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

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Received: 19 February 2021
Accepted: 16 March 2021

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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 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 Pindikodvestana (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), Avayyama (lack of
exercise), 

\textit{Achinta} (lack of mental exercise) are the causes of Madhumeha. \textit{Madhumeha} (type 2 diabetes) is included in the \textit{Ashtamahagudas} (eight deadly and incurable imperative diseases) caused by the involvement of all \textit{Doshas} and ten \textit{Dashyas}. In Ayurveda disease type 2 diabetes can be correlated with Madhumeha.\cite{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.\cite{5,7} 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.\cite{8}

Ayurvedic management of \textit{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 \textit{Madhumehari Vati} was taken, most of the contents of \textit{Madhumehari Vati} are having \textit{Katu} (pungent), \textit{Tikta} (bitter), \textit{Kashaya} (astringent) \textit{Rasa} (taste), \textit{Laghu} (light), \textit{Raksha} (rough) \textit{Guna} (properties), \textit{Katu} (pungent) \textit{Vipaka} (taste after digestion), \textit{Ushna} (hot) \textit{Virya} (potency), \textit{Deepana}, \textit{Pachana} \textit{Kapha-\textit{Pitta Shamaka}} properties and hypoglycaemic, antidiabetic activity, Hepatoprotective, hypolipidaemic and antioxidant effects.

\textbf{Aim and objectives}

Clinical evaluation of \textit{Madhumehari Vati} in the management \textit{Madhumeha} (type 2 diabetes).

\textbf{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.

\textbf{METHODS}

\textbf{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 \textit{Madhumeha}, having signs and symptoms of \textit{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.

\textbf{Inclusion criteria}

Patients having signs and symptoms of \textit{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.

\textbf{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-Macrovascular: Retinopathy, Neuropathy and Nephropathy, -Microvascular: 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.

\textbf{Drug review}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|}
\hline
\textbf{Drug} & \textbf{Botanical name} & \textbf{Parts used (dry)} & \textbf{Qua. (mg)} \\
\hline
Mamajjak & \textit{Enicostemma littorale} Blume & Panchanga & 300 \\
\hline
Meshashringi & \textit{Gymnema sylvestre} RBr & Leaves & 250 \\
\hline
Latakaranja & \textit{Caesalpinia bonduc}cella (Linn.) Roxb. & Nut & 150 \\
\hline
Katuki & \textit{Picrorhiza kurroa} Royle ex Benth. & Root & 50 \\
\hline
Pippali & \textit{Piper longam} Linn. & Fruit & 40 \\
\hline
Rakta maricha & \textit{Capsicum frutescens} Linn. & Fruit & 8 \\
\hline
Indravaruni & \textit{Citronellol} \textit{colocynthis} Linn. & Fruit & 2 \\
\hline
\end{tabular}
\caption{Ingredients of \textit{Madhumehari Vati (Anubhut yoga)}.}
\end{table}

For this clinical trial \textit{Madhumehari Vati} was prepared and provided by Dr Vasishth’s AyuRemedies (named as Glycie tablet).

\textbf{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), Khudadhiyata (polyphasia), Pipasadhiyata (polydipsia), Kara-Pada daha (burning sensation in palms and soles), Kara-Pada Suptata (numbness in palms and foot), Atisweda (excessive sweating), Dourgandhyata (bad smell), Nidradhiyata (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 middle class (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. 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).

**Table 2: Demographic profile of patients.**

| Geographical 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)          |
| Dietary habits       | Samashan      | 24 (77.41)          |
|                      | Adhyashana    | 24 (77.41)          |
|                      | Vishamashan   | 20 (64.51)          |
| Exercise             | Absent       | 18 (58.06)          |
| Work                 | Sedentary    | 20 (70.96)          |
| Addiction            | Tobacco      | 12 (38.70)          |
|                      | 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 Dhatu) (90.32%), Madhyama Satmya (suitability) (67.74%), Madhyama Sattva (physic 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%), Supit (numbness) (77.19%), Karapuda 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)          |
| Sweledadhikya       | 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 B.T. | A.T. | M.D. | Relief % | SD | SE | ‘t’ | P   |
|---------------------|----|-----------|------|------|----------|----|----|-----|-----|
| 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) |
| Sweuda Adhikya      | 29 | 0.83      | 0.50 | 0.33 | 87.78    | 0.60| 0.11| 3.01| 0.005 (S)  |
| Vrisarasar 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 | 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 Aadhikya      | 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 Difference | SD  | SE   | ‘t’   | P       |
|-------------------|-----|-----------------|-----|------|-------|---------|
|                   |     | B.T.            | A.T.|      |       |         |
| 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 Difference | SD  | SE   | ‘t’   | P       |
|-----------------|-----|-----------------|-----|------|-------|---------|
| 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 Mitravaha Srotnas on the basis that most of the ingredients are Tikta-Katu-Kashaya in Rasa having Kleda-Meda Upashoshana properties and Laghu-Ruksha in Gunas. Thus, all these properties may help to regulate the Udakavaha and Medovaha Srotas. Therefore in Prabhatamurtrata (81%) improvement was found. Ati Pipasa is a result of excessive loss of Drava Dhatu due to Prabhatamurtrata, as Madhumehari Vati reduces Prabhatamurtrata therefore simultaneously reduces Ati Pipasa (85% improvement).

Pindikodweshtana found in many 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 Srotnas by their Laghu, Ruksha, and Teekshna Gunas, Medohara and Deepana-Pachhana properties. Therefore, in Gurugratra (100%), Atiswedana (87.78%), Nadra Adhikya (17.80%), Visharasir Gandhi (78.03%) improvement was found. In Annavaha Srotnas like Kshudhadhikya (82.54%) pacified by Madhumehari Vati, Madhumehari Vati by its Tikta-Katu-Kashaya Rasa and Ushna Gunas, Sroto Shodana and Avaranara hara properties pacifies these symptoms. Therefore, in present study significant improvement was found in Kada 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 was 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. Overall statistically significant improvement was found in all subjective parameters and in FBS, PP;BS 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 Madhumehi Vati have known hypoglycaemic, antidiabetic activity, Hepatoprotective, hypolipidaemic and antioxidant effects. In clinical trial Madhumehari Vati showed significant improvement in cardinal symptoms like Pindikodweshtana (calf muscles cramps) (56.06%), Guru Gaarata (heaviness of body) (100%), Supti (numbness) (77.19%), Karapada Daha (burning sensation in palm and soles) (76.98%), Prabhatamurtrata (polyuria) (81%), Atipipasa (polydipsia) (85%), Shithila Angata (numbness) (85%), Jataragni Antidiabetic activity.
(flaccidity of body parts) (62.12%), Swedadhiyka (excessive sweating) (87.78%), Kshudha Adhikya (polyphasia) (82.54%) and Nidra Adhikya (excessive sleep) (58.90%). Biochemical parameter like FBS, PP-BS 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.

ACKNOWLEDGEMENTS

Authors would like to thanks to the authorities of institute of teaching and research in Ayurveda, ministry of AYUSH, govt. of India, Jamnagar, Gujarat, for providing facilities to carry out research work and Dr Vasishth’s AyuRemedies for providing trial drug.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Sharma SK, Dave AR, Vasishth B, Sharma V. A clinical study to evaluate the role of Madhumehari Vati in the management of Madhumaha type 2 diabetes. Int J Adv Med 2021;8:574-9.