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Efficacy of some Ayurvedic Formulations in Type-2 Diabetes mellitus - A Case Study

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ABSTRACT

Diabetes is prevalent in India. This study was conducted to assess the impact of some classical Ayurvedic formulations on fasting blood glucose levels, Post-prandial Glucose levels, glycosylated hemoglobin (HbA1C) levels and urine sugar levels in patients of Type-2 diabetes mellitus.

Aims: To test the efficacy of classical Ayurvedic drugs in type-2 DM in present scenarion.
Materials and Methods: Total 15 patients of Type 2 diabetes mellitus diagnosed were included in the study. Patients were randomly selected as per inclusion criteria. Strict dietary and exercise controls were followed as per the guidelines of American Diabetic Association protocols. Total study was of 2 months duration with three follow-up at 15 day interval.
Results: Statistical analysis shows that there is significant reduction in fasting and PP blood glucose levels at the end of study. Also, significant reduction was found in levels of HbA1c and urine sugar level.

KEYWORDS

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INTRODUCTION

As per WHO report, it is estimated that the Diabetes mellitus is one of the major killers of recent times. Diabetes is a group of disease characterized by elevated blood glucose concentration because of diminished or exhausted insulin secretion from pancreatic β-cells and insulin resistance[1].

Apart from the morbidity and mortality due to retinopathy, nephropathy and neuropathy, adverse cardiac event is one of the leading causes of death in type-II diabetes mellitus[2]. Various risk factors like advancing age, obesity, hypertension and hyperlipidemia must be given equal attention and importance and must be coordinated with proper glycemic control as far as the management of diabetes is concerned. The risk of type-2 Diabetes increases with advancing age. Obesity and physical inactivity are the major but modifiable risk factors for type-2 Diabetes Mellitus[3]. Recent epidemiological studies have suggested that high postprandial blood glucose might be an independent risk factor of cardiovascular disease. Oxidative stress also plays a role in the pathogenesis of CHD and complications in Diabetes Mellitus.

The twenty types of *Prameha* which are described in Ayurvedic classics represent the physical and chemical abnormalities, seen in various urinary and extraurinary tract diseases or when these disorders occur as associated disorders with *Prameha*[4]. *Madhumeha* has been described as a complicated stage or end stage of all the *Prameha*[5]. *Prameha* is of two types by Sushruta; i.e. one is *sahaj* and second is *apathyahar nimitaj*[6]. *Madhumeh* may manifest as a single disease due to excessive *vata vriddhi*[7].

Different management strategies have been outlined in our classics in the form of Ahaar, Vihar and Aushadh according to constitutional profile of the patient and predominance of doshas[8]. Many herbal and herbo-mineral compositions have been mentioned which have been listed in ayurvedic review.

SELECTION OF PATIENTS

A total number of 15 patients of type-2 Diabetes mellitus were taken for clinical study for a period of 2 months with Some Ayurvedic Formulations. They were randomly selected from OPD of Kayachikitsa, Government Post Graduate Ayurved College & Hospital, Varanasi; during the Jan- April 2018. All patients were allowed to have treatment as outdoor patients.

INCLUSION CRITERIA:

a.   Patients with FBS<200 and PPBS<300.

b.   Age between 30-70 years

c.   Patients with Complications like Hypertension, CRF, IHD are excluded from study

Diagnosis of Diabetes is made after all necessary lab investigations and their classification according to WHO criteria[9]. [Table 1]

DIAGNOSTIC CRITERIA

Table 1 Classification of Diabetes as per WHO

Condition	*2-hour PP Glucose* mmol/l (mg/dl)	*Fasting glucose* mmol/l (mg/dl)	*HbA$_{1c}$* %
Normal	<7.8 (<140)	<6.1 (<110)	<6.0
Impaired Fasting glycaemia	<7.8 (<140)	≥6.1(≥110) & <7.0(<126)	6.0–6.4
Impaired Glucose Tolerance	≥7.8 (≥140)	<7.0 (<126)	6.0–6.4
Diabetes Mellitus	≥11.1 (≥200)	≥7.0 (≥126)	≥6.5

SELECTION OF DRUGS:

These drugs were selected as all are described in *Madhumeha* in our Ayurved Classics. These all drugs are mixed altogether and given to patients twice a day with 5 gm Honey. [Table 2]

Table 2 Drugs and its Contents-

	Drugs	Contents	Reference	Dose
1	Vasant Kusumakar Ras	Svarna bhasma, Rajata bhasma, Vanga bhasma, Naga bhasma, Kantaloha bhasma, Rasasindoor, Abhraka bhasma, Pravala bhasma, Mouktik bhasma, Godugdha, Ikshu, Vasa, Chandana (Shveta), Ushira, Rheebera, Haridra, Kadali kanda, Kamala pushpa, Jati pushpa.	Yog Ratnakar	60 mg BD
2	Prameh Gaj Keshari Ras	Lauh Bhasma, Nag Bhasma, Vang Bhasma, Abhrak Bhasma, Shilajeet, Khaksa phool, Nimbu Ras	Ras Tantra Saar	250 mg BD
3	Trivang Bhasm	Nag Bhasm, Vang Bhasm, Yashad Bhasm	Ras Tantra Saar	250 mg BD
4	Shilajatwadi Vati	Nag Bhasm, Vang Bhasm, Yashad Bhasm, Neem patra, Gudmaar Patra, Shilajeet	Siddha Yoga Sangraha	250 mg BD

ASSESSMENT CRITERIA

After selection of 15 patients, full details of history, physical examination and the data of lab investigations of patients were recorded for the study. Total duration of trial is 2 months with 15 days follow-up i.e. 3 consecutives follow up at 15-day interval. The effects of treatment procedure on various clinical parameters were evaluated based on the observations made before and after the course of treatment.

OBSERVATIONS

A.   Effect on Fasting Blood Sugar-

Before treatment mean score of FBS was 146.06± 9.52. After completing follow up FBS was 124.13 ± 3.35 with t value of t=

13.01 and p<0.001. This result suggests the efficacy of these drugs on DM-2. [Table 3]

B. Effect on Post-Prandial Blood Sugar-

Level of PPBS in this study before Treatment was 234.13 ± 12.76 and after treatment it was 192.06 ± 7.85. By comparing the results t value was t= 17.50 and p<0.001 suggesting good efficacy of drugs.

 [Table 4]

Table 3 Effect on Fasting Blood Sugar

Group	Fasting Blood Sugar				Paired t test (BT-FU3)
	BT	FU-1	FU-2	FU-3	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
N=15	149.06 ± 9.52	142.80 ± 8.91	134.20 ± 6.41	124.13 ± 3.35	24.93 ± 7.42
					t= 13.01 p<0.001

Table 4 Effect on Post-Prandial Blood Sugar

Group	Post-Prandial Blood Sugar				Paired t test (BT-FU3)
	BT	FU-1	FU-2	FU-3	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
N=15	234.13 ± 12.76	225.80 ± 11.05	225.26 ± 9.63	192.06 ± 7.85	42.06 ± 9.30
					t= 17.50 p<0.001

C. Effect on HbA1C level-

Level of HbA1C in this study before treatment was 8.47 ± 0.58 and after treatment it was 7.28±0.50. By comparing the results t value was t= 17.04 and p<0.001 suggesting good efficacy of drugs. [Table 5]

Table 5 Effcet on HbA1C level

Group	HbA1C Level				Paired t test (BT-FU3)
	BT	FU-1	FU-2	FU-3	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
N=15	8.47 ± 0.58	8.27 ± 0.56	7.79 ± 0.54	7.28 ± 0.50	1.19 ± 0.27
					t= 17.04 p<0.001

D. Effect on Urine Sugar Level-

Before treatment mean score of Urine Sugar Level was 2.53±1.06. After completing follow up score was 0.26±0.45 with t value of t= 7.54 and p<0.001. This result suggests the efficacy of these drugs on urine sugar level. [Table 6]

Table 6 Effect on Urine Sugar Level-

Group	Urine Suagr Level				Paired t test (BT-FU3)
	BT	FU-1	FU-2	FU-3	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
N=15	2.53 ± 1.06	1.66 ± 0.89	0.60 ± 0.63	0.26 ± 0.45	2.26 ± 1.16
				t= 7.54 p<0.001	

Comparison of Blood sugar levels before and after treatment-

Before treatment mean of FBS level was 149.07. After 1st follow up it was 142.80, after 2nd it was 134.20 and after 3rd it was 124.13. Before treatment mean of PPBS level was 234.13. After 1st follow up it was 225.80, after 2nd it was 205.27 and after 3rd it was 192.07. [Figure 1]
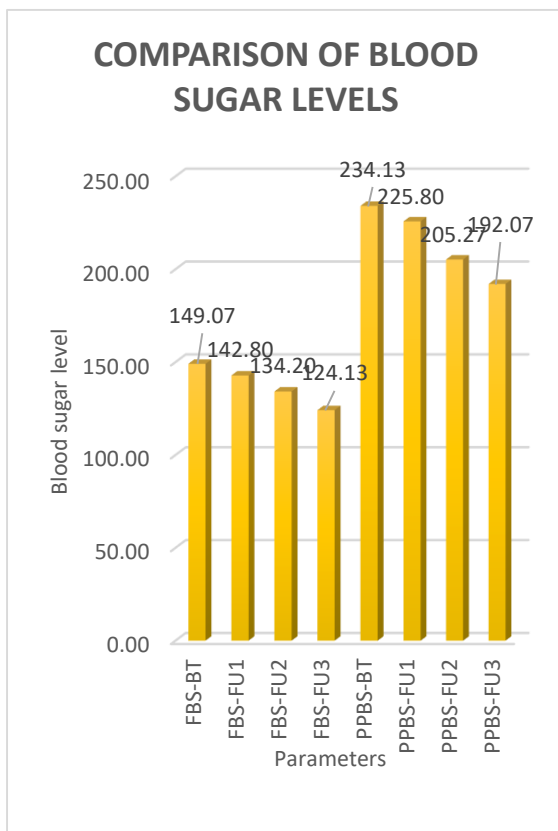
COMPARISON OF BLOOD SUGAR LEVELS

Fig 1 Blood sugar Levels comparison

DISCUSSION

Since diabetes is lifelong process requiring proper maintenance of blood glucose levels as close to the normal range as possible, a safer remedial measure is of clinical importance. With appropriate glycemic control, the risk of micro-vascular and neuropathic complications is decreased significantly. Further, if the cases of type - 2 DM are treated classically and timely, the risks of various micro-vascular and macro-vascular complications are reduced and thus their incidence can be prevented or minimized significantly. The above drugs can be better remedial measure, free form side effects and effective in the management of type-II diabetes mellitus and thus prevents or delays the micro and macrovascular complications caused due to hyperglycemia.

The results of present study in a small group of patients show very promising effect of above mentioned Ayurvedic formulations. After evaluating the observations made from the present series of investigation it is proposed that above drugs have a beneficial role in the management of diabetes mellitus cases. Though the sample size is small and comprehensive clinical trials are required for a definite conclusion.

CONCLUSION

Though the study is preliminary in nature, it can be established that above drugs prevents postprandial hyperglycemia, decreases fasting plasma glucose, and reduces urine sugar levels, in type-II diabetes mellitus cases. Thus, the drug is

effective in the prevention and management of type-2 diabetes.

FINANCIAL SUPPORT AND SPONSORSHIP-

Nil.

CONFLICTS OF INTEREST-

There are no conflicts of interest.

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