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EFFECT OF SHILASANA COMPOUND IN NIDDM A CLINICAL STUDY

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ABSTRACT

A clinical trial was undertaken to evaluate the efficacy of the compound drug of *Pterocarpus marsupium heartwood* extract and *Shilajatu (Shilasana* compound) in treatment of mild to moderate non-insulin dependent diabetes mellitus (NIDDM) patients. The dose of the trial drug was fixed at 2 grams twice a day, half an hour before breakfast and dinner. In 6 weeks significant ($p<0.05$) and highly significant ($p<0.01$) reduction was observed in fasting and postprandial blood glucose levels respectively. Symptomatic relief was reported by patients regarding polyuria, weakness, cramps, burning and tingling sensations. Also no side effects were reported by the Patients during the study Hence, it can be concluded that *Shilasana* compound is useful in treatment of mild to moderate NIDDM patients.

KEYWORDS: Diabetes mellitus, fasting, postprandial, Shilasana compound.

INTRODUCTION

Diabetes mellitus is one of the most burdensome chronic diseases that in increasing in epidemic proportions throughout the world. It is estimated that the global prevalence of type 2 diabetes will be doubled from 171 million in 2000 to 334 million by 2025. India bears a sizeable burden of this epidemic of diabetes and it is projected that cases of diabetes in India will increase from 31.7 million in 2000 to 79.4 million in 2030. The disease with similar aetiology and clinical manifestations is mentioned in Ayurvedic literature by the name of *Madhumeha*.

In the present study *Asana* (Pterocarpus marsupium) of *Salsaradi* group of *Sushrut Samhita* is taken along with *Shilajatu (*Asphaltum punjabinam). The compound drug so formed is

given the name *'Shilasana yoga* 'Pterocarpus marsupium has been proved time and again to possess hypoglycaemic activity both in experimental as well as clinical studies. Heartwood of P. marsupium was found effective in the management of NIDDM in a flexible dose open clinical trial conducted at four centre across India by ICMR. Another drug *Shilajatu (*Asphaltum punjabinam) is also a potent antidiabetic as proved by various scholars. The subcutaneous administration of processed *Shilajatu* along with insulin potentiates and prolongs the insulin induced hypoglycaemia, and chronic administration of processed *Shilajatu* inhibits the development of STZ induced diabetes.

MATERIALS AND METHODS

Selection of patients

40 patients of Diabetes Mellitus were selected from the O.P.D. of Department of Dravyaguna, S. S. Hospital, Banaras Hindu University. All the cases were recorded with the help of special proforma prepared for this purpose. Patients were subjected to detailed case history taking, physical examination and laboratory investigations like fasting blood sugar and postprandial blood sugar, urine routine and microscopic examination, lipid profile. To exclude other physical abnormalities normal blood picture i.e. TC, DC, Hb%, ESR, Blood urea, serum creatinine etc. were done. ECG was done to exclude any cardiac abnormalities.

Inclusion Criteria

- Patients having classical symptoms of diabetes without marked weight loss.
- Increased fasting blood sugar ≥126 mg/dl, more than two occasion in different days.
- Increased postprandial blood sugar ≥200 mg/dl.
- Patients in age group between 30 years to 70 years.

Exclusion Criteria

- Fasting blood sugar more than 250 mg/dl.
- Postprandial blood sugar more than 350mg/dl.
- Sever complicated patient and patients who were dependent on Insulin therapy.

Method of preparation of drug

First, authentic pieces of heartwood of *Pterocarpus marsupium* were procured from the Medicinal Garden, Department of Dravyaguna, I.M.S., B.H.U. Varanasi and solidified water extract was obtained from it. Raw *Shilajatu* was procured from hans Pharmaceuticals, Haridwar and was identified by the experts of Department of Dravyaguna and Department of

Ras Shastra, BHU. This raw *Shilajatu* was purified by the classical *Agnitapi* method using *Triphala Kwatha.*

Purified *Shilajatu* and solid extract of *Asana* were taken in equal amount by weight (1:1) and triturated well until a homogenous mixture was formed. The *'Shilasana* compound 'so formed was kept in an airtight jar for further use.

Administration of the Drug

The drug was given orally in dose of 1 gram twice a day, half an hour before breakfast and dinner with lukewarm water.

A special diet plan was prepared for every patient keeping in view the weight, activities, age and blood sugar level of the individual. The diet was planned in accordance to Ayurvedic modern principle of nutrition. Every patient was advised to take a morning walk daily along with some mild exercises and *yogasana.*

Criteria for Assessment

Assessment was done under the two headings Subjective assessment and objective assessment.

Subjective assessment

In each follow up all the patients were assessed for the subjective improvement i.e. polyuria, polydipsia, polyphagia, weakness, cramps on walking , tingling sensation, burning palms and soles by means of scale of grading. All these symptoms were divided in four grades (0-3) on the basis of severity and duration. (Table 1).

Objective assessment

Under the objective parameters laboratory findings were assessed as follows fasting and postprandial blood sugar were done in each follow up (every 2 weeks) urine examination for sugar was done in each follow up, lipid profile before and after completion of treatment, haemoglobin of every patient was done before and after treatment.

Estimation of blood glucose level was done by method of Trinder et al (GOD-POD method) Statistical analysis: changes in the blood glucose were assessed by using students 't' test.

Duration of study

All the selected patients were advised to come for the follow up every 15 days interval up to three consecutive occasion (i.e.45 days).

OBSERVATIONS AND RESULTS

Under the study of demographic profile (fig. 1-8) of 40 patients it was noted that maximum number of patients (50%) had 41-50 years age at onset of diabetes mellitus. This shows that above 40 years of age group maximum onset of disease is in prevalence. Gender distribution of the disease showed that males (70%) were more prone to the disease as compared to female sex. 92.5% of the cases registered belonged to Hindu community. This may be due to Hindu dominant attendance of patients in Ayurvedic Hospitals.

Majority of patients (72.5%) were from urban area as compared to 27.5% from rural area. This corroborate with earlier studies done in different areas by different scholars like Ramachandran et al (1997) in Chennai, Zaager et al (2000) in Kashmir, Misra et al (2001) in New Delhi etc.

Regarding socio-economic status, group was 70 percent and minimum 12.5 percent cases registered belonged to lower income group, indicating higher rate of development of DM in middle socio-economic group.

Sedentary lifestyle is considered a cause for diabetes and in present study also similar trend was seen as 42.5% of cases were leading sedentary life followed by moderate 35% and strenuous life (22.5%). *Prakriti* of the patients was assessed and about 55% of cases were found to have *Vata Kaphaja* predominant *Prakriti* the criteria to assess *Prakriti* was according to ancient texts. In the present study it was seen that maximum (30%) number of patients that appeared for treatment in Ayurveda hospital had history of the disease of about 1 year. This duration depends upon the alertness of the patient as well as changeover the treatment from allopathic system of medicine.

Basal metabolic rate (BMI) of patients was measured and it was found that 65% were within the normal limits (19-25 kg/m^2).

Fat distribution study revealed that over 66% of female and 28.6% of male were having abnormal body fat distribution, as assessed by WHR. This abnormal WHR is considered to be responsible for high incidences of diabetes in Indian subcontinent irrespective of low

percentage of Although 40 patients were registered for the study, but 7 cases dropped out of the trial at various time points during the 6 week treatment period without any specific complaints made by these patients is described below in detail. Complaint of Polyuria (n=33) improved in 30 cases (91%) whereas 3 cases (9%) showed no improvement.

Regarding polydipsia (n=24) improvement was seen in 9 cases (37.5%) whereas in another 15 cases (62.5%) no improvement was seen.

Polyphagia was reported in 21 cases initially which improved in 9 cases (43%) after treatment.

Weakness was a very common in all the registered cases. After treatment of 6 weeks 28 (84%) cases recovered whereas no improvement was seen in rest 5 (16%) cases.

Similarly, improvement was seen in 57.2%, 66.6%, 71.5% cases regarding cramps on walking, tingling sensation and burning palm and soles respectively. (Table 2).

The mean serum cholesterol level (mg/dl) reduced from 169.178 ± 30.41 to 160.83 ± 17.66 in 6 weeks. This was a non-significant change. ($p<0.05$) (Table 3).

Blood glucose level (fasting and 2 hours postprandial) was measured in all the registered cases before and on each follow-up after treatment (Table 4). Mean (±SD) for fasting blood sugar level reduced from initial level of 158.27 ± 36.45 to 131.55 ± 25 after treatment (6 weeks). This decrease in mean blood sugar level was found to be statistically significant ($p<0.05$).

Similarly mean (SD) for 2 hours postprandial blood sugar level reduced from initial level of 266.36 ± 51.62 to 227.09 ± 54.92 after treatment (6 weeks). This decrease in mean blood sugar level was found to be statistically highly significant ($p<0.01$). There was no appreciable change in mean bodyweight of the patients over the 6 weeks period. None of the patients reported any side effects ascribable to the trial.

Table 1: Grading of subjective symptoms

Symptoms	Score	Grade	Grading criteria of Symptoms
Polyuria	0	Absent	Normal frequency 1-4 times a day, 0-2 times at night
	1	Mild	5-7 times a day, 3-5 times at night
	2	Moderate	8-10 times a day, 6-8 times at night
	4	Sever	>10 times a day ,> 8 times at night
Polydipsia	0	Absent	Normal, 1.5-3 L/day
	1	Mild	Increased but controlled, 3-4 L/day
	2	Moderate	Increased but uncontrolled, 4.5 L/day
	3	Sever	Very much increased, >5 L/day
Weakness	0	Normal	No weakness
	1	Mild Increased	With feeling of weakness
	2	Moderate	Routine activities disturbed with
		increased	feeling of weakness
	3	Excessive increased	Severe weakness leads to bed ridden
Cramps on walking	0	Absent	No cramps
	1	Mild	Cramps after walking 1 km
	2	Moderate	Cramp after walking half km
	3	Severe	Inability to walk even up to half km
Tingling sensation	0	Absent	No tingling
	1	Mild	Present but tolerable
	2	Moderate	Sometimes intolerable
	3	Severe	Severe limitations of movement, very much reduced activity
Burning palms and soles	0	Absent	No Burning
	1	Mild	Present but tolerable
	2	Moderate	Sometimes intolerable
	3	Severe	Severe limitations of routine activities
Polyphagia	0	Absent	Normal meal
	1	Mild	Meal 2, light breakfast 2-3/day
	2	Moderate	Main Meal 2 or 3 but light breakfast 3-5/day
	3	Severe	Main Meal 2 or 3 but light breakfast 3-5 /day

Table 2: Improvement in subjective symptoms.

Parameter	Improved	Percentage	No change	Percentage
Polyuria (n=33)	30	91	3	9
Polydipsia (n=24)	9	37.5	15	62.5
Polyphagia (n=21)	9	43	12	57
Weakness (n=33)	28	84	5	16
Cramps on walking (n=21)	12	57.2	9	42.8
Tingling sensation (n=24)	16	66.6	8	33.4
Burning palms and soles (n=21)	15	71.5	6	28.5

Table 3: Statistical improvement in Serum Cholesterol mg/dl fasting (mean ± SD).

Parameter	BT (0 weak)	AT(6 weak)	Within the group Comparison (BT-AT) Paired 't" test
Serum cholesterol (fasting)	169.178 ± 30.41	160.83 ± 17.66	8.3 ± 13.19 t=1.54, p>0.05 NS

Table 4: Statistical improvements in Blood Sugar mg/dl (mean ± SD).

Parameter	BT (0 week)	FU 1 (2 week)	FU 2 (4 week)	FU (6 week)	Within the Group comparison (BT-FU3) Paired 't' test
Fasting	158.27 ± 36.45	135.00 ± 26.81	136.82 ± 26.81	131.55 ± 25.15	26.72 ± 32.41 t = 2.74, p<0.05 S
Postprandial	266.36 ± 51.62	231.45 ± 53.08	235.55 ± 54.80	227.09 ± 54.92	39.27 ± 34.51 t = 3.78, p<0.01 HS

DISCUSSION

Different clinical trials have established *Pterocarpus marsupium* and *Shilajatu* as potent anti-diabetic agents. The aim of the present study was to evaluate the combined effect of both the drugs (the *Shilasana* compound) in patients of NIDDM.

Symptomatic relief was observed in 91%, 37.5%, 43%, 84%, 57.2%, 66.6% and 71.5% cases regarding polyuria, polydipsia, polyphagia, weakness, cramps, tingling and burning sensations respectively.

Mean fasting blood glucose level (mg/dl) dropped from 158.27 ± 36.45 to 131.55 ± 25.15. This was a significant change. Similarly reduction in postprandial blood glucose levels was highly significant. This reduced from 266.36 51.62 to 227.09 54.92.

Mean serum cholesterol levels (mg/dl) reduced from 169.178 30.41 to 160.83 17.66 in the duration of 6 weeks. This was a non-significant change which can be attributed to maximum number of patients in the study having normal serum cholesterol levels initially and also to the short duration of the study.

CONCLUSION

Looking at the results it may be concluded that compound *Shilasana* is a promising anti diabetic agent. However, long term study comprising of larger group of patients is further required to reach the definite conclusion.

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