



Research Article

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MADHUMEHAHARA (ANTIHYPERGLYCEMIC) ACTION OF KALAMEGHA (*ANDROGRAPHIS PANICULATA* (BURM.F.) WAL. EX-NEES): A CLINICAL STUDY

Veera Venkata Durga prasad M^{1*}, Hegde Prakash L², Harini A³

¹PG Scholar, Department of Dravyaguna, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

²Professor, Department of Dravyaguna, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

³Associate professor, Department of Dravyaguna, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

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*Corresponding author

E-mail: drdurgaprasad28@gmail.com

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ABSTRACT

Diabetes mellitus is one of the most common chronic global diseases affecting in both the developed and developing nations. India is one of the five countries which have highest sufferers of Diabetes Mellitus; Ayurveda is enriched with herbs for treatment of Madhumeha. Madhumeha is a condition which is similar to diabetes mellitus. It's one type of Vataja Prameha and explained as yapya (incurable), it should be controlled with effective and longtime medication. The aim of the study is to prove that Kalamegha Vati is highly effective in Madhumeha. Study was carried out randomly in total of 30 patients of Non Insulin Dependent Diabetes Mellitus (NIDDM) and administered Kalamegha Vati 2 tablets, thrice a day before food for one month. The drug was well tolerated in the dosage used. After completion of treatment it was found to be effective in objective parameters like FBS, FUS, PPBS showed statistically significant result and non significance in PPUS, shown statistical significance with subjective parameters like micturition during night, micturition during day, turbidity of urine, burning sensation in soles and palms, increase of appetite and debility. This was found that Kalamegha is more beneficial in improving the quality of life of all the patients. This study shows single drug treatment of Kalamegha Vati which can be highly effective in Type II Diabetes.

Keywords: Madhumeha, Kalamegha, Anti Hyperglycemic, Diabetes Mellitus.

INTRODUCTION

Acharya Charaka has quoted "as the birds are attracted towards the tree where their nests lies, similarly Madhumeha affects people who are voracious eaters and have aversion to physical exercise¹. The disease Madhumeha, its definition, etiology, clinical features and principles of treatment appear to be similar with the disease "Diabetes Mellitus", which is considered as "Ice Berg" disease in the present era². Unveiling ancient sculptures and inscriptions by modern society have replenished several valuable directions and descriptions. Susruta and Charaka described urine of certain polyuria patients tasting like Madhu (honey)³. Madhumeha is one of Vataja Prameha vitiated Vata draws the Dhatus (constituents of the body) Majja (Bone Marrow), lasika (lymph) and ojas (essence of total body constituents) to Vasti dosas situated in Vasti (urinary bladder) vitiate Mutra (urine) to produce Meha and explained as yapya (incurable)⁴, the Indian description of that period distinguished two forms of diabetes, one affecting the older and obese, and the other affecting thin people who did not survive long; the fortuitous parallel with the present day sub-divisions of diabetes into insulin-dependent and non-insulin-dependent types. It is considered as a sweet disorder with bitter mortality rate & multiple complications with a myriad of disorders associated with it. Man has been using herbs and plant products for combating diseases since time immemorial. The Indian subcontinent is enriched by a variety of flora- both aromatic and medicinal plants even though many research works have been carried out for Meha (anti-diabetic) activity of many herbal drugs, still efficacious drug is elusive and there are certain unexplored drugs like Kalamegha (*Andrographis paniculata* (Burm.F.) Wall. ExNees), which may be an answer. Kalamegha (*Andrographis paniculata* (Burm.F.) Wall. exNees) was proven

for its anti-hyperglycemic effects experimentally⁵, but it has to be established with clinical support. Kalamegha is having properties like Tikta rasa (bitter taste), Usna Virya, (hot in potency) Katu Vipaka (pungent in taste in end product)^{6,7,8} and for Madhumehahara (anti-diabetic) has to be proved on scientific lines.

Aims and objectives

To evaluate the efficacy of powder of whole plant of Kalamegha (*Andrographis paniculata* (Burm.f.) Wall. Ex Nees) in the management of Madhumeha with special reference to diabetes mellitus.

MATERIALS AND METHODS

Source of data

The present study was carried out in accordance with ethical principles by following international conference of harmonization – good clinical practices guidelines (ICH- GCP). Kalamegha (*Andrographis paniculata* (Burm.f.) Wall. ExNees) belongs to Acanthaceae family the drug was collected from the SDM Ayurveda college herbal garden and authenticated by Department of Dravya guna SDM college of Ayurveda and hospital, Hassan, Karnataka, India.

Preparation & Place of work

Medicine was prepared at Department of Rasa shastra and Bhaishajya kalpana SDM College of Ayurveda & Hospital, Hassan. Analytical study was carried out at SDM College of Ayurveda & Hospital, Udipi. Clinical trial was conducted at SDM College of Ayurveda & Hospital, Hassan.

Source of patients

Patients were selected after subjecting for thorough clinical examinations from OPD and IPD of SDM Ayurveda College and Hospital, Hassan, Karnataka, India. Ethical clearance number for this study is SDMCAH/IEC/113/13-14.

Preparation of medicine

The problem due to palatability of drug which was faced during pilot study due to its larger dosage of 6 gm and bitter taste. According to Sarangadhara Samhita, Madhyama khanda, Kwatha kalpana⁹. Bhavana of the fine powder is done with the Kashaya for three days¹⁰ and rolled in to tablets of 500 mg each and dried in shade for 5 days and packed in a plastic container and enclosed with cap. And the drug was neatly labeled with the standard protocol and dispensed.

Method of collection of data

Written & informed consent was taken based on classical signs and symptoms of Madhumeha, the patients of both the sexes between the age group of 30 to 60 years were selected from the OPD and IPD of SDM college of Ayurveda and hospital. Total 30 patients were selected for study by random sampling method following exclusive and inclusive criteria.

Research design

30 patients of Madhumeha were randomly selected and 2 Kalamegha vatis of each 500mg dose were administered thrice a day before food. Diet and exercise were strictly advised.

Duration of Treatment: One month.

Inclusion Criteria

The patients who agree for their participation and who signed in the written and informed consent form. Patients between the age 30 to 60years of either gender irrespective of chronicity were taken. Specific biochemical investigations were done. The patients with Fasting Blood Sugar level between 120 to 180 mg/dl and Post Prandial Blood Sugar level 160 to 280 mg/dl selected for the study. Patients who have discontinued hypoglycemic drugs and first time diagnosed were included

Exclusion Criteria

Patients with type 1 Diabetes mellitus, patients with type 2 Diabetes mellitus who are insulin dependent, patients of Gestational Diabetes, patients with complications like cardiac disorder, diabetic foot, nephropathy and other secondary complications are excluded.

FBS

- 70 to 120 mg/dl normal
- 121 to 170 mg/dl mild
- 171 to 220 mg/dl moderate
- 220 above severe

Assessment criteria

Subjective Parameters

For the assessment of the subjective parameters scoring was given to all the signs and symptoms from grade 0-3 according to the severity and was documented properly before treatment, and after 60 days of the treatment. Assessment was done based on the criteria with their scoring.

Statistical methods

Statistical analysis was done by using SPSS VER-20, 30patients were taken for statistical analysis Wilcoxon sign rank test was applied to analyze the significance of change in subjective parameters, Paired t test was applied for analyzing the significance of objective parameters

RESULTS AND DISCUSSION

Effect of therapy on subjective parameters

Prabhootha mootra during day time (Frequency of micturition in day time) between day1 to day 30 was reduced in 12 subjects which is significant (Z -3.464 p 0.001). Prabhootha mootra (Frequency of micturition in night time) between day1 to day 30 was reduced in 22 subjects which is significant (Z -4.523 p 0.000). Avila mootratha (Turbidity of urine) between day1 to day 30 was reduced in 14 subjects which is significant (Z -3.742 p 0.000). Kshudhaadhikyatha (Increased Appetite) between day1 to day 30 was reduced in 4 subjects which is significant (Z -2.000 p 0.046). Kara pada daha (burning sensation in palms and soles) between day1 to day 30 was reduced in 18 subjects which is significant (Z -4.146 p 0.000). Dourbalya (General debility) between day1 to day 30 was reduced in 19 subjects which is significant (Z -4.264 p 0.000).

Effect of therapy on objective parameter

FBS reduced significantly with the p value at 0.000 after a period of 30 days. FUS reduced significantly with the p value at 0.000 after a period of 30 days. PPBS reduced highly significantly with the p value at 0.000 after a period of 30 days. PPUS is not significant with the p value 0.934 after a period of 30 days. Life style habits which include dietary habits and physical activities appear to have positive effect in modifying many risk factors. Treating hyperglycemia with hypoglycemic drugs without caring to correct the metabolic impairment is something like applying dye to the grey hair though it helps to look younger does not reverse the fundamental process of senescence. So there should be a better management for the Madhumeha. India is very rich in herbal and medicinal plant wealth with suitable geo climatic conditions. It has well documented and well practical knowledge for traditional herbal medicine. so herbal medication is the commonly used alternative therapy for diabetic treatment. Moreover Herbs were known for their safety efficacy cultural acceptability and lesser side effects besides maintaining normo-glycaemia in diabetes up to date 600 traditional plant treatments for diabetes have been reported, a small number of these have scientific and clinical evaluation¹¹. Kalamegha is one drug from that traditional knowledge for diabetes so it was selected for the study.

CONCLUSION

Madhumeha known to be a dangerous disease and an established psychosomatic disorder. It is combined with anxiety, fears and fear of death¹² and should be attentive as early as possible to stop onset of complications. Kalamegha Vati has shown significant result in fasting blood sugar and post meal blood sugar levels in Madhumeha (NIDDM.). Pharmacognostical study confirmed its identity and genuine nature. Kalamegha (*Andrographis paniculata* (Burm.F.) Wall. Ex Nees) is an easily available drug can be considered as a major drug to heal Madhumeha. Kalamegha has improved quality of life of all the patients who have undergone a clinical trial. Single drug treatment like Kalamegha Vati can proved to be a boon in the wide population who is suffering from Diabetes mellitus comprising of Pathya Aahara-Vihara followed with regular practices of Yogasanas.

Table 1: Assessment criteria with scoring

Sl.no	Criteria	Details	Score
1	Frequency of urine day time (polyuria)	3-5 times per day	0
		6-8 times per day	1
		9-11 times per day	2
		More than 11 times per day	3
2	Frequency of urine night time (polyuria)	Does not wake up	0
		Wake up once	1
		Wake up twice	2
		Wake up more than 2 times	3
3	Turbidity of urine	Crystal clear fluid	0
		Turbidity visible	1
		Buffy	2
		Milky white	3
4	Appetite	Feels hunger at next annakala only	0
		Feels hunger for once in between annakala	1
		Feels hunger more than twice in between annakala	2
		Feels hunger always	3
5	Burning sensation over limbs	No burning sensation in hands & feet	0
		Mild burning sensation in hands & feet	1
		Moderate burning sensation in hands & feet	2
		Severe burning sensation in hands & feet	3
6	Weakness	Can do routine exercise/work	0
		Can do moderate exercise with hesitancy	1
		Can do mild exercise only, with difficulty	2
		Can't do mild exercise too	3

Table 2: Results Effect of Kalameghavati for objective parameters

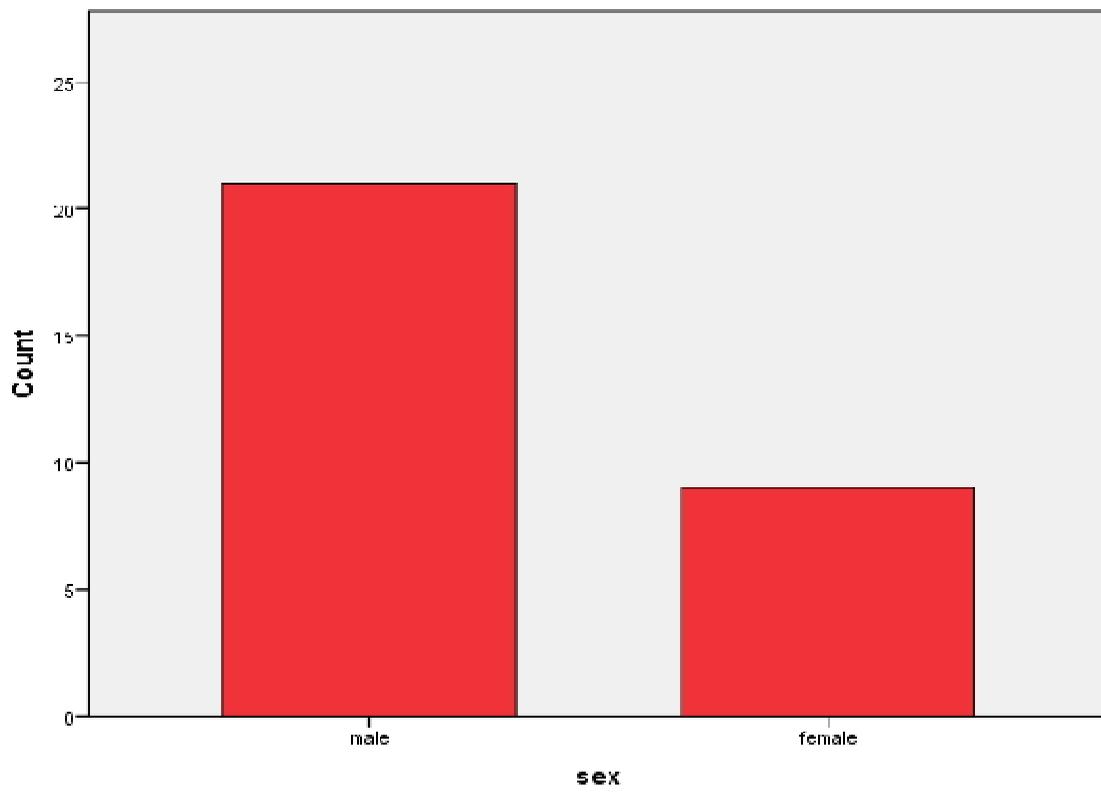
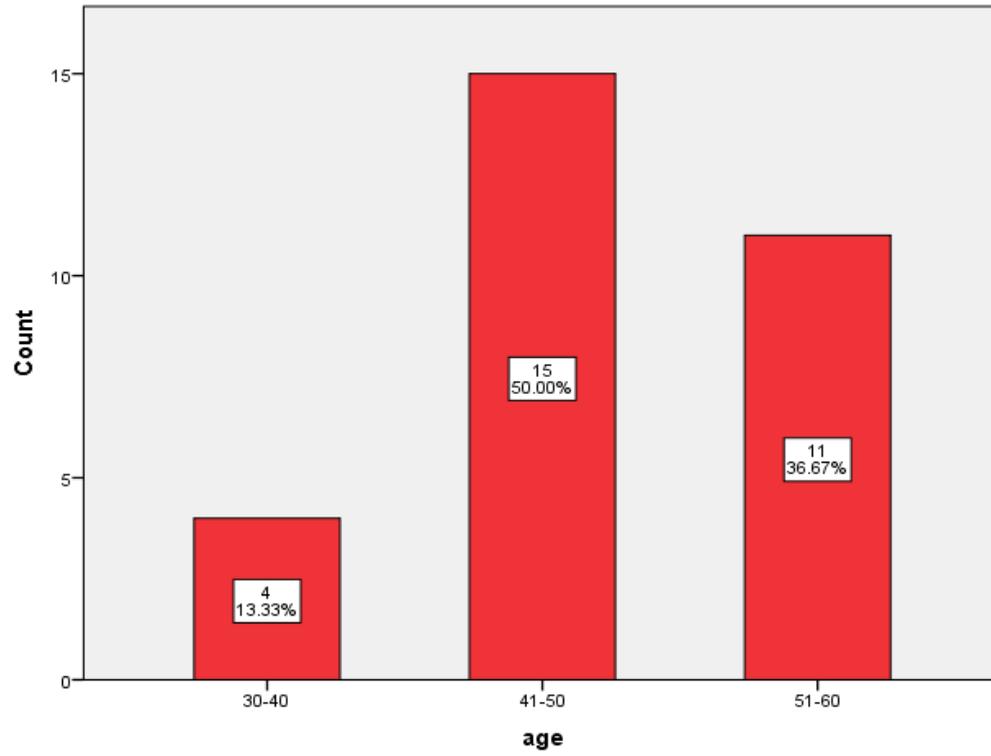
Signs and symptoms	Mean BT	Mean AT	Difference in mean	% Relief	S.D(±)	S.E.M	t	Sig
F.B.S	158.83	134.57	24.25	15.1	11.73	2.142	11.319	0.000
F.U.S	0.27	0.02	0.25	92.5	0.360	0.067	3.610	0.000
P.P.B.S	224.6	182.1	42.55	18.9	27.196	4.965	8.573	0.000
P.P.U.S	0.930	0.957	-0.0267	2.87	1.736	0.317	-0.084	0.934

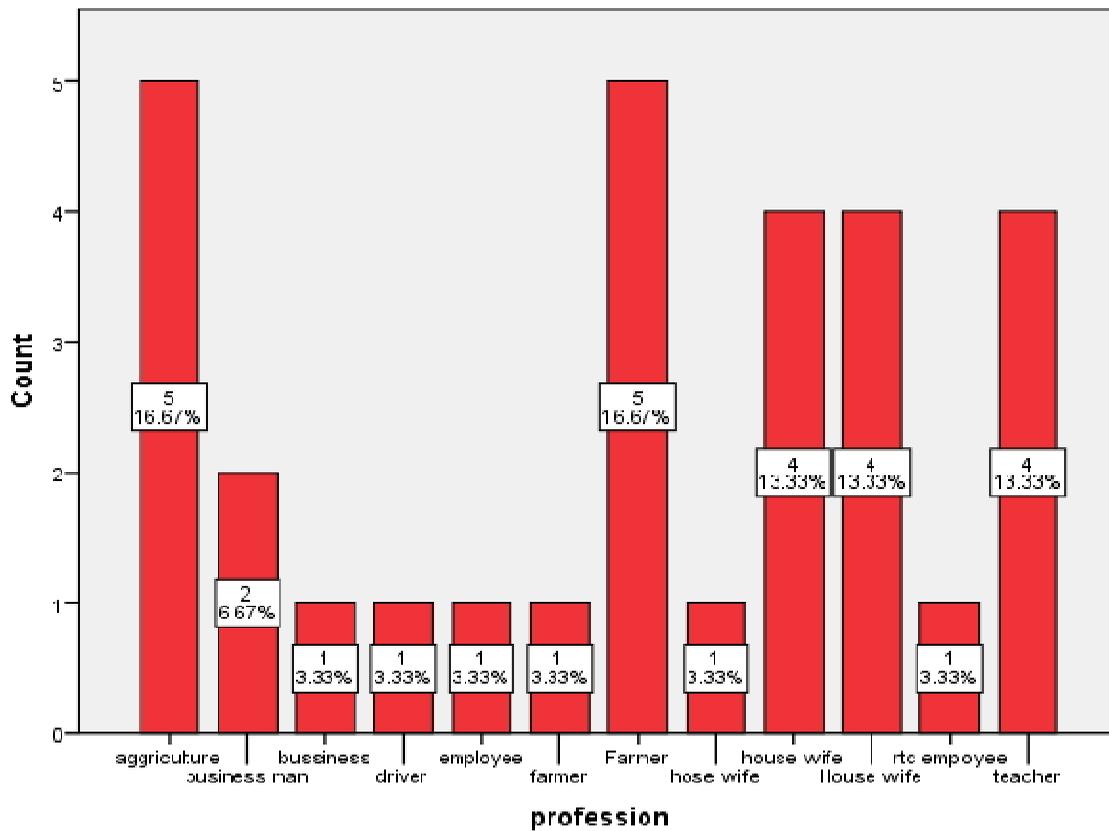
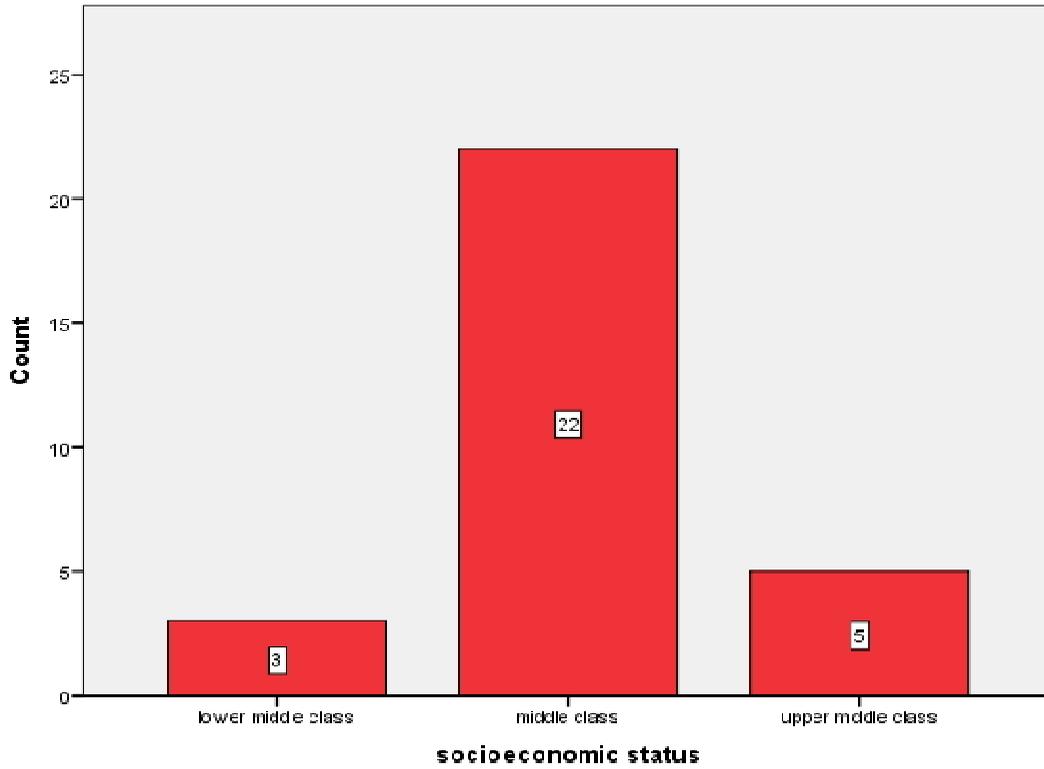
P= 0.05= Significant p=0.00 = Highly significant

Table 3: Results Effect of Kalameghavati for subjective parameters

Parameter	Negative ranks			Positive ranks			Ties	Total	Z Value	P value	Remark
	N	MR	SR	N	MR	SR					
Frequency of micturition in day time	12	6.50	78.00	0	0.00	0.00	18	30	-3.464	0.001	S
Frequency of micturition in night time	22	11.50	253.0	0	0.00	0.00	8	30	-4.523	0.000	HS
Turbidity of urine	14	7.50	105.0	0	0.00	0.00	16	30	-3.742	0.000	HS
Appetite	4	2.50	10.00	0	0.00	0.00	26	30	-2.000	0.046	S
Karapadadaha	18	9.50	171.0	0	0.00	0.00	12	30	-4.146	0.000	HS
Dourbalya	19	10.00	190.0	0	0.00	0.00	11	30	-4.264	0.000	HS

*S= Significant **HS= Highly Significant





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