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A clinical study to evaluate the role of *Madhumehari Vati* in the management of *Madhumeha* type 2 diabetes

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ABSTRACT

Background: Type 2 Diabetes is a major, non-communicable disease with increasing prevalence at the global level. Type 2 diabetes is a metabolic disorder which can be correlated with *Madhumeha*. *Madhumeha* is *Tridoshaj* in origin with predominance of *Vata* and *Kapha*. Type 2 diabetes results when the body produces insufficient insulin or the body cannot use the insulin it produces. Most of the contents of *Madhumehari Vati* are having *Katu* (pungent), *Tikta* (bitter), *Kashaya* (astringent) *Rasa* (taste), *Laghu* (light), *Ruksha* (rough) *Guna* (properties), *Katu* (pungent) *Vipaka* (taste after digestion), *Ushna* (hot) *Virya* (potency), *Deepana, Pachana Kapha-Pitta Shamaka* properties and hypoglycaemic, antidiabetic activity, Hepatoprotective, hypolipidemic and antioxidant activities which are essential in the management of *Madhumeha* (type 2 diabetes). So, this study was taken up to evaluate the effectiveness of *Madhumehari Vati* in the management of *Madhumeha* (type 2 Diabetes). Aim of the study was to evaluate the efficacy of *Madhumehari Vati* in the management of *Madhumeha* w.s.r type 2 diabetes.

Methods: Total 31 patients were selected from OPD of *Kayachikitsa*, department, I. T. R. A., Jamnagar. In this study *Madhumehari Vati* was given in dose of one tablet (1000 mg each) three times in a day with plain water before meal. **Results:** After the course of therapy for 8 weeks, statistically highly significant improvement was found in subjective parameters like *Pindikodwestana* (calf muscles cramps), *Guru Gatrata* (heaviness of body), *Supti* (numbness), *Karapada Daha* (burning sensation in palm and soles), *Prabhutamutrata* (polyuria), *Atipipasa* (polydipsia) whereas *Shithila Angata* (flaccidity of body parts), *Swedadhikya* (excessive sweating), *Kshudha Adhikya* (polyphasia) and *Nidra Adhikya* (excessive sleep) remained statistically significant (p<0.05). In objective parameters statistically highly, significant improvement was found in post prandial blood glucose whereas statistically significant improvement was found fasting blood glucose and HbA1C.

Conclusions: *Madhumehari Vati* is effective in the management of *Madhumeha* (type 2 diabetes). No ADR (adverse drug reaction) was reported during the study.

Keywords: Ayurveda, Madhumeha, Madhumehari Vati, Type 2 diabetes mellitus

INTRODUCTION

According to Ayurveda excess Asyasukham (sedentary life style), Svapnasukham (excess sleeping), Dadhi (Excessive consumption of curds and its preparations), Gramya-Oudaka-Anupa Mamsa (flesh or meat soup of animals

living in water and marshy regions), *Payamsi* (Excessive consumption of milk, its derivatives and preparations), *Navaanna Panam* (food, drinks and dishes prepared from new grains etc), *Guda Vaikruti* (Jaggery, its derivatives and dishes made out of it), life style activities which increase *Kapha*, use of *Guru* (heavy to digest), *Snigdha* (unctuous), *Atinidra* (excess sleep), *Avyayama* (lack of

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exercise), *Achinta* (lack of mental exercise) are the causes of *Madhumeha*. *Madhumeha* (type 2 diabetes) is included in the *Ashtamahagadas* (eight deadly and incurable imperative diseases) caused by the involvement of all *Doshas* and ten *Dushya*. ¹⁻³ In *Ayurveda* disease type 2 diabetes can be correlated with *Madhumeha*. ^{4,5}

Diabetes mellitus is a group of metabolic disorder in which a person has a high blood sugar, because body does not produce sufficient amount of insulin or lack of conversion of glucose into glycogen in the cells and tissues. It has been estimated that the number of diabetes sufferers in the world will double from the current value of about 190 million to 325 million during the next 25 years. ^{6,7} Individuals with type-2 diabetes are at a high risk of developing a range of debilitating complications such as cardiovascular disease, peripheral vascular disease, nephropathy, changes to the retina and blindness that can lead to disability and premature death. It also imposes important medical and economic burdens. WHO projects that diabetes will be the seventh leading cause of death in 2030.⁸

Ayurvedic management of Madhumeha (type 2 diabetes) aims not only to achieve a good glycaemic control but also to find out the root cause of disease and its prevention. In present study Madhumehari Vati was taken, most of the contents of Madhumehari Vati are having Katu (pungent), Tikta (bitter), Kashaya (astringent) Rasa (taste), Laghu (light), Ruksha (rough) Guna (properties), Katu (pungent) Vipaka (taste after digestion), Ushna (hot) Virya (potency), Deepana, Pachana Kapha-Pitta Shamaka properties and hypoglycaemic, antidiabetic activity, Hepatoprotective, hypolipidaemic and antioxidant effects.

Aim and objectives

Clinical evaluation of *Madhumehari Vati* in the management *Madhumeha* (type 2 diabetes).

Ethical clearance

Study was started after obtaining ethical clearance from the institutional ethics committee, I.T.R.A., G.A.U., Jamnagar. IEC No. PGT/7/-A/Ethics/2016-17/2734, dated: 21/11/2016 and study was registered in clinical trial registry of India. CTRI No.-CTRI/2017/05/008618, dated: 23/05/2017.

METHODS

Selection of patients

The present clinical trial was interventional open labelled randomized clinical trial with efficacy as an end point. A series of 31 patients, newly diagnosed or known case of *Madhumeha*, having signs and symptoms of *Madhumeha* (type 2 diabetes) and fulfilling inclusion criteria were selected from OPD and IPD of *Kayachikitsa* departments of I.T.R.A. Hospital, Jamnagar irrespective of their race, religion, caste and sex.

All details of the patients are recorded and maintained in the specially prepared proforma.

Before registering the patients informed consent was taken.

Inclusion criteria

Patients having signs and symptoms of *Madhumeha* (type 2 diabetes), age \geq 20 years and \leq 70 years and fasting plasma glucose \geq 126 mg/dl or post prandial glucose level \geq 200 mg/dl were included from the study.

Exclusion criteria

Patients had age less than 20 years more than 70 years, patients of diabetes mellitus receiving insulin, Patients having chronic complications of diabetes mellitus-Microvascular: Retinopathy, Neuropathy and Nephropathy, -Macrovascular: Coronary artery disease, Peripheral vascular disease and cerebrovascular disease. Other chronic debilitating disease like STD etc. and pregnant and lactating women were excluded from the study.

Drug review

Table 1: Ingredients of *Madhumehari Vati (Anubhut yoga)*.

Drug	Botanical name	Parts used (dry)	Qua. (mg)	
Mamajjak	Enicostemma littorale Blume	Panchanga	300	
Meshashringi	Gymnema sylvestre RBr	Leaves	250	
Latakaranja	Caesalpinia bonducella (Linn.) Roxb.	Nut	150	
Katuki	Picrorhiza kurroa Royle ex Benth.	Root	50	
Pippali	<i>Piper longam</i> Linn.	Fruit	40	
Rakta maricha	Capsicum frutescens Linn.	Fruit	8	
Indravaruni	Citrullus colocynthis Linn.	Fruit	2	

For this clinical trial *Madhumehari Vati* was prepared and provided by Dr Vasishth's AyuRemedies (named as Glycie tablet).

Investigations

All the investigations were carried out before starting and

after completion of therapy. Blood-Hb%, TLC, DLC, ESR, PCV. Biochemical-FBS, PP2BS, RFT, HbA1C and urine-Routine and microscopic examination.

Posology

1 tablet (1000 mg each) thrice a day, before meal with plain water orally was given for 8 weeks. Follow up was carried out at 15 days interval for the duration of 1 month on continue routine medicine.

If patient was taking any other medication it was discontinued for 7 days and during this period *Vijaysaradi Kwath* was given 20 gm in morning before meal, after that research drug was given.

Criteria for assessment

The effect was assessed based on changes in subjective and objective parameters. Assessment was done starting from the first day of the treatment followed by weekly. Patients were assessed on the basis of specially prepared proforma containing detail history, symptoms of the disease as well as necessary examinations.

Subjective parameters

The assessment of effect of treatment was on the basis of changes in signs and symptoms of *Madhumeha* like *Prabhuta mutrata* (polyuria), *Avila mutrata* (turbid urine), *Kshudadhikyata* (polyphasia), *Pipasadhikyata* (polydipsia), *Kara-Pada daha* (burning sensation in palms and soles), *Kara-Pada Suptata* (numbness in palms and foot), *Atisweda* (excessive sweating), *Dourgandhyata* (bad smell), *Nidradhikyata* (excessive sleep).

Objective parameters

Fasting blood glucose, post prandial blood glucose, fasting urine glucose, post prandial urine glucose and HbA1C were analysed.

Software used

Sigma software was used for all statistical evaluation.

Observations

In the present study total 31 patients of were registered out of them 29 patients have completed the course of treatment. In the present study maximum i.e., 38.70% of the patients belonged to the age group between 40 to 50 years (which indicates maturity onset nature of disease). Majority of the patients in present study were belonging to male (77.41%) category which supports the fact that either sex can be affected by the disease, but still male being at higher side. However, women are more likely to transmit type II diabetes to their offspring. Religion wise maximum patients (93.54%) belonged to Hindu religion. Though population of Hindu community is higher in this

geographical territory, hence Hindu patients were found more in numbers.

Majority of patients i.e., 38.70% were secondary educated, people having just secondary education may less aware about the causes of the diabetes. ¹² Majority of patients (58.06%) belonged to middle class followed by upper middle class. Data analysis revealed that, incidence was higher in middle class and upper middle-class population. This may be because majority of patients reporting to institute hospital are belonging to these classes (Table 2).

The maximum patients i.e., 38.70% each had duration of illness of 2-5 years. Insulin secretion, whether measured as fasting C-peptide, 6-minute C-peptide, or post-glucagon increment in C-peptide concentrations, declined with increasing duration of diabetes. Positive family history for type 2 diabetes (83.87%) showed genetic background of the disease. People with an affected parent or sibling are at 3.5 times greater risk of developing diabetes than people from diabetes-free families. Exercise was absent in 58.06% of patients, it is well-established that increasing physical activity plays an important role in reducing risk of obesity and diabetes. Data shows that tobacco as addiction was observed in most of patients (38.70%) followed by tea addiction (36.66%). Tobacco and smoking appear to increase the risk of diabetes mellitus (Table 3). 16

Table 2: Demographic profile of patients.

Geographic observation	Predominance	No. of patients (%)
Age (year)	40-50	12 (38.70)
Gender	Male	24 (77.41)
Religion	Hindu	29 (93.54)
Education	Secondary school	12 (38.70)
Occupation	Office work	17 (54.83)
Socioeconomic status	Middle class	18 (58.06)
Marital status	Married	30 (96.77)

Table 3: Observations related to personal history and disease.

Observation	Predominance	No. of patients (%)
Chronicity	2-5 years	12 (38.70)
Onset	Acute	14 (45.16)
Genetic pre- disposition	Present	26 (83.87)
	Samashan	24 (77.41)
Dietary habits	Adhyashana	24 (77.41)
	Vishamasham	20 (64.51)
Exercise	Absent	18 (58.06)
Work	Sedentary	20 (70.96)
Addiction	Tobacco	12 (38.70)
Addiction	Tea	11 (36.66)
Sleep	Atinidra	16 (51.61)

Table 4: Rogi Bala Pariksha.

Parameter	Predominance	No. of patients (%)
Sharir Prakriti	Pitta-Kapha	18 (58.06)
Manasa Prakriti	Rajasa	17 (54.83)
Samhanana	Madhyam	21 (67.74)
Sara	Madhyam	28 (90.32)
Pramana	Sama	17 (54.83)
Satmya	Madhyam	21 (67.74)
Sattva	Madhyam	15 (48.38)
Aharashakti	Pravara	18 (58.06)
Vyayamashakti	Madhyam	23 (74.19)
Vaya	Madhyam	23 (74.19)

The data reveals that maximum number of patients had *Pitta* predominant *Kaphaja Prakriti* (physical constitution) (58.06%), *Rajsika Prakriti* (mental constitution) (54.83%), *Madhyama Sara*. In 77.41 patients faulty diet pattern *Adhyashana*, *Samashana* and in 64.51% *Vishamashana* (Excellence of *Dhatus*) (90.32%), *Madhyama Satmya* (suitability) (67.74%), *Madhyama Sattva* (phychic condition) (48.38%), *Madhyama Samhanana* (Compactness of organs) (67.74%), *Sama Pramana* (measurements of body) (54.83%), *Madhyama Vyayamashakti* (exercise capacity) (74.19%), *Pravara*

Abhyavaharanashakti (digestion capacity) (58.06%) and Madhyama Kaal of Vaya (age) (74.19%) as shown in the Table 4.

RESULTS

Improvement in subjective parameters like Pindikodwestana (calf muscles cramps) (56.06%), Guru Gatrata (heaviness of body) (100%), Supti (numbness) (77.19%), Karapada Daha (burning sensation in palm and soles) (76.98%), Prabhuta Mutrata (polyuria) (81%), Atipipasa (polydipsia) (85%) was highly significant (p<0.001) whereas in Shithila Angata (flaccidity of body parts) (62.12%), Swedadhikya (excessive sweating) (87.78%), Kshudha Adhikya (polyphasia) (82.54%) and Nidra Adhikya (excessive sleep) (58.90%) remained statistically significant (p<0.05). Paired 't' test was applied to note the significant change in the symptoms before and after the treatment (Table 6).

Laboratory parameter like PP2BS was reduced by 42.44% which is statistically highly significant (p<0.001). Fasting blood sugar level as well as HbA1c was reduced by 20.30% and 0.97% at the end of 8th week respectively which are statistically significant (p<0.05). During follow up no relapse of symptoms were observed as in Table 8.

Table 5: Chief complaints.

Complaints	No. of patients (%)
Prabhut Mutrata	28 (90.32)
Atipipasa	27 (87.10)
Kara Pada Daha	24 (77.41)
Kara Pada Supti	23 (74.19)
Pindikodwestan	21 (67.74)
Swedadhikya	17 (54.83)
Kshuda Adhikya	16 (51.61)
GuruGatrata	16 (51.61)
Nidra Aadhikya	16 (51.61)
ShithilAngata	14 (45.16)
Snigdha	10 (32.25)

Table 6: Effect of *Madhumehari Vati* on subjective parameters-paired' test.

`Symptoms	N	Mean	Mean		Relief %	SD	SE	ίť,	P
	IN	B.T.	A.T.	M.D.	Kellel 70	SD	SE	·	I
Prabhut Mutrata	29	1.7	0.5	1.2↓	81	0.71	0.13	9.2	<0.001 (HS)
Pindikodwestan	29	1.5	0.26	1.2↓	56.06	0.94	0.17	7.3	<0.001 (HS)
Kara Pada Daha	29	1.3	0.13	1.2↓	76.98	0.85	0.15	7.87	<0.001 (HS)
Kshuda adhikya	29	0.83	0.50	0.33↓	82.54	0.60	0.11	3.0	0.001 (S)
Kara Pada Supti	29	1.36	0.13	1.23↓	77.19	0.85	0.15	7.87	<0.001 (HS)
Ati Pipasa	29	1.96	0.60	1.36↓	85	0.89	0.16	8.41	<0.001 (HS)
Sweda Adhikya	29	0.83	0.50	0.33↓	87.78	0.60	0.11	3.01	0.005 (S)
Visrasarir Gandha	29	0.43	0.20	0.23↓	78.03	0.43	0.07	2.97	0.006 (NS)
Guru Gatrata	29	0.50	0.00	$0.50 \downarrow$	100	0.50	0.09	5.3	<0.001 (HS)
Shithil Angata	29	0.43	0.13	0.30↓	62.12	0.46	0.08	3.5	0.001 (S)
Nidra Adhikya	29	0.73	0.30	0.43↓	58.90	0.67	0.12	3.49	0.002 (S)

Note: B.T.=before treatment, A.T.=after treatment, SD=Standard deviation, SE=Standard Error, P value=Indicates significance of treatment on specific symptom.

Table 7: Effect of Madhumehari Vati on objective parameters-paired't' test.

Symptoms	N	Mean B.T.	A.T.	M.D.	SD	SE	't'	P
TLC	29	7727.58	7731.03	3.44↑	1624.69	301.69	0.01	0.99
RBC	29	4.99	4.95	0.04↓	0.55	0.10	0.41	0.68
Hb	29	13.60	13.49	0.11↓	0.78	0.14	0.76	0.45
PCV	29	39.676	39.669	0.006↓	2.31	0.43	0.01	0.98
ESR	29	27.03	24.82	2.20↓	20.74	3.85	0.57	0.57
Urea	29	25.13	24.72	0.41↓	8.18	1.52	0.27	0.78
Creatinine	29	1.121	1.117	0.003↓	0.24	0.04	0.07	0.94
Total Protein	29	7.021	7.090	0.069↑	0.41	0.07	0.90	0.37
Albumin	29	3.72	3.71	0.01↓	0.22	0.04	0.24	0.80
Globulin	29	3.31	3.37	0.06↑	0.48	0.90	0.76	0.45

Note: B.T.=before treatment, A.T.=after treatment, SD=Standard deviation, SE=Standard Error, P value=Indicates significance of treatment on specific criteria

Table 8: Effect of Madhumehari Vati on blood sugar-paired't' test.

Parameter	N	Mean		Mean	SD	SE	649	D
r ar ameter	IN	B.T.	A.T.	Difference	SD	SE	·	Γ
FBS	29	166.86	146.55	20.30↓	38.95	7.23	2.80	0.009 (S)
PPBS	29	228.75	186.31	42.44↓	61.75	11.46	3.7	<0.001(HS)
HbA1C	29	8.45	7.47	0.97↓	1.34	0.25	3.91	0.003 (S)

DISCUSSION

Madhumehari Vati helped in pacifying Mutravaha Srotodushti lakshana because most of the ingredients are Tikta-Katu-Kashaya in Rasa having Kleda-Medo Upashoshana properties and Laghu-Ruksha in Gunas. Thus, all these properties may help to regulate the Udakavaha and Medovaha Srotas, Therefore in Prabhutamutrata (81%) improvement was found. Ati Pipasa is a result of excessive loss of Drava Dhatu due to Prabhutmutrata, as Madhumehari Vati reduces Prabhut mutrata therefore simultaneously reduces Ati Pipasa (85% improvement).

Pindikodweshtana found in many of patients because of less glucose uptake by muscle tissue for the energy.

Madhumehari Vati, being predominantly Tikta and Kashaya

Rasa and Kaphagna property is expected to clear the srotasas (channels) and facilitates the entry of glucose (nutrition) to generate Bala (vitality). So, Madhumehari Vati nourishes the body and reduces Pindikodweshtana (56% improvements). Madhumehari Vati helped in pacifying Medovaha Srotodushti lakshanas by their Laghu, Ruksha, and Teekshna Guna, Medohara and Deepana-Pachana properties. Therefore, in Gurugatrata (100%), Atiswedana (87.78%), Nidra Adhikya (17.80%), Visrasarir Gandha (78.03%) improvement was found. In Annavaha Srotodushti lakshanas like Kshudhadhikya (82.54%) improvement was found, because of its action at the level of Jataragni and Dhatwagni.

Kara Pada Suptata and Daha caused by involvement of Vata Dosha with Pitta and Kapha respectively were

pacified by Madhumehari Vati. Madhumehari Vati by its Tikta-Katu-Kashaya Rasa and Ushna Guna, Sroto Shodana and Avarana hara properties pacifies these symptoms. Therefore, in present study significant improvement was found in Kara Pada Suptata (77.19%) and Daha (76.98%).

Madhumehari Vati was found to reduce the fasting blood glucose and post prandial blood glucose levels calculated by 'paired 't' test'. Mean Difference in fasting blood glucose, post prandial blood glucose and HbA1C is 20.30 (at p<0.05) and 42.44 (at p<0.001), 0.97 (at p<0.05) respectively, which are statistically significant. It has been found that most of the ingredients of Madhumehari Vati are having hypoglycaemic, antidiabetic activity, hepatoprotective, hypolipidaemic and antioxidant effects. ¹⁷⁻²³ Overall statistically significant improvement was found in all subjective parameters and in FBS, PP₂BS level after eight weeks.

CONCLUSION

The Madhumehari Vati has all the potential to be used as a standard Ayurvedic model protocol for Madhumeha (DM) patients. Most of the ingredients of Madhumehari Vati have known hypoglycaemic, antidiabetic activity, Hepatoprotective, hypolipidaemic and antioxidant effects. In clinical trial Madhumehari Vati showed significant improvement in cardinal symptoms like Pindikodwestana (calf muscles cramps) (56.06%), Guru Gatrata (heaviness of body) (100%), Supti (numbness) (77.19%), Karapada Daha (burning sensation in palm and soles) (76.98%), Prabhutamutrata (polyuria) (81%), Atipipasa (polydipsia) (85%), Shithila Angata

(flaccidity of body parts) (62.12%), *Swedadhikya* (excessive sweating) (87.78%), *Kshudha Adhikya* (polyphasia) (82.54%) and *Nidra Adhikya* (excessive sleep) (58.90%). Biochemical parameter like FBS, PP₂BS and HbA1c was reduced by 20.30%, 42.44% and 0.97% at the end of 8th week respectively which are statistically significant. So. we can conclude that *Madhumehari Vati* is found to be very effective in *Madhumeha* (type 2 diabetes). The effect of *Madhumehari Vati* can be further studied on a large number of patients to substantiate the results of the present study.

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