International Research Journal Of Integrated Medicine & Surgery

Research Article

"CLINICAL EVALUATION OF ANTI- HYPERGLYCEMIC ACTIVITY OF *BHUMYAMALKI (PHYLLANTHUS AMARUS LINN.*)WITH SPECIAL REFERENCE TO DIABETES MELLITUS (*MADHUMEHA*)."

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ABSTRACT

Diabetes mellitus is the one of the five most attention needy diseases throughout the world. This disease is presently a burden not only on the individuals affected by the disease but also on society. *Bhumyamalaki*being*tikta*, *kashaya*in *rasa*, is act as *medohara* in the manifestation of the disease. So this drug is being used in *madhumeha*as folklore medicine.Open labeled randomized study was done in Seth R.V.Mahavidyalaya,Sion; Mumbai-022.The study comprises total 60 patients. Group A include 30 patients which were given 3gms of *Bhumiamyamalki churna*twice orally with *ushnodak* as *anupan* and group B was control group of 30 patients were given *yavachurna*. Subjective criteria was assessed based on following symptoms-*Daurbalya* (Weakness both generalized and of a particular part),*Ksheenakameccha* (Diminished libido), *Hastapadataldaha*(Burning sensation)**,***Shula* (Pain)*, Pindikodwesta*(Cramps)*, Kshudavruddhi* (Excessive Hunger). Objective improvement was done on the basis ofFasting& post prandial blood sugar levels at start and end of study in diabeticpatients.Subjective improvement is shown in percentage. Unpaired t test was applied to objective parameters which was highly significant at 1% level of significance i.e. $p<0.01$.in patients taking *Bhumyamalkichurna*while in other group it was significant at 5% level of significance,concluding definitely *Bhumyamalkichurna* has anti-hyperglycemic activity.There was significant improvement in *hastapadtaldaha, pindikodweta, kshudavruddi* symptoms.

Keywords: *Bhumyamalki*, anti-hyperglycemic activity, diabetes mellitus, *madhumeha*

INTRODUCTION

Ayurveda, which literally means the science of life (Ayur = Life, Veda = Science), *ayurveda* is an ancient medical science which was developed in India thousands of years ago. Believed to have been passed on to humans from the Gods themselves, *Ayurveda* developed and evolved into what it is today from several ancient treatises, most notably *Atharva*Veda which dates back to five thousand years. The ancient Vedic literature by sages has clearly laid out instructions to maintain health as well as fighting illness through therapies, massages, herbal medicines, diet control and exercise.[1]*Ayurveda* can be defined as a system, which uses the inherent principles of nature, to help maintain health in a person by keeping the individual's body, mind and spirit in perfect equilibrium with nature.[2]

D.M. is the most common metabolic disorder encountered in clinical practice. India has more diabetics than any other country in the world. The disease affects more than 62 million Indians, which is more than 7.1% of India's Adult Population. An estimate shows that nearly 1 million Indians die due toDiabetesevery year.[3] The high incidence is attributed to a combination of genetic susceptibility plus adoption of a high-calorie, low-activity lifestyle by India's growing middle class.[4] It is strongly linked to obesity. It is characterized by abnormal carbohydrate and lipid hemostasis, leading to evasion in plasma glucose or hyperglycaemia&abnormality of serum lipids, or dyslipidemia.[5] Control of *madhumeha* and its complications pays excellent dividends health and increases the expectancy of life. So a humble clinical trial is being made with an indigenous drug.

"*Bhumyamalki*" is used in *madhumeha*.[6] "*Bhumyamalki*" is already said to be effective *pramehagna*, besides its properties *Deepan* and *pachan* and *pita shamaka*properties,"*Bhumyamalki*" being *Tikta,kashya* in *rasa*, is *medohara* and *kaphahara*.Since*meda*and*kapha* are the predisposing factors in the manifestation of the disease.And also this drug is bitter and astringent in taste; it may act on gastrointestinal mucosa and perhaps on metabolism of the carbohydrate as well.[7,8].

MATERIALS AND METHODS

Selection of cases-There was random selection of patient fromopd and ipd of Sheth R. V. Ayurvedic Hospital, Sion; Mumbai, India. Known cases of *madhumeha* were taken.
Type of study
Parallel group,openlabeledrandomized study.

Study design
Total no. Of cases: - 60
Patients will be divided into '2' groups as follows:-
Group A – 30 patients –*Bhumyamalkichurna (total 6gms twice a day)*
Group B – 30 patients – Control group (*yavachurna*) (total 6gms twice a day)

Duration of study: 30 days

Inclusion criteria:[9]
Either sex
Age between 30 years to 65 years
Blood sugar- fasting > 126 and =<200 mg/dl or PP > 200 mg/dl and <= 350 mg/dl
Recently diagnosed < 6 month cases of Type-2 Diabetes mellitus not taking any anti Diabetic drug.

Exclusion criteria:[9]
1. Age below 30 and above 65 years
2. Blood sugar – fasting =< 126 and > than 200 mg/dl or PP =< 200 mg/dl >350 mg/dl
3. Malignant and accelerated hypertensive
4. CVS disorder (CAD)
5.Pregnant woman and planning to be pregnant within six months.
6. Lactating mother
7. Secondary Diabetes mellitus
8. Patient undergoing regular treatment for Diabetes or any other severe illness
9.CNS disorder e.g. encephalopathy

Study center: Ayurved Hospital, Sion,Mumbai- 22.

Drug source:*Panchangchurna*of *Bhumyamalki* (*Phyllanthusamarus Linn.*)

Mode of administration: Oral

Formulation: *churna*

Dosage:3gms. (Total 6 gms)
Kal:*Vyaan* and *Apankal*

Anupana: *Koshnodak* (Lukewarm water)

Follow-up: Clinical follow-up was advised every 07 days for the duration of 30 days.

STATISTICAL ANALYSIS:

The **UnpairedT- Test**was applied to objective criteria. Also subjective improvement is shown in Percentage relief. [10]

Assessment of Efficacy:
Subjective improvement:[11]
General & systemic examination of patients at every 7 days
Judged by weekly assessment in the reduction of following symptoms in patients:
Daurbalya(Weakness both generalized and of a particular part)
Kshinakameccha(Diminished libido)
Hasta talapadadaha(Burning sensation**)**
Shula(Pain)
Pindikodveshtana(Cramps)
Kshudhavruddhi(Excessive Hunger)
2. Objective improvement:
1. Fasting & post prandial blood sugar levels at start and end of study in diabetic patients.

Gradation of symptoms

1. *Daurbalya*(Weakness both generalized and of a particular part)-
Grade 0: Routine activity without feeling weakness
Grade 1: Weakness is experienced during routine activity
Grade 2: Routine activity of patient is disturbed due to weakness but the patient is not bed ridden
Grade 3: Patients become bedridden or even has to be hospitalized

***Kshinakameccha* (Diminished libido)-**
Grade 0: Normal sexual performance
Grade 1: Decreased frequency with normal performance
Grade 2: Decreased frequency with inefficient performance
Grade 3: No stimulation to sexual stimulus

***Hasta talapadadaha*(Burning sensation)-**
Grade 0: No burning sensation of the peripheries
Grade 1: Burning sensations that is not continuous and does not disturb the routine activity of the patients.
Grade 2: Continuous burning sensation of the peripheries not disturbing normal activity.
Grade 3:Severe burning sensation of the peripheries disturbing normal activity.

***Shula* (Pain)-**
Grade 0: No pain in the routine activity
Grade 1: Pain in the limb/joint which does not disturb routine activity
Grade 2: Continuous pain with slight limitation of movement and activity reduced remarkably.
Grade 3: Continuous pain in resting phase also.

***Pindikodveshatana* (Cramps)-**
Grade 0: No cramps while walking
Grade 1: Patients experiences cramps after walking for about 1 km
Grade 2: Patients experiences cramps after walking for about ½km
Grade 3: Patients experiences cramps after walking for about ¼ km

***Kshudhavridhhi*(Excessive Hunger)-**
Grade 0-Hunger during meal times
Grade 1-Severe hunger between two meal times
Grade 2-Having hunger pangs frequently between meals
Grade 3- Hunger pangs immediately after meals

RESULTS

Symptomatic relief obtained within groups:

SYMPTOMS	Group A(%)	Group B(%)
Daurbalya	73.34	66.67
Kshinakameccha	73.68	66.67
Hasta talapadadaha	72.23	73.50
Shula	72.23	52.17
Pindikodvestana	69.56	62.50
Kshudhavrudhi	55.75	42.80

BLOOD SUGAR LEVELS OF GROUP A and GROUP B

S. No	Interval	Group A (Fasting)	Group B (Fasting)	Group A (Post prandial)	Group B Post prandial)
1	Basal	$113.3^{+}.12.26$ SE=2.23	$78.83^{+}\_9.73$ SE=1.77	$236.8^{+}.40.48$ SE=7.39	$130.2^{+}.12.78$ SE=2.334
2	After 4 week	$105.2^{+}.10.49$ SE=1.91 P=0.063 (NS)		$225.4^{+}.40.87$ SE=7.46 P=0.7348 (NS)	
	Remarks	significant	Not significant	significant	Not significant

Out of 30 patients of group A females were 13 (43%), Males 17(57%).In group B females were 11(37%) males 19 (63%).Age distribution was divided into 6 groups in Group A& Group B into 2 age groups. In group A the data shows 1 patient (3%) belonged to the age group of 35-40yrs. 4 patients (13%) belonged to the age group of 41-45yrs. 9 patients (31%) were belonged to the age group of 46-50yrs. 6 patients (20%) were belonged to the age group of 51-55yrs. 6 patients (20%) were belonged to the age group of 56-55yrs. 4 patients (13%) were belonged to the age group of 61-65 yrs.In group B 22 volunteers(73%) were belonged to the age group of 20-25yrs. 8 volunteers (27%) were belonged to the age group of 26-30 yrs.According dietary habits, In group A there was a maternal family of diabetes in 7 patients (21%) & Paternal family history of 13 patients (43%). Total 20 patients (66.6%) out of 30 were having family history of diabetes.In group A there were 14 vegetarians (47%) and non-vegetarians were 16 (53%). In group B 17 vegetarians (53%) and 13 non-vegetarians (47%).According general activity, in group A 8 patients (27%) were doing heavy physical work. 13 patients (43%) were doing moderate physical work and 9 patients (30%) were sluggish in their activity. In group B 21 individuals (70%) were performing moderate physical work and 9 of 30 (30%) were sluggish in their activity. Subjective evaluation showed all the 30 patients of group A and group B. In group A, 73.34% showed decrease in *daurbalya,* 73.68% showed decrease in *kshinakameccha,* 72.23% showed decrease in *hasta talapadadaha*, 72.23% showed decrease in *shula*, 69.56% showed decrease in *pindikodvestana*, 55.75% showed decrease in *kshudhavrudhi.* While in group B, out of 30 patients, 66.67% showed decrease in *daurbalya*, 66.67% showed decrease in *kshinkameccha,* 73.50% showed decrease in *hasta talapadadaha*, 52.17% showed decrease in *shula,*

62.50% showed decrease in *pindikodvestana,* 42.80% showed decrease in *kshudhavrudhi.*Thus patients of group A showed more symptomatic relief than patients group B.

In objective evaluation the fasting and post prandial sugar of group A patients was reduced significantly; t value is at 1% level of significance i.e. $p < 0.01$. While fasting and post prandial sugar of group B patients was reduced less as compared to group A; t value at 5% level of significance i.e. $p < 0.05$.

DISCUSSION

Bhumyamalki has *tikta, kashaya* in *rasa.* Due to this it shows *medohara* properties. Also it acts on *dushyas*& show*kaphapittaharalakshana* in *madhumeha.*It has significant *deepan, pachankarma* on *mamsadhatu*&*medodhatu*. It acts as *rasayana* in *madhumeha.*

Its possible action mechanism is by anti-inflammatory pathway Diabetes mellitus.Active principles of this drug are known hepatoprotective. Drug ingredient possesses a *Rasayana*property, pertaining specially *Yakrit*(liver) *pitta, raktavahasrotas*, thus restoring the lost strength and replenishing the damage. Drug acts mainly on '*pittajlakshan*' of the disease, suggesting developing the good module or studying design on *pittajprameha.Phyllanthusamarus* owe their blood glucose lowering properties to inhibition of glucose absorption and enhancement of glucose storage.

There were no adverse effects found with *Bhumyamalkichurna*. Only 6 patients complained of *prabhutmutrata* for 8 to 9 times in a day.

It suggests that *Bhumyamalki* is effective as anti-hyperglycemic*dravya* which increases patient's immunity & keeps them healthy. It is hoped that this efforts will provide a guideline for future researchers to plan their studies.

CONCLUSION

At the end of the study it was noted that Group A i.e. patients who were taking *Bhumyamalkichurna*had good symptomatic relief, improvementin fasting and post prandial sugar. In group B i.e. control group in which patients taking *yavachurna*had less symptomatic relief than group

A.Also there is Remarkable symptomatic improvement was found in '*Daha*' and Good symptomatic relief in *hastapadadaha, kshudhavriddhi*. Thus can conclude that *Bhumyamalkichurna*has better reliefin of both subjective as well as objective parameters. Thus *Bhumyamalki*(*Phyllanthusamarus Linn.*) is effective in reducing blood sugar i.e. it shows significant hypoglycemic activity in diabetes mellitus (*madhumeha*) without any adverse effects on the body.

REFERENCES

Dr. Ganesh K.Garde , Sartha Vagbhat , Anmol prakashan , edition 2003, page no.5-6.

A.K.Nadkarni,Indian Material Medica, popular prakashan PVT.LTD 1982 edition;vol.1-,page no.947.

http://healthintelligence.drupalgardens.com/content/prevalence-diabetes-world-2013.

http://en.wikipedia.org/wiki/Epidemiology_of_diabetes_mellitus.

Michael Swish & Michael Glynn, Hutchison clinical method,22nd edition 2007,page no 280.

Dr.K.C.Chunekar; Bhavprakasha Nighantu,Chaukhamba Bharti Acedamy,8th edition,1988,page no.460.

Bapalala G. Vaidya, NighantuAdarsa Vol.2,ChaukhambaBharti Acedamy page, edition 2005, no. 427-428.

Dr. A.P. Deshpande, Dravyaguna Vidnyan, Anmol prakashan, 2007 edition, page no.872-873.

Clinical Research Protocols for Traditional Health Sciences, CCRAS Dept. of AYUSH, page no 467-468.
Mahajan BK, Methods in Biostatistics, Edition 7th, page no 117.

Prof. Ravidutta Tripathi, Charak Samhita part 1, 2nd edition 2005, Nidan Sthan page no.511.

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