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CLINICAL EVALUATION OF PRAMEHANASHAK SANSHAMAN YOG IN THE MANAGEMENT OF MADHUMEHA W.S.R.TO DIABETES MELLITUS

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ABSTRACT:

Diabetes Mellitus has become a global threat. The worldwide prevalence of DM has risen dramatically over the past two decades, from an estimated 30 million cases in 1985 to 285 million in 2010. Based on current trends, the International Diabetes Federation projects that 438 million individuals will have diabetes by the year 2030. This may be presumably because of increasing obesity, reduced activity levels as countries become more industrialized, and the aging of the population¹⁰. In this study we have tried to correlate Ayurvedokta Madhumeha and Diabetes Mellitus.

OBJECTIVE: *To evaluate the efficacy of Pramehanashak Sanshaman Yog in management of Madhumeha with special reference to Diabetes Mellitus.*

METHODS: *Newly diagnosed 60 patients of Diabetes Mellitus, irrespective of sex were randomly selected and open non comparative clinical trial was conducted. The formulation was in tablet form which was administered for 3 months in dose 500mg thrice a day before food. Blood, Urine Sugar Level and HbA1c reports were done periodically. Paired t test was used for statistical analysis.*

RESULTS: *After completion of study highly significant results were observed and improvement in cardinal symptoms of Diabetes mellitus*

CONCLUSION: *Pramehanashak Sanshaman Yog proved to be a potent hypoglycaemic formulation. There was marked reduction in Blood Sugar Level, Urine Sugar Level and HbA1c. No side effects were seen during the study.*

KEY WORDS: *Blood Sugar Level, Diabetes Mellitus, HbA1c, Madhumeha,*

INTRODUCTION

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Diabetes mellitus (DM) refers to a group of common metabolic disorders that share phenotype of hyperglycemia. Several distinct types of DM are caused by a complex interaction of genetics and environmental factors. The metabolic dysregulation associated with DM causes secondary pathophysiologic changes in multiple organ systems that impose a tremendous burden on the individual with diabetes and on the health care system. DM is the leading cause of end-stage renal disease (ESRD), non traumatic lower extremity amputations, and adult blindness. It also predisposes to cardiovascular diseases.

Modern medicine has developed many hypoglycemic agents and also insulin analogues for management of diabetes. But these hypoglycemic agents have many adverse effects like Anemia; Renal failure etc ... The management of DM still remains unsatisfactory in spite of many advanced medicines. Hence, a herbal formulation described by *Acharya*

*Charaka, Pramehanashak Sanshaman Yog*¹³, has been chosen for clinical trial.

Charakacharya in his *Charaka Samhita* has described a disease called *Madhumeha* with symptoms of foul breath, voracious appetite, languor as well as the sweetness of urine in addition to the polyuria^{11, 12}.

There is a need to develop an herbal formulation which breaks the pathological process of DM, prevent its complication and also which is cost effective. The formulation is mentioned as Decoction but to avoid the bitter taste and for proper dose administration it was decided to use it in the form of *Ghanavati*.

MATERIALS AND METHODS

PLAN OF STUDY

An open clinical trial was conducted, where 60 patients of newly diagnosed DM type II were chosen randomly. Patients were given treatment with specific duration with every 1 month follow up. Oral Hypoglycemic Agents were not given during trial period. Institutional Ethics Committee (IEC) approval was obtained and written consent was taken from the patients prior to the initiation of the study.

SELECTION OF PATIENTS

Patients who reported to Outdoor Patient Department (OPD) and Indoor Patient Department (IPD) of YMT Ayurvedic Medical College & Hospital were carefully selected on the basis of Diagnostic, inclusion criteria, etc.

DIAGNOSTIC CRITERIA

- Patients having the classical signs and symptoms of Diabetes mellitus
- Blood Glucose Levels fasting > 120 mg/dl.
- Blood Glucose Levels post prandial > 180 mg/dl.

INCLUSION CRITERIA

- Patients irrespective of sex, between 18 to 75 years of age.
- Newly diagnosed patients of DM by above criteria and having BSL within 300 mg/dl.
- Willing to sign the consent for study participation.

EXCLUSION CRITERIA

- Patients having age < 18 yrs and > 75 yrs.
- BSL > 300 mg/dl.
- Patients with any major systemic diseases e.g. Cardiac, Hepatic, Renal, Endocrinal etc...
- Patients with acute complications like Ketoacidosis, Diabetic coma, Hyper-osmolar non ketotic state, acute infections of any part of body and gangrene.
- Patients on insulin and steroid therapy.
- Pregnancy and lactating mothers.

- Blood sugar fasting and post prandial initially and at the end of every month for consecutive 3 months.
- Urine sugar fasting and post prandial initially and at the end of every month for consecutive 3 months.
- Glycosylated Haemoglobin at the initiation and on completion of the study.

SUBJECTIVE CRITERIA

Symptom	
Prabhut mutrata (polyuria)	
< 6 times/day	0
6-8 times/day	1
8-10 times/day	2
>10 times/day	3

Symptom	Grade
Pipasa ativrudhi (polydypsia)	
No urge of thirst	0
Urge of thirst every 3-4 hrs.	1
Urge of thirst Only relieved for 1-2 hrs after water intake.	2
Persistent thirst	3

Symptom	Grade
Nocturnal urination	
No Nocturnal urination	0
<2 times at night	1
2-4 times at night	2
>4 times at night	3

CRITERIA FOR ASSESSMENT

OBJECTIVE CRITERIA

Symptom	Grade
Kshudhavruddhi (polyphagia)	
Lunch dinner with light breakfast	0
Two breakfasts, lunch and dinner.	1
Two heavy breakfasts, lunch and dinner.	2
Even with Two heavy breakfasts, lunch and dinner feels hungry in between.	3

Symptom	Grade
Weight Loss	
No weight loss	0
0-3 Kgs weight loss	1
3-6 Kgs weight loss	2
>6 Kgs weight loss	3

Symptom	Grade
Hasta-Paad - Tala Daha (Peripheral Neuritis)	
Absent	0
Only on soles/palms	1
On area more than soles/palms	2
Both upper and lower extremities	3

Symptom	Grade
Madhurasyata	
Absent	0
Only after meals	1
Whole day except in morning.	2
Whole day with fruity odor in mouth.	3

Symptom	Grade
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Swedatipravrutti (excessive sweating)	
Absent	0
Excessive sweating on exertion.	1
Excessive sweating on slight exertion.	2
Excessive sweating at rest.	3

Symptom	Grade
Buccal cavity hygiene	
No dental tarter/stains on teeth.	0
Dental stains but no dental tarter.	1
Dental stains with extra dental tarter.	2
Dental stains, dental tarter with gingivitis.	3

Symptom	Grade
Delayed healing (minor injuries)	
Normal wound healing	0
Healing within a week	1
Healing takes more than a week.	2
Healing requires medical treatment.	3

Symptom	Grade
Anutsah (Debility)	
No feeling of debility	0
Debility only for heavy work.	1
Debility for routine work.	2
Debility even at rest.	3

INVESTIGATIONS

- Routine hematological, bio-chemical and urine investigations were recorded.
- BSL Fasting and Post Prandial.
- HbA1C

METHODOLOGY

The contents of *Pramehanashan Sanshaman Yog* are *Haritaki, Amalaki, Bibhitaki, Devdaru, Daruharidra, Musta*. Each was taken in equal quantity and *Ghanavati* was prepared according to textual reference. This formulation was given for 3 months to the patients in dose of 2 tablets (each

mg) thrice a day before food. Follow up was planned monthly for 3 months.

OBSERVATIONS

It was observed that 29 patients (48%) were male and 31 patients (52%) were female. Maximum numbers of patients were in the age of 46 to 60 yrs i.e. 57%. Maximum numbers of patients were observed in the range of 61-80 Kgs weight. Most of the patients were housewives, retired or doing sedentary desk bound work.

EFFECT OF TREATMENT

After treatment, the patients in grade 0 were considered as relieved and the patients which shifted to grade 2,1 were considered as improved.

Table 2

Sr.No.	Signs & Symptoms	Total no. of cases (%)	Relieved (%)	Improved (%)
1	<i>Prabhut mutrata</i> (polyuria)	100	53.33	46.66
2	Nocturnal urination	100	51.66	48.34
3	<i>Pipasa ativriddhi</i> (polydypsia)=	100	66.66	33.34
4	<i>Kshudhavruddhi</i> (polyphagia)	91.66	76.67	41.99
5	Weight Loss	61.66	61.67	0
6	<i>Hasta-Paad Tala Daha</i> (Peripheral Neuritis)	86.66	63.33	23.33
7	<i>Madhurasyata</i>	48.33	41.67	6.66
8	<i>Swedatipravrutti</i> (excessive sweating)	100	78.33	21.67
9	Buccal cavity hygiene	40	23.33	16.67
10	Delayed healing (minor injuries)	23.33	16.67	6.66
11	<i>Anutsah</i> (Debility)	100	72	28

Effect on Blood Sugar Level Fasting & Post prandial: Table 3:

Blood Sugar (F)	1 st FU	2 nd FU	3 rd FU
Mean difference	28.828	45.327	60.930
SD	38.897	29.307	21.250
Paired T test	6.703	14.507	17.134

Table 4:

Blood Sugar (PP)	1 st FU	2 nd FU	3 rd FU
Mean difference	39.322	66.718	89.838
SD	47.544	43.949	37.128
Paired T test	11.790	15.141	19.778

These tables show the statistical analysis for Blood Sugar Level F & PP Which shows the significant difference in subsequent follow ups. It means that the said therapy used for Blood Sugar Level is highly effective.

Effect on HbA1c: Table 5

HbA1c	BT	AT
Mean	9.530	7.290
SD	1.503	1.037

The table shows the statistical analysis for Glycosylated Haemoglobin where Z score (6.737) shows the significant difference at the end of study. It means that the said therapy used for Glycosylated Haemoglobin is highly effective.

Effect on Urine Sugar Fasting and Post Prandial: Table 6

Urine Sugar (F)	1 st FU	2 nd FU	3 rd FU
Mean difference	0.634	0.9	1.0503

SD	0.873	0.585	0.252
Z stats	5.708	5.557	5.513

Table 7

Urine Sugar (PP)	1 st FU	2 nd FU	3 rd FU
Mean difference	0.766	1.466	2.05
SD	1.075	0.892	0.563
Z stats	6.500	6.885	6.884

These tables show the statistical analysis for Urine Sugar Level F & PP where Z score shows the significant difference in subsequent follow ups. It means that the said therapy used for Urine Sugar Level is highly effective.

DISCUSSION

Pramehanashak Sanshaman Yog is said to be *Sarvapramehahar*. *Bahudrava Kapha* is present in *Madhumeha*. Most of the drugs in the formulation have *Tikta-Kashay rasa*, *Laghu-Ruksha guna*, *Katu vipaka*. These are said to be *Kaphaghna*, *mehaghna* and *medoghna*. *Ushna veerya* and *Tikta-Kashay rasa* helps to restore the function of *Jatharagni*, *Dhatvagni*. This helps in proper formation of *Dhatu*s Quantitatively as well as qualitatively. *Tikta rasa* has the property of *Prasadana* and helps in reducing *Avilatwa* if urine.

Previous research work was reviewed during study which helped to understand the properties of contents of the formulation e.g. An antidiabetic and renoprotective effect of *T. chebula* Retz seeds (*Haritaki*) in Streptozotocin -

induced diabetic rats was proved. ^{[1][2][3]}
Insulin sensitizing effect, Hepatoprotective
activity of *Amalaki*. Chromium in *Amalaki*
helps to bring down BSL. ^[8] Anti-
hyperglycaemic, Anti-hyperlipidaemic
activity and property of increasing C-
Peptide levels of *Bibhitaki* are proved. ^[6]
Antihyperglycaemic activity, Antioxidant
activity of *Musta* as it showed the strong
DPPH radical scavenging action in vitro.
^[7] Inhibition of hepatic gluconeogenesis,
hypoglycemic effects, hypolipidaemic
effects of *Daruharidra* are proved.
^[5] *Devdaru* possess Hypoglycemic,
hypolipidaemic property. ^[4]

CONCLUSION

Signs and symptoms as well as
biochemical parameters were controlled
significantly with the formulation.
Formulation has consistent hypoglycemic
effect over 3 months. The drug shows
some amount of hypolipidaemic results
which may be helpful in preventing in
microvascular complications. The
formulation is effective in reducing
Glycosylated haemoglobin which helps in
preventing in microvascular complications.
Drugs contained in the formulation are
easily available and cost effective. No any
kind of side effect of the formulation was
seen in the study.

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