

Dietary interventions and life style modifications on biochemical parameters in type2 diabetes mellitus (Madhumeha) - a clinical study

Abstract

Background: *Sahaja/Kulaja/Jataja* (Hereditary) and *Apathyanimittaja Prameha/Madhumeha* (diabetogenic diet & activity) are the two important etiological factors explain the heterogenous nature of Type 2 diabetes mellitus. Habitual consumption of roasted or dry Barley (*Hordeum vulgare*) flour, *Mudga* (*Phaseolus aureus*) and *Amalaka* (*Emblica officinalis*) prevents the manifestation of *Prameha*.

Aim: To evaluate the effect of dietary interventions and life style modifications in *Madhumeha* (T2DM) on biochemical parameters and other subjective criteria's.

Settings and design: Randomly 100 patients of *Madhumeha* (Type2DM) from OPD & IPD of S.S. Hospital *Ayurveda* wing and Endocrine O.P.D were selected for the present study. Selection of patients was done by using subjective and objective criteria's.

Methods and material: Randomly 64 patients of T2DM were selected from S.S. Hospital, BHU for the present study. Dietary interventions and life style modifications schedule was prepared based on Ayurvedic principles and advised the patients to follow this regimen for three months at one month interval. Statistical Package of Social Science (SPSS) version 20.0 used to analyze the data. Chi square test was used to analyze the urine sugar results.

Observation & results: We have observed that improvement in FPG, 2hPG, HbA1c, S. Cholesterol, S. Triglyceride, S. HDL, S. VLDL. Statistical analysis shows that the improvement was highly significant.

Conclusion: Dietary interventions and life style modifications are the two important tools to control newly diagnosed T2DM patients and in patients who are on antidiabetic medication but not properly controlled.

Keywords: Madhumeha; T2DM; Yava; Mudga; Amalaka; Blood Sugar; HbA1c; Lipid Profile

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Archana Gupta,¹ PS Byadgi,¹ Agarwal NK²¹Department of Vikriti Vigyan, Banaras Hindu University, Varanasi²Department of Endocrinology, Banaras Hindu University, Varanasi

Correspondence: PS Byadgi, Assistant Professor, Department of Vikriti Vigyan, Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi-221005, India, Tel 08375-281233, Email psbyadgi@rediffmail.com

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Introduction

Madhumeha (T2DM) is a multi factorial disease develops due to abnormal interaction of *vata* dominant three *doshas* with ten *dusyas*.^{1,2} It is a group of metabolic disease characterized by polyuria, polydipsia, polyphagia and reduction of weight. *Madhumeha* (T2DM) is a heterogenous disorder that results from all interaction between genetic predisposition and environmental factors.³ *Sahaja/Kulaja/Jataja* and *Apathyanimittaja*.⁴ (diabetogenic diet & activity) are the two important etiological factors explain the heterogenous nature of this disease. Incidence of this disease increases with age due to natural dominancy of *vata* in the old age.⁵ The global pandemic principally involves type 2 diabetes mellitus and is associated with greater longevity, obesity, unsatisfactory diet, sedentary life style and increasing urbanization. Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use can prevent or delay the onset of type 2 diabetes mellitus.⁶ Treatment principle of *Madhumeha* includes biopurification therapy, palliative care, rejuvenation therapy and dietary interventions and life style modifications. *Ayurvedic acharayas* have widely described the role of diet and activities to control *Madhumeha* along with medications. Habitual consumption of roasted or dry Barley (*Yava*) flour, *Mudga* and *Amalaka* prevents the manifestation of *Prameha*.¹ In new cases of diabetes, adequate glycemic control can be obtained by diet and life style advice alone in approximately 50%, only 20-30% will need oral anti diabetic drugs and 20-30% will require insulin.⁶

The drastic disease diabetes can be controlled by giving comprehensive attention to 3 aspects. They are *Ahara* (Diet), *Vihara* (life style modifications) and *Aushadha* (medicine).^{1,4} The role of *Ahara* & *Vihara* are equally or even more important in diabetes to control blood sugar level as well as to prevent complications of this disease. In a patient with suspected type 2 diabetes mellitus, the first line of therapy involves advice about dietary & life style modifications.

Aim of study

To evaluate the effect of dietary interventions and life style modifications in *Madhumeha* (T2DM) on biochemical parameters.

Materials and methods

Registration of subjects and sample collection

The present study was carried out in the OPD & IPD of *Ayurveda* wing and Endocrine O.P.D of the Sir Sunderlal Hospital, Institute of Medical Sciences, Banaras Hindu University from August 2011 to November 2012. The study was approved by the ethical committee of the Institute of Medical Sciences (IMS), Banaras Hindu University (BHU). This clinical study was not registered under The Clinical Trial Registry. Consent form was taken by each and every patient. 64 patients of *Madhumeha* (Type2DM) from OPD & IPD of S.S. Hospital *Ayurveda* wing and Endocrine O.P.D were selected for the present study. Selection of patients will be done by using subjective

and objective criteria. Registered patients were advised to follow dietary interventions (Especially emphasis on *Amalaki*, *Yava*, and *Mudga*) and life style modifications strictly as per our advice and informed them to come to next follow up at one month interval for 3 consecutive months along with ancillary investigations (Plasma glucose level, Lipid profile, HbA1c, Urine investigations) to report the changes in biochemical parameters after following the dietary interventions and life style modifications.

Compliance method to assess life style modifications and dietary changes

Habitual consumption of roasted or/and dry Barley (*Yava*) flour, *Mudga* and *Amalaka* prevents the manifestation of *Prameha* mentioned in *Ayurveda*. In new cases of diabetes, adequate glycaemic control can be obtained by diet and life style advice alone in approximately 50%, only 20-30% will need oral antidiabetic drugs and 20-30% will require insulin. Knowledge, motivation, skills, and resources of both sciences were provided to patients to follow recommendations related to life style modifications and dietary changes. Compliance to life style modifications and dietary changes mediates or facilitates achievement of the desired outcome were convinced to each and every patient and also educated the benefits and consequences of the intervention. Compliance with recommendations may vary from patient to patient and within individual patients. Hence each patient counseled thoroughly and convinced the importance of therapy. Moreover interventions are designed in such a way that a patient can incorporate those recommendations into his or her daily routine without much difficulty. In each follow up patients were motivated to adhere to strategies. We provided them diaries to maintain daily records. We also maintained follow up through phone calls in case if the patient denies writing daily record or if patient is uneducated. Visual analogue scales were used to assess the regimen follow up. We included those patients who adhered to 100% compliance. Inability to pay care for interventions of therapy resulted in drop out from the study. Hence out of 100 patients only 64 patients were included because they followed regimen as per our advice to the fullest extent. Patient's were also skilled to learn tasks such as reading food labels, selecting appropriate foods in restaurants, and incorporating taking medications into his or her daily routine. Sometimes multiple skills were adopted for patients to comply with new behaviors and maintain

them over time or to give up established unhealthy behaviors. Once they convinced after that they registered for our study. Patients were advised to incorporate self-reminders into their daily routine, and advised them to adapt to changes in their schedules and environment.

Inclusion criteria

Age of patients in between 25-75 years and who fulfilled the criteria of diagnostic features of *Madhumeha* (Type 2 Diabetes Mellitus) were included in the present study. Freshly diagnosed patients were included in our study.

Exclusion criteria

Patients with Type 1 DM, Patients with Type 2 DM who were insulin dependent and with severe diabetic complications like cardiovascular diseases, nephropathy, and retinopathy. Total 100 patients were registered for the study out which only 64 completed follow ups. Hence data mentioned only for 64 patients. Patients who are not willing to participate in the study are rejected.

Statistical analysis

To enable the appropriate statistical analysis by using the Statistical Package of Social Science (SPSS) version 20.0.⁷ Data was analyzed statistically in terms of Mean score (M), Standard Deviation (S.D.). Paired 't' test was carried out at the level of 0.05, 0.01, 0.001 of 'P' value. Statistical comparison was made between initial and final follow up results. Therefore paired 't' test was used. Chi square test was used to analyze the urine sugar results.

Observations and results

Food is an important substance to cause strength, color and vitality of living beings. Increase, decrease and homeostasis of *doshas* depend on the influence of various tastes. From present clinical study, after three consecutive follow up we have observed the significant improvement in biochemical parameters.

The study reveals that mean gradually decreases in both FPG and 2hPG at I, II and III consecutive follow up which was done for 3 months at the interval of one month. Improvement in FPG and 2hPG are 51.22% and 57.90% respectively. Statistical analysis shows that the improvement was highly significant at P < 0.001 (Table 1).

Table 1 Improvement in Fasting Plasma Glucose (FPG) and 2h Plasma Glucose (2hPG) Level

Blood Sugar	Mean ± SD(n=64)			
	(Initial)I	(1 st Follow) F1	(2 nd Follow) F2	(3 rd Follow) F3
FPG	211.42±64.17	154.91±45.15	122.79±28.01	103.13±17.22
2hPG	332.76±84.65	239.18±67.60	180.88±48.16	140.06±26.96

The study reveals that mean initial score for HbA1C was 9.91, which reduced to 6.72, i.e. 32.19% improvement occurred. Statistical analysis shows that the improvement was highly significant at P < 0.001 (Table 2).

Table 2 Glycosylated hemoglobin(HbA1c)

HbA1C	Mean±SD(n=64)		Within the Group Comparison (Paired t-Test) 3.19±1.53 t = 16.66 p < 0.001*(H.S.)
	Initial(I)	Final(F)	
HbA1C	9.91±2.25	6.72±1.19	

The study reveals that mean score for Serum Cholesterol was 209.18 in the beginning, which was reduced to 147.75, showing 29.37% improvement. Mean score for Serum Triglyceride, before dietary interventions was 198.29 which was reduced to 141.45 with 28.67% relief. Serum HDL means increases after dietary interventions and life style modifications. 36.16% improvement occurs. The mean score for Serum VLDL was 54.51 in the beginning, which was reduced to 35.76 at the end of final follow up, showing 34.40% improvement. Statistical analysis of all values shows that the improvement was highly significant at P < 0.001 (Table 3).

Table 3 Lipid profile

	Mean ± SD(n=64)			
	(Initial) I	(1 st Follow) F1	(2 nd Follow) F2	(3 rd Follow) F3
S. Cholesterol	209.18±58.51	175.76±42.12	149.75±38.24	147.75±37.35
S. Triglyceride	198.29±84.30	171.06±59.02	153.80±52.28	141.45±48.39
S. HDL	39.38±7.31	45.89±6.93	53.20±6.35	53.62±6.77
S. VLDL	54.51±26.29	47.05±18.34	38.98±14.46	35.76±12.84

The study reveals that slightly mean difference was observed in case of blood urea between before and after dietary interventions and life style modifications which shows statistically improvement at P<0.05. But there is no significant mean difference occurred in case of serum creatinine which is statistically insignificant at P>0.05 (Table 4).

Table 4 Blood Urea & Serum Creatinine

	Mean ± SD(n=64)			
	(Initial) I	(1 st Follow) F1	(2 nd Follow) F2	(3 rd Follow) F3
B. Urea	26.73±6.42	26.27±6.24	26.37±5.84	25.55±4.37
S. Creatinine	0.96±0.18	0.95±0.13	0.96±0.10	0.92±0.11

The study reveals that before dietary and life style interventions majority of the patient's i.e. 81.25% were having sugar in the urine but after dietary and life style interventions follow up it decreases i.e. only 21.88% patients were having sugar in the urine. Statistically it shows highly significant results (Table 5).

Table 5 Urine Sugar

Urine Sugar	Before Dietary Interventions & Lifestyle Modifications (No and % of patients)	After Dietary Interventions & Lifestyle Modifications (No and % of patients)	χ ² test
Present	52(81.25)	14(21.88)	χ ² =45.14 P<0.001
Absent	12(18.75)	50(78.12)	
Total	64(100.00)	64(100.00)	

Discussion

Prameha (Madhumeha), a syndrome, is not a new challenge for *Ayurveda*, rather it's a challenge for new generation following Ayurvedic principles. It is elaborately described since ancient age and its incidence is increasing day by day because of erratic lifestyle and diet leading to obesity followed by *Madhumeha* along with their complications. Diabetes mellitus may be correlated to *Madhumeha* which is a sub-type of *Vataja Prameha*. Acharaya *Sushruta*² and *Vagbhata*⁸ have similar opinion regarding the etiological factors. The *Apathya-nimittaja Prameha* may be due to intake of foods which aggravates *kapha, meda and mutra*, lack of exercise and other sedentary life styles and it may be compared to Type 2 Diabetes mellitus. Excessive sleep during day and night, lack of exercise, laziness and frequent and excessive use of new grains, use of new peas, black gram and other pulses along with *Ghrta, Tila, Tilapisti* etc. and the use of sugar cane juice, milk and its products, fresh wine, *Dadhivikara*, meat soups of different animals, residing in water or near water and all other materials vitiating *Kapha*, results into *Prameha* in susceptible individuals. Consuming foods that are low in fibre and high in glycemic loads is associated with increased risk of DM. The overall metabolic dysregulation associated with *Madhumeha* (DM) causes secondary patho-physiologic changes in multiple organ system that imposes a tremendous burden on the individual with DM & on the health care system. All the above etiological factors of *Prameha* are similar to the modern concept of Diabetes mellitus, which is a major health hazard affecting millions of people all over the world⁹

So *Prameha* patients must take diet which nourish the body elements but will not contribute to pathogenesis by generating excessive *Kapha, Meda, Kleda* and *Mutra*.¹⁰ It must be planned according to *agni* of patient. According to *Charaka*, Habitual consumption of roasted or/and dry Barley (*Yava*) flour, *Mudga* and *Amalaka* prevents the manifestation of *Prameha*. *Yava* (*Hordeum vulgare/Barley*) must constitute the major portion of *ahara* of *prameha* patient. *Yava* causes *santarpana* of patient without vitiating *doshas*. *Yava* possesses properties of reducing urine, mitigating fat, *pitta & kapha* & bestowing stability.¹¹ Earlier study have shown that *yava* has property of antihypertensive effect, gastrointestinal effects, sympathomimetic effects, glyceic/insulinemic effect, metabolic effects and lowers the serum cholesterol level.¹¹⁻¹³ *Amalaki* (*Emblca officinalis*) is highly nutritious and is an important dietary source of Vitamin C, minerals and amino acids. The edible fruit tissue contains protein concentration 3-fold and ascorbic acid concentration 160-fold compared to that of the apple. Several studies have shown their antioxidant & antidiabetic property also useful in heart & eye disorders.^{14,15} *Mudga* (*Phaseolus aureus*) contains 64.04% protein and fair source of calcium, iron, vitamins A and B. Sprouts are a good source of vitamin B which is important for proper functioning of nerve conduction. Several studies have also proves their hypolipidemic, hypotensive and chronotropic effects.^{16,17} *Apatarpana* i.e. weight reduction with the help of *Vihara* in the treatment of *Prameha* is described by all *Acaryas*.^{14,10} All these maneuver help to reduce *Meda* and *Kapha* which are the culprits in *Prameha*. *Sushruta* has described different types of exercises helpful for *Prameha* patients.¹⁸

In the present century, emphasis has been laid again on the importance of exercise and it is accepted all over the world now. The diabetic patient is physically an unfit individual, so far as his work performance is concerned and his work efficiency is also extremely poor. Exercise can play major role in improving the efficiency of the diabetics both through improved fitness and also through weight loss. It has also been reported that exercise improves the sensitivity of the insulin receptors even before any weight loss has occurred and also lowered blood glucose values and even normalization of the glucose tolerance test (G.T.T) in clinical diabetes.¹⁹ There is decrease in the serum triglyceride level and a fall in the total cholesterol values and improvement in the delivery of oxygen to the periphery. Vagbhata has given great importance to exercise for the treatment of diabetes and suggested walking even for a few miles for long time.²⁰ Limitations of the present clinical study are registration of less number of samples, scarcity of fund, study is part of time bound programme and no inclusion of individuals from various places i.e. south, east and west. The major limitation of the study includes non inclusion of a control group.

Conclusion

Dietary interventions and life style modifications are adequate to control the newly diagnosed *Madhumeha* (T2DM) patients. These tools are also helpful for glycemic control in patients who are on anti-diabetic medication but not properly controlled. Dietary interventions and life style modifications improved glycemic control, insulin sensitivity and cardiovascular fitness. Hence, reduction of plasma glucose level, hyperlipidaemia and hypertension was observed in our study. Reduction of the signs and symptoms, weight and body mass index (BMI) also indicates that dietary interventions and life style modifications are important tools for the management of *Madhumeha* (T2DM).

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Conflict of interest

The authors declare that there is no conflict of interest.

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