



“A STUDY TO EVALUATE THE THERAPEUTIC EFFICACY OF HERBAL FORMULATION IN THE MANAGEMENT OF MADHUMEHA W.S.R TO DIABETES MELLITUS”

Ayurveda

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ABSTRACT

Diabetes is a common chronic metabolic disorder prevalent all over the world. It is a sweet disorder with bitter mortality rate and multiple complications associated with it. The heterogenous etiopathology includes defects in insulin secretion, insulin action or both resulting in chronic hyperglycaemia with altered carbohydrate, protein and fat metabolism. The most common type being type 2 diabetes mellitus which accounts for 90% of total known cases. In Ayurveda diabetes mellitus is symptomatically equivalent to madhumeha (subtype of vataj prameha). According to IDF (International Diabetes Federation) diabetes is one of the fastest growing health challenges of 21st century.¹ In spite of the tremendous advancement of modern system of medicine, an ideal Oral Hypoglycemic Agent which can control diabetes and manage the complications associated with it effectively is not available yet. So to develop a more effective and safer drug this clinical study is conducted using a herbal formulation prepared in the form of a *ghanvati* consisting of *Karvellaka* (Momordica Charantia), *Meshshringi* (Gymnema Sylvestre), *Rakta Chandana* (Pterocarpus santalinus), *Methika* (Trigonella foenum graecum), *Bilva* (Aegle marmelos), *Amalaki* (Embelica officinalis), *Guduchi* (Tinospora cordifolia) and *Ashwagandha* (Withania somnifera) and its clinical effects are observed on diabetes mellitus based on symptomatic relief and changes in the plasma glucose concentration before and after taking the above mentioned herbal formulation.

KEYWORDS

Diabetes mellitus, Madhumeha, Ghanvati, Herbal Formulation

INTRODUCTION

The scope of medical practice keeps evolving with the constantly changing patterns of the diseases, their therapies, mode of treatments and prognosis. One such disease which has become a baffling enigma in recent times is Diabetes Mellitus (DM). It is a major public health problem that is approaching epidemic proportions globally. Diabetes results from a complex interaction of genetic, environmental, and lifestyle factors resulting in insulin resistance in peripheral tissue or insulin secretory defect of the beta cell (type 2 diabetes) or an absolute insulin deficiency because of destruction of beta cell by an autoimmune process (type 1 diabetes)² resulting in chronic hyperglycaemia with altered carbohydrate, protein and fat metabolism. According to IDF (International Diabetes Federation) diabetes is one of the fastest growing health challenges of 21st century, in current scenario approximately 463 million adults are living with diabetes and this number will increase up to an approximate figure of 700 million by the year 2045. Out of these given numbers approximately 77 million cases were reported in India alone³. 90% of the total known diabetic cases are of type 2 DM (formerly known as Non Insulin Dependent Diabetes Mellitus-NIDDM). According to 2019 guidelines of WHO,⁴ diagnostic tests which are currently recommended for diabetes are fasting plasma glucose ≥ 126 mg/dl (7.0 mmol/L), 2-hour(2-h) post-load plasma glucose after a 75g oral glucose tolerance test (OGTT) ≥ 200 mg/dl (11.1 mmol/L), HbA1c $\geq 6.5\%$ (48 mmol/mol), and a random blood glucose ≥ 200 mg/dl (11.1 mmol/L) in the presence of signs and symptoms are considered to have DM⁴. The common symptoms of hyperglycaemia include polyuria, polydipsia, blurry vision, weight loss, fatigue, frequent superficial infections (vaginitis, fungal skin infections), and slow healing of skin lesions after minor trauma⁵. DM if left untreated can cause chronic complications affecting major organ systems and that is responsible for majority of morbidity and mortality associated with the disease.

In Ayurveda classics *madhumeha* and *prameha* share a common aetiology as *madhumeha* is one of the subtype of *vataj prameha*.⁶ The common aetiology in all types of *prameha* hinges on *kapha dosha*, thus all the factors which enhance *kapha dosha* in the body are considered as the causative factors of *prameha*. It includes lifestyle factors also. Along with these factors psychological factor such as stress also acts as aggravating factor for the disease. *Prameha* is considered as *kapha pradhan tridoshaja vyadhi*,⁷ the aggravated *kapha* is responsible for clinical manifestation of *prameha*. The common symptoms produced on manifestation of the disease are *Prabhutmutrata*- excessive and frequent micturition, *Avilmutrata*- urine having hazy consistency and turbidity.⁸ The *purvarupa* of the disease mentioned by various *acharyas* such as *karpaddaha*-burning sensation in palm and sole,

pipasa-excessive thirst, *kshudha* *Adhikya*-excessive hunger etc, also appear as symptoms in present era. In *madhumeha* the specific characteristic of urine is sweet, *rooksha* consisting of *oja* and it resembles with honey.⁹ According to various *Acharyas*, all types of *prameha* if not resolved properly on time will ultimately convert into *madhumeha*. Thus, a timely and effective management of the disease is utmost necessary to avoid its progression towards *asadhyata*. So, a palliative combination is selected as the treatment protocol for the management of Diabetes Mellitus consisting of herbal formulation prepared in the form of a *ghanvati* which possess various properties to combat the disease effectively.

AIM AND OBJECTIVES

- 1) To access the efficacy of herbal formulation in the management of diabetes mellitus.
- 2) To find out an effective, low cost and safe *Ayurvedic* remedy to resist diabetes mellitus.

MATERIAL AND METHODS

Selection of sample:

Patients were randomly selected irrespective of their sex, religion, occupation etc.

Source of patients:

10 clinically diagnosed patients of diabetes mellitus, registered in OPD/IPD of Pt. Khushilal Sharma Govt. Hospital, Bhopal, who fulfil inclusion criteria were selected.

Drug and dose:

Drugs namely *Karvellaka*, *Meshshringi*, *Rakta Chandana*, *Methika*, *Bilva*, *Amalaki*, *Guduchi*, and *Ashwagandha* were taken in ratio 1:1:1:1:1:1:1:2 by weight respectively and *ghanvati* is prepared by classical method.

Plan of study:

Modern medication of patient for DM was discontinued during the study period.

2 *ghanvati*, 250 mg each was given twice a day before meal

Duration of study: 30 days

CRITERIA FOR INCLUSION

- 1) Patient of either sex having age between 30 years to 65 years
- 2) Fasting plasma glucose > 126 mg/dl and ≤ 200 mg/dl or Post load plasma glucose > 200 mg/dl and ≤ 350 mg/dl HbA1c $> 6.5\%$ and $< 10\%$
- 3) Recently diagnosed (< 6 months) cases of DM

CRITERIA FOR EXCLUSION

- 1) Patient of either sex having age below 30 years or above 65 years
- 2) Fasting plasma glucose ≤ 126 mg/dl and > 200 mg/dl
Post load plasma glucose < 200 mg/dl and > 350 mg/dl
HbA1c $\leq 6.5\%$ and $\geq 10\%$
- 3) Chronic (> 6 months) old cases of DM
- 4) Malignant and accelerated hypertension
- 5) CVS disorder (CAD)
- 6) Pregnant women and lactating mother
- 7) Secondary DM
- 8) CNS disorder e.g., encephalopathy etc.

CRITERIA FOR WITHDRAWAL

- 1) If any serious illness or condition is found in the patient during the course of the trial.
- 2) Fasting plasma glucose rises to > 200 mg/dl or post load plasma glucose increases to > 350 mg/dl and are not controllable
- 3) Any serious complication develops which require urgent treatment with any other drug/therapy

PARAMETERS FOR ASSESSMENT

The assessment was done based on the changes in subjective and objective parameters. Objective parameter includes fasting plasma glucose and post load plasma glucose, the values of these 2 were recorded on the 1st and 30th day of the study

PATIENT WISE OBSERVATION DURING THE STUDY**Table 1: Effect of herbal formulation on objective parameter**

PATIENT	AGE (years)	SEX	BT		AT	
			FPG (mg/dl)	PPG (mg/dl)	FPG (mg/dl)	PPG (mg/dl)
1.	62	F	215	333	150	222
2.	48	F	195	200	130	160
3.	45	F	176	225	120	170
4.	43	M	170	230	120	200
5.	65	M	184	273	122	180
6.	39	F	188	220	110	160
7.	62	F	200	299	118	170
8.	42	M	190	280	116	160
9.	65	M	169	204	110	162
10.	28	M	184	210	122	156

Table 2: RESULT

PARAMETER	MEAN		MD	% RELIEF	SD	SE	P VALUE
	BT	AT					
FPG	187	121.8	65.30	35.29	9.98	3.159	0.015
PPG	247	174	73.44	29.55	36.42	11.518	0.027

Table 3: Effect of herbal formulation on subjective parameter

Sr. No	Symptom	BT	AT
1	Prabhutnutrata	+++	+
2	Avilmutrata	++	+
3	Karpaddaha	+++	+
4	Madhuryam Asyata	+++	+
5	Pipasa	++	+
6	Kshudha Adhikya	+++	++

Interpretation:

Effect of herbal formulation on fasting plasma glucose reveals that before treatment the mean score on fasting plasma glucose was 187 with SD ± 14.059 which was brought down to 121.8 with SD ± 11.526 after treatment, which shows significant result given at 95% CI and P value is extremely significant.

Effect of herbal formulation on post load plasma glucose reveals that before treatment mean score on post load plasma glucose was 247 with SD ± 45.695 which was brought down to 174 with SD ± 21.354 after treatment which shows extremely significant result given at 95% CI and P value is extremely significant.

DISCUSSION

The herbal formulation used in this study is a combination of multiple drugs namely *Karvellaka* (Momordica Charantia), *Meshshringi* (Gymnema Sylvestre), *Rakta Chandana* (Pterocarpus santalinus), *Methika* (Trigonella foenum graecum), *Bilva* (Aegle marmelos),

Amalaki (Embellica officinalis), *guduchi* (Tinospora cordifolia) and *ashwagandha* (Withania somnifera)

The above mentioned formulation is specially designed to provide comprehensive benefits with respect to glucose metabolism, lipid metabolism, insulin production and utilisation. With these properties it is able to alleviate symptoms like fatigue, weight loss, excessive thirst etc. The essential nutrients for the well-being of diabetic patient such as glycosides, bioflavonoids, tannins and several micronutrients etc. are present in abundant quantity in the given formulation. Thus, it acts as cardioprotective and pancreotropic agent, it also activates the liver for effective glucose and lipid metabolism.

Along with these properties it also delays absorption of glucose from gastrointestinal tract, decreases the release of glucose into blood from glycogen, fats and protein and simultaneously, enhances the formation of glycogen and fat from glucose. The formulation has immunomodulatory and anti allergic effects too. All these phenomenon's collectively assist in maintaining the normal plasma glucose level, and by doing so it works as synergistic to oral hypoglycemic agents and insulin therapy.

Individual benefits of the contents of herbal formulation-

- 1) **Karvellaka** (Momordica charantia)- It has a compound that functions similar to insulin by reducing the blood glucose levels in both type 1 and type 2 diabetics. It is rich in antioxidants and vitamin A and C
- 2) **Meshshringi** (Gymnema sylvestre)- It helps to regulate glucose levels by promoting the secretion of insulin, regenerating pancreatic cells and increasing the activities of enzymes responsible for healthy glucose utilisation. The herb helps prevent triglyceride accumulation in the muscles and liver and supports maintenance of healthy body weight.
- 3) **Rakta Chandana** (Pterocarpus santalinus)- It works on diabetes by improving insulin secretion and alterations in the carbohydrate metabolism.
- 4) **Methika** (Trigonella foenum graecum)- Methi seeds water has the ability to lower blood glucose levels, it contains fibre and helps in slowing down digestion process, and thus further regulating the absorption of carbohydrate and sugar.
- 5) **Amalaki** (Embellica officinalis)- Amalaki possess anti diabetic effect through its anti oxidant and free radical scavenging properties. It is also reported to prevent hyperglycaemia, diabetic nephropathy, neuropathy and protein wasting.
- 6) **Bilva** (Aegle marmelos)- It contains dietary polysaccharides which enhances pancreatic beta cell mass and alleviates beta cells dysfunction. Thus by doing so it produces hypoglycemic, hypolipidemic and anti inflammatory effects.
- 7) **Guduchi** (Tinospora cordifolia)- The plant contains alkaloids which possess insulin mimicking and insulin releasing effect. It also increases the production of beta cells of pancreas which results in smooth regulation of insulin and plasma glucose.
- 8) **Ashwagandha** (Withania somnifera)- The flavonoids present in the plant have hypoglycemic and hypolipidemic effect. It also helps in alleviating stress by reducing cortisol (stress hormone).

All these drugs collectively works on balancing the vitiated *tridosha* and helps in managing *madhumeha* (DM) and increasing the quality of life of the individual.

CONCLUSION

The present study shows that herbal formulation may work effectively in the management of *madhumeha* (DM). Though this study is a pilot study with limited number of patients in a fixed stipulated time, it shows significant results in managing FPG and PPG effectively. In order to establish the anti hyperglycemic effect of the given formulation, a broad spectrum study is required as per

ABBREVIATIONS

FPG: Fasting Plasma Glucose
PPG: Post Load Plasma Glucose
IDF: International Diabetes Federation
WHO: World Health Organisation
DM: Diabetes Mellitus
BT: Before Treatment
AT: After Treatment
MD: Mean Difference
SD: Standard Deviation
SE: Standard Error
CI: Confidence Interval

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