Int. J. Ayur. Pharma Research, 2015;3(2):51-59 **ISSN: 2322 - 0910**

International Journal of Ayurveda and Pharma Research

Research Article

CLINICAL EVALUATION OF *MADHUPRAMEHARI VATI* IN THE MANAGEMENT OF *APATHYANIMITTAJA PRAMEHA* W.S.R. TO DIABETES MELLITUS TYPE II

Naresh Kumar Kumawat[1]*, Harish Bhakuni[2], Daya Shankar Mishra[3]

[*1]Assistant professor, Ayurved vishwabharti, GVM, sardar shahar, Churu, Rajasthan, India.

[2]Lecturer, [3]Associate Professor, P.G. Dept. of Kayachikitsa, National Institute of Ayurveda, Jaipur, India.

Received on: 25/01/2015 Revised on: 15/02/2015 Accepted on: 22/02/2015

ABSTRACT

Type-2 Diabetes Mellitus is a persistent health problem that requires innovative strategies to improve health and needs a multifactorial approach for the treatment. *Madhupramehari Vati* an *Ayurvedic* medicine consists of maximum number of *Rasayana* and *Yogvahi* drug i.e. *Shilajatu* (Black Bitumen), *Swarnamakshika* (Copper Pyrites), *Amalaki* (*Emblica officinalis*), *Haridra* (*Curcuma longa*) etc. which act as a *Naimittika Rasayana*. The total number of Patients 33 were divided into two groups named as group A (16 patients of prediabetes or impaired fasting glucose {IFG} and impaired glucose tolerance {IGT} clinically diagnosed) was given *Madhupramehari Vati* 500 mg in tablet form twice a day before taking meal for 60 days and group B (17 patients of diabetics clinically diagnosed) was given *Madhupramehari Vati* 500 mg with *Triphala Kwath* of 50 ml twice a day before taking meal for 60 days. The patients were provided a proper diet chart planned according to the classics and to maintain a routine of 30 minutes walk in the morning and in the evening hours, *Pranayama* daily for 30 min in morning hours. Glycosylated hemoglobin (serum HbA1c) was evaluated in eight patients which showed statistically highly significant results. There were also statistically significant results in the fasting blood sugar (FBS) and post prandial blood sugar (PPBS) parameters, both groups.

KEYWORDS: *Madhupramehari Vati*, Apathyanimittaja Prameha, Diabetes Mellitus, Hb1Ac, *Pranayama*, *Naimittika Rasayana*.

INTRODUCTION

The World Health Organization (WHO) report shows that 32 million people had diabetes in the year 2000[1]. Type-2 diabetes is the result of a progressive impairment of pancreatic β-cell function in the setting of worsening insulin resistance. Studies have demonstrated that during progression to diabetes, β-cells have declining function and lose the first phase of insulin secretion, resulting in less than adequate suppression of hepatic glucose production following meals. Type-2 diabetes mellitus is one of the most prevalent life style disorders in present era. The disease affects more than 50 million Indians (7.1% of the Nation's adults) and kills about 1 million Indians in a year. In Ayurveda, the science of life mentions, '*Madhumeha*' is considered as disease of vitiated *Vata* and *Kapha Dosha* and *Agnimandya* is present in *Madhumeha*. *Acharya Charaka* has used term "*bahudrava shleshma tatha avabadha meda*" in the description of *Prameha* and *Dushyas* involved in it are mainly *Meda, Mamsa, Kleda, Shukra, Shonita, Vasa, Majja* etc. are all *Kapha vargiya*. The trial drugs *Madhupramehari Vati* and *Triphala Kwath* are having properties of *Naimittika Rasayana and Yogvahi.*

Aims and Objectives

- To assess the efficacy of the *Madhupramehari Vati* in the management of a series of patients of *Madhumeha* in relation with D.M.II.
- To assess the efficacy of the *Madhupramehari Vati* in the management of a Series of patients of *Madhumeha* in relation with D.M.II with *"Triphala Kwath"* as an *Anupana.*
- To compare the effectiveness of *Madhupramehari Vati* and *Madhupramehari Vati* with *Triphala Kwath.*

Materials and Methods

Madhupramehari Vati[2] having following contents: *Vanga Bhasma* (Stannum), *Sudha*

Shilajatu (Black Bitumen), *Loha Bhasma* (Ferrum), *Swarnamakshika Bhasma* (Copper Pyrites) in one part each and *Lodhra Ghana* (*Symplocos racemasa, root*), *Udumbara Saar* (*Ficus golmerata* root bark), *Jambu* (*Syzygium Cumini,* fruit seed), *Daruharidra* (*Berberis aristata, root*), *Haridra* (*Curcuma longa, rhizome*) in forth part of each. Firstly make *Udumbara Saar* and *Lodhra Ghana* than 75 gms each of *Vanga Bhasma, Sudha Shilajatu, Loha Bhasma* & *Swarnamakshika Bhasma* mixed in *"Lodhra Ghana".* Finally, each 300gms of *Jambu* Seeds *Churna, Haridra Churna, Daruharidra Churna and Udumbara Saar* mixed in *"Lodhra Ghana".* After mixing of all ingredients, a 500 mg tablet was prepared by adding *Triphala Kwath.*

***Triphala Kwath*:** *Haritaki* (Terminalia Chebula), *Vibitaki* (Terminalia bellerica), *Amalaki* (Emblica officinalis) in equal quantity and make *Kwath* in the dose of 50 ml with *Madhu.* Each 8 gms of *Haritaki, Vibitaki and Amalaki* packed in one pouch of total 24 gms for 1 day. This is used in twice a day. All the procedure was done in the department of *Rasa Shastra* and *Bhaisajya Kalpana* (pharmacy) at NIA, Jaipur.

Selection of Cases: The study was an open trial, randomized, clinical trial using pretest-posttest design and the study population was collected from the OPD and IPD of P.G. Department of Kayachikitsa at Arogyashala, National Institute of Ayurveda and SSBH, Jaipur (Raj.) The study was conducted on 30 clinically and pathologically diagnosed patients of *Madhumeha* [DM 2].

Inclusion Criteria

The following inclusion criteria was followed for selecting the patients-

- Type II DM- patients
- Patients having hyperglycemia confirmed by Laboratory Investigation.
- Patients with impaired fasting glucose {IFG} and impaired glucose tolerance {IGT} clinically diagnosed.
- Age group between 30-70 yrs of either sex.

Exclusion Criteria

Following patients excluded from clinical trial:

- Patients having Type - DM I [IDDM]
- Age below 30 and above 70 years.
- Patient of type II DM who are on Insulin therapy.
- DM associated with any type of Malignancy.
- DM with complications.
- Diabetes insipidus.
- Patient having any serious illness.
- Drug induced DM.
- FBS [>250mg/dl]
- PPBS [>300mg/dl]
- DM with coronary artery diseases.

Parameters of evaluation: Subjective parameters:

1) *Prabhoot Mutrata* (Polyurea)

a) Quantity of urine

1.50 to 2.00 litters / 24 hrs.	:	0
>2.00 to 2.50 litters / 24 hrs.	:	1
>2.50 to 3.00 litters / 24 hrs.	:	2
>3.00 litters / 24 hrs.	:	3

b) Frequency of urine

3 – 5 times per day, no or rarely at night	:	0
6 – 8 times per day, 1 – 2 times per night	:	1
9 – 11 times per day, 3 – 4 times per night	:	2
> 11 times per day, > 4 times per night	:	3

2) *Pipasa - Adhika* (Polydipsia)

Feeling of thirst 7 – 9 times/24 hours, either/or Intake of water 5 – 7 times/24 hours with quantity 1.5 – 2.0 litter/24 hours	:	0
Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - 9 times/24 hours with quantity 2.0 - 2.50 liter/24 hours	:	1
Feeling of thirst 11 – 13 times/24 hours, either/or Intake of Water 9 – 11 times/24 hours with quantity 2.50 -3.00 liter/24hours	:	2
Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours	:	3

3) *Avila Mutrata* (Turbidity in urine)

Sp. Gravity	Urine Sugar	Alb.	Total score	score
1020-1025 (0)	Nil (0)	Nil (0)	0	0
1026-1030 (1)	+ (1)	+ (1)	1-3	1
1031-1035 (2)	++(2)	++(2)	2-6	2
1036-1040 (3)	+++(3)	+++(3)	3-9	3
1041-1045 (4)	++++(4)	++++(4)	4-12	4

4) *Kshudha Adhika* (Polyphagia)

As usual / routine(1 – 2 meals)	:	0
Slightly increased (3-4 meals)	:	1
Moderately increased (4– 5 meals)	:	2
Markedly increased (> 5 meals)	:	3

5) *Kara-Pada Suptata* (numbness in hand and feet)

No suptata	:	0
Kara-Pada Suptata incontinuous	:	1
Kara-Pada Suptata continuous but bearable & not severe	:	2
Kara-Pada Suptata continuous and severe & unbearable	:	3

6) *Kar Pada Daha* (Burning sensation in hands & feet)

Absent	:	0
Occasional	:	1
Continuoes	:	2
Continuous & Require some medication	:	3
Continuous & Require some medication but doesn't get relief	:	4

7) *Swedadhikya* (Perspiration)

Sweating after some strenuous or heavy work or in hot & humid weather	:	0
Profuse sweating after moderate work and movement	:	1
Sweating after little extra work than routine and movement	:	2
Profuse sweating after routine work	:	3
Sweating even at rest or in cold climate	:	4

8) *Daurbalya* (Weakness)

Can do routine exercise/work	:	0
Can do moderate exercise with hesitancy	:	1
Can do mild exercise only, with difficulty	:	2
Cannot do mild exercise too	:	3

9) *Shula* (Joint Pain)

No pain	:	0
Pain in joint, routine movements normal	:	1
Pain in joint, slight limitations of movements	:	2
Pain in joint, limitations of movements with much reduced activity	:	3

10) *ShramaSwasa* (Dyspnoea) {ATS scale}

Not troubled by shortness of breath on level or uphill	:	0
Troubled by shortness of breath on level or uphill	:	1
Walks slower than persons of same age	:	2
Stops after walking 100 yards	:	3
Breathlessness at rest		

11) *Nidradhikya* (Sleep)

Normal & sound sleep for 6 – 8 hrs. /24 hrs. with feeling of lightness and relaxation in the body & mind	:	0
Sleep> 8 -9 hrs. /24 hrs. with slight heaviness in the body	:	1
Sleep >9- 10 hrs. /24 hrs. with heaviness in the body associated with *Jrimbha*	:	2
Sleep >10 hrs. /24 hrs. with heaviness in the body associated With J*rimbha* & T*andra*	:	3

12) *Purishabadhdhata* (Constipation)

Stool passes as per normal schedule	:	0
Passes stool with strain, sometimes takes purgative	:	1
Passes stool after more than 24 hours, frequently takes purgative	:	2
Passes stool after gap of one day, normal purgatives does not work	:	3

13) *Mathunavaraisaya* (Libido)

Normal	:	0
Decreased frequency with normal performance	:	1
Decrease frequency with insufficiency	:	2
No sexual stimulation at all	:	3

14) *Pindikodveshtana* (Cramps):

No cramps	:	0
Cramps after walking more than 1 km	:	1
Cramps after walking ½ km	:	2
Inability in walking even ½ km	:	3

15. Objective Parameters: Assessment of B.M.I. (weight in kg/height in meter^2)

18.5-24.9	:	0
25 – 29.9	:	1

30 -34.9	:	2
35 -39.9		3
>40	:	4

16) Laboratory Parameters

- Hemoglobin, Total Leucocyte Count (TLC), differential leucocyte count, Erythrocyte Sedimentation Rate (ESR), CBC.
- Urine for routine and microscopic examination.
- Biochemical investigations: FBS, PPBS, lipid profile, and Serum Glycosylated Haemoglobin (S. HbA1c).

Treatment protocol

In group A (16) patients with clinically diagnosed impaired fasting glucose {IFG: 100 to 125 mg/dl} and impaired glucose tolerance {IGT: 140 to 199 mg/dl}, not taking any medication were administered *Madhupramehari Vati* 500 mg in tablet form twice a day before taking meal for 60 days and group B (17) patients with diagnosed type-2 diabetes mellitus(FBS >126 mg/dl and PPBS >200 mg/dl), not taking any medication were given *Madhupramehari Vati* 500 mg with *Triphala Kwath* of 50 ml twice a day before taking meal for 60 days.

The patients under both the groups were provided a proper diet chart planned according to the classics and keeping glycemic index of the dietary substances and calorie requirement of the patients. Simultaneously they were asked to maintain a routine of 30 min walk in the morning and in the evening hours, *Pranayama* a daily of 30 min in morning hours, 7 days a week. There was Fortnight (15 day) of follow-up, after completion of 2 months of the treatment

Statistical analysis

Evaluation of the data through statistical estimation within the group and comparison between the groups BT (Before Treatment) and AT (After Treatment) were assessed using paired and unpaired Student's t test, respectively. For comparison of the subjective parameters, Mann Whitney test was used and for comparison of the objective parameters, unpair t test with Welch correction was used. $P < 0.05$ was considered as statistically significant, $P>0.05$ was considered as statistically non significant.

Results and Observation

A total of 33 patients, in group A, 15 and in group B, 15 patients completed the study. In the clinical study maximum number (33%) of patients belonged to the age group of 40-49 years and 70% were males. Majority of them belonged to Hindu religion (70%), married (97%), urban area (70%), govt. employees (36%) and educated (84%), non vegetarian (55.5%) and were from middle class (52%) of the society. Positive family history for type-2 diabetes was found in 42% of the patients.

Mean FBS and PPBS values were 121 mg/dl and 171.46 mg/dl in group A, respectively. In group B, mean FBS and PPBS values were 172.66 mg/dl and 235.7 mg/dl, respectively, before the commencement of the treatment. In group A, mean serum cholesterol and serum triglyceride values were 187.33 mg/dl and 148.53 mg/dl, respectively. In group B, S. cholesterol and S. triglyceride were having mean values of 213.73 mg/dl and 171.33 mg/dl, respectively. In group A, mean serum LDL and serum VLDL values were 107.56 mg/dl and 29.45 mg/dl, respectively. In group B, S. LDL and S. VLDL were having mean values of 124.53 mg/dl and 35.21 mg/dl, respectively. In group A, mean value of S. HDL (Serum High Density Lipoprotein) was 49.13 mg/dl and in group B mean value for S. HDL was 51.33 mg/dl. Mean S. HbA1c value in eight patients of group B was 7.22 %. In group A, 2+ urine sugar was present in 13.33 % of the patients and 1+ in 18.75 % patients. In group B, 4+ urine sugar was found in 11.76 % of the patients, followed by 3+ in 17.64 %, 2+ in 23.52 %, and 1+ urine sugar in 29.4 % of the patients.

Effect of the therapies on subjective parameters

There was a statistically significant result on subjective parameters in both groups except in *Hasta Padtal Daha, Swedadhikya*, *Shrama Swasa Mathunavaraisaya,* and *Pindikodveshtana* in group A and *Swedadhikya*, *Sandi Shula in* Group B, respectively. [Table No.1 & 2]

Effect of the therapies on Objective parameters

In Fasting blood sugar values (FBS), there was statistically high significant ($P < 0.001$) reduction of 13.88 % in group A and 14.98 % in group B, respectively. In Post Prandial blood sugar (PPBS), there was statistically highly significant ($P < 0.001$) reduction of 11.93 % in group A and 10.76 % in group B, respectively. In urine sugar fasting, there was statistically non significant ($P > 0.05$) reduction of 40 % in group A and statistically highly significant reduction ($P < 0.001$) of 58.33 % in group B. In S. cholesterol, there was statistically significant ($P < 0.05$) reduction of 6.93 % in group A and statistically highly significant reduction ($P < 0.001$) of 13.06 % in group B. In S. triglyceride, there was statistically non significant ($P > 0.05$) reduction of 12.74 % in

group A and statistically significant reduction ($P < 0.05$) of 12.52 % in group B. In S. HDL, there was statistically significant increase ($P < 0.05$) of 4.34 % in group A and statistically non significant increase ($P > 0.05$) of 3.89 % in group B. In S. LDL, there was statistically non significant ($P > 0.05$) reduction of 4.12 % in group A and statistically highly significant reduction ($P < 0.001$) of 14.73 % in group B. In S. VLDL, there was statistically non significant ($P > 0.05$) reduction of 4.25 % in group A and statistically significant reduction ($P < 0.05$) of 17.03 % in group B. [Table No. 3&4]. In BMI, there was statistically non significant ($P > 0.05$) reduction of 27.27 % in group A and statistically significant reduction ($P < 0.05$) of 27.27 % in group B. [Table No. 5&6]. There was insignificant increase in S. creatinine and S. urea in group A and group B. [Table No. 7]. There was statistically highly significant ($P < 0.001$) reduction of 7.78 % in S. HbA1c. [Table No. 8].

In intergroup comparison, subjective symptoms *Kar-Pada Suptata, ShramaSwasa* shows good relief in group B than group A and Laboratory parameters Fasting Blood Sugar, LDL shows good relief in group B than group A. [Table No. 9,10,11]

DISCUSSION

Ayurvedic texts mention *Prameha* as one of the first disease as a manifestation of obesity, which is the most prominent predisposing factor in the incident of type-2 diabetes mellitus. Life style and diet style factors such as sedentary habits, high sugar content food articles such as milk products, and sweets, which make an individual prone for the incidence of type-2 diabetes mellitus, are also mentioned in Ayurvedic texts as predisposing factors for *Apathyanimittaja Prameha*. Thus in this study, the treatment regime both in the form of lifestyle modifications as well as pharmacological intervention used. *Madhupramehari Vati* provided significant relief in almost all the cardinal symptoms. In FBS, there was statistically high significant ($P < 0.001$) reduction of 13.88 % in group A and 14.98 % in group B, respectively. Reduction of fasting blood glucose can be attributed β-cell protective and regenerative effect of the drugs like *Shilajatu*[3], *Daruharidra, Haridra*, *Udumbara*[4] and *Amalaki* in the combination which might have improved the basal insulin secretion and thus, might have reduced the hepatic gluconeogenesis also. In PPBS and Urine sugar showed statistically significant. It can be attributed insulin secretagogues effects and increase the glucose uptake in insulin sensitive tissues such as muscles and fat, also such drugs like *Haridra, Jambu*[5] *and Triphala. Triphala*[6] proves an antibacterial, antiviral, antioxidant, maintain GIT motility, and have Lipid Lowering and Antiatherosclerotic Effects.

The *Rasa* like *Tikta* has also potency to improve the basic cellular metabolism due to their *Shodhana* properties while *Kasaya Rasa* not only reduces the peripheral resistance as well as clinical manifestation of the disease. *Katu rasa* stimulates *Pachakagni* desiccants the food, removes obstruction and dilates the passages and allays *Kapha Doshas*. Its main pharmacological action is *Amapachana* and make *Ama* stable (it obstructs the processing of product of digestive impairment i.e. *Ama*) which helps in glucose uptake in insulin sensitive tissues like as muscle, fats etc. by enhancing activity of insulin receptor. (*Aavaranagana* effects).

Madhura Rasa being habituated since birth produces greater strength in *Srotasa*, *Dhatus* (tissues) and improves the strength of *Oja* due to their *Ojovardhaka*, *Rasayana* and *Yogvahi* properties which play an important role in pathogenesis of *Madhumeha.* In pathogenesis of Madhumeha, *Vata Dosha* is predominant factor. For controlling of *Vata Dosha,* the contents of *Madhupramehari vati* and *Triphala Kwath* have properties of *Rasayana* and *Yogvahi* effects.

There was statistically highly significant reduction ($P < 0.001$) in S. HbA1c levels carried out in a selected number (n =8) of the patients in group B. This reduction can be attributed to the multifactorial, i.e., *Pramehaghna* (*Jambu, Amalaki, Haridra etc.*), *Medohara* (*Haridra, Udumbara etc.*), *Rasayana*[7] (*Triphala*, *Amalaka etc.*) effect of the ingredients of the combination. Significant reduction in S.HbA1c levels shows good glycemic control for the long term as well as significant improvement in the lipid profile besides reduction in oxidative stress related to hyperglycemia. There was insignificant results in the S. urea and S. creatinine indicate that there is no harmful in the renal functions and thus *Madhupramehari Vati* does not cause any renal impairment.

CONCLUSION

The treatment regime mentioned for *Madhumeha* can be a worth for the management of the type-2 diabetes by countering its complex pathology. The *Pramehaghna* (Antidiabetic), *Medohara* (Antihyperlipidemic), and *Rasayana* (Anti-oxidant and rejuvenate action) property of the Ayurvedic drugs not only ensures good glycemic control when supported by *Pathya* and *Apathya* mentioned for *Prameha* but also will delay its complications.

Table 1: Table showing Effect of therapeutic trial on clinical symptomatology in 15 patients of *Madhumeha* (DM) on Group A

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Prabhoot Mutrata (polyurea) a)Quantity of urine	2.13	1.2	0.93	0.25	0.06	14	<0.001	43.75	H.S.
b) Frequency of urine	1.46	0.6	0.86	0.35	0.09	9.53	<0.001	59.09	H.S.
Pipasaadhikya (Polydipsia)	1.4	0.8	0.6	0.50	0.13	4.58	<0.05	42.85	S.
Avila mutrata (Turbidity in urine)	1.33	0.66	0.66	0.48	0.12	5.29	<0.05	50	S.
Kshudhadikya (Polyphagia)	1.4	1.13	0.26	0.70	0.18	1.46	>0.05	19.04	N.S.
Kar-Pada Suptata (Numbness in hand and feet)	0.73	0.33	0.4	0.50	0.13	3.05	<0.05	54.54	S.
KarPada Daha (Burning in hand and feet	0.73	0.4	0.33	0.48	0.12	2.64	>0.05	45.45	N.S.
Swedadhikya (Perspiration)	1	0.66	0.33	0.81	0.21	1.58	>0.05	33.33	N.S.
Daurbalya (weakness)	1.4	0.6	0.8	0.41	0.10	0.02	<0.001	57.14	H.S.
Sandhi Shula (Pain in joints)	1.06	0.6	0.46	0.63	0.16	2.82	<0.05	43.75	S.
Shramaswasa (dyspnoea)	1.13	0.93	0.2	0.67	0.17	1.14	>0.05	17.64	N.S.
Nidradhikya (Sleep)	1.13	0.33	0.8	0.41	0.10	7.48	<0.001	70.58	H.S.
Purishabadhdhata (Constipation)	1.53	0.53	1	0.65	0.16	5.91	<0.001	65.21	H.S.
Mathuna Varyasaya (loss of libido)	1.2	0.93	0.26	0.59	0.15	1.73	>0.05	22.22	N.S.
Pindikodveshtana (Cramps)	0.93	0.6	0.33	0.72	0.18	1.78	>0.05	35.71	N.S.

Table 2: Table showing Effect of therapeutic trial on clinical symptomatology in 15 patients of *Madhumeha* (DM) on Group B

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Prabhoot Mutrata (polyurea) a)Quantity of urine	2	1.13	0.86	0.51	0.13	6.5	<0.001	43.33	H.S.
b) Frequency of urine	1.6	0.93	0.66	0.48	0.12	5.29	<0.05	41.66	S.
Pipasaadhikya (Polydipsia)	1.8	0.93	0.86	0.35	0.09	9.53	<0.001	48.14	H.S.
Avila mutrata (Turbidity in urine)	2	1.13	0.86	0.35	0.09	9.53	<0.001	43.33	H.S.
Kshudhadikya (Polyphagia)	1.8	1.33	0.53	0.63	0.16	3.22	<0.05	28.57	S.
Kar-Pada Suptata (Numbness in hand and feet)	1.6	0.66	0.93	0.25	0.06	14	<0.001	58.33	H.S.
KarPada Daha (Burning in hand and	1.06	0.6	0.46	0.51	0.13	3.5	<0.05	43.75	S.

feets									
Swedadhikya (Perspiration)	1.13	1	0.13	0.83	0.21	0.61	>0.05	11.76	N.S.
Daurbalya (weakness)	1.46	0.66	0.8	0.56	0.14	5.52	<0.001	54.54	H.S.
Sandhi Shula (Pain in joints)	1.2	1.06	0.13	0.74	0.19	0.69	>0.05	11.11	N.S.
Shramaswasa (dyspnoea)	2.13	1.46	0.66	0.61	0.15	4.18	<0.05	31.25	S.
Nidradhikya (Sleep)	1.53	0.46	1.06	0.25	0.06	16	<0.001	69.56	H.S.
Purishabadhdhata (Constipation)	1.8	0.8	1	0.53	0.13	7.24	<0.001	55.55	H.S.
Mathuna Varyasaya (Libido)	1.4	1.06	0.33	0.72	0.18	1.78	>0.05	23.80	N.S.
Pindikodveshtana (Cramps)	1.13	0.73	0.4	0.63	0.16	2.44	>0.05	35.29	N.S.

Table 3: Table showing Effect of therapeutic trial on Laboratory parameters in 15 patients of *Madhumeha* (DM) based on Group A

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Fasting Blood Sugar (mg/dl)	121	104.2	16.8	7.58	1.95	8.57	<0.001	13.8	H.S.
Post Prandial Blood Sugar (mg/dl)	171.4	151	20.4	11.38	2.94	6.96	<0.001	11.93	H.S.
Urine Sugar(fasting)	0.33	0.2	0.13	0.51	0.13	1	>0.05	40	N.S.
S. Cholesterol mg/dl	187.3	174.3	13	17.3	4.47	2.9	<0.05	6.93	S.
S. Triglycerides mg/dl	148.5	129.6	18.93	37.55	9.69	1.95	>0.05	12.74	N.S.
HDL mg/dl	49.13	51.2	2.13	2.16	0.55	3.81	<0.05	4.34	S.
LDL mg/dl	107.5	103.1	4.43	18.3	4.72	0.93	>0.05	4.12	N.S.
VLDL mg/dl	29.45	28.2	1.25	8.96	2.31	0.54	>0.05	4.25	N.S.

Table 4: Table showing Effect of therapeutic trial on Laboratory parameters in 15 patients of *Madhumeha* (DM) on Group B

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Fasting Blood Sugar (mg/dl)	172.6	146.8	25.86	15.66	4.04	6.39	<0.001	14.98	H.S.
Post Prandial Blood Sugar (mg/dl)	235.7	210.	25.36	21.95	5.66	4.47	<0.001	10.76	H .S.
Urine Sugar(fasting)	1.6	0.66	0.93	0.593	0.15	6.08	<0.001	58.33	H.S.
S. Cholesterol mg/dl	213.7	185.8	27.93	23.0	5.93	4.70	<0.001	13.06	H.S.
S. Triglycerides mg/dl	171.3	149.8	21.46	30.31	7.82	2.74	<0.05	12.52	S.
HDL mg/dl	51.3	53.33	2	6.40	1.65	1.65	>0.05	3.89	N.S.
LDL mg/dl	124.5	106.1	18.34	8.90	2.29	0.24	<0.001	14.73	H.S.
VLDL mg/dl	35.2	29.21	6	6.34	1.63	0.24	<0.05	17.03	S.

Table 5: Table showing Effect of therapeutic trial on objective parameters in 15 patients of *Madhumeha* (DM) on Group A

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
1.Weight (Kg)	67.46	65.73	1.73	2.43	0.62	2.75	<0.05	2.56	S.
2. BMI (Kg/m2)	0.73	0.53	0.2	0.41	0.10	1.87	>0.05	27.27	N.S.

Table 6: Table showing Effect of therapeutic trial on objective parameters in 15 patients of *Madhumeha* (DM) on Group B

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
1.Weight (Kg)	72	69.2	2.8	4.95	1.28	2.18	<0.05	3.88	S.

2. BMI (Kg/m2)	1.2	0.86	0.33	0.48	0.12	2.64	<0.05	27.77	S.

Table 7: Table showing Effect of therapeutic trial on S. Creatinine and S. Uric acid in 8 patients of *Madhumeha* (Diabetes Mellitus) (n=8)

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
1.S.Creatinine mg/dl	5.56	5.7	0.13	0.26	0.092	0.122	>0.05	2.47	N.S.
2. S. Uric acid mg/dl	1.03	1.11	0.07	0.23	0.081	0.122	>0.05	7.22	N.S.

Table 8: Table showing Effect of therapeutic trial on Glycosylated Hemoglobin (Hb1Ac) in 8 patients of *Madhumeha* (Diabetes Mellitus) (n=8)

Variable	Mean		Mean Diff.	S.D. ±	S.E. ±	Paired t-test	P-value	% Relief	Sign.
	BT	AT							
Hb1Ac	7.22	6.66	0.56	0.25	0.08	6.35	<0.001	7.78	H.S.

Table 9: Intergroup comparison in subjective symptoms (Group A and Group B)

Variable	Mann Whitney U value	P-value	Sign.
1.*Prabhoot Mutrata* (polyurea) a)Quantity of urine	104.50	0.63	N.S.
b) Frequency of urine	90	0.21	N.S.
2.*Pipasaadhikya* (Polydipsia)	82.5	0.11	N.S.
3.Avila mutrata (Turbidity in urine)	90	0.21	N.S.
4. *Kshudhadikya* (Polyphagia)	88.5	0.21	N.S.
5.*Kar-Pada Suptata* (Numbness in hand and feet)	52.5	0.002	S.
6.*KarPada Daha* (Burning in hand and feets	97.5	0.47	N.S.
7.Swedadhikya (Perspiration)	97	0.50	N.S.
8.*Daurbalya* (weakness)	111	0.95	N.S.
9. *Sandhi Shula* (Pain in joints)	84.5	0.21	N.S.
10.*ShramaSwasa* (dyspnoea)	68.5	0.04	S.
11.*Nidradhikya* (Sleep)	84	0.04	S.
12.*Purishabadhdhata* (Constipation)	107	0.77	N.S.
13.*Mathuna Varyasaya* (Libido)	103.50	0.69	N.S.
14.*Pindikodveshtana* (Cramps)	108.50	0.87	N.S.

Table 10: Intergroup comparison in objective symptoms (Group A and Group B)

Variable	t value	P value	Sign.
1.Weight (Kg)	0.74	0.46	N.S.
2. BMI (Kg/m2)	0.80	0.42	N.S.

Table 11: Intergroup comparison in Laboratory parameters (Group A and Group B)

Hb gm%	**1.825**	**0.082**	**N.S.**
TLC / cumm	0.1448	0.88	N.S.
TRBC /mill/μL	0.4693	0.64	N.S.
TPLC/ lac/μL	0.00	0.9	N.S.
ESR(mm/h)	0.8541	0.40	N.S.
Fasting Blood Sugar (mg/dl)	2.017	0.05	N.S.
PP Blood Sugar (mg/dl)	0.7672	0.45	N.S.
Urine Sugar(fasting)	3.938	0.0005	H.S.
S. Cholesterol mg/dl	2.008	0.055	N.S.
S. Triglycerides mg/dl	0.2033	0.840	N.S.
HDL mg/dl	0.076	0.940	N.S.
LDL mg/dl	2.647	0.015	S.
VLDL mg/dl	1.674	0.106	N.S.

REFERENCES

1. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: Estimates for the year 2000 and projections for 2030. Diabetes Care 2004; 27:1047-53. [PUBMED]
2. Vaidhyaka Chikitsa saar, part 2, page no 93, Kalidas rachita, Director, CCRAS, New Delhi, 2008.

3. Effects of *shilajit* on blood glucose and lipid profile in alloxan-induced diabetic rats. (Indian Journal of Pharmacology (*Department of Pharmacology, Medical College, Baroda - 390 001*).
4. Hypoglycemic and Antioxidant activities of *Ficus Recemosa* Linn. Fruits. Natural product Research 2009; 23(4):399-4.
5. S.B. Sharma and A. Nasir et.al., Antihyperglycemic Effect of the fruit pulp of Eugenia Jambolana in Experimental Diabetes Mellitus. Journal of Ethan pharmacology; Voll. 104; 2006:367-373.
6. Hypoglycemic effect of Triphala on selected non insulin dependent Diabetes mellitus subjects (Department of Foods and Nutrition, RVS College of Arts and Science, KVK Thottam, Sulur, Coimbatore - 641402, India). Sowmya S. Rajan and Seema Antony et .al. Anc Sci Life. 2008 Jan-Mar; 27(3): 45–49.
7. Sushruta, Sushruta Samhita, Chikitsa Sthana, 27/1, Nibhandha Samgraha commentary, Dulhana Krita, Multilingual e-Samhita with Search Option by CCRAS, New Delhi, 2010.

Cite this article as:
Naresh Kumar Kumawat, Harish Bhakuni, Daya Shankar Mishra. Clinical Evaluation of Madhupramehari Vati in the Management of Apathyanimittaja Prameha w.s.r. to Diabetes Mellitus Type II. Int. J. Ayur. Pharma Research. 2015;3(2):51-59.
Source of support: Nil, Conflict of interest: None Declared

***Address for correspondence**
Dr. Naresh Kumar Kumawat
Assistant professor
Ayurved Vishwabharti
GVM, Sardar shahar, Churu
Rajasthan, India.
Email: drnareshbps3584@gmail.com
Ph: +918058616715