginning, six, and twelve months. The GEE model analysis revealed no significant impacts of Intervention Time on TG (p=0.682). However, there was a significant decline in TG in the exercise group after 6 and 12 months compared to baseline, but only after 6 months in the yoga group compared to baseline.

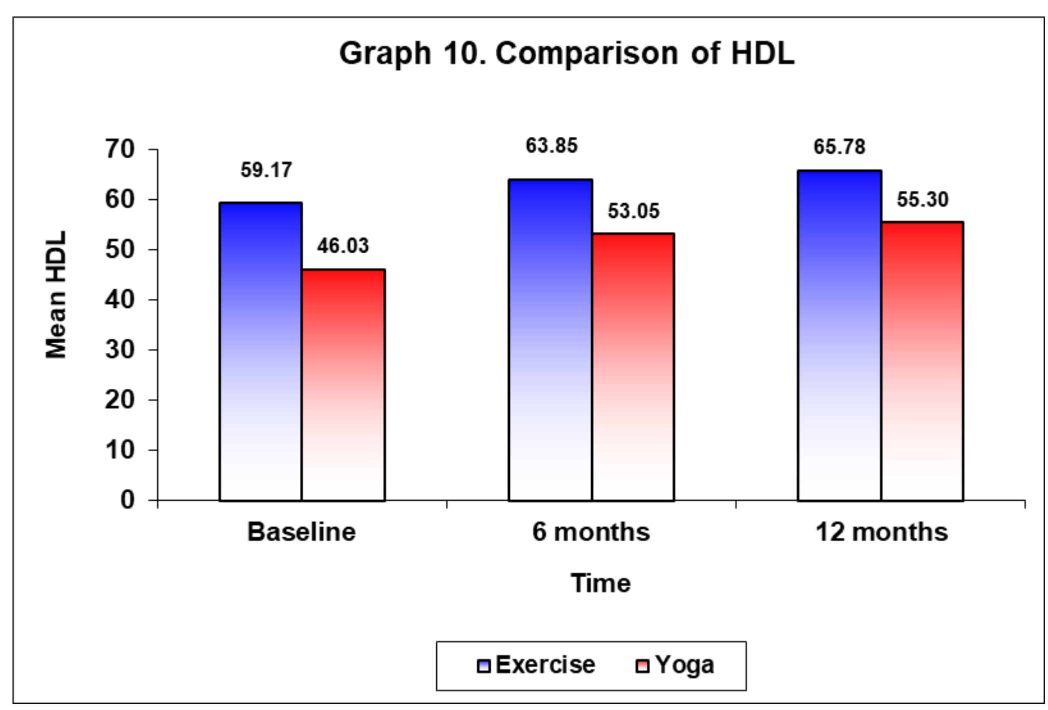


Table 3 and Graph 10 demonstrate a comparison of mean HDL levels at the beginning, six, and twelve months. According to the GEE model analysis, the intervention time had no significant influence on HDL (p=0.252). When compared to the baseline, both groups experienced a significant increase in HDL after 6 and 12 months.

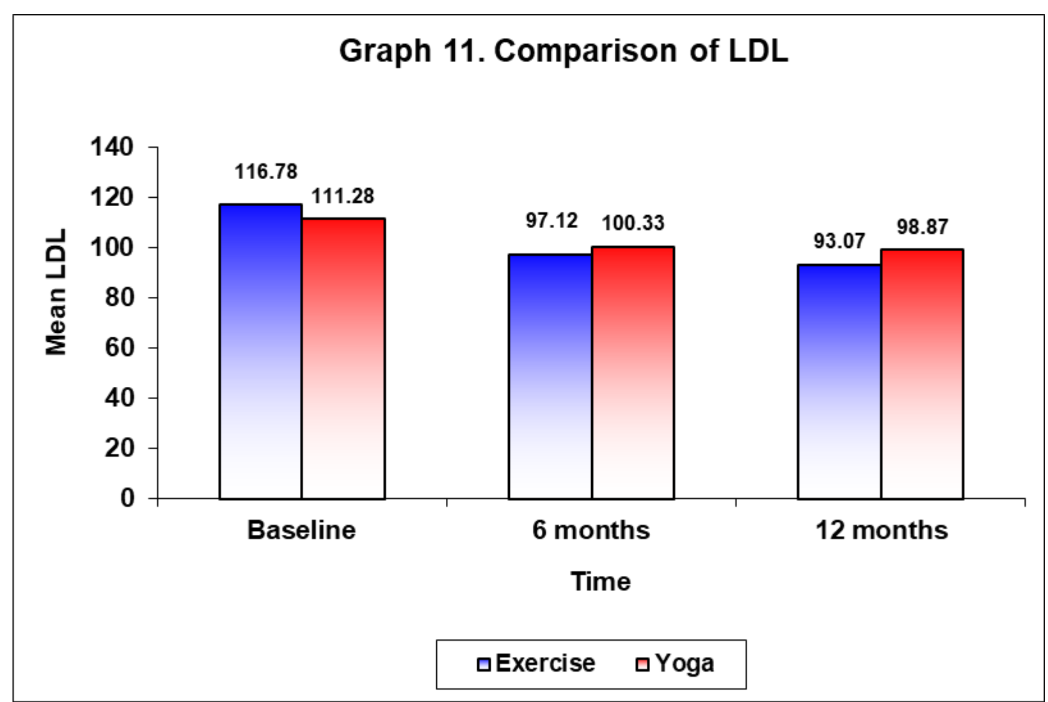


Table 3 and Graph 11 provide a comparison of mean LDL levels at the start, six, and twelve months. According to the GEE model analysis, the Intervention Time had a significant effect on LDL (p=0.006). LDL was significantly reduced in both groups over time, although exercise intervention reduced cholesterol and TG significantly more than yoga.

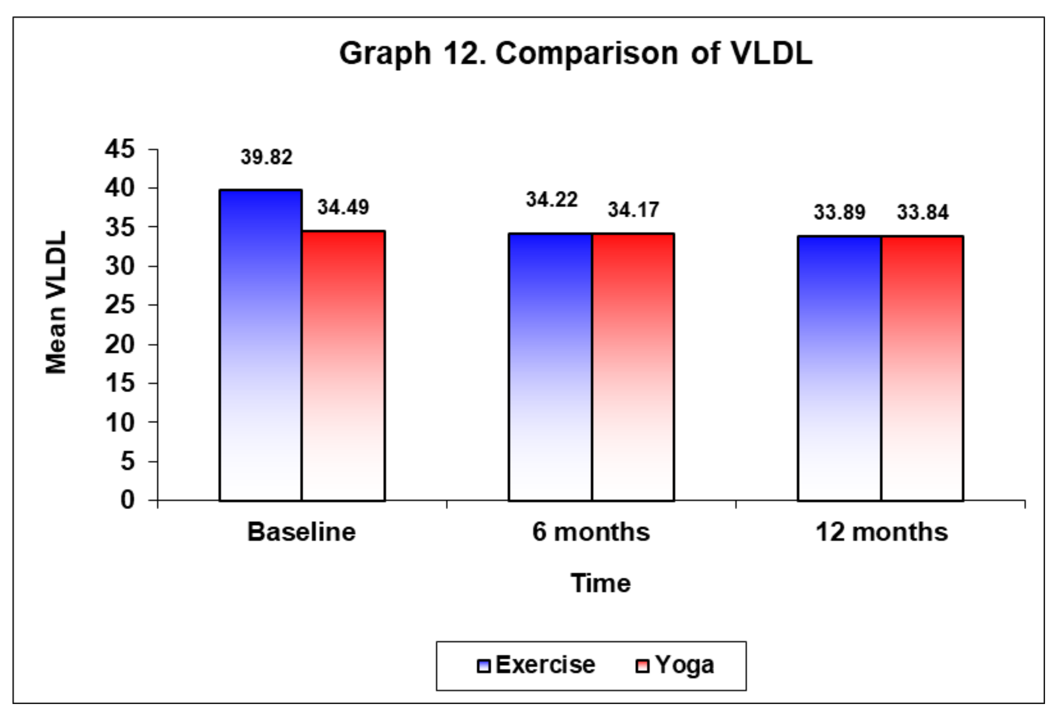


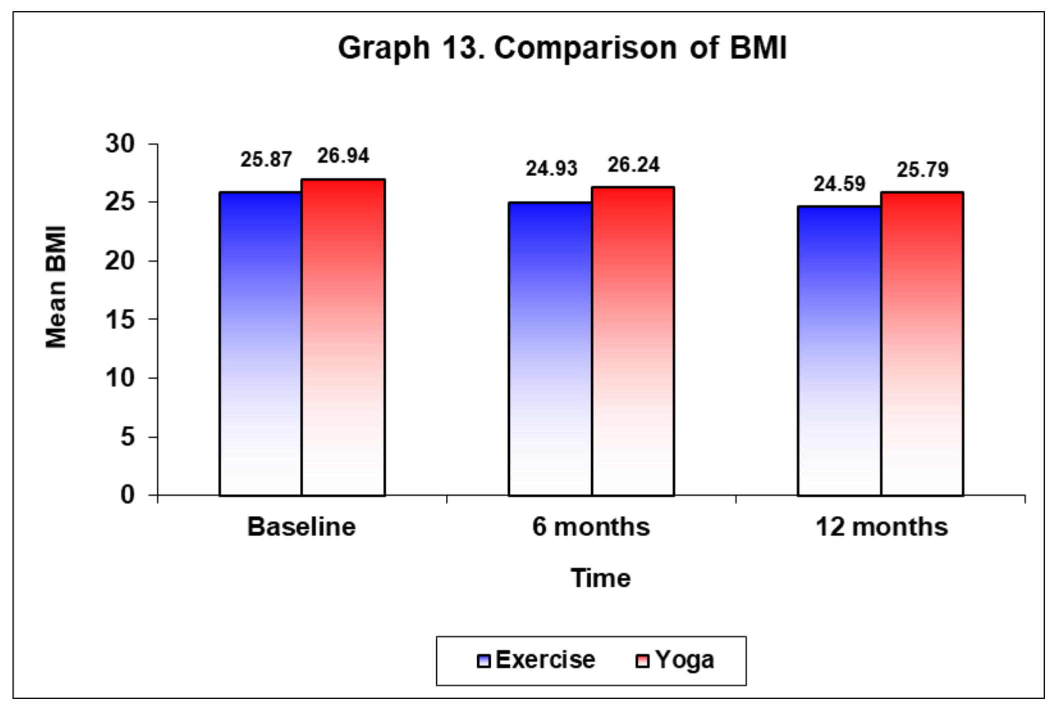
Table 3 and Graph 11 provide a comparison of mean LDL levels at the start, six, and twelve months. According to the GEE model analysis, the Intervention Time had a significant effect on LDL (p=0.006). LDL was significantly reduced in both groups over time, although exercise intervention reduced cholesterol and TG significantly more than yoga.

Table 4. Comparison of BMI between exercise group and yoga group at different points of time

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

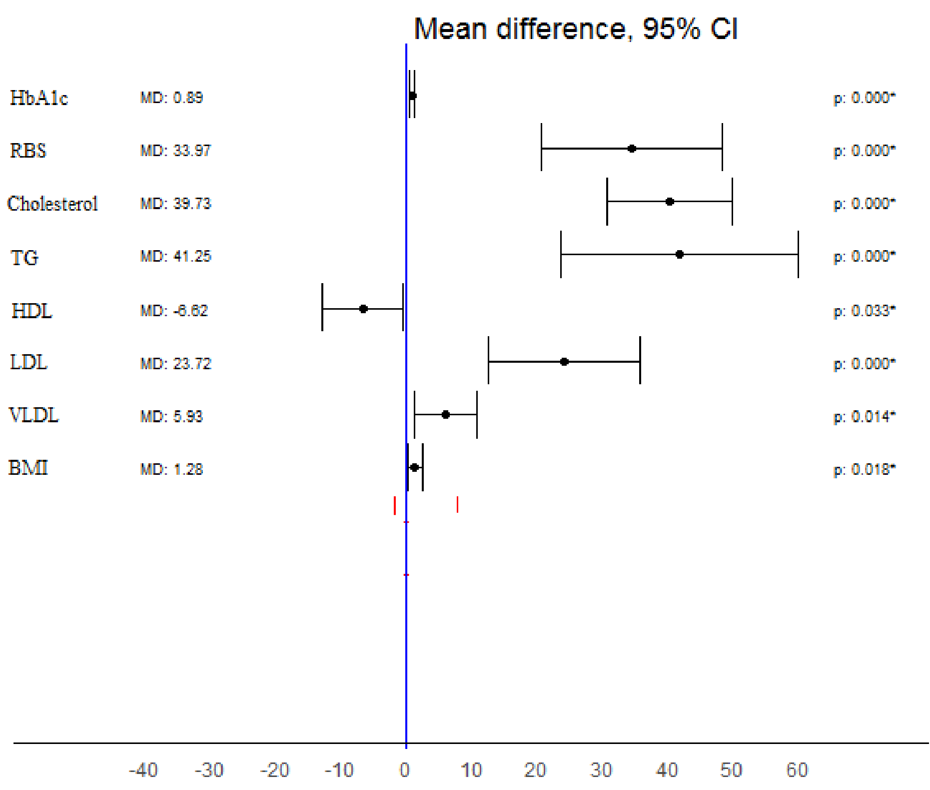
P-value is for the interaction effect between Intervention and Time*

*** denotes significant difference between baseline and follow-up time (6 months & 12 months)*



In table 4 and graph 13 provide a comparison of mean BMI at the beginning, six, and twelve months. The GEE model analysis revealed that there was no significant influence of Intervention Time on BMI (p=0.247). However, there was a significant drop when compared to the baseline in both groups after six and twelve months.

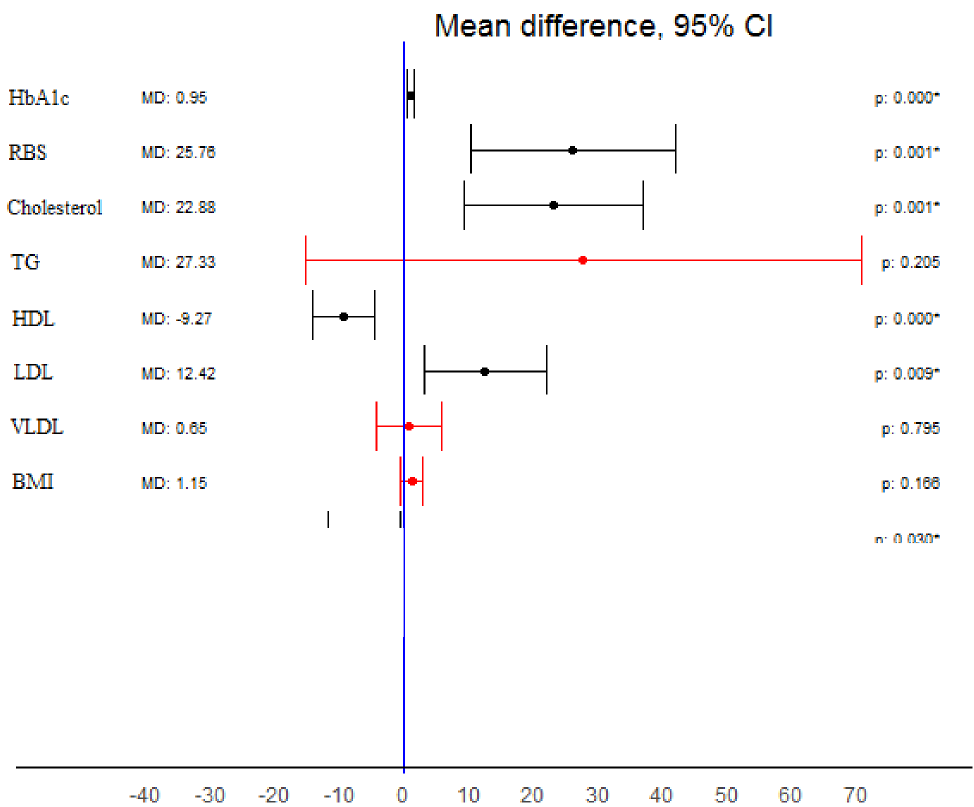
Figure 7. Mean difference of different dependent variables in the exercise group



Note: Mean difference (MD) = Baseline minus 12 months follow-up

In the present study, the effect of exercise was found statistically significant on HbA1c, RBS, Cholesterol, TG, HDL, LDL, VLDL and BMI ($p<0.05$). The mean HbA1c, mean RBS, mean cholesterol, mean TG, mean LDL, mean VLDL and mean BMI were found statistically lower after 12 months follow-up as compared to baseline. The mean HDL was found statistically higher after 12 months follow-up as compared to baseline. The exercise brought about a maximum change in TG (MD: 41.25) followed by Cholesterol (MD: 39.73).

Figure 8. Mean difference of different dependent variables in the yoga group



Note: Mean difference (MD) = Baseline minus 12 months follow-up

In this study, the effect of yoga was found statistically significant on HbA1c, RBS, Cholesterol, HDL, LDL, ($p<0.05$). However, the effect of yoga was not found statistically significant on TG, VLDL and BMI ($p>0.05$). The mean HbA1c, mean RBS, mean cholesterol and mean LDL, were found statistically lower after 12 months follow-up as compared to baseline. mean HDL, was found statistically highest after 12 months of intervention as compared to baseline. Yoga brought about a maximum change in RBS (MD: 25.76) followed by Cholesterol (MD: 22.88).

Table 5. Correlation of Number of days respective intervention practiced with different dependent variables

Variable	Exercise		Yoga	
	Correlation coefficient	P-value	Correlation coefficient	P-value
Change in HbA1c	0.020	0.882	0.017	0.896
Change in RBS	-0.100	0.447	0.095	0.470
Change in Cholesterol	0.060	0.649	0.093	0.481
Change in TG	0.237	0.069	0.075	0.568
Change in HDL	0.126	0.338	0.048	0.718
Change in LDL	0.095	0.470	0.250	0.054
Change in VLDL	0.070	0.594	0.154	0.240
Change in BMI	0.068	0.605	-0.087	0.507

Note: Change= Baseline minus 12 months follow-up

The correlation of the number of days respective intervention practiced with each dependent variable was found to be low and insignificant ($p>0.05$).

Figure 9. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in HbA1c

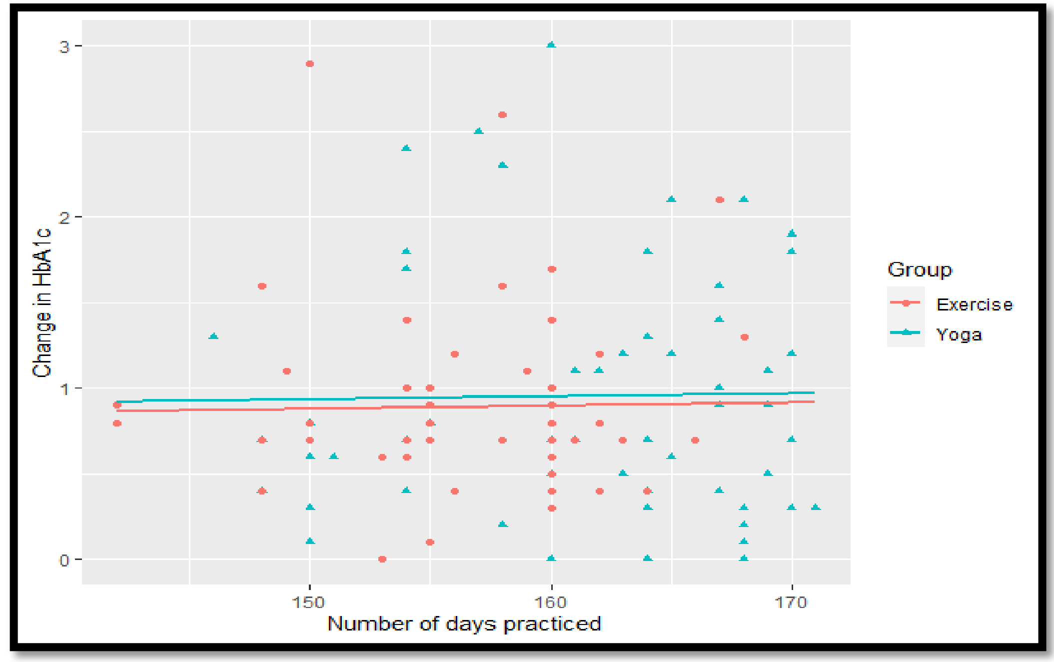


Figure 10. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in RBS

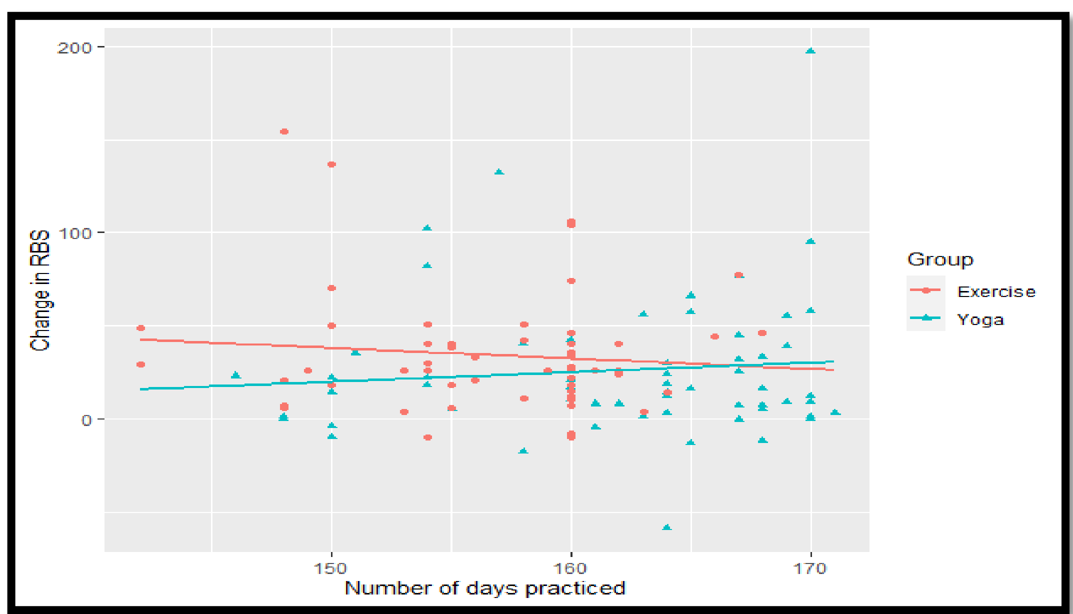


Figure 11. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in cholesterol

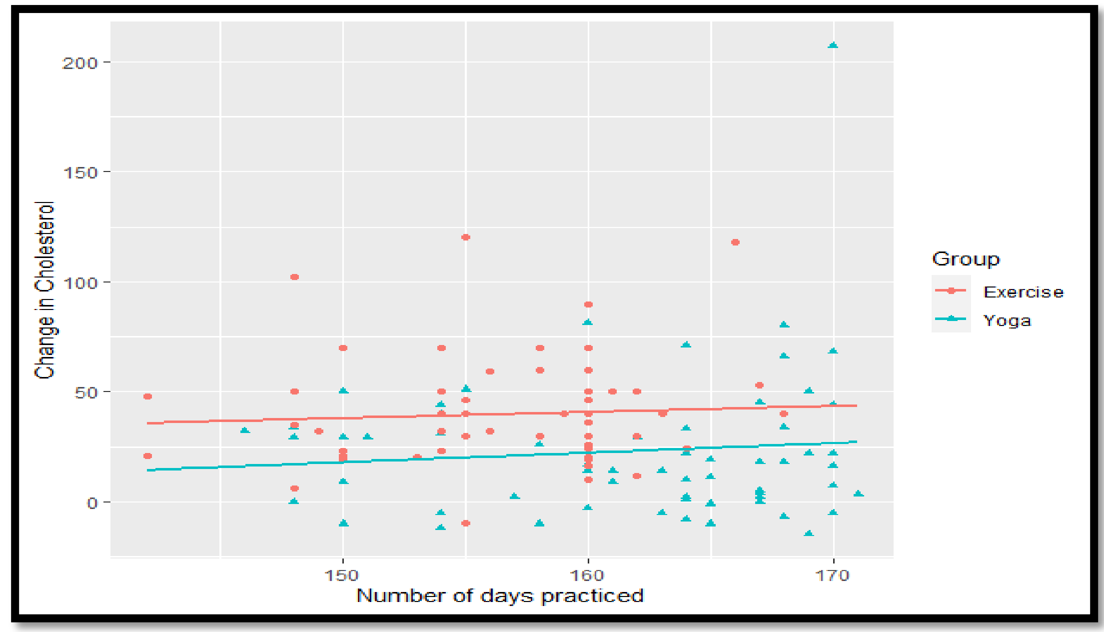


Figure 12. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in TG

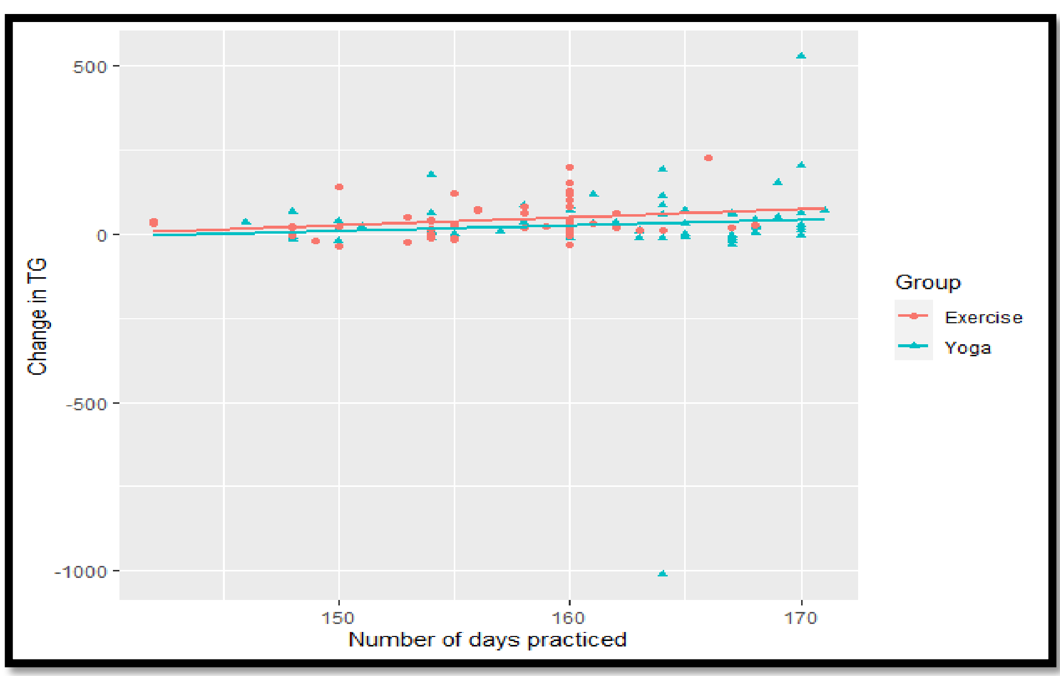


Figure 13. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in HDL

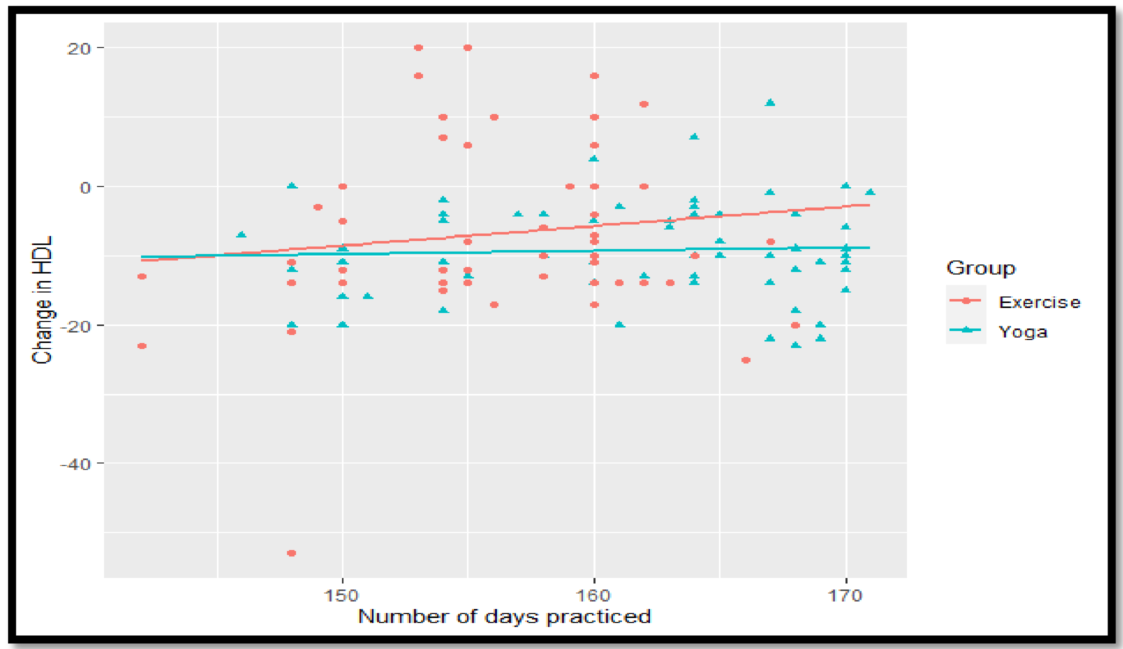


Figure 14. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in LDL

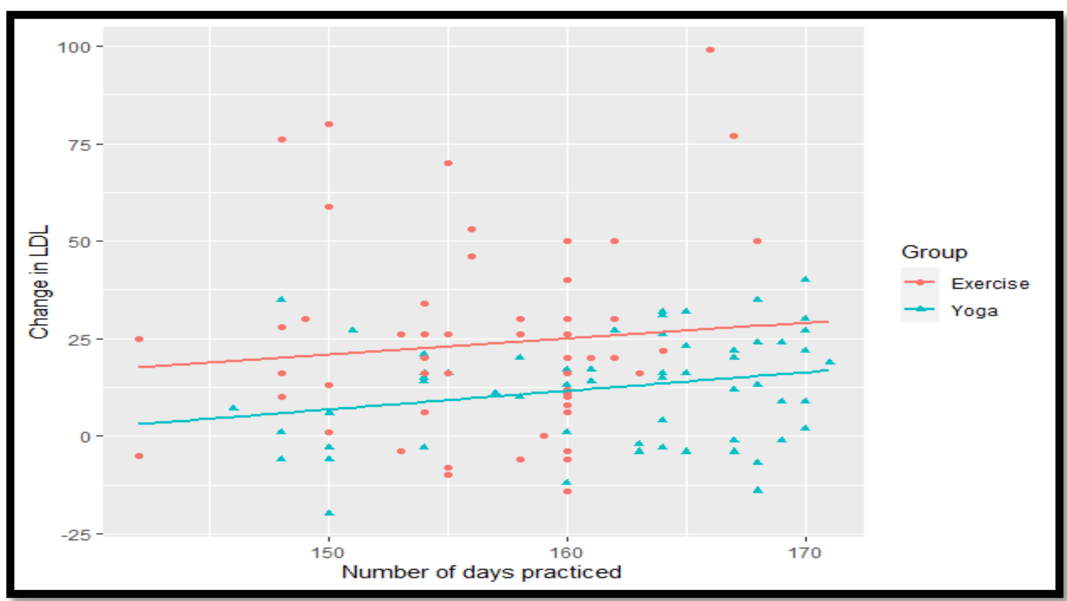


Figure 15. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in VLDL

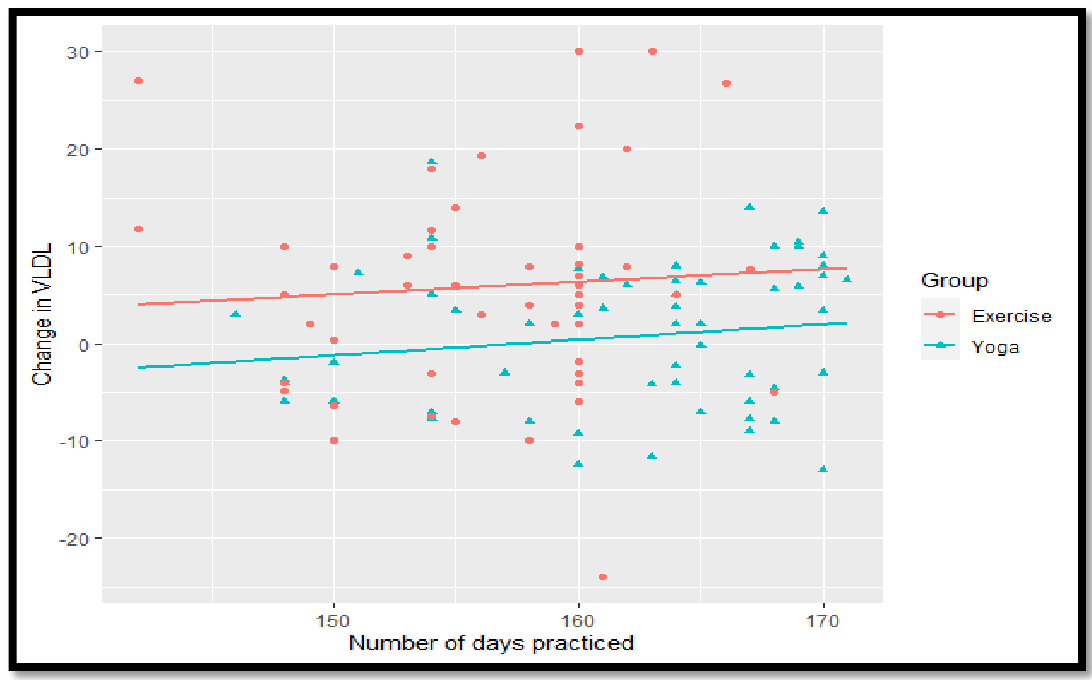


Figure 16. Scatter plot showing correlation between number of days respective intervention practiced under the observation of key person and change in BMI

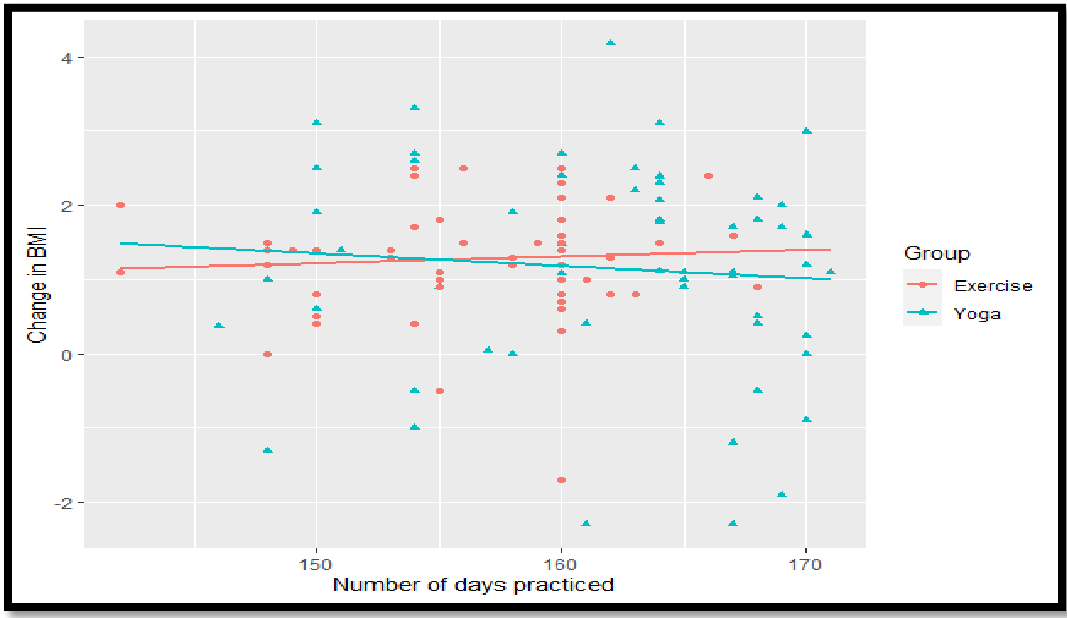


Table 6. Multiple linear regression for determining predictors of change in HbA1c

Variables	Estimate	P-value
Yoga group	0.030	0.810
Age	-0.007	0.320
Number of days practiced	0.002	0.835
Male	0.164	0.224
Socioeconomic status II	-0.060	0.859
Socioeconomic status III	-0.100	0.765
Socioeconomic status IV	0.095	0.810
Duration Of DM	0.002	0.891

Note: Change in HbA1c = Baseline HbA1c minus 12 months follow-up HbA1c

In this study, none of the variables were found significant predictors of change in HbA1c.

Table 7. Multiple linear regression for determining predictors of change in RBS

Variables	Estimate	P-value
Yoga group	-10.595	0.131
Age	-0.783	**0.032***
Number of days practiced	0.546	0.372
Male	-1.578	0.832
Socioeconomic status II	-14.043	0.456
Socioeconomic status III	-10.691	0.566
Socioeconomic status IV	11.089	0.614
Duration of DM	1.390	0.129

Note: Change in RBS = Baseline RBS minus 12 months follow-up RBS

In this study, age was found to be a significant predictor of change in RBS (p=0.032). With each year's increase in age, there was 0.783 times increase in the RBS level keeping other variables constant.

Table 8. Multiple linear regression for determining predictors of change in Cholesterol

Variables	Estimate	P-value
Yoga group	-16.806	**0.006***
Age	0.305	0.323
Number of days practiced	0.287	0.582
Male	-8.517	0.180
Socioeconomic status II	14.509	0.366
Socioeconomic status III	10.819	0.496
Socioeconomic status IV	36.462	0.054
Duration of DM	-0.747	0.337

Note: Change in Cholesterol = Baseline Cholesterol minus 12 months follow-up Cholesterol

The intervention group was found to be a significant predictor of change in cholesterol (p=0.006). The yoga group was found to be 16.806 times less likely to decrease cholesterol levels as compared to the exercise group over time.

Table 9. Multiple linear regression for determining predictors of change in TG

Variables	Estimate	P-value
Yoga group	-19.216	0.422
Age	-0.138	0.911
Number of days practiced	2.343	0.263
Male	-25.113	0.324
Socioeconomic status II	20.590	0.749
Socioeconomic status III	46.087	0.470
Socioeconomic status IV	119.594	0.114
Duration Of DM	-0.116	0.970

Note: Change in TG = Baseline TG minus 12 months follow-up TG

In the present study, none of the variables were found significant predictors of change in TG.

Table 10. Multiple linear regression for determining predictors of change in HDL

Variables	Estimate	P-value
Yoga group	-3.867	0.054
Age	0.115	0.264
Number of days practiced	-0.145	0.405
Male	3.113	0.143
Socioeconomic status II	8.173	0.129
Socioeconomic status III	8.585	0.107
Socioeconomic status IV	7.049	0.261
Duration of DM	0.559	**0.033***

Note: Change in HDL = Baseline HDL minus 12 months follow-up HDL

In this study duration of T2DM was found to be a significant predictor of change in HDL (p=0.033). With each year's increase in the duration of DM, there were 0.559 times decrease in HDL level keeping other variables constant.

Table 11. Multiple linear regression for determining predictors of change in LDL

Variables	Estimate	P-value
Yoga group	-12.300	**0.002***
Age	0.232	0.254
Number of days practiced	0.355	0.301
Male	-3.489	0.403
Socioeconomic status II	1.413	0.893
Socioeconomic status III	6.486	0.535
Socioeconomic status IV	8.028	0.515
Duration of DM	-0.146	0.775

Note: Change in LDL = Baseline LDL minus 12 months follow-up LDL

In this present study intervention group was found to be a significant predictor of change in LDL (p=0.002). The yoga group was found to be 12.3 times less likely to decrease LDL levels as compared to the exercise group over time.

Table 12. Multiple linear regression for determining predictors of change in VLDL

Variables	Estimate	P-value
Yoga group	-6.256	**0.001***
Age	-0.046	0.625
Number of days practiced	0.157	0.329
Male	1.331	0.495
Socioeconomic status II	2.718	0.582
Socioeconomic status III	4.410	0.367
Socioeconomic status IV	1.181	0.838
Duration of DM	0.053	0.826

Note: Change in VLDL = Baseline VLDL minus 12 months follow-up VLDL

In this study intervention group was found to be a significant predictor of change in VLDL (p=0.001). The yoga group was found to be 6.256 times less likely to decrease VLDL level as compared to the exercise group over time.

Table 13. Multiple linear regression for determining predictors of change in BMI

Variables	Estimate	P-value
Yoga group	-0.106	0.644
Age	-0.004	0.722
Number of days practiced	-0.004	0.840
Male	0.036	0.881
Socioeconomic status II	-0.088	0.886
Socioeconomic status III	0.082	0.893
Socioeconomic status IV	-0.257	0.721
Duration of DM	0.009	0.750

Note: Change in BMI = Baseline BMI minus 12 months follow-up BMI

In this study, none of the variables were found significant predictors of change in BMI.

DISCUSSION

The T2DM is most common type of diabetes and is closely related to changes in lifestyle and diet, smoking, alcohol consumption and less vegetable consumption, which increases stress. Moderate to intense aerobic exercise, according to ADA,[62] is crucial in treating diabetes-related metabolic issues. Yoga has been shown to aid in the treatment and prevention of T2DM. Several studies on the effectiveness of yoga in the treatment of T2DM have produced excellent results in terms of BG management, lipid profile anthropometric markers, and quality of life. In addition, people with diabetes who practiced yoga had better mental, and physical, health functional capacity, well-being, sleep and body fitness.[110] However, there has been minimal research on whether yoga can improve quality of life by alleviating stress, anxiety, and depression, as well as motivating people to pursue an active lifestyle. Furthermore, previous research has emphasized the significance of future research to better understand the possible impact of yoga on glucose levels. Hence, the present study was planned to look at the effects of yoga and exercise on the glucose level, lipid and BMI of people with T2DM.

In 14-month single-center randomized controlled experiment was undertaken at Jawaharlal Nehru Medical College, KAHER, Belagavi's Department of Community Medicine. A total of 126 eligible people with T2DM who were registered in the research region were enrolled. Participants were divided into two groups of 60 each based on the computer-generated, randomized number sequence method, participants were divided into two groups of 60 each as the Yoga Group (Participants in this group were on dietary control, anti-diabetic drugs and Yoga therapy) and the exercise group (Participants in this group were on dietary control, anti-diabetic drug and exercise).

The majority of the (95%) study participants in the exercise group chose walking/jogging as unstructured exercise. Both the groups were followed for glycemic control, lipid profile and BMI at six months and one year.

Demographic characteristics

In the current study, more than half of the patients (53.30%) from the yoga group were between the ages of 28 and 56, compared to slightly less than half (46.07%) observed in exercise groups. However, a significant change was not seen as statistically important (p=0.584). Indicating that the age distribution of the participants in both groups was statistically similar. The majority of participants in the yoga group (62.20%) were males, compared to more than one-third (37.80%) in the exercise group. However, the change was not seen as statistically noteworthy (p=0.054). As a result, the gender distribution of participants in both groups was comparable (Table 1). The male preponderance and age distribution pattern noted in the present study was consistent with the observations reported by Das J et al.[106] (2020). In contrast Singh VP and Khandelwal B.[26] (2020) in their study reported maximum number of females in Yoga as well as exercise group.

In the current study, the majority of participants (58.30%) in the yoga group were from the Class II socioeconomic category, compared to slightly less than half (41.70%) in the exercise group. However, this difference was statistically insignificant (p=0.527), showing that participants in both groups had a statistically identical distribution of socioeconomic level (Table 1). The socio economic status noted in the present study was consistent with the results of a study by Singh VP and Khandelwal B.[26] (2020). In the present study all the participants were examined for

vitals, systemic examination and other clinical signs and symptoms. however, no significant abnormalities were evident.

Overall, the comparison of sex, age and socio-economic status showed no statistically significant association between the groups (Table 1) ruling out possible bias in the outcomes.

Diabetic history

With regard to the history of T2DM, the duration of T2DM was ≥5 years among most of the participants (54.50%) in the yoga group compared to slightly less than half of the participants (45.50%) in exercise group. But change was statistically important (p=0.464) (Table 1). Hence, both groups were statistically similar in terms of duration of T2DM suggesting a good randomization.

Practice interval

In the current study, handouts (Booklets) with yoga poses and meditation exercises were distributed typically each two-work week so that members could continue practicing at home and even after the intervention ended. A person in the family who was designated as a key person was given a compliance sheet to monitor whether a member is consistently doing yoga or not assured the compliance of the intervention done at home for the six months. The majority of the key person monitoring the intervention in the yoga group were either husband or wife (83%), followed by brother or sister (12%) and the least (5%) were other than the family members (5%) of the study participant. Similarly, in the exercise group also, the majority of the key persons were either husband or wife (88%), followed by brother or sister (10%) and only a few (2%) were other than the family members of the study

participant. Based on the compliance sheet reported by the key person monitoring the intervention more than half of the participants (57.50%) in the yoga group practiced the intervention for 160 to 171 days compared to slightly less than half of the patients (42.50%). This variance was statistically insignificant (p=0.061) in the exercise group ruling out possible bias in the study results (Table 1). This was one of the important strengths of the study which allowed us to estimate the correlation between the number of days that the participants practiced the intervention and helped to determine the true real effect of the intervention on outcomes precisely. Singh VP and Khandelwal B.[26] (2020) in their study taught pranayama and yoga-asana by an instructor daily for initial 2 weeks, and then, they were called regularly at an interval of 1 month for supervision and compliance for 3 months. At the end of 3 months, all outcome measures were repeated a finding partly in agreement with the present study.

Primary outcomes

Glycaemic control

In the present study, glycaemic control was ascertained by estimating HbA1c levels at the beginning, six- and 12-months intervals. Accordingly, a noteworthy reduction in mean HbA1c levels was seen in follow up group that is, from 8.73±1.54 percent from baseline to 8.01±1.17 percent at six months and 7.77±0.98 percent at 12 months interval (p<0.001). Similarly in the exercise group also, that is from 8.54±1.54 percent from baseline to 7.80±1.02 percent at six months and 7.65±0.93 percent at 12 months interval (p<0.001) (Table 2). However, GEE model analysis showed no noteworthy consequence of intervention with respect to time on HbA1c levels (p=0.318). Overall, the mean difference that is difference between baseline and 12-month follow-up with respect to HbA1c levels was slightly high in the Yoga group

linked to those with exercise (0.95 vs 0.89 percent). Furthermore, the reduction in HbA1c was independent of other confounding parameters including age, number of days practiced, gender and socioeconomic status. Also, the correlation between the duration of respective interventions practiced with each dependent variable was found to be low and insignificant (r=0.017; p=0.896). These observations suggest that yoga compared to exercise is equally beneficial in reducing HbA1c thereby glycaemic control. Considering the mean reduction of HbA1c, although, not statistically significant, yoga compared to exercise seems to be much more beneficial in reducing HbA1c independently. The decrease in HbA1c levels in the yoga group noted in the study was strongly in agreement with the earlier studies done by Malhotra V. et al.[119] (2004) and Selvin E. et al.[120] (2004) who reported a decline of HbA1c by 1%. The significant decrease in HbA1c levels noted in this study was also consistent with A randomized controlled study by Singh VP, et al.[26] (2021) reported a mean change of 0.47 in glycated hemoglobin which was greater than the mean reduction of 0.28 in the exercise group with $p<0.050$. A study by Singh S. et al.[121] (2004) observed better glycemic control (HbA1c from 9.03 to 7.83) after 40 days of yoga intervention. Recently a study by Chen S. et al.[110] (2022) examined the impact of yoga training on diabetes-related markers as compared to standard treatment The standardized mean difference for the effects of yoga on HbA1c was also revealed to be significant (MD = 0.47; 95% CI: 0.77, 0.16; Z = 3.02, p = 0.003). This finding strongly corroborates with the present study. Dash S. et al.[99] (2014) in their study from Odisha, India reported a decrease of HbA1c from 7.72±0.76 to 7.68±0.63 percent but this reduction was statistically not significant (p=0.605) but, change in glycosylated hemoglobin level was seen better in yoga group as compared with to control group. A meta-analysis by Cui J. et al.[102] (2017) on the efficacy of yoga in adults with T2DM also

reported a mutual mean weighted difference as -0.47% (95% CI -0.87 to -0.07; P = 0.02) for hemoglobin A1c. A noteworthy reduction in HbA1 level was seen in studies recently by Rajani S. et al.[122] (2016), Angadi P. et al.[123] (2017) and Bairy S.et al.[124] (2020).

Random blood sugar

In this study, glycaemic control was ascertained by estimating HbA1c levels along with RBS at the beginning, six and 12 months intervals. There was a statistically significant decline of mean RBS in the intervention group that is, from 194.63±53.55 mg/dL from baseline to 174.90±32.74 mg/dL at six months and 168.87±29.06 mg/dL at 12 months interval ($p<0.001$) (Table 2). Similar observations were documented in the exercise group that is, 190.66±45.28 mg/dL at baseline to 165.37±32.57 mg/dL at six months and 156.68±27.67 mg/dL at 12 months interval ($p<0.001$). However, GEE model analysis showed no significant effect of intervention with respect to time on RBS ($p=0.431$). The overall mean difference in RBS levels among baseline and 12-month follow-up was slightly higher in the exercise group compared to those in the yoga group (33.97 vs 25.76 mg/dL). However, age was discovered to be an important predictor of RBS change ($p=0.032$). Keeping other variables constant, there was 0.783 times increase in RBS level with each year of age increase, however, the connection among the number of days respective intervention practiced with each dependent variable was determined to be low and negligible ($r=-0.100$; $p=0.447$). As a result, it is possible to hypothesize that both therapies are equally effective in lowering RBS. The reduction in RBS levels seen in this study was partly consistent with other studies indicating a noteworthy reduction in FBS, and PPBS levels in persons with T2DM ongoing yoga instruction.

Several studies observed a significant reduction of FBG[125,126] or both FBS and PPBG at the end of the study period,[127,128] and several other studies have also observed a nonsignificant reduction of FBG after the study period.[129,130] Most studies have examined the effect of yoga on FBG levels and post-prandial blood glucose (PPBG) levels. Some studies have reported a significant contribution of yogic practices for the reduction of FBG and PPBG, while some studies did not observe a significant reduction of these parameters. A study followed for 40 days observed a reduction of FBG (from 210.7 to 140.4 mg/dL) and PPBG (from 305.5 to 230.5 mg/dL).[131] Another study followed for the same period of time showed a significant reduction of FBG (190.1–141.5 mg/dL) and PPBG (276.5–201.7 mg/dL).[121] A different study conducted for a very short period found a significant reduction of FBG compared with the baseline value.[132] Another study conducted for 6 months found a significant decrease of FBG by 29.48%, while the reduction of the control group was 7.48%.[133] A 3-month course of yoga exercises has observed a reduction of FBG starting from the 15th day but the fall was not statistically significant. At the end of the study period, a significant reduction of both FBG and PPBG was observed.[134] A study of 20 participants (12 males and 8 females) observed a significant reduction of FBG and PPBG.[135] Female individuals showed a greater reduction of FBG compared with male participants. Also, the reduction of FBG in participants within the age group 50–59 years was not significant compared to the age group 40–49 years. Reduction of FBG and PPBG was more significant in patients with poor glycemic control (FPG >126 mg/dL and PPPG >140 mg/dL) than in patients with good glycemic control (FPG;126 mg/dL and PPPG <140 mg/dL).[131] Another 3-month study of yoga intervention showed a significant decrease in FBG and a nonsignificant reduction of PPBG in the sample group while a continuation of medication in the

control group failed to reduce the FBG and PPBG levels at the end of the study period.[136] A recent study by Chen S. et al.[110] (2022) reported standardized mean difference for the effects of yoga to be significant on FBG (SMD = −0.92; p=0.004), PPBG (SMD=−0.53; p=0.001), a finding partly in agreement with the present study. Another study by Yuniartika W et al.[109] (2021) to determine the effect of yoga therapy and walking therapy on DM patients in the community also concluded that there was an effect of yoga therapy and walking therapy on reducing fasting glucose levels with the decline in FBS that is, the average fasting sugar levels in the yoga group pre (217.00) post (187.72) p (0.001), the walking group averaged pre (209.89) post (193.83) p (0.001), and the control group averaged pre (221.50) post (225.17) p (0.067). Dash S. et al.[99] (2014) in their study from Odisha, India reported a decrease in the fasting blood glucose (FBG) from 200.03±42.67 mg/dl to 193.07±43.89 mg/dl, which was significant at a p value of 0.05. Postprandial Blood Glucose (PPG) after two hours also decreased from 259.5±50.39 mg/dl to 251.33±49.02 mg/dl at a p value of 0.05. A meta-analysis by Cui J. et al.[102] (2017) reported pooled weighted mean difference as -23.72 mg/dL (95% CI - 37.78 to -9.65; P=0.001) for FBS. Although, a direct comparison of the observation in the present study with the latter studies by Chen S. et al.[RA8] (2022), Cui J. et al.[102] (2017) and Yuniartika W et al.[109] (2021) is not possible due to methodological differences but in principle, the findings of the present study are in agreement with the results of Chen S. et al.[110] (2022), Cui J. et al.[102] (2017) and Yuniartika W et al.[109] (2021).

Finally, although, statistically not significant, yoga compared to exercise seems to be much more beneficial in providing glycaemic control than exercise despite of significant reduction in RBS with exercise because first, the reduction in RBS was age-dependent and second the reduction in HbA1c was independent of other

confounders and is a reliable test which provides normal blood sugar (glucose) level was since the last 2-3 months precisely. Lifestyle changes are critical for T2DM prevention and control. The majority of people struggle to maintain the necessary levels of physical activity. Yoga is an ancient psychological, physical, and spiritual training regimen that can be practiced by anyone of any age or gender.

Body mass index

In this study, participants were examined for BMI at the beginning, six- and 12-months intervals. The participants in the intervention group had a statistically significant decrease in mean BMI that is, from 26.94±4.96 Kg/m^2 at baseline to 26.24±4.34 Kg/m^2 at six months and 25.79±4.05 Kg/m^2 at 12 months interval ($p<0.001$) (Table 4). Similar observations were noted in the exercise group that is, from 25.87±3.03 Kg/m^2 at baseline to 24.93±2.80 Kg/m^2 at six months and 24.59±2.78 Kg/m^2 at 12 months interval ($p<0.001$). However, GEE model analysis showed not any important effect of intervention with respect to time on BMI ($p=0.247$). The overall, mean difference between baseline and 12-month follow-up with respect to BMI was slightly high in exercise compared to the yoga group (1.28 vs 1.15 Kg/m^2). Furthermore, the decline in BMI was independent of other confounders and the duration of respective interventions practiced. These observations suggest that both interventions are equally beneficial in reducing BMI and thus help in preventing obesity leading to further complications. This considerable decrease in BMI seen in the current study was consistent with the findings of Telles S et al.[137] (2010), who found that yoga intervention reduced BMI, waist and hip circumference. A systematic review and meta-analysis conducted by Shah SZA et al.[107] (2021) found that the exercise intervention reduced BMI ($p=0.04$) and waist circumference ($p=0.007$). In

contrast, a recent study by Chen S. et al.[110] (2022) found no effect of yoga on BMI (MD = 0.63; 95%CI: 1.42, 0.16; p=0.12). The lack of a yoga effect in the study by Chen S. et al.[110] (2022) could be due to a limitation of the studies included, namely insufficient information certain studies did not mention age or session length, which could have an impact on the outcomes. Singh S. et al.[128] (2008) conducted a study on this topic of completion of yoga follows up with a 4.56–6.69% decrease in the level of body weight, 1.2 kg/m^2 of BMI and the average weight reduction was 2.26 kg per person an observation consistent with the present study. However, two studies by Skoro-Kondza L. et al.[138] (2009) and Mullur RS et al.[139] (2015) found no important change in body mass and BMI values when compared to baseline, while Mohammed R. et al.[140] (2016) found a slight reduction in BMI was not statistically noteworthy. Poor attendance at yoga courses, inadequate suppleness, a lack of fundamental fitness, confidence, and the fact that none of the patients practiced yoga regularly at home were identified as factors of poor results.[138] Hegde SV. et al.[141] (2008) discovered a promising effect seen on BMI but not on waist circumference. Overall, yoga and exercises groups had a considerable impact on body weight reduction in obese persons with T2DM.[130]

Lipid profile

In this study participants were investigated for fasting lipid profiles including total cholesterol, TG, LDL, HDL and VLDL at the beginning, six and 12 months interval.

Total cholesterol

In the present study statistically, a noteworthy decrease level of TG was seen noted with respect to mean TC levels among the participants in the yoga with exercise group that is, from 192.60±47.88 mg/dL at baseline to 178.37±30.69 mg/dL at six months and 169.72±22.88 mg/dL at 12 months interval ($p<0.001$). Similar observations were noted in the exercise group that is, from 206.07±32.00 mg/dL at baseline to 176.97±21.60 mg/dL at six months and 166.33±18.76 mg/dL at 12 months interval ($p<0.001$) (Table 3). Further, GEE model analysis also displayed important effects of follow up with respect to cholesterol ($p=0.001$). However, the mean difference between baseline and 12-month follow-up with respect to TC was slightly high in the exercise group compared to those in the yoga group (39.73 vs 22.8 mg/dL). Furthermore, the yoga group was found to be a significant predictor of change in cholesterol ($p=0.006$). The yoga group was found to be 16.806 times less likely to decrease cholesterol levels as compared to the exercise group over time and this observation was independent of the duration of intervention. Hence, both interventions are beneficial in reducing TC but, yoga is significantly more effective in controlling TC levels compared to exercise intervention. Where analysis done by Cui J. et al.[102] (2017) also reported pooled weighted mean difference as -18.50 mg/dL (95% CI -29.88 to -7.11; $P = 0.001$) for cholesterol level which was comparable with the present study. Telles S et al.[137] also reported that yoga intervention led to decreased total cholesterol. levels. In contrast, a recent study by Chen S. et al.[110] (2022) reported a lack of yoga effect on total cholesterol. The lack of yoga effectively in the study by Chen S. et al.[110] (2022) may be the limitation of the studies included that is, insufficient information, like such studies did not report age or session length, that affects the outcomes.

Triglycerides

In this study, a statistically noteworthy decrease was noted in mean triglyceride levels in together groups. In the yoga group, the mean triglyceride levels reduced from 189.20±101.54 mg/dL at baseline to 150.80±44.85 mg/dL at six months and 144.92±101.54 mg/dL at 12 months interval ($p<0.001$). Similarly in the exercise also there was an important decline in mean triglyceride levels that is, from 192.23±65.24 mg/dL at baseline to 154.43±27.04 mg/dL at six months and 150.98±23.53 mg/dL at 12 months interval ($p<0.001$) (Table 3). However, (GEE) model analysis presented that, no important effects of Intrusion with respect to time on (Triglyceride) levels ($p=0.682$). Overall, the mean difference between baseline and at 12 months follow-up with respect to TG was slightly increased in the exercise group when compared to the yoga group (41.25 vs 27.33 mg/dL). Furthermore, the decline in TG in both groups was independent of other confounders and the duration of intervention practiced. These observations suggest that both interventions are equally beneficial in reducing TG and thus help in preventing lipid abnormalities leading to further complications. Likewise, analysis by Cui J. et al.[102] (2017) also reported the weighted mean differences of -12.57 mg/dL (95% CI -29.91 to 4.76; $p=0.160$;) TG. A recent study by Chen S. et al.[110] (2022) also reported that the consistent significant mean difference in yoga therapy was perceived as noteworthy on TG levels (SMD = −0.32; 95%CI: −0.54, −0.10; $Z = 2.86$, $p = 0.004$). The outcome of this study was comparable with observations reported by Cui J. et al.[102] (2017) and Chen S. et al.[110] (2022).

High density lipoprotein

In the present study statistically, a significant increase was noted in mean HDL levels in both groups. In the yoga group, the mean HDL levels increased from 46.03±12.96 mg/dL at baseline to 53.05±12.26 mg/dL at six months and 55.30±13.18 mg/dL at 12 months interval (p<0.001) (Table 3). Similarly in the exercise group also was a significant increase in mean HDL levels that is, from 59.17±15.35 mg/dL at baseline to 63.85±15.65 mg/dL at six months and 65.78±18.10 mg/dL at 12 months intervals (p<0.001). However, based on the GEE model analysis, there was seen that no significant change in intervention with respect to the time on HDL level (p=0.252). The mean difference between baseline and at 12 months follow-up with respect to HDL was slightly higher in the yoga group when compared to with exercise group (9.27 vs 6.62 mg/dL). Furthermore, the increase in HDL in both groups was the independent period of intervention practiced then reliant on the type and duration of diabetes as the duration of DM was found to be a significant predictor of change in HDL (p=0.033). With each year's increase in the duration of DM, there were 0.559 times decrease in HDL level keeping other variables constant. These observations suggest that, although both interventions are equally beneficial in improving HDL levels, yoga is more effective in improving HDL compared to exercise intervention but this effect is significantly dependent on the duration of DM. A meta-analysis done by Cui J. et al.[102] (2017) reported weighted mean differences of 4.30 mg/ dL (95% CI 3.25 to 5.36; P < 0.00001; I 2 = 10%) for HDL a finding which was reliable with the present study.

Low-density lipoprotein

This study significantly reduced LDL levels in both groups. In the intervention group, the mean LDL levels decreased from 111.28±27.05 mg/dL at baseline to 100.33±25.69 mg/dL at six months and 98.87±24.17 mg/dL at 12 months interval ($p<0.001$). Likewise, in the case of the exercise group noteworthy decrease in mean LDL levels was noted that is, from 116.78±34.46 mg/dL at baseline to 97.12±30.35 mg/dL at six months and 93.07±28.32 at 12 months intervals ($p<0.001$) (Table 3). Specially GEE model shows a significant effect of intervention with the timeline on LDL and VLDL was significantly reduced in both groups over time. However, overall the difference between baseline and 12 month intervention with respect to LDL was slightly higher in the exercise therapy group compared with those participants in the yoga group (23.72 vs 12.42 mg/dL). The yoga intervention was found to be 12.3 times less likely to decrease LDL levels as compared to exercise intervention over time ($p=0.002$). The decrease in LDL in both groups was the independent duration of intervention practiced. These observations suggest that, although both interventions are equally beneficial in lowering LDL levels, yoga compared to exercise is less effective in lowering LDL. Further study by Cui J. et al.[102] (2017) reported that weighted mean differences of - 12.95 mg/dL (95% CI -18.84 to -7.06; P < 0.0001; I 2 = 37%) for LDL which was comparable with the present study.

Very low-density lipoprotein

In this study, the mean VLDL level significantly reduced was noted both groups. In the yoga group, the mean VLDL levels decreased from 34.49±153.17 mg/dL at baseline to 34.17±12.76 mg/dL at six months and 33.84±12.07 mg/dL at 12 months interval ($p<0.001$) (Table 3). Similarly in the exercise group also a significant

decrease in mean VLDL levels was noted that is, from 39.82±14.91 mg/dL at baseline to 34.22±11.84 mg/dL at six months and 33.89±10.71 at 12 months interval ($p<0.001$). In the case of GEE analysis not seen significant effects of the intervention on the VLDL level with regard to time ($p=0.001$). Exercise intervention significantly decreased VLDL over time but there was no significant difference in VLDL over the time in yoga group. However, overall, the mean difference between baseline and at 12 months follow-up with respect to VLDL was slightly high in the exercise group compared to the intervention group (5.93 vs 0.65 mg/dL). Furthermore, the yoga group was found to be 12.3 times less likely to decrease LDL levels as compared to the exercise group over time ($p=0.002$). The decrease in VLDL in both the groups was independent of the duration of intervention practiced but, the yoga group was found to be 6.256 times less likely to decrease VLDL level as compared to the exercise group over time. These observations suggest that, although both interventions are equally beneficial in lowering VLDL levels, yoga is less effective in lowering VLDL compared to the exercise intervention. These observations require further validation due to a lack of supporting data in the literature.

Overall, with regard to lipid profile the present study showed that both the interventions that is, yoga and exercise are equally effective in preventing lipid abnormalities but the effect of yoga intervention is significant in reducing total cholesterol, LDL and VLDL. In a meta-analysis encompassing 13 studies, Dutta et al.[142] discovered that people who practiced yoga had seen meaningly reduced levels of TG and an increase in levels of LDL-C and higher levels of HDL-C. In addition, in a recent study, the "yoga training" group had significantly higher HDL cholesterol than the other group. People who engaged in the most rigorous physical exercise decreased levels of LDL, Cholesterol.[143]

The present study showed that both the interventions that is, yoga and exercise are beneficial and offer excellent glycaemic control with prevention of lipid derangement and obesity thereby further complications and deaths linked with T2DM. Given the equal effect of yoga and exercise, People who have morbidities or are unable to exercise can practice yoga at home, which will aid in glycemic control and the prevention of lipid abnormalities and obesity. However, due to the study's inherent limitations, these findings need to be validated further. The study was a robust study design with a careful selection of participants and meticulous monitoring, follow-up, and collection of data with detailed analysis. The data regarding compliance/adherence to the intervention was obtained from the family member of the participant who was provided with a checklist that helped in ensuring the reliability of practicing intervention also the follow up by staff nurse during the intervention makes the results of this study more valid and reliable.

SUMMARY

Lifestyle therapies have been shown to lessen the prevalence of T2DM and its consequences. Yoga is simple, easy to understand and learn easy to practice at home for those who are ill, overweight, or elderly. The purpose of this study was to see how yoga treatment affected glycemic control, lipid profile, and BMI in people with T2DM.

This 14-month single-center randomized controlled experiment was undertaken at Jawaharlal Nehru Medical College, KAHER, Belagavi, under the Department of Community Medicine. A total of 126 eligible people with T2DM who were registered in the research region were enrolled. Participants were subdivided into two groups of 60 each using a computer generated, randomized number sequence method: Yoga group participants are on dietary control, taking anti-diabetic medications, and Yoga treatment, But in the case of the exercise group we have included exercise. At six months and one year, the subjects were assessed for glycemic control, lipid profile, and BMI. The study's key findings are described in the table below.

Most of the participants (53.30%) in the yoga group were aged between 28 to 56 years compared to 46.07% in the exercise group (p=0.584).

Most of the participants (62.20%) in the yoga group were males compared to 37.80% in the exercise group (p=0.054).

Most of the participants (58.30%) in the yoga group belonged to Class II socio economic status compared to 41.70% in the exercise group (p=0.527).

The duration of T2DM among 54.50% of the participants in the yoga group was ≥5 years compared to 45.50% in exercise group (p=0.464).

Most of the participants (57.50%) in the yoga group practiced the intervention for 160 to 171 days compared to 42.50% in the exercise group (p=0.061).

There was not seen significant effect of the intervention on HbA1c (p=0.318) and RBS (p=0.431) over some time. HbA1c and RBS were significantly lower in both groups at 6 and 12 months compared to baseline (p< 0.001).

There was observed that meaningfully decreased levels of total cholesterol, TG, LDL, and VLDL in together the groups after 6 months and 12 months of interventions as compared to baseline (p<0.001).

The GEE model showed significant effects of follow up with respect to time on cholesterol (p=0.001). Cholesterol significantly reduced in both the groups over time.

When compared to the yoga group, the exercise intervention significantly decreased cholesterol and TG level.

LDL was significantly lowered in both groups over time; though, the exercise intervention was found to reduce cholesterol and TG significantly more than the yoga group.

There was a substantial rise in HDL levels in together groups at 6 and 12 months as compared to baseline (p<0.001).

Here is a substantial rise in HDL levels in both groups at 6 and 12 months compared to baseline.

The GEE model shows significant impacts of Intervention on VLDL over the period ($p<0.001$).

The physical activity (Exercise intervention) therapy proved to significantly reduce VLDL over time, but the yoga follow up group showed no significant difference in VLDL over time.

There was BMI decreased significantly in both groups at six and twelve months compared to baseline (p0.001).

GEE model analysis showed no significant effect of Intervention with respect to period on BMI ($p=0.247$).

The effect of exercise was seen as significant on HbA1c, RBS, CH (Cholesterol), TG, HDL, VLDL, LDL, and BMI ($p<0.05$).

The mean HbA1c, mean RBS, mean cholesterol, mean TG, mean LDL, mean VLDL and mean BMI were found statistically lower after 12 months of interventions as compared to baseline.

The mean HDL level was found statistically increased in 12 months of intervention as related to baseline. The exercise brought about a maximum change in TG (MD: 41.25) followed by Cholesterol (MD: 39.73).

Yoga had a statistically significant effect on HbA1c, RBS, Cholesterol, HDL, LDL, ($p=0.05$). However, the effect of yoga on TG, VLDL, and BMI was not seen as statistically significant ($p>0.05$).

The mean HbA1c, mean RBS, mean cholesterol and mean LDL, were found statistically lower after 12 months' time intervention as linked to baseline. The mean

HDL was found statistically greater than 12 months follow-up as correlated to baseline.

Yoga brought about a maximum change in RBS (MD: 25.76) followed by Cholesterol (MD: 22.88).

The correlation of the Number of days respective intervention practiced with each dependent variable was found to be low and insignificant ($p>0.05$).

Age was found to be a significant predictor of change in RBS ($p=0.032$). With each year's increase in age, there was 0.783 times increase in the RBS levels keeping other variables constant.

The intervention group was found to be a significant predictor of change in cholesterol ($p=0.006$). The yoga group was found to be 16.806 times less likely to decrease cholesterol levels as compared to the exercise group over time.

Duration of T2DM was found to be a significant predictor of change in HDL ($p=0.033$). With each year's increase in the duration of DM, there was 0.559 times decrease in HDL level keeping other variables constant.

The intervention group was found to be a significant predictor of change in LDL ($p=0.002$). The yoga group was found to be 12.3 times less likely to decrease LDL levels as compared to the exercise group over time.

The intervention group was found to be a significant predictor of change in VLDL ($p=0.001$). The yoga group was found to be 6.256 times less likely to decrease VLDL level as compared to the exercise group over time.

None of the variables were found significant predictors of change in TG, HbA1c and BMI.

Overall, both the interventions that is, yoga and exercise are equally effective and offer excellent glycaemic control with prevention of lipid derangement and obesity thereby further disease and death associated with T2DM. Given the equal effect of yoga and exercise, people with morbidities or who are unable to go for exercise can practice yoga at home which will help them in glycaemic control and prevent lipid abnormalities and obesity.

CONCLUSION

Based on the outcomes of this study, it is possible to infer that both therapies, yoga and exercise, are equally helpful and provide great glycemic control and also helps in reducing BMI and for correcting lipid derangement, by reducing significantly the levels of cholesterol, TG, LDL, VLDL, HDL.

LIMITATIONS

- The findings in this study were based on the data from a single centre
- The data regarding OHA and its dosage was not considered which may have effects on glycemic control, parameters of lipid profile and BMI .

RECOMMENDATIONS

- The study recommends introduction of yoga at a primary health care which is feasible and safe.
- Display of yoga poses in waiting area of urban as well as rural health centres and at private clinics.
- Display of Information, Education & Communication (IEC) materials regarding various yoga postures through Audio visual aids and display charts - in patient wards of Taluka hospitals, District hospitals and at Tertiary/ Teaching hospitals.
- As AYUSH practitioners are included in the health care delivery system their involvement in implementing yoga ensures better practice and adherence among diabetic patients

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ANNEXURE A - DATA COLLECTION INSTRUMENT

Effectiveness Of Yoga versus Exercise On Glycemic Control Among Patients With Type II Diabetes Mellitus - A Community Based Randomized Control Trial

1. Personal Details

a) Name :

b) Age :

c) Sex :

d) Occupation :

e) Socioeconomic status :

f) Religion :

g) Address :

h) Contact number-

i) Duration of T2DM-

2. HISTORY

A. Personal history:

a) History of any respiratory illness :

b) History of any muscular disorder :

c) History of any neurological problems :

d) History of any mental illness :

e) History of any cardiac problem :

f) History of long time drug treatment :

2. GENERAL PHYSICAL EXAMINATION

1. Built –Heavy \Moderate \Poor	9.Clubbing \ Kylonochia Pr /Ab
2. Nutrition – Adequate \ Inadequate	10.Lymphadenopathy Pr /Ab
3. Pallor – Pr \ Ab	11.Skin N \ Ab
4. Icterus – Pr \ Ab	12.Height_____cms Weight ____Kgs 13.BMI _______
5. Spine-N\AbN	14.PR _______\min
6. Joints- N\AbN	15. BP______mmHg
7. Temperature Febrile\Afebrile	16. RR______\min
8. Oedemea Pr / Ab	

3. SYSTEMIC EXAMINATION

1. CVS	6. MSS
2. RS	7. SKIN AND STD
3. GIT	8. ORAL CAVITY
4. CNS	9. MENTAL HEALTH
5. GUT	10.EYES Lt Rt
	EARS Lt Rt

3. OUTCOME PARAMETERS

Serial No	Baseline	Six Months	One year
Height(cm)			
Weight(kg)			
Body mass index (kg/m^2)			

4) BIOCHEMICAL TESTS:

Serial No	Baseline	Six Months	One year
Blood Glucose Levels			
HbA1c level			
Lipid Profile			
Cholesterol			
Triglycerides			
HDL			
LDL			
VLDL			
Total Chol: HDL			
LDL: HDL			

Compliance sheet

Name of the patient:

Name of the Patient attainder:

Relation to Patient:

Date From:
To:

I week

Day 1 Monday	Day 2 Tuesday	Day 3 Wednesday	Day 4 Thursday	Day 5 Friday	Day 6 Saturday	Day 7 Sunday

II week

Day 1 Monday	Day 2 Tuesday	Day 3 Wednesday	Day 4 Thursday	Day 5 Friday	Day 6 Saturday	Day 7 Sunday

III Week

Day 1 Monday	Day 2 Tuesday	Day 3 Wednesday	Day 4 Thursday	Day 5 Friday	Day 6 Saturday	Day 7 Sunday

IV Week

Day 1 Monday	Day 2 Tuesday	Day 3 Wednesday	Day 4 Thursday	Day 5 Friday	Day 6 Saturday	Day 7 Sunday

Reasons for Non adherence

ANNEXURE B - INFORMED CONSENT & PATIENT INFORMATION SHEET

Introduction

We are requesting you to enrol yourself in the study titled **"Effectiveness of Yoga with Exercise On Glycemic Control Among Patients With Type II Diabetes Mellitus - A Community Based Randomised Control Trial"** conducted by Dr Rajesh Kulkarni, Research Scholar, under the guidance of Dr. Padmaja Walvekar, Prof & head , Dept. of Community Medicine, JNMC, Belagavi.

You have been requested to participate in the research because you are selected into either yoga intervention group or exercise group. The purpose of this study is to evaluate the effect of yoga on glycemic control in patients diagnosed with Type 2 Diabetes Mellitus and compare it with exercise interventional group who are involved in unstructured exercise programme.

Procedure

If you agree to participate in this study, you will be given a set of Questionnaire to which you are supposed to answer to the best of your knowledge. Anthropometric measurements will be taken and 5 ml of your blood will be drawn for the analysis of fasting blood sugar, glycosylated haemoglobin level and fasting lipid profile after explaining to you the nature and procedure of those tests and after taking ethics into consideration. These blood test will be carried at the beginning of the study, after six months and at the end of one year. If you are selected under yoga intervention group then you are suppose to attend Yoga teaching sessions which will be conducted by research yoga teacher. Next four months you are suppose to do yoga under observation of your recognized family member. If you are selected under exercise intervention group then you are suppose to do "physical activity" which refers to any

College, Belagavi or Dr. Rajesh kulkarni, Research scholar, Department of Community Medicine, Jawaharlal Nehru Medical College, Belagavi.

If you have any question about your right as study participant, you may contact Chairman, Human Ethics Committee on Human Subjects Research, Jawaharlal Nehru Medical College, Belagavi.

Institutional/sponsor policy

There is no commitment from the researchers involved in the research plan to provide any compensation for research related injury.

Financial incentives for participation

Your participation is voluntary and you will not be paid any remuneration for your participation in the study or for your expenses.

Contact details

If you have any queries/questions regarding the study, you may contact the study investigators Dr. Rajesh Kulkarni (Mobile: 9886010047), Research scholar, Department of Community Medicine, Jawaharlal Nehru Medical College, Belagavi.

Authorization to publish results

The researchers may use the information gathered from this study for presentation in scientific forums and for publication in scientific journals. However your identity will not be disclosed in such presentation or publication.

INFORMED CONSENT FORM

CONSENT STATEMENT

I am making a voluntary decision to allow myself to participate in this study. My signature below indicates that I have read (or have been read) the information provided above, that I have been given the opportunity to ask questions and the said questions have been answered to my satisfaction. I have been explained the nature of the study. I have received a copy of this signed consent form. I have right to withdraw from the study at any time.

Signature or left thumbprint of participant or legally authorized Representative

Participant name _______________ Participant signature/thumb print____________

Experimenter's name____________ Experimenter signature__________________

Witness name __________________ Witness signature____________________

Relationship with Participant ____________________

Date_____________________

Signature:

ಒಪ್ಪಿಗೆ ಹೇಳಿಕೆ

ಪರಿಚಯ :

ನಾವು ನಿಮ್ಮಲ್ಲಿ ನಮ್ಮ ಸಂಶೋಧನಾ ಅಧ್ಯಯನವಾದ "ಎರಡನೇ ಬಗೆಯ ಮಧುಮೇಹ ರೋಗಿಗಳು, ಸಕ್ಕರೆಯ ಅಂಶಿನ ಮೇಲೆ ಯೋಗ ಮತ್ತು ವ್ಯಾಯಾಮದ ಪರಿಣಾಮಕಾರಿತ್ವ ಯಾದದ್ದಕ್ಕೆ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ" ಒಂದು ಭಾಗವಾಗಲು ವಿನಂತಿಸುತ್ತೇವೆ. ಈ ಸಂಶೋಧನೆಯನ್ನು ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿಯಾದ ಡಾ.ರಾಜೇಶ ಕುಲಕರ್ಣಿ ಅವರು ಡಾ. ಪದ್ಮಜಾ ವಾಲ್ವೇಕರ ಪ್ರಾಧ್ಯಾಪಕರು ಹಾಗೂ ವಿಭಾಗದ ಮುಖ್ಯಸ್ಥರು ಸಮುದಾಯ ವೈದ್ಯಕೀಯ ವಿಭಾಗ ಜೆ.ಎನ್.ಎಮ್.ಸಿ ಬೆಳಗಾವಿ ಇವರ ಮಾರ್ಗದರ್ಶನದಲ್ಲಿ ಮಾಡುತ್ತಿದ್ದಾರೆ.

ನಿಮ್ಮನ್ನು ವಿನಂತಿಸಿಕೊಳ್ಳಲು ಮುಖ್ಯ ಕಾರಣವೆಂದರೆ ನೀವು ಯೋಗ ಅಥವಾ ವ್ಯಾಯಾಮ ಎರಡರಲ್ಲಿ ಒಂದು ಗುಂಪಿಗೆ ಆಯ್ಕೆ ಆಗಿದ್ದಿರಿ. ಈ ಸಂಶೋಧನೆಯ ಮುಖ್ಯ ಉದ್ದೇಶ ಎರಡನೆ ಬಗೆಯ ಮದುಮೆಹ ರೋಗಿಗಳ ಸಕ್ಕರೆ ಅಂಶಿನ ಮೇಲೆ ಯೋಗ ಮತ್ತು ವ್ಯಾಯಾಮದ ಪರಿಣಾಮಕಾರಿತ್ವದ ಕುರಿತು ತಿಳಯುವುದು.

ವಿಧಾನ :

ನೀವು ಈ ಅಭ್ಯಾಸದಲ್ಲಿ ಭಾಗಿಯಾಗಲು ಒಪ್ಪಿದರೆ ನಿಮಗೆ ಆಯ್ದ ಪ್ರಶ್ನಾವಳಿಗಳನ್ನು ನೀಡಲಾಗುವುದು. ಆ ಪ್ರಶ್ನೆಗಳಿಗೆ ನಿಮ್ಮ ತಿಳುವಳಿಕೆ ಇದ್ದಷ್ಟು ಉತ್ತರವನ್ನು ನೀಡಬಹುದಾಗಿದೆ. ಅದೇ ರೀತಿ. ನಿಮ್ಮ ತೂಕ ಮತ್ತು ಎತ್ತರಳತೆಗಳನ್ನು ನೋಡಲಾಗುವುದು. ನಿಮ್ಮ ಒಪ್ಪಿಗೆಯ ನಂತರ ನಿಮ್ಮ ರಕ್ತನಾಳಗಳಿಂದ ಐದು ಮಿಲ್ಲಿ ರಕ್ತವನ್ನು ಸಕ್ಕರೆ ಹಾಗೂ ಕೊಬ್ಬಿನ ಅಂಶವನ್ನು ಪರಿಕ್ಷಿಸಲು ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಈ ಪರೀಕ್ಷೆಗಳನ್ನು ಸಂಶೋಧನೆಯ ಪ್ರಾರಂಭದಲ್ಲಿ ಆರು ತಿಂಗಳ ನಂತರ ಹಾಗೂ ಒಂದು ವರುಷದ ನಂತರ ಮಾಡಲಾಗುವುದು. ನೀವು ಯೋಗ ಗುಂಪಿಗೆ ಸೇರಿದರೆ ನಿಮಗೆ ಯೋಗ ಗುರುಗಳಿಂದ ಎರಡು ತಿಂಗಳು ಯೋಗ ತರಬೇತಿಯನ್ನು ನಮ್ಮ ಅಶೋಕ ನಗರ ಆರೋಗ್ಯ ಕೇಂದ್ರದಲ್ಲಿ ನೀಡಲಾಗುವುದು. ನಂತರದ ದಿನಗಳಲ್ಲಿ ನಿಮ್ಮ ಮನೆಯ ಒಬ್ಬ ಸದಸ್ಯರನ್ನು ಗುರುತಿಸಿ ಅವರಿಗೆ ನೀವು ಯೋಗ ಮಾಡುವ ಬಗ್ಗೆ ಉಸ್ತುವಾರಿಯನ್ನು ನೀಡಲಾಗುವುದು. ನೀವು ವ್ಯಾಯಾಮದ ಗುಂಪಿಗೆ ಸೇರಿದರೆ ನಿಮಗೆ ವ್ಯಾಯಾಮದ ಬಗ್ಗೆ ಸವಿಸ್ತಾರವಾದ ತಿಳುವಳಿಕೆ ನೀಡಲಾಗುವುದು ಹಾಗೂ ನೀವು ಪ್ರತಿದಿನ

45 ನಿಮಿಷಗಳ ಕಾಲ ವಾಯುವಿಹಾರ, ಜಾಗಿಂಗ, ಸೈಕ್ಲಿಂಗ ಅಥವಾ ಈಜು ಇವುಗಳಲ್ಲಿ ಯಾವುದಾದರೂ ಒಂದನ್ನು ಮಾಡಬೇಕಾಗಬಹುದು. ಪ್ರತಿದಿನ ಆಗದೆ ಹೋದರು 150 ನಿಮಿಷ ವಾರದಲ್ಲಿಯಾದರೂ ಮಾಡಬೇಕಾಗಬಹುದು.

ಲಾಭ / ಅಪಾಯ :

ನೀವು ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವದರಿಂದ ನಿಮಗೆ ಯಾವುದೇ ಅಪಾಯವಿಲ್ಲ. ಒಂದು ವೇಳೆ ಯೋಗ ಅಥವಾ ವ್ಯಾಯಾಮ ಮಾಡುವಾಗ ಏನಾದರು ಅಪಾಯವಾದರೆ ನಿಮ್ಮನ್ನು ಕೆ.ಎಲ್.ಇ. ಆಸ್ಪತ್ರೆಗೆ ಕಳಿಸಿಕೊಡಲಾಗುವುದು.

ಸ್ವಯಂ ಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ / ಹಿಂಪಡೆಯುವಿಕೆ :

ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ಸ್ವಯಂ ಪ್ರೇರಿತವಾದದ್ದು, ಯಾವುದೇ ಕ್ಷಣದಲ್ಲಿಯು ಕೂಡ ನೀವು ಈ ಸಂಶೋಧನೆಯಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು. ಇದಕ್ಕೆ ಯಾವುದೇ ದಂಡವಿರುವುದಿಲ್ಲ.

ಪರಿಹಾರ :

ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವದರಿಂದ ನಿಮಗೆ ಯಾವುದೇ ಅಪಾಯವಾದಲ್ಲಿ ಅಥವಾ ಗಾಯವಾದಲ್ಲಿ ನಿಮಗೆ ಚಿಕಿತ್ಸೆಯನ್ನು ನೀಡಲಾಗುವದು ಅಥವಾ ಚಿಕಿತ್ಸೆ ಎಲ್ಲಿ ಸಿಗುತ್ತೆ ಎಂಬುದರ ಬಗ್ಗೆ ಮಾಹಿತಿ ನೀಡಲಾಗುವುದು.

ಗೌಪ್ಯತೆ :

ಅಭ್ಯಾಸದ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಬಗ್ಗೆ ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲ ಮಾಹಿತಿಗಳನ್ನು ಕಾನೂನಿನ ಪ್ರಕಾರ ಒಪ್ಪಿಗೆ ಕೊಟ್ಟಿದ್ದು ಗೌಪ್ಯತೆ ಕಾಪಾಡಲಾಗುವುದು. ಸಂಶೋಧನಾ ದಾಖಲೆಗಳಲ್ಲಿ ನಿಮ್ಮನ್ನು ಕೊಡ ಸಂಖ್ಯೆಯಲ್ಲಿ ಗುರುತಿಸಲಾಗುವುದು. ನಿಮ್ಮನ್ನು ವೈಯಕ್ತಿಕವಾಗಿ ಗುರುತಿ ಸಬಹುದಾದ ಮಾಹಿತಿಯನ್ನು ನಿಮ್ಮ ಒಪ್ಪಿಗೆ ಇಲ್ಲದೆ ತಿಳಿಸಲಾಗುವದಿಲ್ಲ.

ನಿಮ್ಮ ಅಭ್ಯಾಸದ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ ನೀವು ಡಾ. ಪದ್ಮಜಾ ವಾಲ್ವೇಕರ, ಪ್ರಾಧ್ಯಾಪಕರು ಹಾಗೂ ವಿಭಾಗ ಮುಖ್ಯಸ್ಥರು ಸಮುದಾಯ ವೈದ್ಯಕೀಯ ವಿಭಾಗ ಜವಾಹರಲಾಲ ನೆಹರು ಮೆಡಿಕಲ್ ಕಾಲೇಜ ಬೆಳಗಾವಿ ಅಥವಾ ಡಾ. ರಾಜೇಶ ಕುಲಕರ್ಣಿ

ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿ, ಸಮುದಾಯ ವೈದ್ಯಕೀಯ ವಿಭಾಗ, ಜವಾಹರಲಾಲ ನೆಹರು ಮೆಡಿಕಲ್ ಕಾಲೇಜ ಬೆಳಗಾವಿ ಇವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ನಿಮಗೆ ನಿಮ್ಮ ಹಕ್ಕಿನ ಬಗ್ಗೆ ಏನಾದರು ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ ನೀವು ಚೆರಮನ್, ಹ್ಯೂಮನ್ ಎಥಿಕ್ಸ ಕಮಿಟಿ ಅನ್ ಹ್ಯೂಮನ್ ಸಬ್ಜೆಕ್ಟ್ ರಿಸರ್ಚ ಜವಾಹರಲಾಲ ಮೆಡಿಕಲ್ ಕಾಲೇಜ ಬೆಳಗಾವಿ ಇವರನ್ನು ವಿಚಾರಿಸಬಹುದು.

ಸಾಂಸ್ಥಿಕ ನೀತಿ :

ಸಂಶೋಧನಾವಿದ್ಯಾರ್ಥಿಯವರಿಂದ ಸಂಶೋಧನೆಗೆ ಸಂಬಂಧಪಟ್ಟ ಗಾಯಗಳಿಗೆ ಯಾವುದೇ ಪರಿಹಾರ ಕೊಡುವ ಬಗ್ಗೆ ಯಾವುದೇ ಬದ್ಧತೆಯಿಲ್ಲ.

ಆರ್ಥಿಕ ಪ್ರೋತ್ಸಾಹಧನ :

ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆ ಸ್ವ– ಇಚ್ಛೆಯಿಂದ ಇರುವದರಿಂದ ಯಾವುದೇ ಸಂಭಾವನೆಯನ್ನು ನೀವು ಭಾಗವಹಿಸುವದಕ್ಕಾಗಲಿ ಅಥವಾ ಅಭ್ಯಾಸದ ಸಮಯದ ಖರ್ಚು ವೆಚ್ಚಗಳಿಗಾಗಲಿ ಕೊಡುವದಿಲ್ಲ.

ಸಂಪರ್ಕ ವಿವರ :

ನಿಮಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆಗಳಿದ್ದರೆ ಸಂಶಯವಿದ್ದರೆ ಅಭ್ಯಾಸದ ಬಗ್ಗೆ ನೀವು ಸಂಪರ್ಕಿಸಬಹುದಾದವರು

ಡಾ. ರಾಜೇಶ ಕುಲಕರ್ಣಿ : ಮೋ ನಂ. 9886010047

ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿ ಸಮುದಾಯ ವೈದ್ಯಕೀಯ ವಿಭಾಗ ಜವಾಹರಲಾಲ ನೆಹರು ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ಬೆಳಗಾವಿ. ಮಾಹಿತಿಯನ್ನು ಮುದ್ರಿಸಲು ಪರವಾನಿಗೆ ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿಗಳು ತಾವು ಅಭ್ಯಾಸ ಮಾಡುವಾಗ ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ವಿಜ್ಞಾನದ ವೇದಿಕೆ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಜರ್ನಲಗಳಲ್ಲಿ ಉಪಯೋಗಿಸಬಹುದು. ನಿಮ್ಮ ಗುರುತನ್ನು ಇಂತಹ ಪ್ರಸ್ಥುತಿ ಅಥವಾ ಪ್ರಕಟಣೆಯಲ್ಲಿ ಬಹಿರಂಗಪಡಿಸುವದಿಲ್ಲ

ಒಪ್ಪಿಗೆ ಹೇಳಿಕೆ ಪತ್ರ

ಒಪ್ಪಿಗೆ ಹೇಳಿಕೆ

ನಾನು ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಸೇರುವುದರ ಬಗ್ಗೆ ಸ್ವಂ ಇಚ್ಛೆಯ ನಿರ್ಧಾರ ತೆಗೆದುಕೊಂಡಿದ್ದೇನೆ. ನನ್ನ ಕೆಳಗಿನ ಸಹಿಯು ತೋರಿಸುವದೆನೆಂದರೆ ನಾನು ಮೇಲೆ ಕೊಟ್ಟ ಮಾಹಿತಿಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ನನಗೆ ಪ್ರಶ್ನೆ ಕೇಳುವದರ ಬಗ್ಗೆ ಅವಕಾಶ ಕೊಡಲಾಗಿದೆ ಮತ್ತು ಹೇಳಿದ ಪ್ರಶ್ನೆಗಳಿಗೆ ನನ್ನ ಸಮಾಧಾನವಾಗುವಂತೆ ಉತ್ತರ ಪಡೆಯಲಾಗಿದೆ. ನನಗೆ ನನ್ನ ಅಭ್ಯಾಸದ ಬಗ್ಗೆ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡಲಾಗಿದೆ. ನನಗೆ ಸಹಿ ಮಾಡಿದ ಒಪ್ಪಿಗೆ ಪತ್ರ ಕೊಡಲಾಗಿದೆ. ನನಗೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಈ ಅಭ್ಯಾಸದಿಂದ ಹಿಂಪಡೆಯುವ ಬಗ್ಗೆ ಹಕ್ಕು ಇದೆ.

ಸಹಿ ಅಥವಾ ಎಡಹೆಬ್ಬಟ್ಟಿನ ಗುರುತು ಅಥವಾ ಕಾನೂನು ಬದ್ಧ ಪ್ರತಿನಿಧಿ

ಭಾಗವಹಿಸುವವರ ಹೆಸರು :	ಭಾಗವಹಿಸುವವರ ಸಹಿ,/ ಹೆಬ್ಬಟ್ಟಿನ ಗುರುತು
ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿಯ ಹೆಸರು :	ಸಂಶೋಧನಾ ವಿದ್ಯಾರ್ಥಿಯ ಸಹಿ
ಸಾಕ್ಷಿದಾರರ ಹೆಸರು :	ಸಾಕ್ಷಿದಾರರ ಸಹಿ

ಭಾಗವಹಿಸುವವರ ಜೊತೆ ಸಂಬಂಧ

ತಾರೀಖ

ಸಹಿ

माहीतीपुर्ण सम्मती निवेदन

परिचय

आम्ही तुमच्या संशोदन उपध्ययनसाठी "दुसऱ्या तरेचे मधुमेह रूग्नाना सारखेच पातळीवरचे योग आणि व्यायाम ह्यांचे नियंत्रीत प्रयोग करण्यासाठी आम्ही विनंती करतो" हे संशोदन करण्यासाठी संशोधना विद्यार्थी डॉ. राजेश कुलकर्णी, त्यानी डॉ. पद्माजा वाळवेकर प्राध्यापक आणि विभाग मुख्यस्थ समहुदाय वैद्यकीय विभाग जे.एन.एम.सी. बेळगांवी ह्यांचा मार्गसर्शनाखाली करीत आहोत.

तुम्हाला विनंती करायचे कारण म्हणजे तुम्ही योग आणि व्यायाम घ्या दोनी मध्ये एक गटाला निवड झाले आहेत. ह्या संशोधनाचे मुख्य कारण म्हणजे दुसऱ्या तरेचे मधुमेह रूग्णासाठी सारखेचा प्रमाणावर योग आणि व्यायाम ह्यांचे परिणाम काय होते हे समझायचे.

प्रक्रिया :-

तुम्ही ह्यात भाग घेण्यासाठी तयार झाले तर काहीप्रश्न देण्यात येतील. त्या प्रश्नेला तुम्हाला जेवडे समजतील तेवडे उत्तर देणे. तसेच तुमचे वजन आणि उंची बघायचे आहे आणि तुमच्या सम्मतीने तुमच्या रक्तनाळातील ५ मिली रक्त साखर आग्णी चर्णी हे परीक्षणासाठी घेतला जाईल ही परीक्षा संशोधनाच्या सुरूवातीला, ६ महीने नंतर आणि एक वर्षा नंतर करणार आहे. तुम्ही योग गटाला भागी झाले तर योग शिक्षकांच्या सहयोगाने दोन महिने योग शिक्षण आमच्या आशोक केंद्रामध्ये ठेवला जाईल. पुढच्या दिवसात तुमच्या घरातले एक सदस्याला ओळखुन तुम्ही योग करता की नाही ह्याच्यावर लक्ष्य देण्यात येईल.

किंव्हा डॉ. राजेश कुलकर्णी संशोधना विद्यार्थी समुदाय वैद्यकीय विभाग जवाहरलाल नेहरू वैद्यकीय विद्यालय ह्यांना संपर्क करावे.

तुम्हाला तुमच्या आधिकारासाठी काही प्रश्न असेल तर तुम्ही चेअरमन ह्यमत , एथिकस कमिटी ह्युमन सबजेक्ट रिसर्च जवाहरलाल मेडीकल कॉलेज बेळगांवी ह्यांना संपर्क करू शकता.

संस्थापक धोरण :

संशोधना विद्यार्थीयांच्याकडुन संशोधन संबंध असलेले जखमिना कुठलेही भरपाई देण्यात येत नाही.

आर्थिक प्रोत्साहनधन

तुम्ही स्वइच्छेने भाग घेतला तर कुठल्याही आर्थिक मानधन देण्यात येत नाही.

संपर्क विवर

तुम्हला कुठलेही प्रश्न विचारायचे असेल तर आणि अभ्यसासाठी संपर्क करायचे असेल तर डॉ. राजेश कुलकर्णी (मो. नं. ९८८६०१००४७) संशोधन विद्यार्थी समुदाय वैद्यकीय विभाग जवाहरलाल नेहरू वैद्यकीय विद्यालय बेळगांवी ह्यांना संपर्क करावे.

परिणाम प्रकारीत करण्यासाठी अधिकार पत्ता

संशोधना विद्यार्थी संशोधक ह्या अभ्यासात एकत्र माहीती वापरू शकतो. ह्याच्या मध्ये संशोधन सदरीकरणे अथवा वैज्ञानिक पत्रिका प्रकाशन तुमच्या ओळख कुनासमोरही उघल केली जात नाही.

माहीतीपुर्ण सम्मती पत्र :-

सम्मती विधान :-

मी स्वइच्छेने ही शपथ घेतो या संशोधनामध्ये मी स्वइच्छेने स्वहभागी हारण्याचे निर्णय घेतला आहे. माझे खालील हे सही प्रमाणे मी वर दिलेले सगळे माहीती वाचलेली आहे. आणि मला प्रश्न विचारायला संधी दिले आहे. आणि प्रश्नांना माझ्या समाधानाप्रमाणे उत्तर मिळाले आहे. माझ्या अभ्यसाप्रमाणे अभ्यासाचे सर्व माहीती मिळाली आहे. मला स्वाक्षरी केलेला माहीती पुर्ण सम्म्मती पत्र दिलेले आहे. मला कुठल्याही परिस्थित यातुन बाहेर जाण्याचे अधिकार आहे.

सहभार्गाचा स्वाक्षरी किंवा अंगठ्याचा ठसा किंवा कायदेशिर अधिकृत प्रतिनिधी.

सहभार्गाचे नांव : -------------- सहभागीचे हस्ताक्षर / अंगठा--------------

अनुमती पत्र विस्ताराणाचे नांव -----------अनुमती पत्र विचारणाचे अगंठा---------

संशोदक सही ----------------- संशाधक नांव ----------------------

साक्षीदाराचे नांव :----------------- साक्षीदारांचे सही :-----------------

सहभागी बरोबरचे नाते :------------------------------

तारीख : - ------------------

सही :-

तुम्ही व्यायाम गटाला भर्ती झालेतर तुम्हाला व्यायाम विषयी पुर्णपणे प्रशिक्षण आणि माहीती सांगण्यात येईल, आणि तुम्ही रोज ४५ पंचेच्याळीस मिनिट फिरणे आणि जॉगिंग करणे. सायकलींग करणे आणि पोहायचे ह्यात कुठलेही एक करायला पाहीजे. रोज झाले नाही तरी १५० एकसे पन्नास मिनिट एक आठवड्यात करायला पाहीजे.

फायदे आणि धोका :-

तुम्ही संशोधनामध्ये भाग घेतलेतर तुम्हाला काही धोका नाही. एक वेळी योग आणि व्यायाम करताना काही धोका झाले तर तुम्हाला के. एल.ई. दवाखान्यात पाठवण्यात येईल.

स्वइच्छिने भाग घेणे आणि परत घेणे :-

तुम्ही स्वइच्छिने ह्यात भाग घेतले तर कुठल्याही क्षणात इथुन बाहेर जाता येईल. ह्याला कुठलाही दंड नाही.

भरपाई

ह्या संशोधनामध्ये भाग घेतला तर तुम्हाला काही झाले तरी कुठेही लागले तरी चिकित्सा देण्यात येईल आणि उपचार कुठे मिळते ते पण माहीती देण्यात येइेल.

शोपनीयता गो

आभ्यासाच्या वेळेला संग्रहन केलेले सगळ्या माहीती कायद्याप्रकारे शोपनयिता ठेवण्यात येईल. संशोधना दाखल्यात तुम्हापण सख्येंमध्ये ओळखला जाईल. तुमच्या वयक्तित माहिती तुमची परवानगीशिवाय कोणालाही कळविता येणार नाही.

तुम्हाला कुठलाही प्रश्न विचारायचे असले तर तुम्ही डॉक्टर पद्मजा पाळवेकर प्राध्यापक आणि विभाग मुख्यस्थ समुदाय वैद्यकीय विभाग जवाहरलाल नेहरु वैद्यकीय कॉलेज बेळगांवी

ANNEXURE C - ETHICAL CLEARANCE LETTER

KLE UNIVERSITY

(Formerly known as KLE Academy of Higher Education & Research, Belagavi)

[Declared as Deemed-to-be-University u/s 3 of the UGC Act, 1956 vide Government of India Notification No.F.9-19/2000-U.3(A)]

'Accredited **'A' Grade** by NAAC (2nd Cycle) Placed in **Category 'A'** by MHRD (GoI)

Office of the **Director, Academic Affairs**

JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India

☎: 0831-2444444/2493779 **FAX:** 0831-2493777 **Web:** http://www.kleuniversity.edu.in **E-mail:**diracademic@kleuniversity.edu.in

Ref. No. KLEU/EC/17-18/D-101 16th May 2017

To,
Dr. Rajesh R. Kulkarni
Part Time Research Scholar,
2016-17 batch, Faculty of Medicine
J. N. Medical College, Belagavi

Dear Research Scholar,

Sub:- Regarding Ethical Clearance.

The KLE University **Ethics Committee on Human Subjects** for Ph. D Research Project met on **22nd March 2017** to consider your application for approval of the research project **"Effectiveness of Yoga with Exercise on Glycemic Control among Patients with Type II Diabetes Mellitus: A Community Based Randomised Control Trial ".**

As there are no ethical issues involved in your proposed research project, the committee has provided approval for this research project.

You are requested to report to Ethical Committee in case of the following:

1. Any deviation from or change of the protocol.
2. All serious adverse events.
3. Any changes in study documents.

(Dr. Anita Dalal)
Member Secretary,
Ph.D. Ethical Committee(Human),
K.L.E. University,
Belagavi.

(Dr. Anil Hogade)
Chairman
Ph.D. Ethical Committee(Human),
K.L.E. University,
Belagavi.

CC to: - The Director Academic Affairs, KLE University, Belagavi.
- The Director Research Foundation, KLE University, Belagavi.
- The Registrar, KLE University, Belagavi

ANNEXURE D - PUBLICATIONS

Original Article

Effect of one Year of Yoga Therapy on Glycemic Control among Patients with Type 2 Diabetes Mellitus: A Randomized Controlled Trial

Rajesh Kulkarni[1], Padmaja Walvekar[2]

[1]Associate Professor, [2]Professor, Department of Community Medicine, KAHER's J. N. Medical College, Belagavi, Karnataka, India

Abstract

Context: India is well-endowed in using yoga therapy for the management of type 2 diabetes mellitus (T2DM) which is a safe, effective, and easy-to-learn alternative treatment that can be practiced by elderly and persons with disabilities.

Aim: Effect of 1 year of yoga therapy on glycemic control among patients having T2DM: A randomized controlled trial (RCT).

Settings and Design: RCT conducted at and Urban Health Centre (UHC) for 1 year.

Materials and Methods: One hundred and twenty diagnosed and registered for T2DM from UHC enrolled as participants who were divided into exercise and yoga interventional group by computer-generated, randomized number sequence method. The yogic practice was advised to 60 study participants and the reaming 60 participants were advised to do exercises for 1 year. The glycemic outcome was evaluated by Random Blood Sugar (RBS) and HbA1c which were examined at baseline, 6 months, and at the end of 1 year.

Statistical Analysis Used: Paired and unpaired (independent) *t*-test. Generalized estimating equations models were performed on the glycemic control variables to assess the differences between the two intervention groups.

Results: The *post hoc* analysis of 120 T2DM patient's data inferred that yoga and exercise have shown statistically significant ($P < 0.05$) effect on reducing HbA1C. However, no statistically significant difference ($P > 0.05$) was observed when the yoga group was compared with the exercise group on glycemic control (reducing HbA1c).

Conclusions: 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 HbA1c and RBS.

Keywords: Diabetes mellitus, Exercise, HbA1c, Yoga

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a complex metabolic disorder that is distinguished by defects in insulin secretion and insulin action, leading to hyperglycemia.[1] It is considered to be the leading cause of morbidity and mortality worldwide, related with severe cardiovascular manifestations, cerebrovascular ailment, or chronic kidney disease.[2] The prevalence of T2DM was estimated to be 366 million in 2011, which is likely to raise 51%, attaining a prevalence of 552 million in 2030. The estimated prevalence of T2DM in India was 60 million in 2011 and may likely increase to 63%, achieving 98 million by 2030.[3,4] The significant increase in the prevalence poses an alert to the Indian healthcare system to make necessary actions for the management of diabetes.[5]

India is well-endowed in using yoga therapy for the management of T2DM. More worrisome is the rising prevalence in children and young adults.[6] Yoga is a mind/body practice that incorporated three main components namely physical postures, meditation, and breathing exercises.[7,8] The regular practice of yoga is associated with a shift of the autonomic equilibrium toward parasympathetic dominance. The parasympathetic balance is associated with conserving and restoring energies which helps inhibit the heart and alimentary activity, enabling secretion.[9]

Diabetes is estimated to be the seventh prominent cause of death by 2030.[2] The global prevalence of T2DM was assessed to be 6.4%. In Asia, approximately 15% of the population – or 1 in 7 adults – have been stated to have either high fasting blood glucose or impaired glucose tolerance.[10] Among these, 5%–12% of these individuals develop type 2 diabetes every year.[11] As of now, India is the country with the second-highest number of type 2 diabetic patients, and the figure is likely to increase two-fold by 2030.[12] In India, the increased prevalence of T2DM is due to factors such as genetic predisposition and environmental factors contributing to increased abdominal obesity and insulin resistance.[6,13]

Yoga is an effective alternative treatment requiring no equipment, professionals and have sound evidence to possess long-term benefits.[14] The role of exercise in diabetic is known and according to ADA guidelines, adults with diabetes should be counseled to accomplish at least 150 min/week of modest-intensity aerobic physical activity (50%–70% of maximum heart rate), spread over at least 3 days/week with no more than 2 successive days without exercise.[15]

Along with medication, there are a number of treatments modalities are available to manage and treat diabetes such as life style modification, diet, yoga, and exercise. Although studies have been conducted in India to elucidate the impact of yoga on diabetes, most studies involve a limited number of patients with limited follow-up and more importantly involving only blood sugar estimations to evaluate the results. Since the literature is unclear regarding the most beneficial forms of yoga and exercise on glycemic outcome among subjects with T2DM, the present study randomized to compare the effect of yoga versus exercise treatment on glycemic outcome in subjects with T2DM.

SUBJECTS AND METHODS

Subjects

A randomized controlled trial (RCT) was performed at Urban Health Centre, Ashok Nagar, Belagavi. Study participants were recruited from the Diabetic Register maintained at Urban Health Centre, Ashok Nagar, Belagavi. The study was organized from July 2018 to December 2019. Institutional ethics committee had approved the study (ref no. KLEU/EC/17-18/D-102; Dated June 5, 2017) and participants provided informed consent before enrolment in the study.

The patients who will be eligible as per the inclusion criteria will be enrolled at the time of data collection from the OPD of Urban Health Centre, Ashok Nagar, which is Urban Field practice area of the Department of Community Medicine, Jawaharlal Nehru Medical College, KLE University, Belagavi. The sample size was calculated using below-mentioned formula

$$\frac{Z_{1-\beta} + Z_{1-\alpha})^2 \left(SD_1^{\,2} + SD_1^{\,2}\right)}{\left(\bar{x}_1 - \bar{x}_2\right)^2}$$

Where, $Z_{1-\alpha}$ = 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: 0.59 and 3.34,[6,12] X1-X2 = Expected impact size, $n = (0.84 + 1.96)^2 (0.59^2 + 3.34^2)/(9.0 - 7.29)^2 = 57$. Accounting drop-out cases as 10%, then the calculated sample size was = 63 in each group. Participants were randomly divided into exercise and yoga interventional group by computer-generated, randomized number sequence method. T2DM patients of both genders in the age group of 28–60 years, with HbA1c concentrations of 6.5% or more, on medication with oral hypoglycemic agents (OHA) with at least 1-year duration and those who were permanent residents of urban field practice area of Ashok Nagar were included in the study as study participants. T2DM patients with known vascular complication of diabetes, such as coronary artery disease, stroke, nephropathy, retinopathy, and

poly neuropathy 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 and pregnant women were also excluded from the study. 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 by a qualified nutritionist before the beginning of the study and also told about the importance of treatment adherence.

Yoga intervention group

The number of study participants in yoga intervention group is 65. The Yoga intervention comprised of hatha yoga classes with asanas (physical poses), relaxation, pranayama (breathing exercises), and meditation. The yoga instructor explained six yoga asanas to the study subjects.

Yoga teacher taught 60 min session which consisted of Surya namaskara – 20 min which included 12 steps, deep relaxation including muscle relaxation technique for 10 min, and 20 min yoga postures or asnas. The asanas consisted of Pavanamuktasana in the supine position, Bhujangasana and Shalabhasana in the prone position, Ardha Matsyendrasana in the sitting position which was followed by 10 min of pranayama. The time and occurrence of classes were roughly 50–60 min, 3 days in a week for 2 months. In the remaining days of the week, study participants were instructed to practice yoga at their home and to maintain a daily log book for seeing the adherence. For the first 2 months, intensive yoga teaching sessions were conducted by the yoga teacher. For the next 4 months, the patient was instructed to continue yoga under the observation of a recognized family member. The research staff nurse coordinated and did the follow-up of study participants to monitor compliance and provide individualized feedback.

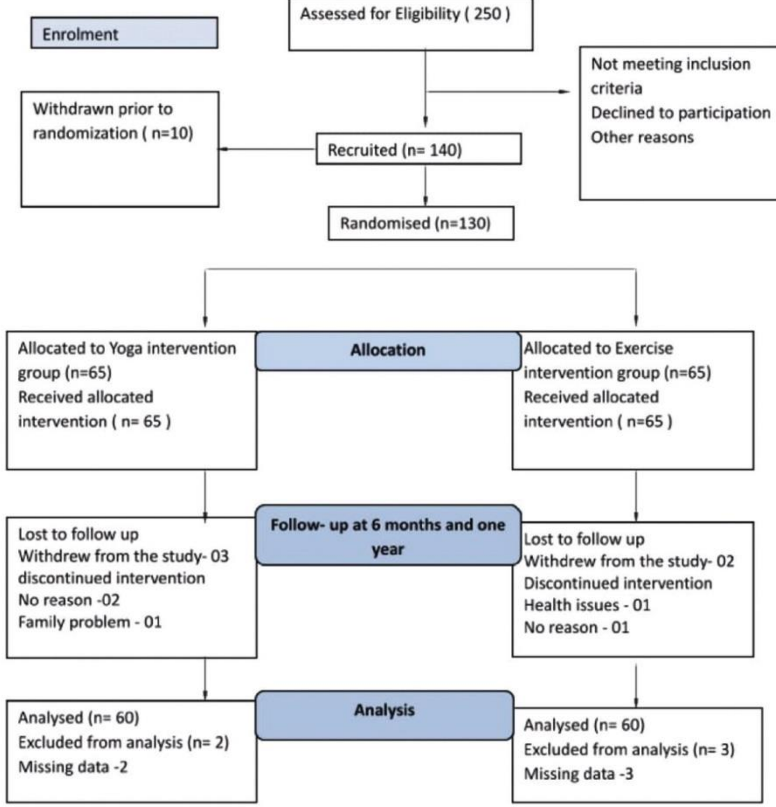

Figure 1: CONSORT flow diagram of participants' allocation, intervention, dropouts, follow-up, and analysis

Every month when the patient comes to the urban health center to collect his anti-diabetic drugs, random blood sugar levels (RBS) were checked, cross verification of participant family member checklist was done, and health education and counseling on nutritional aspects was given on the importance of adherence to proper diet and treatment. After 6 months and at the end of 1 year baseline investigations were repeated.

Exercise intervention group

The number of study participants in exercise group is 65. Exercise intervention refers to any unsupervised exercise training and subjects were counseled to enhance the physical activity that involves expenditure of energy such as a walking, jogging, and cycling for 45 min every day preferably in the morning hours with proper footwears. One person in the family was identified and was given a checklist to monitor whether the participant is regularly doing exercise. A research medico-social worker uses to coordinate and had done the follow-up of study participants.

Measurement

For the estimation of biochemical parameters like rasting blood sugar (RBS, Rxl-Max 500) HbA1c (Bio-Rad D-10) about 5 ml of blood was drawn and analyzed by phlebotomist of Sisco Research Laboratories of Belagavi at Urban Health Centre. Anthropometric measurements like height and weight were obtained by trained researcher. The BMI was obtained using the formula (weight in kg/height (meter)^2.

Statistical analysis

The data analysis was done to understand the descriptive and inferential statistics in terms of the central tendency of glycemic values and variations in yoga and exercise groups. The statistical significance from the baseline to 6 months and baseline to 12 months was measured by paired *t*-test, and variation in the yoga and exercise groups was calculated by an unpaired (independent) *t*-test. Statistical programming package SPSS version 25.0 was used for calculations. As the data violated the normality and homogeneity of variance, generalized estimating equations (GEE) models were performed instead of mixed-model ANOVA. GEE models were performed on the glycemic control variables to assess the differences between the two intervention groups.

RESULTS

The demographic details of the patients are provided in Table 1. Table 1 compares the background characteristics of study participants between the exercise group and yoga group. No significant association was identified between the intervention group and any of the given socio-demographic variables ($P > 0.05$) suggesting a good randomization.

Table 1: Comparison of background characteristics between exercise group and yoga group

Background characteristics	Group, frequency, *n* (%)		*P*
	Exercise (*n*=60)	Yoga (*n*=60)	
Age group			
28-56	32 (53.3)	28 (46.7)	0.584
57-83	28 (46.7)	32 (53.3)	
Sex			
Female	43 (57.3)	32 (42.7)	0.060
Male	17 (37.8)	28 (62.2)	
Socioeconomic status			
I	3 (75.0)	1 (25.0)	0.527
II	15 (41.7)	21 (58.3)	
III	38 (52.8)	34 (47.2)	
IV	4 (50.0)	4 (50.0)	
Duration of DM (years)			
1-4	35 (53.8)	30 (46.2)	0.464
5 or more	25 (45.5)	30 (54.5)	
Number of days practiced			
142-159	29 (61.7)	18 (38.3)	0.061
160-171	31 (42.5)	42 (57.5)	

DM: Diabetes mellitus

Female participants were slightly more than the male participants in the exercise (57.3%) and yoga intervention (42.7%). 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). The majority of study participants belonged to class III socioeconomic status according to Modified B. G. Prasad classification [Table 1].

Comparing glycemic control between exercise group and yoga group at different points of time

The mean change in the HbA1c levels at 6 and 12 months from the baseline for the yoga and exercise intervention groups are provided in Table 2.

GEE model analysis showed no significant effect of Intervention × Time on HbA1c ($P = 0.318$). However, there was a significant decrease of HbA1c in both the groups after 6 months and 12 months compared to baseline. Similarly, there were no significant effects of Intervention × Time on RBS ($P = 0.431$). However, there was a significant decrease ($P = 0.431$) of RBS in both the groups after 6 months and 12 months compared to baseline [Table 3].

Multiple linear regression for determining predictors of change in HbA1c and RBS

On comparing the effect of demographic variables with the change in HbA1c levels, it was identified that none of

Table 2: Mean change in glycated hemoglobin at 6 months and 12 months from the baseline (n=120)

HbA1C group	Yoga					Exercise				
	Baseline	6 months	Mean change	12 months	Mean change	Baseline	6 months	Mean change	12 months	Mean change
<7.5	7.14	6.89	0.25	6.77	0.37	7.38	6.87	0.52	6.78	0.60
7.6-8.9	8.16	7.58	0.58	7.51	0.65	8.09	7.48	0.62	7.34	0.75
>9.0	10.62	9.40	1.23	8.85	1.78	10.20	9.09	1.11	8.84	1.36
Grand total	8.72	8.01	0.71	7.77	0.96	8.54	7.80	0.73	7.65	0.89

HbA1C: Glycated hemoglobin

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

Variable	Time	Intervention (mean±SD)		P*
		Exercise	Yoga	
HbA1C	Baseline	8.54±1.26	8.73±1.54	0.318
	6 months	7.8±1.02**	8.01±1.17**	
	12 months	7.65±0.93**	7.77±0.98**	
RBS	Baseline	190.66±45.28	194.63±53.55	0.431
	6 months	165.37±32.57**	174.9±32.74**	
	12 months	156.68±27.67**	168.87±29.06**	

*P-value is for interaction effect between intervention and time, **Significant difference between baseline and follow-up time (6 months and 12 months). SD: Standard deviation, HbA1C: Glycated hemoglobin, RBS: Random blood sugar

Table 4: Multiple linear regression for determining predictors of change in glycated hemoglobin

Variables	Estimate	P
Yoga group	0.030	0.810
Age	−0.007	0.320
Number of days practiced	0.002	0.835
Male	0.164	0.224
Socioeconomic status II	−0.060	0.859
Socioeconomic status III	−0.100	0.765
Socioeconomic status IV	0.095	0.810
Duration of DM	0.002	0.891

Change in HbA1C=Baseline HbA1C minus 12 months' follow-up HbA1C. HbA1C: Glycated hemoglobin, DM: Diabetes mellitus

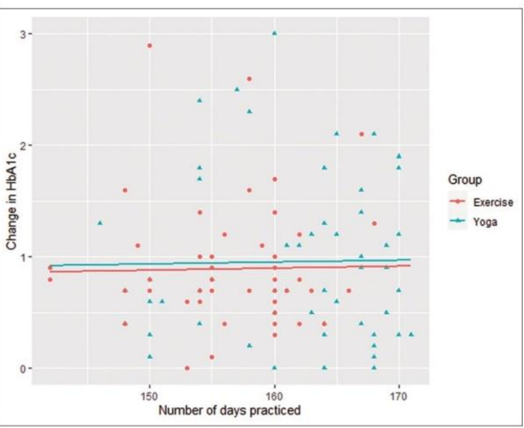

Figure 2: Scatter plot showing correlation between number of days respective intervention practiced and change in HbA1c

the variables were found significant predictors of change in HbA1c [Table 4].

Age was found to be significant predictor of change in RBS (P = 0.032). With each year increase in age, there was 0.783 times increase in RBS level keeping other variables constant [Table 5].

Correlation between number of days respective intervention practiced and change in HbA1c and RBS

The correlation of number of days respective intervention practiced with each dependent variable was found to be low and insignificant (P > 0.05). The correlation of number of days respective intervention practiced with each dependent variable is visualized in Figures 2 and 3.

DISCUSSION

The present study was one of the very few studies which is community-based conducted at urban field practice area for 1 year of time with an adequate sample size among T2DM patients with three times reading baseline, 6 months and at the end 1 year. In our study, we found that both yoga and exercise are equally effective in glycemic control. Results obtained after statistical analysis in this study and its comparison with already published research, we can say that yoga as well as exercise both helps in reducing random blood glucose levels as well as Hb1Ac level in patients with T2DM.

Jayawardena *et al.* performed a meta-analysis involving eight studies with 842 participants to find the influence of yoga on glycemic control in subjects with T2DM. It was identified in the pooled analysis that a substantial reduction in the levels of fasting blood glucose (15.16 mg/dl), post prandial blood glucose (28.66 mg/dl), and glycated hemoglobin (0.39%) were seen in the yoga group compared to the exercise group.[16] Ramamoorthi *et al.* in a meta-analysis involving 12 RCTs and 2 non-RCTs identified that yoga improved fasting blood glucose levels in the prediabetic state.[17]

The beneficial effect of yoga in type II diabetes has been ascribed to improved insulin sensitivity at target tissues decreasing insulin resistance and accordingly increasing peripheral glucose utilization.[18] It has also been hypothesized that yoga can revitalize or restore beta cells of the pancreas.[19] Apart from reducing the dosage

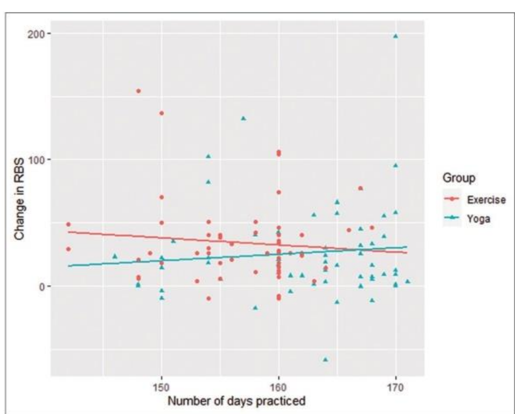

Figure 3: Scatter plot showing correlation between number of days respective intervention practiced and change in RBS

Table 5: Multiple linear regression for determining predictors of change in random blood sugar

Variables	Estimate	*P*
Yoga group	−10.595	0.131
Age	−0.783	0.032*
Number of days practiced	0.546	0.372
Male	−1.578	0.832
Socioeconomic status II	−14.043	0.456
Socioeconomic status III	−10.691	0.566
Socioeconomic status IV	11.089	0.614
Duration of DM	1.390	0.129

*$P \leq 0.05$ is considered as significant Change in RBS=Baseline RBS minus 12 months' follow-up RBS. RBS: Random blood sugar, DM: Diabetes mellitus

of oral hypoglycemic drugs or insulin, yoga can delay the development of the disease process.[20]

In our study, there was a significant decrease of RBS and HbA1c in both yoga and exercise groups. Recent studies showed a significant decline in the levels of FBS and PPBS in type 2 diabetic patients on OHA undertaking yoga training when compared to subjects who are only on OHA.[21,22] Similarly, a significant reduction in FBS and PPBS after yoga training has been proved in T2DM patients on OHA in a study.[23] Keerthi *et al.* analyzed the consequence of yoga on quality of life (QoL) and Indian diabetes risk score in normotensive, diabetic, prediabetic individuals and it was identified that a significant improvement in QoL was seen and yoga diminished the risk of diabetes among Indian prediabetic people and diabetic individuals.[24]

A decrease in HbA1c levels in the yoga group agrees with the earlier studies done by Malhotra *et al.* and Selvin *et al.* reported that a 1% reduction in HbA1c levels is related with a 37% decrease in microvascular complications and a 14% decrease in myocardial infarctions.[25,26] Thus, in this study the observed 1.17% decrease in HbA1c levels might be projected to yield a 40% decline in risk of microvascular complications and a16% decrease in cardiovascular disease risk. In a meta-analysis conducted by Thind *et al.* involving 23 studies with 2473 participants, yoga improved glycemic outcomes and reduced the risks of complications of type 2 diabetes mellitus.[27] Similar to our study, Gordon *et al.* observed that conventional physical training improved glycemic outcome in type 2 diabetic individuals.[28] The present study has few limitations. Since this study is for 1 year and most of the yoga practice and exercise was unsupervised and adherence was mainly based on study participants reporting. Large multicenter 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 HbA1c and blood sugar levels. It appears extremely promising for primary and secondary prevention of diabetes mellitus.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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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-β = 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.

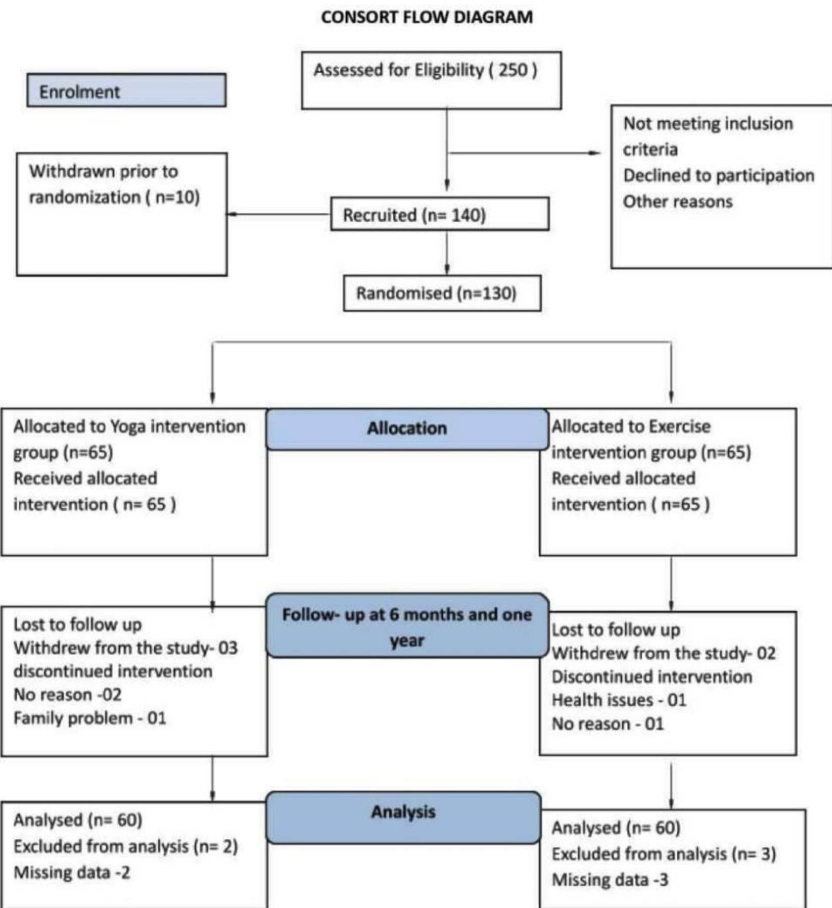

Figure 1: CONSORT flow diagram of participants' allocation, intervention, dropouts, follow-up, and analysis

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 socio-economic 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

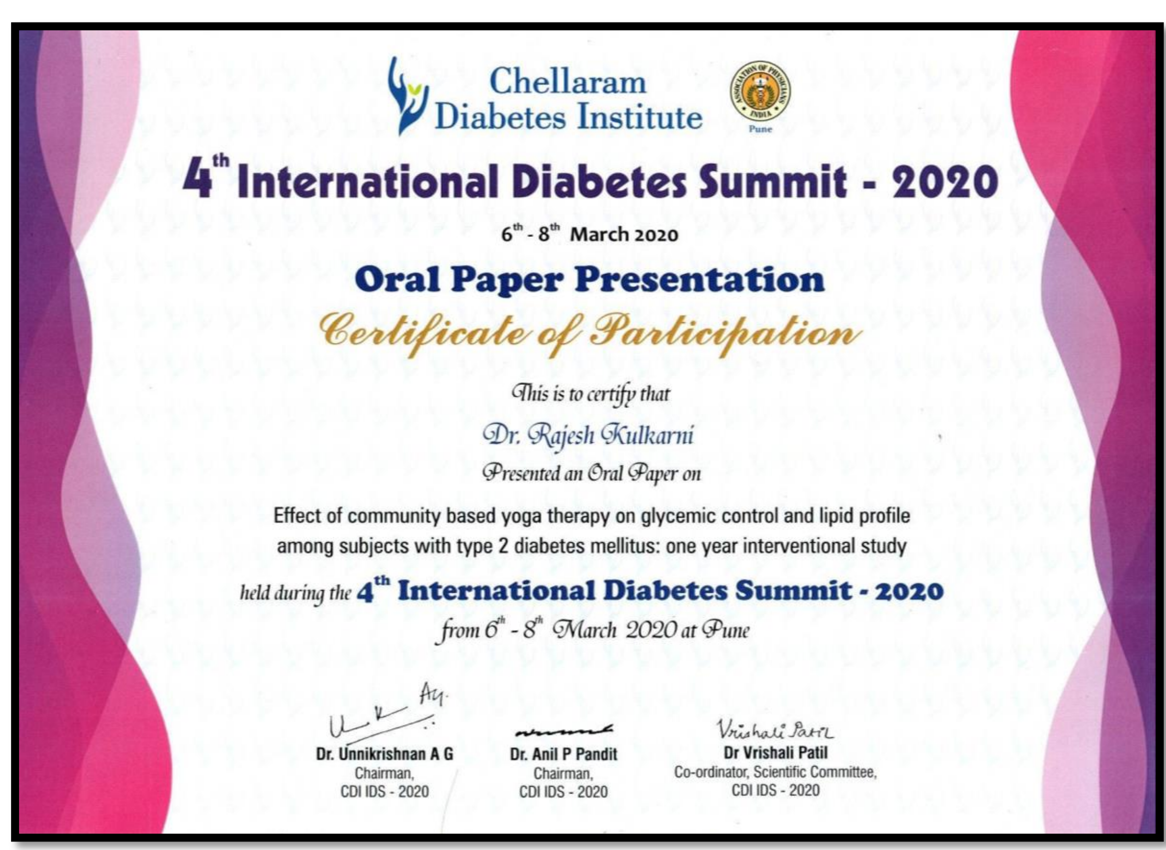
week. Because all participants may be previously sedentary, overweight, and above the age of 50 years, all poses were modified to accommodate limited levels of flexibility, balance, and strength. Props such as chairs, belts or blankets will be used for such modifications to allow for appropriate alignment, 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).

ANNEXURE E - CONFERENCES AND PAPER PRESENTATIONS



INTERNATIONAL MEDICAL CONFERENCE - 2019

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This is to certify that ***Dr. Rajesh R. Kulkarni*** *has presented* ***ORAL PAPER***

entitled as "Determinants of self-care amongst patients with type II diabetes based on health belief model in urban and rural health centre of Belagavi" in the International Medical Conference

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