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A multicenter clinical trial on the anti-diabetic efficacy and safety profile of *Saptavimshatika Guggulu* and *Haridra Churna* in the management of type 2 diabetes mellitus

Avinash K. Jain[1], Surinder K. Sharma[2], Dipsundar Sahu[3], Vinod B. Kumawat[4], Om R. Sharma[2], Pradeep Dua[5], Babita Yadav[1], Shruti Khanduri[1], Sarada Ota[1], Gurucharan Bhuyan[7], Rakesh Rana[1], Richa Singhal[1], Bharti Gupta[6], Madan M. Padhi[1], Kartar S. Dhiman[1]

[1]Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, [2]Regional Ayurveda Research Institute for Nutritional Disorders, Mandi, Himachal Pradesh, [3]Central Ayurveda Research Institute for Drug Development, Kolkata, West Bengal, [4]Regional Ayurveda Research Institute for Drug Development, Gwalior, Madhya Pradesh, [5]Bureau of Indian Standard Hqrs., New Delhi, [6]Central Ayurveda Research Institute for Cardiovascular Disorders, New Delhi, [7]Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar, Odisha, India

Address for correspondence:
Dr. Avinash Kumar Jain, Research Officer, Central Council for Research in Ayurvedic Sciences (CCRAS), 61–65, opp. D' Block, Janakpuri Institutional Area, Janakpuri, New Delhi 110058, India.
E-mail: vaidyaakjain@gmail.com

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Abstract:

BACKGROUND: *Madhumeha* (diabetes mellitus [DM]) disease is one of the very few diseases, which has been found in the history and culture of India and across the globe. Since ages, even in the twenty-first century, this disease is a cause of concern to the world due to its morbidity and long-term complications. Traditional medicines are still found to be very useful in the improvement of quality of life (QOL) of the patients with *Madhumeha*. Ayurvedic formulations are found to be useful in the management of type II DM and in promoting health.

OBJECTIVE: *Saptavimshatika Guggulu* (SG) and *Haridra Churna* (HC) were evaluated to assess their clinical effectiveness in the management of type 2 diabetes. A secondary objective was to assess the changes in the QOL of the patients with type 2 DM and the clinical safety of SG and HC.

MATERIALS AND METHODS: This multicenter clinical study was critically evaluated to assay the clinical efficacy and safety profile of ayurvedic formulations, SG 500 g two tablets two times after food and HC 3 g with luke-warm water after food two times daily for 12 weeks in 146 participants, diagnosed with NIIDM, enrolled as per the selection criteria.

RESULTS: The results were of highly significant in the regulation of FBS (BT-167.44 mg/dL, AT-152.83 mg/dL) and PPBS (BT-261.74 mg/dL, AT-240.59 mg/dL). Statistically highly significant result was found in the improvement of Diabetes Symptoms Questionnaire and SF-36 health survey score; no ADR or any complications were noted.

CONCLUSION: SG and HC used on the subjects of type 2 DM (*Madhumeha*) are clinically effective, safe, and tolerable.

Keywords:

Haridra Churna, *Madhumeha*, *Saptavimshatika Guggulu*, type 2 diabetes mellitus

Introduction

The principles of Ayurveda are ever relevant and applicable; the more sensitive a person is toward his own innate needs, the healthier he can live. When necessity is replaced by desire, a man starts causing the disorder by himself. Sleep, food, and celibacy are the three essential pillars of life, but to live healthily, one must be aware and wise enough to use and implement them appropriately. A faulty lifestyle is considered as the primary cause of all diseases in Ayurveda; therefore, eating food

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and engaging in physical activity are crucial to a healthy and active existence. It is impossible to avoid suffering if these two are not properly regulated. In Ayurveda, *Prameha* (diabetes) is a classical example of a lifestyle disorder and its major cause can be explained by overeating and sedentary lifestyle.[1] In *Charaka Samhita,* it is described that a person who is obese, physically inactive, and eats an excessive amount of food is more prone to diabetes. There are 20 types of diabetes mentioned in Ayurveda and according to ancient seers of Ayurveda, if not treated properly all types of diabetes may be converted into *Madhumeha* (diabetes mellitus [DM]), which is also termed as *Ojomeha* and *Ksaudrameha*.[2-4] The term *Madhumeha* indicates all those who pass sweet, excess, and/or turbid urine known as *pramehi*, urine resembles with *Madhu* (honey) which may be interpreted as increased sugar level in the body.[1,3,5] These findings indicate that this disease has been prevalent in India since ancient times as number of predisposing and etiological factors, pathogenesis sign symptoms, and complications of this disease are described in detail.[1,5,6] In Ayurveda classics, diabetes mellitus (DM) has been described as a type of *Vataja Prameha*, a consistent, chronic condition that is difficult to cure.[7]

DM is an endocrinological metabolic clinical disorder characterized by hyperglycemia due to absolute or relative deficiency of insulin hormone and long-term complications involving the eyes, kidneys, nerves, and blood vessels.[8] Approximately 80% of people with diabetes live in low- and middle-income countries.[9] In India, there were 61.3 million diabetics in 2011,[10] in which type 2 DM accounts for more than 90% of all reported cases.[11]

Despite many treatment modalities available in conventional medicine, the perfect treatment is still in search. The available treatments such as insulin, sulphonylureas, biguanides, alpha-glucosidase inhibitors, meglitinides, and thiazolidenedione derivatives to manage the blood sugar levels in the patients suffering from DM have their own limitations.[12] Drug intolerance, hypersensitivity and resistance to insulin, the danger of acute and chronic complications, and the fear of hypoglycemia make it important to search out for a safe, effective, and cheaper medicine. At this juncture, Ayurveda has the potential to offer an alternative or complementary medical care to the patients of DM, for effective and safe management of the disease. This study was undertaken to validate the effect of classical Ayurvedic formulation in the management of type 2 DM (NIDDM). This study was conceptualized and funded by Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi; clinical trials were conducted in its three peripheral institutes, and also the same study has been conducted in IPGT & RA, Jamnagar, Gujarat state with the same trial compounds and similar study participants.[13]

Objectives

The primary objective of the study was to assess the clinical efficacy of *Saptavimshatika Guggulu* (SG) and *Haridra Churna* (HC) in the management of type 2 DM. The secondary objective of the study was to assess the changes in the QOL and clinical safety of SG and HC in type II DM patients.

Outcome measures

The primary outcome measure was changes in glycosylated hemoglobin (HbA1c %) at the end of 12 weeks from baseline and secondary outcome measures were the changes in symptoms of DM patients, assessed by Diabetes Symptoms Questionnaire (DSQ), changes in blood sugar level, and changes in the QOL by using SF-36-Health Survey Questionnaire.

Materials and Methods

Study design and setting

This multicenter single-arm prospective study was conducted under Intra Mural Clinical Research Programme (IMCRP) during years 2011–2012 at three centers of CCRAS: namely, Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar (Orissa), M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur (Rajasthan), and Regional Ayurveda Research Institute for Nutritional Disorders, Mandi (Himachal Pradesh). The trial was registered with CTRI India (Ref: CTRI/2012/03/002537). The approval of the institutional ethics panel was taken in each center before the initiation of the trial, and participants of each study signed the consent form before they enrolled the study. Laboratory investigations, that is, biochemical and hematological parameters, were done before and after the completion of treatment. The demographic profile, personal history, and history of family-related illness were recorded at baseline in the CRF. The drug was dispensed at each follow-up with an interval of 14 days together with the clinical assessment. Any adverse drug reaction occurred by the trial drug during the treatment period (12 weeks), if any, was reported.

Trial interventions

SG (Ayurvedic Pharmacopoeia of India – Part II; Vol-II) at a dose of 1 g (two tablets each of 500 mg) twice daily was administered orally with lukewarm water, after food for 12 weeks. HC (Ayurvedic Pharmacopoeia of India – Part I; Vo-II) at a dose of 3 g twice daily was administered orally with lukewarm water, after food for 12 weeks. Both the drugs were procured from GMP-certified pharmacy, following the standards of Ayurvedic Pharmacopeia of India.

Study participants

Inclusion criteria

Participants of both sex aged between 30 and 65 years, suffering from NIDDM (type 2 DM), and treatment-naive or on oral hypoglycemic drugs for ≤ 6 weeks with HbA1c % ≥ 6.5% were included in the study.

Exclusion criteria

The patients suffering from brittle DM, those who were having diabetic complications, history of cardiac disorders, clinical evidence of heart failure, poorly controlled hypertension (BP >160/100 mm Hg), hepatic dysfunction, renal dysfunction, uncontrolled pulmonary dysfunction, or other concurrent severe diseases were excluded from the study. Pregnant women, lactating women, women on oral contraceptive pills or estrogen replacement therapy, patients taking steroids, alcohol, drug abusers, having evidence of malignancy, and patients who are suffering from major systemic illness were excluded from the study.

Withdrawal criteria

Every enrolled participant was free to withdraw from the study at any time without the permission of the investigator or the investigator could discontinue the participant in the development of any condition which was not suitable to continue in the study. But efforts had been made to document the condition of that patient at his last visit for drug safety and the validity of study results.

Laboratory investigations

The hematological investigations such as hemoglobin percentage (Hb), erythrocyte sedimentation rate (ESR), total and differential leucocyte count, blood sugar (fasting and postprandial [PP]), HbA1c %, biochemical investigations such as blood urea, serum creatinine, aspartate aminotransferase (AST), alanine aminotransferase (ALT), serum alkaline phosphatase, albumin, bilirubin, serum lipid profile, urine routine examination, and ECG were performed before enrolment of the study participants and after completion the of the treatment period for safety and efficacy evaluation.

Statistical analysis

The data of the subject's who completed the trial and with at least one follow-up visit after the baseline period were analyzed. The data of the last follow-up visit were considered as the data of subsequent follow-up visits up to the end of the study period by "last observation carry forward method (LOCF)" under modified intention-to-treat analysis for missing data. Statistical analysis was performed using the Statistical Packages for Social Sciences (SPSS) version 15.0 for Windows. Baseline characteristics were reported as mean ± standard deviation (SD) and frequency in percentage. The changes in the Diabetes Symptom Questionnaire (DSQ) score and QOL from baseline to 12 weeks were analyzed by using repeated measures analysis of variance (ANOVA). A value of $P < 0.05$ was considered statistically significant.

Observations and Results

A total of 146 participants were recruited, of which 137 completed the study and 9 were dropped out. But data of seven dropout participants have been taken for analysis by the LOCF method. The demographic data of this study have shown that the mean age of participants is 49.1 years. The majority of patients were men (66.7%), married (97.2%), literate (86.1%), those having desk work occupation (33.3%), those who belonged to the above poverty line (91%), urban habitat (57.6%), Hindu religion (95.8%), and nonvegetarian dietary habits (52.8%). The mean body mass index (BMI) of all patients was 24.8995 kg/m^2. The details are presented in Table 1.

Regarding chief complaints, the most common reported symptom was exhaustion/tiredness present in 84% of patients on baseline day (Day 0) and in 55.6% patients on 84th day (after treatment) followed by body ache in 69.4%

Table 1: Demographic and baseline vital data of study participants (*n* = 144)

Variables	*N* (%)	Mean ± SD
Age		49.1±7.4
Gender		
Male	96 (66.7)	
Female	48 (33.3)	
Marital status		
Married	146 (100)	
Unmarried	Nil	
Occupation		
Desk work	48 (33.3)	
Fieldwork	55 (38.2)	
Housewife	41 (28.5)	
Dietary habits		
Veg	68 (47.2)	
Non-veg	76(52.8)	
Prakriti		
Vatapittaja	75 (52.1)	
Pittakaphaja	58 (40.3)	
Vatakaphaja	9 (6.3)	
Height (m)		1.6± 0.1
Weight (kg)		64.4 ± 10.84
BMI (kg/m^2)		24.9 ± 4.1
Waist circumference (cm)		71.3 ± 30.3
Respiratory rate (per min)		17.94 ± 2.35
Pulse rate (per min)		76.7 ± 8.4
Blood pressure		
Systolic (mm Hg)		124 ± 14
Diastolic (mm Hg)		80.7 ± 8.54

BMI = body mass index

patients (on Day 0) and 37.5% (on 84th day), polyuria in 56.9% (on Day 0) and 30.6% (on 84th day), polyneuritis (numbness/tingling) in 55.6% (on Day 0) and 33.3% (on 84th day), visual disturbance in 55.6% (on Day 0) and 50.7% (on 84th day), polyphagia in 54.2% (on Day 0) and 15.3% (on 84th day), polydipsia in 52.8% (on Day 0) and 20.1% (on 84th day), and giddiness in 36.8% (on Day 0), and 13.2% (on 84th day) patients, respectively. The details are presented in Table 2.

Ayurvedic subjective parameters such as flaccidity of muscles were present in 80.6% of patients on baseline day (Day 0) and in 47.2% of patients on 84th day (after treatment), desire for sedentary life in 75.7% (on Day 0) and 40.3% of patients (on 84th day), excessive thirst in 68.6% (on Day 0) and 23.6% of patients (on 84th day), dryness of palate and throat in 68.1% (on Day 0) and 25.7% patients (on 84th day), desire for cold food and environment in 66% (on Day 0) and 21.5% of patients (on 84th day), tartar in teeth) in 61.1% (on Day 0) and 31.3% of patients (on 84th day), excessive urination in 60.4% (on Day 0) and 31.3% of patients (on 84th day), excess perspiration in 59% (on Day 0) and 29.9% of patients (on 84th day), bad body odor in 59% (on Day 0) and 31.3% of patients (on 84th day), burning sensation of hands and feet in 55.6% (on Day 0) and 15.3% of patients (on 84th day), excess glossy/oily skin in 54.9% (on Day 0) and 18.1% of patients (on 84th day), feeling sweetness in mouth in 46.5% (on Day 0) and 11.8% of patients (on 84th day), turbid urination in 42.4% (on Day 0) and 16% of patients (on 84th day), and urine having color of honey in 27.1% (on Day 0) and 7.6% of patients (on 84th day), respectively.

In laboratory investigational parameters, the mean score of hemoglobin before the treatment was 12.656 g/dL and after the treatment was 12.675 g/dL, which was statistically nonsignificant. ESR before the treatment was 14.64 mm first hour and after the treatment was 11.44 mm first hour, which was statistically significant. HbA1c % mean score before the treatment was 8.5459 and after the treatment was 8.877, which was statistically nonsignificant. Blood sugar fasting mean score before the treatment was 167.44 mg/dL and after the treatment was 152.83 mg/dL, which was statistically highly significant. Before the treatment, PP blood sugar mean score was 261.74 mg/dL and after the treatment was 240.59 mg/dL, which was statistically highly significant. DSQ score (mean) before the treatment was 38.74 and after the treatment was 13.41, which was statistically highly significant. In SF-36 Health Survey Score all eight domain was found to be statistically highly significant. The details are presented in Tables 3–6.

Discussion

Enough evidences are available in Ayurveda and modern bioscience, which justify the correlation between diseases *Madhumeha* and diabetes.[14-17] The genetic nature, overeating, and underactivity are endorsed as basic etiological events in both Ayurvedic and modern literature.[18] As per Ayurvedic pathogenesis, diabetes is divided into lean/thin diabetic and obese diabetic.[19] It is on very similar grounds as diabetics are classified in modern medicine as IDDM and NIIDM, respectively. A very similar pattern is also seen in the classification such as congenital DM and DM caused due to overeating and wrong eating habits.[20] In Ayurveda, diabetes is taken into account as a disease of vitiated *Vata* and *Kapha Dosha*.[21] The primary line of management in diabetes is avoidance of causative factors, which emphasizes withdrawal from the afflictions towards the sedentary lifestyle and unhealthy food habits. Because of the physical inactivity, state of mind and food are favorable to the excessive accumulation of prognostic factors for the disease. The faulty dietary and sedentary lifestyle result in impairment of metabolism and thereby cause the deposition of excessive fats in the body. Long-term impairment in metabolism increases the risk of deposition of morbid matter in enormous quantities in the body. These excessive morbid matters together result in wasting of body tissues and may create dysfunction in blood sugar metabolism which further manifest as excessive urination with increased turbidity of urine. The Ayurveda line of therapy recommends treating of obese diabetes that has adequate body strength by Ayurveda Penta-bio purification procedures along with a suitable restriction on diet. On the contrary, thin/lean diabetes is to be treated with a nourishing diet.

Table 2: Effect of drugs on clinical symptoms (*n* = 144)

Clinical symptoms	Baseline *n* (%)	84th day *n* (%)	% of cure	96th day *n* (%)	% of cure
Polyuria (excessive urination)	82 (56.1)	44 (30.6)	46.3	38 (26.4)	53.7
Polyphagia (excessive hunger)	78 (54.2)	22 (15.3)	71.8	27 (18.8)	65.4
Polydipsia (excessive thirst)	76 (52.8)	29 (20.1)	61.8	35 (24.3)	53.9
Exhaustion	121 (84.0)	80 (55.6)	33.9	80 (55.6)	33.9
Body aches	100 (69.4)	54 (37.5)	46	54 (37.5)	46
Giddiness	53 (36.8)	19 (13.2)	64.1	19 (13.2)	64.1
Polyneuritis (tingling sensation)	80 (55.6)	48 (33.3)	80	49 (34)	38.8
Visual disturbances	80 (55.6)	73 (50.7)	8.7	67 (46.5)	16.2

Table 3: Laboratory parameters of study participants (*n* = 144)

Laboratory parameters	Baseline (mean ± SD)	84th day (mean ± SD)	*P* value#
Hematology			
Hemoglobin (g/dL)	12.66 ± 1.5	12.68 ± 1.3	0.769
ESR in mm (at the end of first hour)	14.64 ± 12.7	11.44 ± 8.2	<0.001*
HbA1c%	8.5 ± 1.69	8.8 ± 2.22	0.020*
Bio-chemical parameters			
Blood urea (mg/dL)	25.96 ± 6.04	26.33 ± 5.97	0.438
Serum uric acid (mg/dL)	4.68 ± 1.2	4.85 ± 1.3	0.057
Serum creatinine (mg/dL)	0.93 ± 0.2	0.94 ± 0.12	0.483
SGOT (AST) (U/L)	26.6 ± 8.2	23.08 ± 9.3	<0.001*
SGPT (ALT) (U/L)	27.8 ± 12.5	25.5 ± 8.2	0.004*
Total protein (g/dL)	6.9 ± 0.6	6.97 ± 0.44	0.361
S. albumin (g/dL)	7.7 ± 41.7	4.4 ± 0.6	0.332
S. globulin (g/dL)	2.68 ± 0.44	2.58 ± 0.5	0.014*
Serum alkaline phosphatase (U/L)	168.1 ± 73	193.64 ± 59.5	<0.001*
Serum cholesterol (mg/dL)	189.04 ± 40.9	197.35 ± 42.9	0.005*
Serum triglycerides (mg/dL)	147.67 ± 86	139.39 ± 48.95	0.115
Low density lipoprotein (mg/dL)	119.44 ± 37.7	127.11 ± 35.64	0.006*
High density lipoprotein (mg/dL)	39.4 ± 5.5	39.6 ± 6.3	0.782
Serum cholesterol/HDL ratio	4.87 ± 1.3	5.06 ± 1.35	0.097

#Compared using paired sample *t*-test
*A *P* value of <0.05 has been considered as significant

Table 4: Effect of drug on blood sugar level

Assessment day	Blood sugar fasting (mean ± SD)	*P* value#	Blood sugar (PP) (mean ± SD)	*P* value#
Baseline	167.44 ± 57.4		261.74 ± 83.74	
14th day	175.24 ± 61.97	0.999	268.2 ± 88.3	0.999
28th day	163.34 ± 57.45	0.999	258.1 ± 83.1	0.999
42nd day	159.6 ± 59.7	0.999	239.8 ± 82	0.071
56th day	162.3 ± 57.4	0.999	244.9 ± 86.1	0.862
70th day	154.4 ± 53.9	0.618	236.03 ± 88.9	0.095
84th day	152.83 ± 57.1	0.446	240.6 ± 82.2	0.348
96th day	153.32 ± 53.6	0.476	242.4 ± 89.64	0.778

#Compared using repeated measures ANOVA. Adjusted for multiple comparisons using Bonferroni inequality

Administration of anti-diabetic medicines is a common line in both conditions.[22] Most of the herbal drugs used in the treatment of diabetes are bitter, astringent, and pungent in taste, which increases digestion, act as antihyperlipidemic, antihyperglycemic, and tissue strength promoter and antioxidant.[23] The observed efficacy indicates that the used formulations in this study may have similar actions.

The purpose of this multicenter clinical test was to understand the clinical efficacy of the study compound in numerous demographic factors such as geographical areas, a wider range of study population, ethnicity, culture, environment, etc. and generalizability of the Ayurvedic formulation. During this study, two herbal formulations were selected, HC, a single-drug formulation in powder form and SG, a tablet made from the ingredients like *Zingibar officinale*, *Piper nigrum*, *P. longum*, *Terminalia chebula*, *T. belerica*, *Emblica officinalis*, *Saussurea lappa*, *Embelia ribes*, *Tinospora cordifolia*, *Plumbago zeylanica*, *Hedychinum spicatum*, *Elleteria cardamomum*, *Juniperus communis*, *Cedrus deodara*, *Zanthoxylum aromaticum*, *Saussurea lappa*, *P. chaba*, *Citrullus colocynthus*, *Curcuma longa*, *Barberis aristata*, ammonium chloride, Sochal salt, alkali extracted from *Hordeum vulgare*, alkali extract of *Caroxylon griffithii*, rock salt, *Scindapsus officinalis*, and gum extract of *Commiphora wightii* as a base drug.[24,25] Most of those ingredient drugs that were previously mentioned are attributed for the treatment of DM. It can be assumed that ingredient as a synergistic and cumulative effect may help to disintegrate the pathogenesis of DM. Drugs with bitter taste are an enhancer of digestion and metabolism which are expected to avoid deposition of morbid matters. These drugs are specifically narrated for digestion of fats and lipids.[26] In simple words, these drugs help to cut back the prognostic physiological factors. Drugs with pungent taste may have an effect on the glucose uptake in insulin-sensitive tissues such as muscles, fats, etc., which can be correlated with enhancing the activity of insulin receptors. It can also be interpreted that the drugs have hygroscopic action at the tissue level which

Table 5: Effect of trial drugs in diabetes symptom questionnaire (DSQ) scores

Time of assessment	Mean	SD	*P* value#
Baseline	38.74	21.35	
14th day	31.8	18.2	<0.001*
28th day	26.5	15.5	<0.001*
42nd day	21.7	13.1	<0.001*
56th day	18.01	11.7	<0.001*
70th day	15.3	11.05	<0.001*
84th day	13.4	10.8	<0.001*
Follow-up at the end of 14th week	14.7	10.8	<0.001*

#Compared using repeated measures ANOVA. Adjusted for multiple comparisons using Bonferroni inequality
*A *P* value of <0.05 has been considered as significant

Table 6: Effect of trial drugs on quality of life (*n* = 144)

Health domain	Baseline (mean ± SD)	84th day (mean ± SD)	98th day (mean ± SD)	*P*-value
Physical functioning	65.2 ± 21.4	72.5 ± 72.5	70.9 ± 21.4	<0.001
Role limitations due to physical health	37.3 ± 39.4	47.4 ± 40.7	46.7 ± 40.2	<0.001
Limitations due to emotional problems	52.1 ± 50.9	62.5 ± 39.2	62.3 ± 39.3	<0.001
Energy/fatigue	46.6 ± 14	52.01 ± 13.4	51.94 ± 12.8	<0.001
Emotional well-being	56.8 ± 13.9	60.7 ± 13.4	60.2 ± 13.1	<0.001
Social functioning	65.8 ± 22.37	70.2 ± 20.4	68.3 ± 20.95	<0.001
Pain	111.02 ± 553.74	74.8 ± 19.4	71.9 ± 20.6	<0.001
General health	45.5 ± 14.8	50.5 ± 14.5	50.2 ± 14.4	<0.001

may help in increasing absorption or retention of body fluid and thereby avoid loss of minerals required to maintain muscle strength. This interpretation is done based on the positive effect observed in decreasing general debility among studied participants. The attributes of the drugs used in the formulation are such that they help in re-establishing the normal functioning of Ayurveda physiological factors, that is, *Vata* and *Kapha*.[27] Similarly, the fluid retention capacity and antihyperglycemic potential of drugs having astringent taste are also additional advantages in increasing the total effect of the therapy.[28] This property of drugs with astringent taste may specifically help to filter the urine, which reduces the turbidity of urine within the patients. Fasting glucose and PP blood glucose were statistically highly significant ($P < 0.001$) attributed to cell protective and regenerative effect of the ingredient such as *B. aristata*, *C. longa*, *T. cordifolia*, and *E. officinalis* within the combination which could have improved the basal insulin secretion and thus, might need to be reduced the hepatic gluconeogenesis also. Blood glucose levels are reduced by insulin secretagogues effects and increase the glucose uptake in insulin-sensitive tissues like muscle and fat. The ingredients like *C. longa*, *T. cordifolia*, *T. chebula*, *T. cordifolia*, and gum extract of *C. wightii* were proven to have antioxidant (protects the beta cells from oxidative stress), hypolipidemic immunomodulatory, and adaptogenic properties. The fluid retention and body channel purification properties of those compounds can also be considered in resulting in reduced insulin sensitivity and improved tissue metabolism. This might be mainly because of the increased functional ability of metabolism at the tissue level. Thus it can be claimed that the studied formulations as an entire increases the peripheral tissue use of glucose, increases hepatic and muscle glycogen content, promotes cell repair/regeneration, and increases the C-peptide level. No improvement was found in HbA1c % levels. The reason is unknown, however, considering that the trial was conducted for 84 days only and it may require an extended duration of treatment to note considerable change in HbA1c % and also thanks to the chronicity of diabetes for years. To see the effect of formulations in relation to reduction in the HbA1c %, same trial can be planned with a longer study duration. The observed reduction in the serum creatinine indicates that there is no harmful effect on the renal functions and thus the study formulations prove its safety on clinical ground. It has also been found that during the study period no complications, side effects, adverse effects, and toxic effects are detected in any patient. Another study has been conducted on the clinical safety and efficacy of HC and SG suggests that these medicines administered in four clinical trials did not show any adverse events and adverse drug reactions and are clinically safe and effective in the management of type 2 DM.[29]

Conclusion

This multicenter clinical trial conducted by CCRAS, at different locations across India, shows the Ayurvedic herbal formulations namely, SG and HC reduce fasting and PP blood sugar marginally. The interventions are useful in improvement of QOL of diabetic patients, which was assessed through DSQ and SF-36–health questionnaire. On the basis of the effect on serum

creatinine and the absence of any adverse drug reaction in the studied population, it is clear that the studied formulations are safe for clinical application. Therefore, SG and HC can be further studied to establish their clinical significance in the management of DM.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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हिंदी सारांशश

टाइप २ डायबिटीज मेलिटस के प्रबंधन में सप्तविंशतिका गुग्गुलु और हरिद्रा चूर्ण की एंटीडायबिटिक प्रभावकारिता और सुरक्षा प्रोफ़ाइल पर एक बहुकेंद्रीय नैदानिक परीक्षण

अविनाश के. जैन, सुरिंदर के. शर्मा, दीपसुंदर साहू, विनोद बी. कुमावत, ओम आर शर्मा, प्रदीप दुआ, बबीता यादव, श्रुति खंडूरी, शारदा ओटा, गुरुचरण भुयान, राकेश राणा, ऋचा सिंघल, भारती गुप्ता, मदन एम पाधी, करतार एस धीमान

मधुमेह के रोगियों के जीवन की गुणवत्ता में सुधार के लिए पारंपरिक दवाएं अभी भी बहुत उपयोगी पाई जाती हैं। टाइप २ मधुमेह के प्रबंधन और स्वास्थ्य को बढ़ावा देने में आयुर्वेदिक फॉर्मूलेशन उपयोगी पाए गए हैं। प्रस्तुत अध्ययन मे सप्तविंशतिका गुग्गुलु और हरिद्रा चूर्ण का मूल्यांकन टाइप २ मधुमेह के प्रबंधन में उनकी नैदानिक प्रभावशीलता का आकलन करने के लिए किया गया था। एक माध्यमिक उद्देश्य टाइप २ डीएम वाले रोगियों के जीवन की गुणवत्ता में परिवर्तन और सप्तविंशतिका गुग्गुलु और हरिद्रा चूर्ण की नैदानिक सुरक्षा का आकलन करना था। आयुर्वेदिक योगों की नैदानिक प्रभावकारिता और सुरक्षा प्रोफ़ाइल को परखने के लिए इस बहुकेंद्रीय नैदानिक अध्ययन का गंभीर मूल्यांकन किया गया था। इस अध्ययन मे सप्तविंशतिका गुग्गुलु 500 ग्राम दो गोलियां भोजन के बाद दो बार और हरिद्रा चूर्ण 3 ग्राम गुनगुने पानी के साथ भोजन के बाद दिन में दो बार १२ सप्ताह तक टाइप २ मधुमेह के रुग्नो मे दिये गए। FBS के नियमन में परिणाम अत्यधिक महत्वपूर्ण पाए गए (BT-167.44 mg/dL, AT-152.83 mg/dL) and PPBS (BT-261.74 mg/dL, AT-240.59 mg/dL). मधुमेह लक्षण प्रश्नावली और एसएफ-36 स्वास्थ्य सर्वेक्षण स्कोर के सुधार में सांख्यिकीय रूप से अत्यधिक महत्वपूर्ण परिणाम पाए गए। कोई प्रतिकूल दवा प्रतिक्रिया या कोई जटिलता नोट नहीं की गई। इसलिए यह निष्कर्ष निकाला जा सकता है कि टाइप २ मधुमेह के विषयों पर प्रयुक्त सप्तविंशतिका गुग्गुलु और हरिद्रा चूर्ण चिकित्सकीय रूप से प्रभावी, सुरक्षित और सहनीय हैं।