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Therapeutic trial of an Ayurvedic compound in *Madhumeha* (Diabetes Mellitus)

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ABSTRACT

Diabetes mellitus has been emerged as one of the major health problems, which is found commonly all over the world. In Ayurveda, inclusion of *Madhumeha*, in eight major diseases (*Ashthamahagada*) indicates the gravity and significant attributed to it. In this study a comparative trial between an Ayurvedic compound (*Kalpit*) named as *Madhudaman Yoga*, and Glipizide as control drug was carried out. 50 patients of Diabetes mellitus were registered from the OPD and IPD of NIA, Jaipur for this study. These patients were divided into two groups. Group A (control drug) – 25 patients took Glipizide 5 mg twice daily for 75 days. Group B (trial drug) - 25 patients took 2 capsules of *Madhudaman Yoga* 500 mg, twice daily for 75 days. At the end of the study it was observed that the trial drug showed significant improvement in FBS, PPBS, and HbA1c ($p<0.001$). Significant relieves in many symptoms were also observed. The overall effect of *Madhudaman Yoga* was approximately similar to that of the control drug. No side effects were noticed in any of the patients of the trial group.

Key words: *Madhumeha, Diabetes mellitus, Madhudaman yoga, Glipizide.*

INTRODUCTION

Diabetes mellitus has been classified among one of the major health problems, which is found commonly in socio-economically improved societies all over the world.

According to WHO about 422 million people worldwide have diabetes, the majority living in low and middle income countries, and 1.5 million death are directly attributed to diabetes each year. Both the number of cases and the prevalence of diabetes have been steadily increasing over the past few decades.[1] With an increasing incidence worldwide, DM will be a leading cause of morbidity and mortality for the foreseeable future.[2]

The disease *Madhumeha* is described in almost all available texts of Ayurveda under the sub type of *Vataja Prameha.* Its inclusion in eight major disease (*Asthamahagada*) indicates the gravity and significant attributed to it.[3,4] Acharya Charaka has described the character of excrete urine like pale in appearance, *Kashaya* and *Madhura* in taste and warm and *Ruksha* in *Guna.*[5] *Prabhuta Mutrata* (excessive urination) and *Avila Mutrata* (turbid, unclear appearance) are general cardinal symptoms of *Prameha.*[6] *Vata* is provoked due to *Dhatu Kshaya* both *Gambhira* and *Sarabhoot*. The provoked *Vata* vitiates *Oja* and excrete by *Basti* and leads to *Madhumeha.*[7]

Non enzymatic Glycosylation and Intercellular Hyperglycemia with disturbances in Polyol pathways are two metabolic events appear to be involved in the genesis of the genesis of complication of diabetes.[8]

Ayurveda is the ray of hope, which can contribute in this regard. Diabetes mellitus can be correlated to

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'Madhumeha' because they have similarities in etiology, pathogenesis, symptomatology, complications etc. Keeping in view the developing interest in therapeutic diabetology, the realization of the need to analyze *Madhumeha* from the therapeutic standpoint has emerged. There is no satisfactory treatment available in modern system of medicine for this disease. Therefore, it was decided to evaluate certain Ayurvedic drugs which could be safe, effective economical, easily available having no side effects. For this purpose, an Ayurvedic formulation (*Madhudaman Yoga*) was selected as trial drug.

Material and Methods

This study was conducted under a strict protocol to prevent bias and to reduce the sources of error in the study. This control trial study was conducted under the following steps:-

1) Selection of patients
2) Administration of Drug
3) Follow up study
4) Assessment of progress

Selection of patients

A written information and consent letter had been given to patients. The patients were explained about the purpose, procedures and possible dangers of the trial.

The patients for this study were selected from OPD and IPD of NIA hospital, Jaipur after screening them as per Ayurvedic and modern criteria for *Madhumeha*. Total 50 patients were registered for the study.

Criteria for the selection of the patient

A. Inclusion criteria

1. Patients in the age group between 20 to 80 years.
2. Diagnosed cases of Diabetes mellitus

B. Exclusion criteria

1. Patients of age less the 20 yrs and above 80 years.
2. Pregnant woman.
3. Patients with serious disorders like MI, CHF, cirrhosis of liver, severe complicated DM etc.
4. Patients taking drugs like corticosteroids, tricycle antidepressant, cycloheptadine which leads to weight gain.

Diagnostic Criteria

The criteria were developed to select the cases on clinical ground. Which is based on the signs and symptoms, described in Ayurvedic and modern texts and lab investigations.

The following laboratory criteria were used on investigation ground:

- Haematological - Hb%, TLC, DLC, ESR
- Biochemistry - FBS, PPBS, Lipid Profile
- Urine Examination - Routine & microscopic
- Specific Test - HbA_1C

Administration of drug

For this trial two drugs *Madhudaman Yoga* and Glipizide were selected. Each 500 mg capsule of *Madhudaman Yoga* consists of 250 mg of *Suddha Shilajita* and 250 mg *Ghana Satva* of seven drugs - *Puga, Khadira, Paneer Phala, Guduchi, Nimba, Tulsi, Haritaki.* This drug was prepared by classical methods in Pharmacy of N.I.A. Jaipur.

Fifty (50) selected patients of *Madhumeha* were divided into 2 groups for the drug administration as follows:

a) **Control Group (Group A) :** In this group 25 clinically and pathologically diagnosed patients of *Madhumeha* were registered. these patients were recommended one table Glipizide 5 mg twice daily, with the water before meal as allopathic drug, for 75 days.

b) ***Madhudaman Yoga - Kalpit* (Group-B) :** In this group 25 diagnosed patients of *Madhumeha* were registered. These were recommended *Madhudaman Yoga* (*Kalpit*) in the dose of 500mg two capsule twice daily with lukewarm water, for 75 days.

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Follow Up Study

- Patients were followed up after every 25 days.
- Laboratory investigation was repeated after completion of trial
- Improvement and any side effects were noted down.

Assessment of progress

The assessment of progress was made by the observations and examination of patients. Subjective & objective parameters were decided for the clinical assessment.

Subjective Parameters

- Sign and symptoms of Diabetes mellitus
- Sign and symptoms of *Madhumeha*
- *Purvaroopa* of *Prameha*
- *Dashavidha Pariksha*
- *Upadrava* of *Prameha*

for the subjective assessment, different symptoms were graded as follows:

Symptoms Grade

- Absent 0
- Mild 1
- Moderate 2
- Severe 3
- Very severe 4

These parameters were those, which a physician cannot be measure

In this study following parameters used.

1. *Prabhoot Mootrata* (Polyurea)
2. *Aavil Mootrata* (Turbidity in urine)
3. *Pipasa Adhikya* (Polydipsia)
4. *Kshuda Adhikya* (Polyphagia)
5. *Swedatipravriti* (Excessive sweating)
6. *Daurbalya* (Weakness)
7. *Atinidra* (Excessive Sleep)
8. *Kandu* (Itching)
9. *Mukhmadhuraya* (Sweetness of mouth)
10. *Hast Pada Daha* (Burning sensation in hands of feet)
11. *Mukh Talu Shosha* (Dryness of mouth)
12. *Malavritta Jihwa* (Coated tongue)
13. *Drishti Daurbalyata* (Blurry vision)
14. Tingling or numbness in hands or feet
15. Frequent infections
16. Delayed wound healing

Objective Parameters

The following parameters were assessed objectively

- Weight
- BMI
- Waist circumference
- Hip circumference
- Skin fold thickness

All investigations done on Patients in Rog Nidana evam Vikriti Vigyan Lab. NIA, Jaipur.

Result & Discussion

All the 50 patients of Diabetes mellitus registered and completed their trial were assessed for the subjective, objective, and investigational changes, if any after the study. It was observed that there was a considerable improvement in feeling of wellbeing in all the patients of both groups after the course.

Subjective Assessment

While assessing the clinical improvement after the administration of tab. Glipizide 5 mg twice daily in group- A and after administration of *Madhudaman Yoga* 2 capsules (500 mg each) twice daily in group B. The following statistical results were found according to wilcoxon matched pairs signed-rank test.

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Wilcoxon matched-pairs signed-ranks test for Subjective Assessment

T+ = Sum of positive ranks

T- = Sum of negative ranks

W = Sum of all signed rank

P = Two tailed 'p' value

Table 1: Improvement in *Prabhoota Mootrata*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.80	0.88	0.92	0.812	0.162	190	0	190	<0.0001
B	1.16	0.56	0.60	0.645	0.129	91	0	91	0.0002

Table 2: Improvement in *Avila Mootrata*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.56	0.96	0.60	0.707	0.141	78	0	78	0.0005
B	1.40	0.88	0.52	0.7141	0.143	85	6	79	0.0034

Table 3: Improvement in *Pipasadhikya*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.56	0.80	0.76	0.779	0.156	146	7	139	0.0003
B	1.24	0.68	0.56	0.820	0.164	55	0	55	0.0020

Table 4: Improvement in *Kshudhadhikya*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.36	0.64	0.72	1.021	0.204	150	21	129	0.0034
B	0.79	0.56	0.23	0.779	0.159	21	7	14	0.2969

Table 5: Improvement in *Swedatipravritti*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.36	0.72	0.64	0.568	0.114	161.5	9.5	152	0.0003
B	1.00	0.60	0.40	0.764	0.153	67	11	56	0.0269

Table 6: Improvement in *Daurbalyata*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.44	0.72	0.72	0.614	0.123	136	0	136	<0.0001
B	1.60	0.76	0.84	0.943	0.189	130.5	5.5	125	0.0003

Table 7: Improvement in *Atinidra*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	0.96	0.44	0.52	0.963	0.192	51	4	47	0.0137
B	1.36	0.84	0.52	0.770	0.154	106	14	92	0.0067

Table 8: Improvement in *Kandu*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.52	0.68	0.84	0.624	0.125	171	0	171	<0.0001
B	0.52	028	0.24	0.523	0.105	31.5	4.5	27	0.0547

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Table 9: Improvement in *Mukhamadhurya*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.28	0.60	0.68	0.627	0.125	162	9	153	0.00003
B	1.24	0.84	0.40	0.816	0.163	57	9	48	0.0322

Table 10: Improvement in *Hast-Pada Daha*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	0.92	0.36	0.56	0.583	0.116	91	0	91	0.00002
B	0.96	0.52	0.44	0.583	0.116	84	7	77	0.00046

Table 11: Improvement in *Mukh-Talu Shosha*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.68	0.96	0.72	0.678	0.135	162.5	8.5	154	0.00002
B	1.64	0.80	0.84	1.068	0.213	114.5	5.5	109	0.00006

Table 12: Improvement in *Malavritta Jihwa*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.68	0.96	0.72	0.737	0.147	120	0	120	<0.00001
B	1.56	1.04	0.52	0.653	0.130	66	0	66	0.001

Table 13: Improvement in *Drishti Daurbalayata*

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	0.68	0.20	0.48	0.586	0.117	97.5	7.5	90	0.0023
B	1.00	0.76	0.24	0.436	0.087	21	0	21	0.03313

Table 14: Improvement in Tingling and Numbness

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	0.68	0.48	0.20	0.50	0.10	24	4	20	0.1094
B	0.80	0.60	0.20	0.50	0.10	24	4	20	0.1094

Table 15: Improvement in Frequent infections

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.76	0.96	0.80	0.866	0.173	175	15	160	0.00005
B	0.72	0.40	0.32	0.476	0.095	36	0	36	0.00078

Table 16: Improvement in delayed wound healing

Group	Mean		Mean diff.	SD Diff	SE Diff	T+	T-	W	'p' value
	BT	AT							
A	1.04	0.68	0.36	0.490	0.098	45	0	45	0.0039
B	1.00	0.56	0.44	0.583	0.116	55	0	55	0.0020

Group A

Extremely significant improvement was noticed in *Prabhoota Mootrata* (p<0.0001), *Avila Mootrata* (p=0.0005), *Pipasadhikya* (p=0.0003), *Swedatipravritti* (p=0.0003), *Daurbalyata* (p<0.0001), *Kandu* (p<0.0001), *Mukh Madhurya* (p=0.0003), *Hast-Pada Daha* (p=0.0002), *Mukh-Talu Shosha* (p=0.0002), *Malavritta Jihwa* (p<0.0001) and in frequent infections (p=0.0005).

Statistically very significant improvement was noticed in *Kshudhadhikya* (p=0.0034), *Drishti Daurbalyata* (p=0.0023) and delayed wound healing (p=0.0039).

Significant improvement was noticed in *Atinidra* (p=0.0137).

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Improvement in tingling or numbness in hands and feet was considered not significant statistically (p=0.1094).

Group B

Extremely significant improvement was noticed in *Prabhoota Mootrata* (p=0.0002), *Daurbalyata* (P=0.0003) and *Malavritta Jihwa* (p=0.001) and *Mukh-Tatu Shosha* (p=0.0006).

Statistically very significant improvement was noticed in *Avila Mootrata* (p=0.0034), *Pipasadhikya* (p=0.002), *Atinidra* (p=0.0067), *Hast-Pada Daha* (p=0.0046), frequent infections (p=0.0078) and delayed wound healing (p=0.002).

Significant improvement was noticed in *Swedatipravritti* (p=0.0269), *Mukhmadhuryata* (p=0.0322) and *Drishti Darubalyata* (p=0.0322) and *Drishti Daurbalyata* (p=0.0313).

Statistically not quite significant improvement was noticed in *Kandu* (p=0.0547) and insignificant improvement in *Kshudhadhikya* (p=0.2969) and tingling or numbness in hands or feet (p=0.1094).

Objective Assessment

Body weight, Body mass index, waist circumference, hip circumference and skin fold thickness parameters were used for the objective assessment.

Objective improvement in Group - A

Objective parameter	Mean		Dif.	% of Change	SD	SE	't'	'p'
	BT	AT						
Weight	68.76	68.01	0.75	1.09	0.82	0.16	4.58	<0.001
BMI	26.02	25.72	0.30	1.14	0.32	0.06	4.67	<0.001
Waist Circumference	32.50	32.14	0.36	1.10	0.41	0.08	4.37	<0.001
Hip Circumference	35.16	34.80	0.36	1.04	0.55	0.11	3.31	<0.01
Skin fold thickness	18.28	18.04	0.24	1.33	0.30	0.06	4.05	<0.001

Objective improvement in Group - B

Objective parameter	Mean		Dif.	% of Change	SD	SE	't'	'p'
	BT	AT						
Weight	67.16	66.14	1.02	1.52	0.80	0.16	6.40	<0.001
BMI	24.98	24.59	0.39	1.55	0.30	0.06	6.40	<0.001
Waist Circumference	31.56	30.67	0.88	2.80	0.95	0.19	4.65	<0.001
Hip Circumference	36.15	35.92	0.23	0.63	0.22	0.04	5.25	<0.001
Skin fold thickness	16.01	15.68	0.33	2.05	0.37	0.07	4.42	<0.001

Group – A

Improvement in weight (p<0.001), BMI (p<0.001), waist circumference (p<0.001) and skin fold thickness (p<0.001) is statistically highly significant.

Significant improvement was observed in Hip circumference (p<0.01).

Group – B

Statistically highly significant improvement was considered in weight (p<0.001), BMI (p<0.001), waist circumference (p<0.001), Hip circumference (p<0.001) and skin fold thickness (p<0.001). These data shows that *Madhudaman Yoga* is also an effective drug for obese diabetes patients.

Changes in Hematological Investigation in Group - A

Investigation	Mean		Dif.	% of Change	SD	SE	't'	'p'
	BT	AT						
Hb	12.91	12.77	0.14	1.06	0.92	0.18	0.74	>0.1
TLC	7532.80	7652.00	119.20	1.58	11200.61	224.12	0.53	>0.1

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DLC-N	62.76	62.44	0.32	0.51	4.27	0.85	0.37	>0.1
DLC -L	32.80	32.52	0.28	0.85	4.83	0.97	0.29	>0.1
DLC -E	2.60	2.68	0.08	3.08	1.29	0.26	0.31	>0.1
DLC -M	2.08	2.40	0.32	15.38	1.25	0.25	1.28	>0.1
ESR	18.88	19.80	0.92	4.87	2.98	0.60	1.54	>0.1

Changes in Hematological Investigation in Group-B

Investigations	Mean		Dif.	% of Change	SD	SE	T	P
	BT	AT						
Hb	13.32	12.74	0.58	4.33	1.56	0.31	1.84	<0.1
TLC	7402.00	7192.00	210.00	2.84	1161.72	232.34	0.90	>0.1
DLC-N	62.00	62.44	0.44	0.71	4.85	0.97	0.45	>0.1
DLC -L	32.76	33.20	0.44	1.34	3.73	0.75	0.59	>0.1
DLC -E	2.48	2.48	0.00	0.00	1.55	0.31	0.00	-
DLC -M	2.72	2.12	0.60	22.06	1.68	0.34	1.78	<0.1
ESR	19.84	23.52	3.68	18.55	7.39	1.48	2.49	0.02

Changes in Biochemical and HbA_1C & Urine Investigation in Group – A

Investigations	Mean		Dif.	% of Change	SD	SE	T	P
	BT	AT						
FBS	148.21	119.63	28.58	19.28	14.25	2.85	10.03	<0.001
PPBS	216.56	163.15	53.41	24.66	29.28	5.86	9.12	<0.001
HbA_1C	9.10	7.45	1.65	18.12	1.15	0.23	7.16	<0.001
Cholesterol	197.91	197.04	0.87	0.44	14.75	2.95	0.29	>0.1
Tg	138.35	135.85	2.50	1.81	9.84	1.97	1.27	>0.1
HDL	46.52	47.00	0.48	1.02	2.78	0.56	0.86	>0.1
LDL	123.72	122.88	0.85	0.69	15.48	3.10	0.27	>0.1
VLDL	27.67	27.16	0.50	1.82	1.97	0.39	1.28	>0.1
FUS	0.20	0.04	0.16	80.00	0.37	0.07	2.14	<0.05
PPUS	1.04	0.32	0.72	69.23	0.84	0.17	4.27	<0.001
U. Protein	0.32	0.28	0.04	12.50	0.45	0.09	0.44	>0.1

Changes in Biochemical and HbA_1C & Urine Investigation in Group - B

Investigations	Mean		Dif.	% of Change	SD	SE	T	P
	BT	AT						
FBS	161.10	112.62	48.48	30.09	39.48	7.90	6.14	<0.001
PPBS	238.77	164.43	74.34	31.13	54.57	10.91	6.81	<0.001
HbA_1C	8.10	6.80	1.29	15.96	1.26	0.25	5.12	<0.001
Cholesterol	198.53	179.50	19.03	9.58	34.87	6.97	2.73	<0.02
Tg	147.22	136.94	10.29	6.99	27.10	5.42	1.90	<0.1
HDL	47.75	52.17	4.42	9.25	8.51	1.70	2.60	<0.02
LDL	118.50	101.57	16.93	14.28	34.97	6.99	2.42	<0.05
VLDL	30.23	27.40	2.83	9.35	6.77	1.35	2.09	<0.05
FUS	0.36	0.04	0.32	88.89	0.69	0.14	2.32	<0.05
PPUS	1.04	0.40	0.64	61.54	0.70	0.14	4.57	<0.001

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U. Protein	0.52	0.48	0.04	7.69	0.45	0.09	0.44	>0.1

Insignificant changes were observed in hematological investigations i.e., Hb (p>0.1), TLC (p>0.1), DLC (p>0.1), ESR (p>0.1) in Group A. But in Group B significant change in ESR was observed (p=0.02), rest hematological investigations Hb (p<0.1), TLC (p>0.1), DLC (p>0.1), like in Group A were insignificant.

Statistically highly significant improvement was observed in fasting Blood sugar, Post prandial Blood sugar, and HbA_1C in both Groups (p<0.001).

The patients of Group-A showed insignificant improvement in the level of S. Cholesterol (p>0.1), S. Triglycerides (p>0.1), HDL (p>0.1). LDL (p>0.1) and VLDL (p>0.1).

In Group B, significant reduction was reported in the level of S. Cholesterol (p<0.02), LDL (p<0.05) and VLDL (p<0.05), significant elevation in HDL (p<0.02) and insignificant reduction in S. Triglycerides (p<0.1) was reported in Group-B patients.

Statistically significant improvement was reported in fasting urine sugar level in Both groups (p<0.05). Highly significant reduction was reported in post prandial urine sugar level in Group-A and Group-B (p<0.001). Insignificant changes were found in urine protein in Both groups (p>0.1)

Discussion regarding effect of drug

Almost all ingredients of *Madhudaman Yoga* have been described in Ayurvedic Samhitas as parts of *Anti Madhumeha Yogas.* These all ingredients of *Madhudaman Yoga,* individually have the capacity to lower blood sugar but in *Ghana Satva* combination form, the results are tremendous, not only on controlling blood sugar but also dyslipidemia & obesity.

Most of the drugs contained in *Madhudaman Yoga* have properties like *Vata-Kapha Shamak, Deepana, Rasayana, Pachan, Medohara, Shoshana.* These are likely to break down the *Samprapti* of *Madhumeha* (DM).

This drug probably may increase insulin secretion from pancrease, decrease hepatic gluconeogenesis, increase glucose uptake in the periphery or decrease insulin resistance, further research is required to establish these mechanisms.

No any side effect was detected during the drug trial.

Conclusion

Significance of symptomatic relief in patients taking *Madhudaman Yoga* is just similar to the effect of the control drug, Glipizide. But no side effect of *Madhudaman Yoga* was observed in this trial. There is highly significant improvement in FBS, PPBS, HbA_1C and PPUS in the patients who were treated with the trial drug. Statistically significant results was observed in controlling dyslipidemia and this drug was found to be beneficial in weight reduction.

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