Research Article

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A RANDOMISED CLINICAL STUDY TO EVALUATE THE EFFICACY OF AN AYURVEDIC FORMULATION IN THE MANAGEMENT OF MADHUMEHA WITH SPECIAL REFERENCE TO DIABETES MELLITUS

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ABSTRACT

Stress at work with various physical, biological, chemical and socio-economic factors contribute to day to day increased incidence of diabetes mellitus. Ayurveda is a rich treasure of safe and traditional materia medica which provides a promising field of drug research. An indigenous drug may not be as potent in lowering the blood sugar level as insulin but it may possess many other qualities which may make it more useful for the holistic management of the disease. In present study, an Ayurvedic formulation i.e. Madhumehar Yoga was assessed in terms of blood sugar levels as well as symptomatic relief in Madhumeha. A clinical trial was conducted on 69 subjects in whom 61 subjects completed the study. In trial Metformin (group I) shows 34.57% reduction in FBS while 26.85% reduction was observed in Ayurvedic formulation (group II). Reduction in FBS was statistically highly significant ($p<0.001$) in both the groups and the intergroup difference was statistically insignificant ($p>0.05$). Urine sugar was reduced by 100% in metformin and 93% in Ayurvedic formulation which is statistically highly significant ($p<0.001$) in both the groups and the intergroup difference was statistically insignificant ($p>0.05$). Considerable improvement in blood sugar levels and all signs and symptoms was observed in both groups. The study revealed that both the therapies were significantly effective in the management of Madhumeha, Ayurvedic drugs showed better efficacy on subjective parameters but Metformin was somewhere superior in lowering down the blood sugar levels.

Keywords: Madhumeha, Diabetes Mellitus, Ayurvedic formulation, Metformin.

INTRODUCTION

Diseases are like curse to the healthy life and manifest themselves as a hindrance in leading a happy and prosperous living. Day to day stress at work and at home adds to the hostile environment against good health. In this pursuit, it has always been felt useful to explore the Ayurvedic resources to prevent and control the diseases like diabetes.

Recent WHO report revealed that in 1998, 135 million adults were diabetic worldwide and the figure is projected to reach 300 million by 2020. 20% of the current diabetic population resides in South East Asia, with many of them being unaware of their general body sugar levels. Parental administration of insulin has not been accepted up to the required extent both by the patients and by the doctors. Oral hypoglycemic agents have many untoward effects, so there has been a keen desire to find out safer oral hypoglycemic agents.

In Charaka Samhita it has been emphasized that one etiological factor may produce different disorders or same etiological factor may produce only one disease, similarly multiple etiological factors may be involved in causation of one or many diseases. [1] Hence one pacifier measure is useful in many disorders or in single disorder, likewise many measures are required for a single disorder as well as multiple ones.[2]

The inventory of Ayurveda provides various medications in different dosage forms to act as pacifier in Madhumeha. Hence an attempt has been made to study the effect of Ayurvedic drugs in Madhumeha, which have been reported to possess hypoglycemic property on the basis of some experimental studies.

Aims and objectives of the study

To clinically assess the comparative efficacy of trial drug i.e. Anti-Diabetic formulation (Madhumehar Yoga) in the management of hyperglycemia on various scientific parameters and to explore the classical texts for the description of Madhumeha in relation to diabetes mellitus.

MATERIALS AND METHODS

Trial drug is selected on the traditional as well as modern knowledge of herbs while the second drug is considered as standard drug. The study is carried out as per the International Conference Harmonization - Good Clinical Practices Guidelines. (Table 1)

Second drug used as standard is Metformin.

Selection of subject - A total of 69 patients were selected for the present study from O.P.D. and I.P.D. of Kayachikitsa Department, R.G.G.P.G. Ayurvedic College Hospital, Paprola, irrespective of their sex, religion and socio economic status etc. Written & informed consent of patients was taken before trial.

Criteria for diagnosis

Subjective criteria- Classical signs and symptoms of Madhumeha mentioned in Ayurvedic texts as well as in modern literature.
Objective criteria- Fasting blood glucose > 126 mg/dl reference

Inclusion criterion

- Patients willing for the trial
- Only uncomplicated cases of type-2 DM with FBS > 126 mg/dl and < 200 mg/dl.
- Patients in the age group of 35-80 years.

Exclusion criterion

- Patients not willing for the trial.
- Patients presenting with complications like severe renal disease, ischemic heart disease, severe hypertension etc.
- Patients with type-1 DM.

Laboratory Analysis

- Blood –Hb gm%, TLC, DLC, ESR, FBS, Blood Urea, Serum Creatinine, SGOT, SGPT, Lipid Profile
- Urine-Routine & Microscopic

Method of Study

IEC & Consent: Approval from the Institutional Ethics Committee (IEC) was taken prior to begin with this study vide No.6/2012 dated 15.05.2012. Written & informed consent of the patients was taken before their registration for the study.

Patient Information Sheet & CRF: All the patients were given an information sheet stating all the details of the study protocol, benefits of the trial & any expected side effect. A clinical research Performa was prepared to note down all the details of the patients and their disease.

Trial Groups: Total 69 patients of diabetes mellitus (Madhumeha) were selected for the present clinical study, they were randomly divided into two groups and treatment was given as follows-

a. Group I: Total 35 patients were registered in trial group I and out of them 4 patients discontinued the treatment, only 31 patients completed the study, the selected patients were given Metformin in a dose of 500 mg once a day with plain water ½ hour before breakfast.
b. Group II: Total 34 patients were registered in trial group II and out of them 4 patients discontinued the treatment and only 30 patients completed the study, the selected patients were given the trial drugs in the dose of 10 gm, twice a day with plain water before breakfast and dinner. (Figure 1-3)

Duration of Trial: Duration of trial was 45 days.

Assessment: Patients of both the groups were thoroughly assessed for any improvement in the subjective and objective criteria after every 15 days till the completion of trial period of 45 days. Hematological, biochemical and urine examination were done both before and after the therapy. Various signs and symptoms and urine sugar were accorded grades according to the severity as tabulated in Table 2.

Statistical Analysis: The obtained data was analyzed statistically and expressed in terms of mean, standard deviation (± SD) and standard error (± SE). The "*t*" test was applied to observe the significance of results obtained after treatment. The results obtained were interpreted in Table 3.

Grading of overall effect of therapy

Tabulated in Table 4

OBSERVATIONS AND RESULTS

Total 69 subjects enrolled in which 61 subjects completed the study. Maximum numbers of patients, that is, 37.70% were in age group of >60 years, 52.45% females and 97.24% Hindus, majority of the patients i.e. 52.45% were housewives and 59.01% belonged to middle socioeconomic status (with income Rs. 3000-10000 per month), most of the patients i.e. 65.58% were on mixed diet, no addiction was found in 62.29% of patients and the incidence were more i.e. 39.34% in patients with Vata Kaphaja Prakriti, all the patients were married, maximum i.e. 34.42% were educated to primary school only and most of them 77.04% belonged to rural area. Maximum patients 47.54% were of normal weight with BMI in between 20 - 24.9, 37.72% of the patients had the disease for less than one year and majority of the patients i.e. 78.69% had no family history or were not aware of this. The blood pressure of majority of patients i.e. 49.18% was normal and FBS was <160mg/dl in 54.09% of patients, 47.54% had normal appetite. Bowel habit was normal and regular in 59.01% and 88.53% of patients had moderate physical activity.

In the present clinical trial polyuria was observed in forty-seven (77.04%) patients, polydipsia and joint pain each was observed in twenty-six (42.62%) patients, polyphagia was observed in twenty (32.78%) patients, fatigue in thirty-nine (63.93%), numbness was observed in twenty-three (37.70%), dryness of mouth was found in thirty-seven (60.65%) patients, burning sensation in hands & feet and calf tenderness each in thirty-one (50.81%) patients and pruritus vulvae/balanitis in eighteen (29.50%) patients.

In trial group-I, 34.57% reduction in FBS was observed while 26.85% reduction was observed in group-II. Reduction in FBS was statistically highly significant ($p<0.001$) in both the groups and the intergroup difference was statistically insignificant ($p>0.05$). (Table 5)

Urine sugar was reduced by 100% in group-I and 93% in group-II, statistically highly significant ($p<0.001$) in both the groups and the intergroup difference was statistically insignificant ($p>0.05$). (Table 6)

The effects of therapy in group-I on some features like fatigue, dryness of mouth and vulval pruritis/balanitis was highly significant statistically ($p<0.001$). The features like polyuria and numbness were improved statistically moderately ($p<0.01$) whereas all other features like polydipsia, polyphagia, burning sensation in hands and feet, calf tenderness and joint pains were statistically mildly improved ($p<0.05$). Effects of therapy in group-II showed statistically highly significant improvement ($p<0.001$) on maximum features like polyuria, fatigue, numbness, burning sensation in hands and feet, calf tenderness and dryness of mouth and moderately significant improvement ($p<0.01$) on polydipsia and joint pains while statistically mild improvement was observed on polyphagia and vulval pruritis/balanitis. (Table 7)

Overall effect of therapy showed that in group-I, six (19.35%) patients were markedly improved, ten (32.25%) patients were moderately improved and fifteen (48.38%) patients were mildly

improved. In group-II, four (13.33%) patients were markedly improved, thirteen (43.33%) patients were moderately improved, eight (26.66%) patients were mildly improved and five (16.66%) patients did not show any improvement. (Table 8)

Most of the routine hematological and biochemical investigations remained within normal limits in both the groups before and after therapy and only serum cholesterol and LDL were significantly reduced in both the groups while serum triglycerides were significantly reduced in group-II only. (Table 9)

Table 1: Composition of trial drug

S. no.	Name	Part used	Botanical name	Ratio
1	Karvellaka	Fruit	*Momordia charantia*	1
2	Meshshringi	Leaf	*Gymnema sylvestre* R.Br.	1
3	Jambu	Seed	*Syzygium cumini* Skeels	1
4	Vijaysaar	Hard wood	*Pterocarpus marsupium*	1
5	Tej Patra	Leaf	*Cinnamomum tamala*	1
6	Arjuna	Stem bark	*Terminelia arjuna*	1
7	Amalaki	Pericarp	*Emblica officinalis* Gaertn.	1
8	Methika	Seed	*Trigonella foenumgraecum*	1
9	Rakta Punarnava	Panchang	*Boerhaavia diffusa* Linn.	1

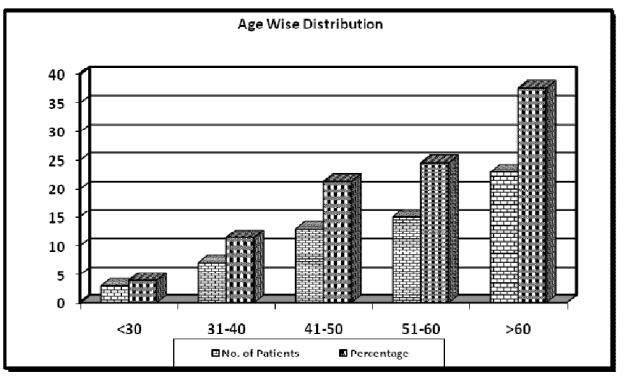

Figure 1: Age wise distribution of patients under trial

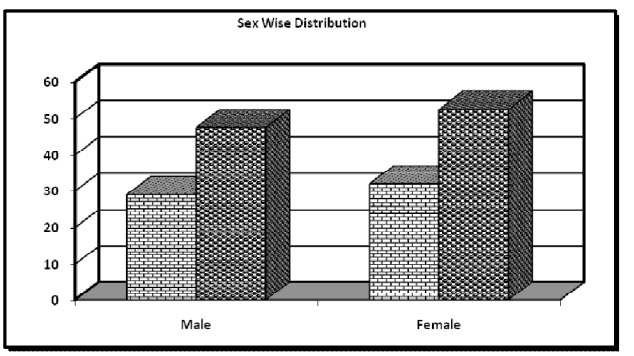

Figure 2: Sex wise distribution of patients under trial

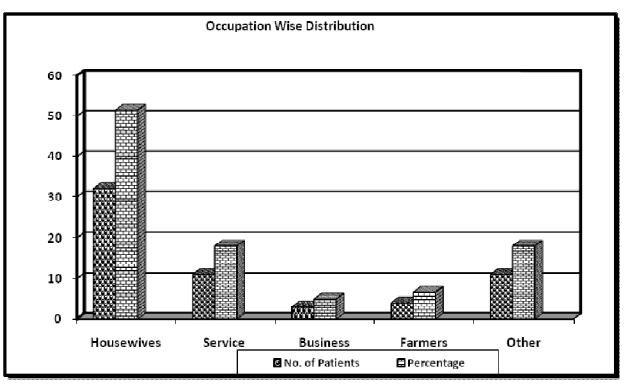

Figure 3: Occupation wise distribution of patients under trial

Table 2: The results of urine sugar study were graded into following four categories

S. no.	Symptoms	Grade	Urine Sugar	Grade
1.	Absent	0	Nil	0
2.	Mild	1	Trace	1
3.	Moderate	2	+	2
4.	Severe	3	++ or more	3

Table 3: Efficacy of drug is calculated on the basis of P value

S. no.	Effect	P value
1.	Insignificant	p>0.05
2.	Significant	p<0.05
3.	Moderate Significant	p<0.01
4.	Highly Significant	p<0.001

Table 4: Results of study were graded into following four categories

S. no.	Effect of therapy	Criteria
1	Highly improved	>75% relief in symptoms, and/or >25% reduction in FBS
2	Moderately improved	50-74.9% relief in symptoms, and/or 20-24% reduction in FBS
3	Mildly improved	25-49.9% relief in symptoms, and/or 15-19% reduction in FBS
4	Not improved	<25% relief in symptoms, and/or <15% reduction in FBS

Table 5: Effect of therapies on Fasting Blood Sugar

Variable	Group-I				Group-II			
	Mean		% relief	P	Mean		% relief	P
	BT	AT			BT	AT		
FBS	164.3	107.5	34.57	<0.001	160.5	117.4	26.82	<0.001

BT: Before Treatment, AT: After Treatment

Table 6: Effect of therapies on urine sugar

Variable	Group-I				Group-II			
	Mean		% relief	P	Mean		% relief	P
	BT	AT			BT	AT		
Urine sugar	0.51	0.00	100	<0.001	0.43	0.03	93	<0.001

BT: Before Treatment, AT: After Treatment

Table 7: Effect of therapies on clinical features

S. No	Signs / Symptoms	Group-I				Group-II			
		Mean		% relief	P	Mean		% Relief	P
		BT	AT			BT	AT		
1	Prabhuta Mutrata (Polyuria)	1.60	1.17	33.12	<0.01	2.33	0.62	73.39	<0.001
2	Pipasa (Polydipsia)	1.61	1.01	33.54	<0.05	1.84	0.69	62.50	<0.01
3	Kshudha (Polyphagia)	1.30	0.90	30.76	<0.05	2.36	1.36	42.37	<0.05
4	Shaithilya (Fatigue)	1.90	0.52	72.63	<0.001	2.00	0.88	56.00	<0.001
5	Karpada suptata (Numbness)	1.14	0.64	52.63	<0.01	1.60	0.10	93.75	<0.001
6	Karpada daha (Burning sensation)	1.37	0.87	36.47	<0.05	1.93	0.80	58.54	<0.001
7	Pindikodveshtana (Calf tenderness)	1.62	1.00	37.03	<0.05	2.46	1.00	59.34	<0.001
8	Mukhashosha (Dryness of mouth)	1.89	0.63	66.66	<0.001	2.05	0.55	73.17	<0..001
9	Sandhishoola (Jointpain)	1.71	1.42	16.95	<0.05	1.75	0.50	71.42	<0.01
10	Vulval pruritis / balanitis	1.40	0.50	64.28	<0.001	1.75	1.25	28.57	<0.05

BT: Before Treatment, AT: After Treatment

Table 8: Overall effects of therapy

Sr. No.	Overall effect of the therapy	Group-I	Group-II
1	Highly improved	6 (19.35%)	4 (13.33%)
2	Moderately improved	10 (32.25%)	13 (43.33%)
3	Mildly improved	15 (48.38%)	8 (26.66%)
4	Unimproved	0 (0.00%)	5 (16.66%)

Table 9: Effect of therapy on Haematological and Biochemical profile

S. No	Variable	Group-I				Group-II			
		Mean		% Diff	P	Mean		% Diff	P
		BT	AT			BT	AT		
1	Haemoglobin	11.11	11.35	02.11	>0.05	11.10	11.14	00.35	>0.05
2	TLC	6496.7	6529.0	00.49	>0.05	8256.6	8066.6	02.30	>0.05
3	ESR	7.25	6.70	07.58	>0.05	15.33	15.00	02.15	>0.05
4	Polymorphs	65.06	65.09	00.04	>0.05	60.53	60.90	00.44	>0.05
5	Lymphocytes	31.64	31.61	00.09	>0.05	33.86	33.00	02.53	>0.05
6	Monocytes	1.29	1.48	12.83	>0.05	1.73	1.63	05.78	>0.05
7	Eosinophils	2.00	1.77	11.50	>0.05	4.06	4.53	10.37	>0.05
8	B.Urea	24.16	23.48	02.81	>0.05	27.86	26.46	05.02	>0.05
9	S.Creatinine	0.62	0.62	00.00	>0.05	0.78	0.83	06.02	>0.05
10	SGOT	26.82	26.83	00.03	>0.05	28.16	24.53	12.89	>0.05
11	SGPT	28.37	25.51	10.08	>0.05	26.83	26.46	01.37	>0.05
12	S.Cholesterol	178.03	171.75	03.52	<0.01	172.46	168.00	02.58	<0.05
13	S.Triglyseride	143.44	142.58	00.59	>0.05	132.83	125.16	05.77	<0.05
14	HDL	41.86	41.48	00.90	>0.05	40.26	40.96	01.70	>0.05
15	LDL	107.03	101.82	04.86	<0.05	106.53	102.06	04.19	<0.05
16	VLDL	28.68	28.44	00.76	>0.05	26.56	25.30	04.74	>0.05

BT: Before Treatment, AT: After Treatment

Table 10: Pharmacokinetic properties of Ayurvedic formulation[6]

S.No.	Name	Rasa	Guna	Virya	Vipaka	Prabhava
1	Karvellaka	Tikta,katu	Laghu,ruksha	Ushna	Katu	Kapha-pitta shamaka
2	Meshshringi	Tikta,kashaya	Laghu,ruksha	Ushna	Katu	Kapha-vata shamaka
3	Jambu	Kashaya,madhura	Laghu,ruksha	Sheeta	Katu	Kapha-pitta shamaka
4	Vijaysara	Kashaya,tikta	Laghu,ruksha	Sheeta	Katu	Kapha-pitta shamaka
5	Tejpatra	Tikta,madhura	Tikshna,laghu	Ushna	Katu	Kapha-vata shamaka
6	Arjuna	Kashaya	Laghu,ruksha	Sheeta	Katu	Kapha-pitta shamaka
7	Amalaki	Panch rasa	Guru,ruksha	Sheeta	Madhura	Tridosha shamaka
8	Methika	Katu	Laghu,snigdha	Ushna	Katu	Vata Shamaka
9	Rakta Punarnava	Tikta,madhura	Laghu,ruksha	Ushna	Madhura	Tridosha shamaka

DISCUSSION

The present study was completed to evaluate the efficacy of an Ayurvedic formulation on Madhumeha. The outcome of the study showed ample evidence in regard to the action of the drug. The drug was prepared using fresh ingredients.

Ayurvedic pharmacology depends on five principles of Rasa- Guna- Virya- Vipaka and Prabhava.[3] Acharya Charaka has mentioned that any dravya can have similar Rasa, Virya and Vipaka but a different mode of action which can be explained on the basis of prabhava.[4]

In Ayurvedic classics, Kapha and Vata play important role in the pathogenesis of Madhumeha, in Sushruta Samhita while describing the principle of management of Madhumeha it has been mentioned that the drugs which are Tikta, Katu, and Kashaya in taste, Sara in property with Katu Vipaka and Ushna Virya with Soshaka and Chedana actions should be selected for the treatment of Madhumeha.[5]

In the present study, a combination of 9 herbs was used to assess its efficacy in management of Madhumeha. The drugs, which are used in the present study, are tikta, katu and kashaya rasa predominant and have the property of vata & kapha saman. (Table 10)

All of these drugs have been studied separately for their hypoglycemic action. Their probable mode of action is different as suggested below:

- On the level of glucose absorbtion : Tejpatra[6] *Cinnamomum tamala,* Methika[7] *Trigonella foenumgraecum,* Vijaysara[8] *Pterocarpus marsupium,* Amalaki[9] *Emblica officinalis.*
- On the level of insulin receptors/ sensitivity : Methika[10] *Trigonella foenumgraecum,* Arjuna[11] *Terminelia arjuna.*
- On the level of pancreas stimulation : Meshshringi[12] *Gymnema sylvestre*, Jambu[13] *Syzygium cumini*, Vijaysara[8] *Pterocarpus marsupium*, Punarnava[14,15] *Boerhaavia diffusa*, Amalaki[9] *Emblica officinalis.*
- Repair of beta cells : Jambu[13] *Syzygium cumini*, Vijaysara[8] *Pterocarpus marsupium.*
- Conversion of pro-insulin to insulin : Jambu[13] *Syzygium cumini.*
- Increases glucose utilization : Vijaysara[8] *Pterocarpus marsupium.*

CONCLUSION

The present study concluded that these drugs are effective in relieving signs and symptoms of Madhumeha and also possess significant hypoglycemic effect. Though both the therapies were found significantly effective in the management of Madhumeha but Ayurvedic drugs showed definitely better efficacy over Metformin on various subjective parameters but metformin was found to be superior in lowering down the sugar levels. No untoward effect was noted during treatment and follow up period in both groups, however, this is only a preliminary study conducted as a part of educational research program with small number of patients, in fixed duration of time. Further multi-centre, clinical and experimental studies are required with larger sample to establish anti-diabetic (Madhumehahara) effect of these drugs.

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