ORIGINAL RESEARCH ARTICLE

Evaluation of *Gokshuradi Guggulu* and *Guduchi Churna* in the Management of Type II Diabetes Mellitus (*Madhumeha*)

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Abstract

Background: Diabetes mellitus (DM) has become an increasing global health problem among all socioeconomic groups, leading to various complications such as nephropathy, neuropathy, and retinopathy which are responsible for morbidity and mortality. Ayurvedic approach to pathogenesis of *Madhumeha* can provide solution in managing the incidence of diabetes among population by using various preparations. *Gokshuradi Guggulu* and *Guduchi Churna* are such Ayurvedic preparations.

Objective: The objective of the study was to assess the clinical efficacy and safety of *Gokshuradi Guggulu* and *Guduchi Churna* in the management of type II DM using Diabetes Symptom Questionnaire (DSQ) score, short-form health survey (SF-36) score, and laboratory investigation.

Materials and methods: It was an open-label, prospective, clinical trial conducted on 50 patients of type II DM (*Madhumeha*). *Gokshuradi Guggulu* 1 g (two tablets of 500 mg) twice daily after food (chew the tablets before swallowing) and *Guduchi Churna* 3 g twice daily after food with lukewarm water for 12 weeks were given to all study participants. The DSQ was assessed with the help of Visual Analog Scale (VAS; 0–10). Health-related quality of life was recorded at baseline and end of the 84th day by using RAND-36 items SF-36 questionnaire. In laboratory investigations, blood sugar levels, hematological parameters, renal function tests, liver function test, lipid profile, and glycated hemoglobin (HbA1c) were performed at baseline and at the end of 84th day for efficacy and safety evaluation of the drugs.

Results: The DSQ score and clinical symptoms reduced significantly from baseline to the end of the treatment in 50 subjects aged between 30 years and 60 years of both sexes. The RAND SF-36 health survey showed an improvement in quality of life of all the participants.

Conclusion: This study demonstrated the effectiveness of *Gokshuradi Guggulu* along with *Guduchi Churna* in the management of type II DM.

Keywords: *Gokshuradi Guggulu*, *Guduchi Churna*, *Madhumeha*, Type II diabetes mellitus.

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Introduction

Diabetes mellitus (DM) has emerged as a major worldwide health issue in all socioeconomic classes. According to the World Health Organization (WHO), India is the fastest growing country toward the DM. Basically, the word diabetes mellitus has been derived from two words, diabetes (Greek) which means "siphon through" and mellitus (Latin) which means "sweetened with honey." The problem with this disease is that it is very difficult to diagnose in the early stages. It is a metabolic disorder in which there is high blood sugar level over a prolonged period.[1] Diabetes mellitus is caused due to the malfunctioning of the beta cells of the islets of Langerhans in pancreas, which is responsible for the production of the insulin hormone.[2]

The four main types of DM are type I DM resulting from the pancreas's failure to produce enough insulin. This form was previously referred to as "insulin-dependent diabetes mellitus" or "juvenile diabetes." Type II DM begins with insulin resistance, a condition in which cells fail to respond to insulin properly.[3] "Diabetes mellitus type 1.5" or maturity onset diabetes of the young (MODY) is an autosomal dominant inherited form of diabetes, due to one of several possible single-gene mutations causing defects in insulin production.[4] It is significantly less common than the other three types. This disease varies in age at presentation and in severity according to the specific gene defect; thus, there are at least 13 subtypes of MODY. People with MODY often can control it without using insulin. Gestational diabetes is the fourth main form and occurs when pregnant women without a previous history of diabetes develop high blood sugar levels.[5]

In 2016, the WHO reported that worldwide 422 million people will have diabetes. It also estimated that DM resulted in 1.5 million deaths in 2012, making it the eighth leading cause of death. However, another 2.2 million deaths worldwide were attributable to high blood glucose, the increased risks of cardiovascular disease, and other associated complications (e.g., kidney failure), which often lead to premature death and are often listed as the underlying cause of death, rather than diabetes.[6] The International Diabetes Federation estimated that diabetes resulted in 4.9 million

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deaths worldwide, using modeling to estimate the total amount of deaths that could be directly or indirectly attributed to diabetes.[7] Diabetes mellitus occurs throughout the world but is more common (especially type II) in more developed countries. The greatest increase in rates has, however, been seen in low- and middle-income countries,[8] where more than 80% of diabetic deaths occur.[9] The fastest prevalence increase is expected to occur in the year 2030 in Asia and Africa, where most people with diabetes will probably live and the increased rates in developing countries follow the trend of urbanization and lifestyle changes, including increasingly sedentary lifestyles, less physically demanding work, and the global nutrition transition marked by increased intake of foods that are high energy dense but nutrient poor (often high in sugar and saturated fats, sometimes referred to as the Western-style diet).[10]

The symptoms of untreated diabetes are weight loss, polyuria (increased urination), polydipsia (increased thirst), and polyphagia (increased hunger). Symptoms may develop rapidly (weeks or months) in type I DM, while they usually develop much more slowly and may be subtle or absent in type II DM.[11] Glycated hemoglobin is better than fasting glucose for determining the risks of cardiovascular disease and death from any cause of DM.[12] Prevention and treatment involve maintaining a healthy diet, regular physical exercise, a normal body weight, and avoiding the use of tobacco. Control of blood pressure and maintaining proper foot care are important for people with the disease. Type I DM must be managed with insulin injections.[13] Type II DM may be treated with medications. Metformin is generally recommended as a first-line treatment for type II diabetes in allopathic medicine.[14] Ayurveda has mentioned a disease by the name of *Madhumeha* under the chapter of *Prameha* which is symptomatically similar to DM. *Prameha* is divided in to three major types (and total 20 subtypes). All these types are diagnosed by means of the nature of urine. *Kaphaja* type (10 types), *Pittaja* (6 types), *Vataj* (4 types), and juvenile diabetes in children (for unhealthy practices of parents and/or due to the sins of past birth).[15] In Ayurveda, the number of single herb and compound formulations are described for the management of *Prameha* as well as *Madhumeha*. The present study was undertaken to validate the effect of *Gokshuradi Guggulu*[16] and *Guduchi Churna*[17] [powder of *Tinospora cordifolia.* (Thunb.) Miers.] on patients of type II DM (*Madhumeha*).

Materials and Methods

It was an open-label, noncomparative, prospective, clinical trial. The trial protocol and related documents were reviewed and approved by the Institutional Ethics Committee. The study was conducted at outpatient department/inpatient department of Regional Ayurveda Research Institute for Drug Development, Gwalior, Madhya Pradesh from 2014 to 2016 in accordance with Schedule Y of Drugs and Cosmetics Act, India, amended in 2005 and Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human participants, adopted from World Medical Association—Declaration of Helsinki. Trial was registered in the clinical trial registry of India (CTRI/2014/09/005048).

Primary and Secondary Outcome Measures

Primary outcome measure of study was to evaluate the efficacy of Ayurvedic formulations *Gokshuradi Guggulu* and *Guduchi Churna* in the subjects suffering from DM by assessing the change in HbA1c. The secondary outcome measures were to evaluate the changes in the fasting blood sugar (FBS; 10–12 hours after dinner), changes in postprandial blood sugar (PPBS) levels (100–120 minutes after breakfast), changes in symptoms per diabetes symptoms questionnaire (DSQ), and health survey score per RAND SF-36.

Trial Interventions

Therapeutic combination of *Gokshuradi Guggulu* 1 g (two tablets of 500 mg) twice daily after food (chew the tablets before swallowing) and *Guduchi Churna* 3 g twice daily after food with lukewarm water were given to the participants for a period of 12 weeks. All the trial drugs were procured from Indian Medicines Pharmaceutical Corporation Limited a good manufacturing practice-certified company and manufactured as per Ayurvedic Pharmacopoeia of India guidelines.

Inclusion Criteria

Subjects of either sex, age between 30 and 60 years, having symptoms of DM with FBS 126–200 mg%, PPBS 180–300 mg%, who are not taking any oral hypoglycemic agent, and willing to participate in the study for 12 weeks were included in the study.

Exclusion Criteria

The subjects suffering from the complications of diabetes like diabetic neuropathy, diabetic nephropathy, diabetic retinopathy, past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke, or severe arrhythmia in the last 6 months. Further, uncontrolled hypertension (>160/100 mm Hg), prolonged (>6 weeks) medication with corticosteroids, antidepressants, anticholinergics, severe renal or hepatic disorders, and pregnant and lactating woman were also excluded from the study.

Withdrawal Criteria

The subjects were free to withdraw from the trial at any time without the permission of investigator or for any reason. Further, the investigator could discontinue the subject if he/she develops any adverse effect or in case of noncompliance with the treatment regimen (minimum 80% compliance was essential to continue in the study). In these cases, the actions were taken to know the reason for the withdrawal and recorded in the case report form.

Study Procedures

On screening visit, subject's voluntary written informed consent was taken. General and systemic examinations as well as biochemical investigation, clinical symptoms, Diabetes Symptoms Questionnaire (DSQ), Ayurvedic parameters were assessed. Health related quality of life was assessed by SF-36 health survey questionnaire.

A total of 50 subjects who fulfilled the inclusion and exclusion criteria were enrolled in the study. All enrolled subjects were given a combination of *Gokshuradi Guggulu* at a dose of 1 g (two tablets of 500 mg) twice daily after food (chew the tablets before swallowing) and *Guduchi Churna* 3 g twice daily after food with lukewarm water for 12 weeks. Recruited subjects were advised to carry on their daily activities and exercises that they had been doing before the enrollment and also advised to continue the same till the end of study period. DSQ, Health related quality of life was assessed by SF-36 health survey questionnaire and safety laboratory parameters were also done at baseline and end of the 84th day. Patient's compliance was monitored through a regular follow-up of the patients by personal contact and telephonic communication. Subjects were advised to return the empty containers of trial medicines on every follow-up visit in order to check the drug compliance.

Follow-up Assessment

Detailed checkup per the protocol was done on follow-up visits on the 14th day (visit 1), 28th day (visit 2), 42nd day (visit 3), 56th day (visit 4), 70th day (visit 5), and 84th day (visit 6). On each follow-up visit, the patient's general and systemic physical examination was done. Assessment of the symptoms of diabetes by using questionnaire and SF-36 health survey score was done. In laboratory investigations, hematological assessment, i.e., complete blood count, hemoglobin percent, and erythrocyte sedimentation rate (ESR), was done. Fasting Blood Sugar level (FBS), Post Prandial Blood Sugar level (PPBS), HbA1c and lipid profile were assessed at the baseline and at the end of the 84th day to evaluate the efficacy of the intervention. Liver function test and renal function test were evaluated at the beginning and end of the trial to assess the safety profile of the intervention.

Adverse Event or Adverse Drug Reaction

Any adverse event or adverse drug reaction (ADR) observed during treatment period, if any, was documented and its appropriate and timely management were done and recorded in the clinical record forms.

Statistical Analysis

The data on qualitative parameters has been represented as *n* (%) and on continues variable has been represented as Mean (SEM). The data related to chief complaints was analyzed using mc-nemar test. The data related to outcome parameters was assessed by using paired sample t-test. The data was analyzed using SPSS Version 15.0. A p-value of <0.05 has been considered significant.

Observations and Results

A total of 50 subjects were enrolled in the trial, of which 48 completed the study and 2 dropped out due to loss to follow-up and imputation technique was applied on the 2 cases. The data of the two subjects were taken for analysis along with the data of completed cases by last observation carry forward method for intention-to-treat analysis. The demographic data of 50 subjects are provided in Table 1. Majority of the subjects were male and the mean body weight was 69.12 ± 11.58 kg. Most of the subjects (72%) did not have any addiction, 68% had normal sleep, 48% had regular bowel, and 52% had frequent urination. No significant changes were observed at the end of treatment from baseline in any of the vital signs, i.e., pulse rate, body temperature, respiratory rate, systolic and diastolic blood pressure, appetite, and body weight.

Effect of Treatment on Outcome Measures

At baseline visit, the mean HbA1c was 8.27 ± 0.23, which insignificantly reduced to 7.99 ± 0.33 after 84 days of treatment with these medicines (Fig. 1). At baseline visit, the mean FBS was 147.92 ± 2.05, which insignificantly reduced to 139.14 ± 3.72 after 84 days of treatment with these medicines. At baseline visit, the mean PPBS was 241.34 ± 4.63, which was also insignificantly reduced to 238.02 ± 7.35 after 84 days of treatment with these medicines (Fig. 2). At baseline visit, the mean DSQ score was 23.18 ± 2.133, which significantly ($p < 0.001$) reduced to 12.18 ± 1.20 after 84 days of treatment with these medicines (Fig. 3). The percentage of relief on chief complaints such as polyuria was 84.61, polyphagia 61.11, polydipsia 44.82, exhaustion/tiredness 38.46, body ache 48.38, giddiness 54.54, and polyneuritis 36.84% was observed in the trial participants (Table 2). Laboratory parameters such as total

Table 1: Demographic profile and baseline characteristics of study subjects ($n = 50$)

Variables	*n (%)*
Age (in years)	
31–35	02 (4.0)
36–39	07 (14.0)
40–44	09 (18.0)
45–49	15 (30.0)
50–53	10 (20.0)
54–58	07 (14.0)
Gender	
Male	40 (80.0)
Female	10 (20.0)
Marital status	
Married	50 (100)
Educational status	
Illiterate	02 (4.0)
Read and write	48 (96.0)
Habitat	
Urban	48 (96.0)
Semi-urban	01 (2.0)
Rural	01 (2.0)
Economic status	
Above poverty line	49 (98.0)
Below poverty line	01 (2.0)
Occupation	
Desk work	23 (46.0)
Field work	18 (36.0)
Housewife	09 (18.0)
Dietary habits	
Veg	31 (62.0)
Nonveg	19 (38.0)
Sharirikaprakriti	
Pitta-Kaphaja	27 (54.0)
Vata-Pittaja	23 (46.0)

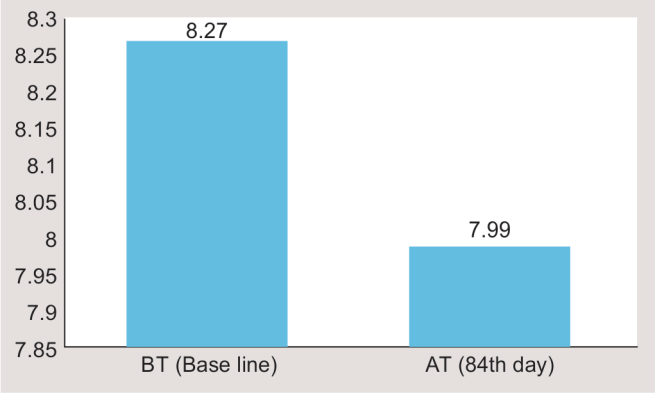

Fig. 1: Effect of therapy on glycosylated hemoglobin ($n = 50$)

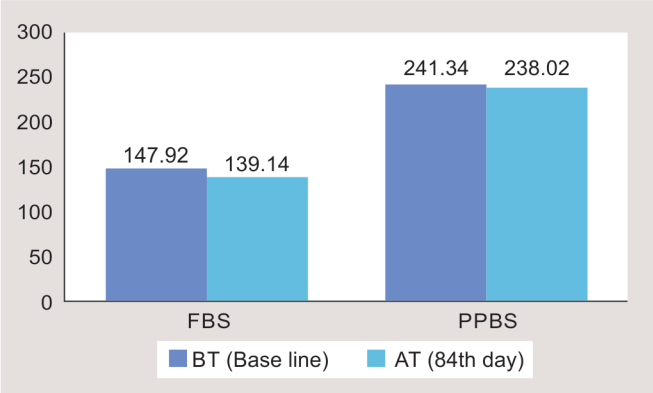

Fig. 2: Effect of therapy on blood sugar level ($n = 50$)

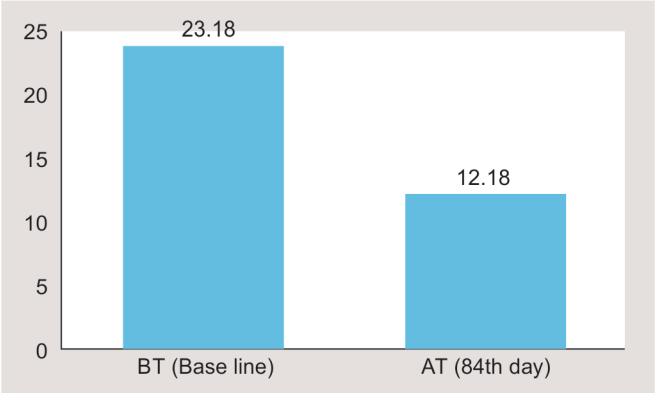

Fig. 3: Effect of therapy on diabetes symptom questionnaire

Table 2: Effect of treatment on chief complaints in the subjects of type II DM ($n = 50$)

	No. of patients			
Clinical symptom	*Start of the treatment*	*End of the treatment*	*Percentage of relief (%)*	*p value*
Polyuria (excessive urine)	39	06	84.61	<0.001
Polyphagia (excessive hunger)	36	14	61.11	<0.001
Polydipsia (excessive thirst)	29	16	44.82	0.004
Exhaustion/tiredness	39	24	38.46	0.001
Bodyache	31	16	48.38	0.001
Giddiness	11	05	54.54	0.146
Polyneuritis (numbness/tingling)	19	12	36.84	0.118

leukocyte count, basophil count, monocyte count, SGOT levels changed significantly ($p > 0.05$) but within physiological limit at the end of the trial (Table 3). All domains of SF-36 HSQ and DSQ score changed significantly after 84 days of treatment with these medicines (Table 4).

Discussion

Diabetes mellitus is symptomatically similar to *Madhumeha*[18] and it is as old as the history of mankind. The word "*Madhumeha*" is a combination of two terms "*Madhu*" and "*Meha*" meaning honey and excessive flow, respectively. *Madhumeha* is a disease entity characterized by the sweetness of the body tissues along with the passage of the turbid and sweet urine in excessive amount, which is due to various physical and chemical changes in body tissue. *Kaphaja Prameha* is due to malfunctioning of the pancreas, which results in improper insulin secretion and resistance. *Pittaja Prameha* is due to overfunctioning of adrenal, thyroid, glucagon, and cortisol; and *Vatik Prameha* is because of insulin deficiency due to autoimmune or idiopathic destruction of β-cells of islet of Langerhans of pancreas. In Ayurveda, *Madhumeha* is considered as the disease of vitiated *Vata* and *Kapha Dosha*. *Acharya Charak* has used the term "*Bahudrava Shleshma Dosha Vishesha*" in the description of *Prameha*. The *Dushyas* involved in it are mainly *Bahuabaddha Meda* (free fatty acids), *Mamsa*, *Kleda*, *Shukra*, *Shonita*, *Vasa*, *Majja*, *Lasika*, *Rasa*, *Oja*, etc. All are *Kaphavargiya*.[19]

According to modern medicine, DM is a collection of disorders characterized by defective regulation of carbohydrate, lipids, and protein metabolism. The clinical manifestations of DM range from asymptomatic type II diabetes to the dramatic life-threatening condition of diabetic ketoacidosis and hyperosmolar nonketosis. In addition, pathological hyperglycemia sustained over several years may produce functional and structural changes within certain tissues; these microvascular complications (retinopathy, nephropathy, and neuropathy), which ultimately become irreversible, are a major cause of morbidity and premature mortality.

In Ayurveda, the first-line of management in *Madhumeha* is *Nidana Parivarjanam* (avoidance of causative factors). *Sthoola Pramehi* with adequate body strength and having intense increase in *Doshas* and *Dushyas* are advised to take Panchakarma or emaciation therapy (*Apatarpana Chikitsa*), while *Krusha Pramehi* are advised to take *Brumhana* or nourishing therapy (*Santarpanachikitsa*).[20] The herbal drugs used in the treatment of *Madhumeha Roga* are bitter, astringent, and pungent in taste, which check the extra fluidity of *Dhatus* and give them good strength and compactness.

In this study, the effect of *Gokshuradi Guggulu* and *Guduchi Churna* on type II DM is evaluated. Insignificant changes were observed in HbA1c and blood sugar levels. While symptoms of diabetes (assessed in DSQ score) were reduced significantly.

In Ayurvedic classics, *Gokshuradi Guggulu* is commonly used in diseases of *Mootravahasrotas* and indicated in *Prameha*. It has *Rasayana*, *Balya*, *Raktaprasadak*, *Basti-Shodhaka*, *Kledaghna*, *Medoghna*, *Mehaghna*, *Tridoshaghna*, *Shothaghna*, and *Lekhana* properties.[21,22] It acts by different ways in *Madhumeha*. It acts due to *Kledaghna*, *Medoghna*, and *Tridoshghna* effects on the pathogenesis of *Madhumeha*. Second, it has *Mootravaha Srotodushtinashak*, *Rasayana*, *Balya*, *Raktaprasadak*, *Lekhana*, and *Shothaghna* properties, and so it prevents complication such as diabetic nephropathy. *Lekhana* property (scraping) is useful in removing any blockage in micro vessels as well as macro vessels. Thus, it corrects *Srotorodha* in *Mootravaha* as well as *Medovahasrotas* in *Madhumeha*. *Gokshuradi Guggulu* improves nourishment and maintains potency of *Mootravahasrotas* and improves resistance of kidney tissues against any adversity and thus helps in repairing and preventing damage to kidney vasculatures and tissues.[23] *Guduchi* is considered as a bitter, astringent, diuretic and potent aphrodisiac tonic and curative against skin infections, jaundice, diabetes, chronic diarrhea, and dysentery.[24] It is also reported as a rejuvenator and indicated in several diseases causing debility.[25] There were some limitations

Table 3: Assessment of pathological and bio-chemical investigation ($n = 50$)

Laboratory parameters	*Start of the treatment*	*End of the treatment*	*p value*
FBS (blood sugar fasting) mg/dL	147.92 ± 2.05	139.14 ± 3.72	0.315
PPBS (post prandial blood sugar) mg/dL	241.34 ± 4.63	238.02 ± 7.35	0.886
HbA1c%	8.27 ± 0.23	7.99 ± 0.33	0.473
Hemoglobin (g/dL)	14.12 ± 0.18	14.07 ± 0.17	0.725
Total leucocytes count/cu.m.m.	8110.00 ± 253.58	7592 ± 262.93	0.040
Neutrophil (%)	63.42 ± 1.37	62.32 ± 1.40	0.483
Eosinophil (%)	03.27 ± 0.380	03.26 ± 0.37	0.977
Basophil (%)	00.16 ± 0.02	00.25 ± 0.03	0.017
Lymphocytes (%)	28.85 ± 1.27	28.82 ± 1.38	0.987
Monocytes (%)	04.18 ± 0.43	05.13 ± 0.41	0.036
Erythrocyte sedimentation rate (mm at the end of 1st hour)	13.58 ± 1.57	12.94 ± 1.40	0.678
Blood urea (mg/dL)	19.62 ± 0.69	20.18 ± 0.74	0.489
Serum uric acid (mg/dL)	3.98 ± 0.13	4.00 ± 0.14	0.847
Serum creatinine (mg/dL)	0.937 ± 0.026	0.932 ± 0.029	0.855
SGOT(AST) IU/L	31.91 ± 3.52	38.83 ± 4.57	0.029
SGPT(ALT) IU/L	35.27 ± 3.02	39.99 ± 5.20	0.371
Total Protein (gm/dL)	7.52 ± 0.06	7.62 ± 0.08	0.294
S. Albumin (g/dL)	4.597 ± 0.03	4.590 ± 0.04	0.907
S. Globulin (g/dL)	2.92 ± 0.06	3.02 ± 0.07	0.191
Conjugated bilirubin (mg/dL)	0.19 ± 0.01	0.20 ± 0.01	0.793
Unconjugated bilirubin (mg/dL)	0.65 ± 0.048	0.61 ± 0.046	0.518
Serum alkaline Phosphates (IU/L)	88.90 ± 3.65	85.48 ± 4.11	0.367
Serum cholesterol (mg/dL)	178.28 ± 5.23	175.79 ± 6.35	0.713
Serum triglycerides (mg/dL)	157.07 ± 12.80	164.99 ± 15.67	0.529
LDLc (mg/dL)	113.77 ± 4.31	116.82 ± 4.40	0.495
HDLc (mg/dL)	42.35 ± 1.79	42.21 ± 1.46	0.943
VLDLc (mg/dL)	31.81 ± 2.65	33.02 ± 3.13	0.647

Data: Mean ± SEM

SGOT, serum glutamic oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase

in this study as no comparator group was taken to compare the efficacy of the trial drug. In the future study, these points will be taken in to account.

Conclusion

The present study data shows that *Gokshuradi Guggulu* along with *Guduchi Churna* impacted on glycemic index insignificantly however it was successful in significantly improving the symptoms of type II DM. The study reveals that the selected management has the potential to reduce symptoms of type II DM with added advantage of being free from adverse reaction.

Table 4: Effect of therapy on SF-36 health survey questionnaire and DSQ ($n = 50$)

Domain	*Start of the treatment*	*End of the treatment*	*p value*
Physical functioning	86.70 ± 1.52	92.60 ± 1.18	<0.001
Role limitations due to physical health	50.00 ± 5.62	80.50 ± 4.86	<0.001
Limitations due to emotional problems	51.99 ± 6.11	81.33 ± 4.87	<0.001
Energy/fatigue	55.30 ± 2.28	63.40 ± 2.43	<0.001
Social functioning	89.75 ± 2.82	94.00 ± 1.64	0.114
Pain	78.10 ± 2.54	84.30 ± 1.96	0.013
General health	60.63 ± 3.45	72.52 ± 2.52	<0.001
Diabetes symptoms questionnaire	23.18 ± 2.13	12.18 ± 1.20	<0.001

Data: Mean ± SEM

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हिंदी सारांश

टाइप 2 डायबिटीज (मधुमेह) के प्रबंधन में गोक्षुरादि गुग्गुलु एवं गुड़ची चूर्ण के प्रभाव का चिकित्सकीय मूल्यांकन

अनिल मंगल, अंकुश डी. जाधव, शारदा ओता, श्रुती खण्डूड़ी, भगवान सहाय शर्मा, राकेश राणा, नारायणम् श्रीकान्त

भूमिकाः वर्तमान समय में मधुमेह सभी सामाजिक-आर्थिक समूहों में विश्वव्यापी स्वास्थ्य समस्या के रूप में बहुत तीव्रगति से बढ़ रहा है। साथ ही विभिन्न जटिलताओं जैसे नेफ्रोपैथी, न्यूरोपैथी और रेटिनोपैथी जैसे दुष्प्रभावों के लिए भी जिम्मेदार है। आयुर्वेद में मधुमेह को प्रमेह का एक प्रकार बताया गया है और उसके रोकथाम हेतु व्यवस्थाओं का सुझाव दिया है। गोक्षुरादि गुग्गुलु एवं गुड़ची चूर्ण आयुर्वेद में वर्णित ऐसी ही आयुर्वेदिक औषधियां हैं जो कि मधुमेह की रोकथाम करने में सक्षम हो सकती हैं।

उद्देश्यः प्रस्तुत अध्ययन का उद्देश्य टाइप-2 डायबिटीज के प्रबंधन में गोक्षुरादि गुग्गुलु एवं गुड़ची चूर्ण की प्रभावकारिता और सुरक्षितता का आकलन डीएसक्यू स्कोर, एस एफ-36 और प्रयोगशाला की जांच द्वारा करना है।

सामग्री एवं विधिः ओपन लेबल स्तर का बहुसंकेतक अध्ययन केन्द्रीय आयुर्वेदीय अनुसंधान परिषद् के अधीनस्थ संस्थान में किया गया जिसमें संस्थान के बाह्य रोगी विभाग से 50 लोगों को शामिल किया गया जो कि चयन मापदंडों को पूर्ण कर रहे थे। रोगियों को गोक्षुरादि गुग्गुलु 1 ग्राम (500 मिग्रा की दो गोलियां) तथा गुड़ची चूर्ण 3 ग्राम की मात्रा का गर्म पानी के साथ दिन में दो बार भोजन के बाद 12 सप्ताह तक दिया गया तथा प्रत्येक 14 दिवस पर औषध के प्रभाव का आंकलन किया गया। रैंड एस एफ 36 स्वास्थ्य सर्वेक्षण, डीएसक्यू स्कोर और चिकित्सीय लक्षणों एवं प्रयोगशाला परीक्षणों के आधार पर औषधि की प्रभावकारिता एवं सुरक्षितता का मूल्यांकन किया गया।

परिणामः रैंड एस एफ 36 स्वास्थ्य सर्वेक्षण, डीएसक्यू स्कोर एवं चिकित्सकीय लक्षणों में महत्वपूर्ण परिवर्तन प्राप्त हुए। रक्त शर्करा, ग्लाइकोसाइटेड हीमोग्लोबिन, अध्ययन में कमी पायी गयी। वृक्क की कार्यक्षमता एवं यकृत की कार्यक्षमता सामान्य रही। संपूर्ण अध्ययन के दौरान औषधि की किसी भी प्रकार की प्रतिकूल प्रतिक्रिया प्राप्त नहीं हुई।

निष्कर्षः उपरोक्त निर्दिष्ट मात्रा में गोक्षुरादि गुग्गुलु एवं गुड़ची चूर्ण की प्रभावकारिता मधुमेह के रोगियों में सुधार करने में सक्षम एवं सुरक्षित है।

शब्दः मधुमेह, गोक्षुरादिगुग्गुलु, गुड़चीचूर्ण, टाइप 2 डायबिटीज।