IJAPC

INTERNATIONAL JOURNAL OF AYURVEDA AND PHARMACEUTICAL CHEMISTRY

Greentree Group Publishers

Int J Ayu Pharm Chem

RESEARCH ARTICLE

www.ijapc.com

e-ISSN 2350-0204

A Clinical Study on the Efficacy of *Haridradi Kashaya* in the Management of *Madhumeha* (Type2 Diabetes Mellitus)

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ABSTRACT

According to Diabetes Atlas 2017, 8th edition, published by International Diabetes Federation, Diabetes is one of the largest global health emergencies of the 21st century. There are 425 million people estimated to have diabetes in 2017, which will be estimated 629 million in 2045 in the age group of 20-79 years. *Madhumeha* is one among the *VatajaPrameha* that has been considered as a *mahagada* and sequel of all varieties of *Prameha*. As per *AcharyaCharaka* in case of *Madhumeha* along with *mutra* there is excretion of *Ojha* which is *madhura* in nature. *Madhumeha* may be correlated with Diabetes Mellitus.Though different herbal compound has been described in *Ayurvedic* classics,more research and clinical evaluation are going on to establish *Ayurvedic* medicine as an effective treatment of *Madhumeha* (Type 2 Diabetes Mellitus).The present clinical study was on the efficacy of *HaridradiKashaya* (*Curcuma longa, Berberis aristata,Embelia ribes* and *Valeriana wallichii*) in the management of *Madhumeha* which is explained in *Charak Samhita, Chikitsa Sthan*, Chapter 6,*sloka* 27.This open clinical trial study was conducted on 100 patients, out of which 84 patients completed the study. The duration of study was 90 days and follow up was taken after 15 days. The results were prepared as per statistical analysis and the result shows that *HaridradiKashaya* is a potent drug in the management of *Madhumeha*.

KEYWORDS

Prameha, Madhumeha, Ojha, HaridradiKashaya

Greentree Group Publishers

Received 08/05/18 Accepted 27/05/18 Published 10/07/18

INTRODUCTION

As the birds are attracted towards the trees where their nest lies, similarly *Prameha* affects the persons who are voracious eaters, less enthusiastic physically as well as mentally, over corpulent and over unctuous[1].

Acharya Charaka has mentioned that indulgence in the etiological factors results in the aggravation of *Kapha,Pitta,Meda* and *Mamsa* & obstruct the normal pathway of *Vata*. Aggravated *Vata* carries the *Ojha* to the *Basti* resulting in the illness[2].He also has mentioned that *Madhumeha* is one among the *VatajaPrameha* that has been considered as *Mahagada*[3].Again *Sushruta* has mentioned in his text that *Madhumeha* is a variety of *VatajaPrameha*,which is referred to as sequel of all varieties of *Prameha*[4].

As per *AcharyaCharaka* in case of *Madhumeha* along with *mutra* there is excretion of *Ojha* which is *madhura* in nature[5].Due to this *madhurata* the ants get attracted towards this type of *mutra*. So,*Madhumeha* may be correlated with Diabetes Mellitus.

Diabetes mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Depending on the etiology of the Diabetes mellitus, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization and increased glucose production[6].

According to diabetes atlas 2017,8th edition published by International Diabetes Federation,Diabetes is one of the largest global health emergencies of the 21st century.There are 425million people estimated to have diabetes in 2017,which will be estimated 629 million in 2045 in the age group of 20-79 years. Approximately, 4.0(3.2-5.0) million people aged between 20 and79 years are estimated to die from diabetes in 2017 which is equivalent to one death every eight seconds.This is higher than the combined number of deaths from infectious diseases.[1.1 million deaths from HIV/AIDS, 1.8 million from tuberculosis and 0.4 million from malaria in 2015].

India which is presently in the second position among the top ten countries after China with 72.9 million people of the age group of 20-79 years are estimated to have diabetes in 2017,which is estimated to be 134.3 million in 2045 and thus India will become the top most country in the tally.

Increasing incidence of *Madhumeha* become a burning challenge for *Ayurvedic* Physicians to search for an effective treatment. Though different herbal

compound have been described in *Ayurvedic* Classics but lot of research and clinical evaluation are going on to establish *Ayurvedic* medicines as an effective treatment for *Madhumeha* .The present study is focused on clinical study on the efficacy of *HaridradiKashaya* (*Haridra*, *Daruharidra*, *Vidanga* and *Tagar*) in the management of *Madhumeha* (Type2 Diabetes Mellitus). *Haridradikashaya* is mentioned in *Charak Samhita ,Chikitsa Sthan,* Chapter 6, *sloka* 27[7] .

AIMS & OBJECTIVES

1. To study the clinical effect of *Haridradi Kashaya* (prepared of *Haridra*, *Daruharidra*, *Vidanga* and *Tagar*) in the management of *Madhumeha*(Type2 Diabetes Mellitus).
2. To find out an effective,low cost and safe remedy to combat the disease.

MATERIAL & METHODS

SELECTION OF PATIENTS:

Total 100 patients of either sex diagnosed to be suffering from *Madhumeha* were selected randomly fulfilling inclusion and exclusion criteria attending OPD and IPD of the Dept. of Kayachikitsa of Govt. Ayurvedic College & Hospital, Guwahati-14.

PRE-TREATMENT OBSERVATION:

After taking the consent of the patient ,the study was carried out along with the registration and necessary information. After preliminary registration diagnostic medical history was taken according to both *Ayurvedic* and Modern clinical methods.

DIAGNOSTIC CRITERIA:

Initial diagnosis of *Madhumeha* (Type 2 Diabetes Mellitus) was typically based on the patient's general complains with sign and symptoms indicating towards *Madhumeha* along with assessment of sugar level in blood after fasting,PP and Glycosylated Hemoglobin (HbA1C).

INCLUSION CRITERIA

1. Males and females belonging to age group between 30 -70 yrs.
2. Newly diagnosed cases of Madhumeha (Type 2 DiabetesMellitus) .
3. Patient already on oral hypoglycemic drug for over a year.

EXCLUSION CRITERIA

1. Patient taking regular insulin/secondary diabetic (Cushing's syndrome, Acromegaly, glucocorticoid induced etc)
2. Malignancy, Tuberculosis patient
3. Pregnant women
4. Surgical interventions
5. Patient with severe cardiac problem
6. Patient with significant renal and hepatic impairment.

LABORATORY INVESTIGATIONS

1. Fasting Blood Sugar (FBS)
2. Postprandial Blood Sugar (PPBS)
3. Glycosylated Hemoglobin (HbA1C)
4. Urine –sugar

STUDY DESIGN

A single clinical trial.

SAMPLE SIZE: Total number of 100 patients registered

DROP OUTS: 16

DURATION OF TREATMENT: 90 days

FOLLOW UP: At 15 days interval x 6 follow up.

SOURCE OF FORMULATION:

The *Yavakuta Churna* of *Haridradi Kashaya* was prepared in the State *Ayurvedic* Pharmacy, Govt.Ayurvedic College & Hospital, Guwahati-14.

INTERVENTIONS:

The *Haridradi Kashaya* (*Haridra*, *Daruharidra*, *Vidanga* and *Tagar*) was given in a dose of 25ml (12.5 gm in 200ml water reduced to 25ml) before meal twice in a day for 3 months. (Table1)

CRITERIA FOR ASSESSMENT:

1. Improvement in sugar level for both fasting and PP (After every 15 days and at the end of complete trial).
2. Improvement in HbA1C at the end of 3 months.

Table 1 Composition of trial drug

Sanskrit name	Botanical name	Part used	Qty.
Haridra	*Curcuma longa*linn	Rhizome	1 part
Daruharidra	*Berberis aristata*	Root	1 part
Vidanga	*Embeliaribes* burm	Seed	1 part
Tagar	*Valeriana wallichii*	Root	1 part

ETHICAL CLEARANCE

The prior consent of the patients was taken before administrating the drug by fulfilling the conditions as per IEC (Institutional Ethical Committee).

IEC/16 20-122 Dated 9/5/16

OBSERVATIONS AND RESULTS

A total of 100 patients were enrolled for the present study out of which 16 patients dropped out leaving 84 patients for the study. Maximum number of patients in this study, i.e. 38.09% belonged to the age group of 41 to 50 yrs,53.57% patients male and 69% Hindus, majority number of patients i.e., 44.05% had completed their secondary/H.S.L.C. education,30.95% patients were household,57.14% belonged to lower middle socioeconomic status, most of the patients i.e., 84.52% were married,53.57% were Urban,32.14% had the disease for less than 1 year,51.19% had positive family history,94.04% patients were on non-vegetarian diet,maximum patients i.e., 55.95% were overweight with

BMI in between (25-29.9), 45.23% patients were addicted to betel nut/ tobacco, 70.23% of patients were with mild physical activity, 36.90% of patients were having hypertension as an associated complication.

1) Effect of Trial Drug on FBS:

The initial mean ± SD of FBS level was 171.2±50.77 which was reduced to 153.1±45.93 after 15 days,150.7±42.39 after 30 days,143.5±37.31 after 45 days,139.3±31.36 after 60 days,131.3±29.64 after 75 days and 124.4±27.01 after 90days respectively.The reduction of FBS after 15days &30days is statistically significant and after 45 days,60 days,75 days & 90 days is statistically highly significant. It implies that the effect of the trial drug on FBS after 90 days i.e., after treatment is highly significant.(Table 2,Figure1).

Table 2 Effect of Trial Drug on FBS

N=84	BT	FU1	BT-FU1	FU2	BT-FU2	FU3	BT-FU3	FU4	BT-FU4	FU5	BT-FU5	AT	BT-AT
Mean	171.2	153.1		150.7		143.5		139.3		131.3		124.4	
SD	50.77	45.93		42.39		37.31		31.36		29.64		27.01	
SE			7.5		7.21		6.87		6.51		6.41		6.27
Zvalue			2.41		2.84		4.03		4.9		6.22		7.46
Pvalue			P<0.02		P<0.01		P<0.001		P<0.001		P<0.001		P<0.001
Remarks			Significant		Significant		Highly Significant		Highly Significant		Highly Significant		Highly Significant

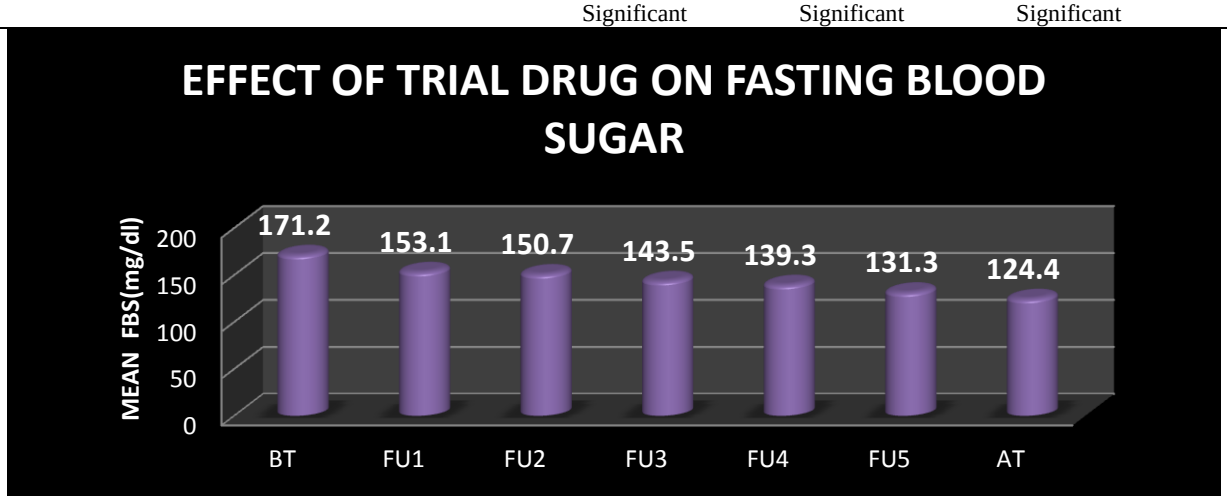

Fig 1 Effect of Trial Drug on FBS

2) Effect of Trial Drug on PPBS:

The initial mean ± SD of PPBS level was 267.2±69.85 which was reduced to 239.2±62.71 after 15 days, 223.2±60.14 after 30 days, 206.3±52.74 after 45 days, 197.9±45.32 after 60 days, 189.5±43.56 after 75 days and 179.5±34.98 after 90days. The reduction of PPBS after 15days is statistically significant and after30 days, 45 days,60 days,75 days & 90 days is statistically highly significant.It implies that the effect of the trial drug on PPBS after 90 days i.e. after treatment is highly significant. (Table 3,Figure 2)

Table 3 Effect of Trial Drug on PPBS

N=84	BT	FU1	BT-FU1	FU2	BT-FU2	FU3	BT-FU3	FU4	BT-FU4	FU5	BT-FU5	AT	BT-AT
Mean	267.2	239.2		223.2		206.3		197.9		189.5		179.5	
SD	69.85	62.71		60.14		52.74		45.32		43.56		34.98	
SE			11		10.06		9.54		9.08		8.98		8.52
Zvalue			2.54		4.37		6.38		7.63		8.65		10.29
Pvalue			P<0.02		P<0.001		P<0.001		P<0.001		P<0.001		P<0.001
Remarks			Significant		Highly Significant		Highly Significant		Highly Significant		Highly Significant		Highly Significant

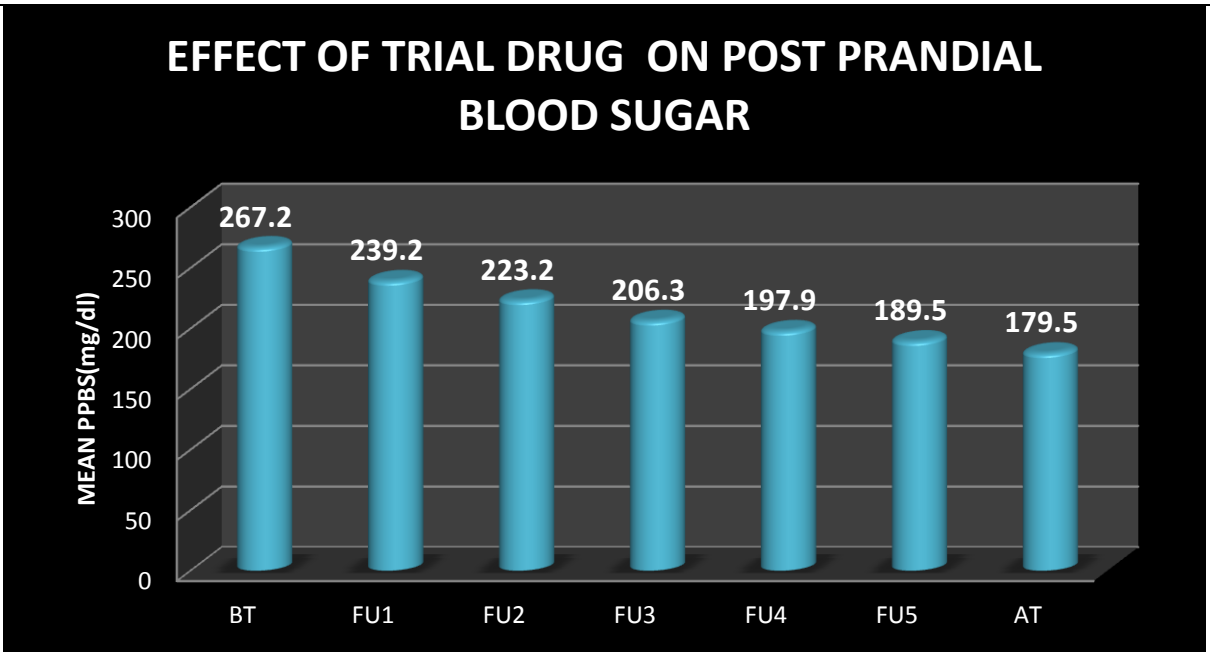

Fig 2 Effect of Trial Drug on PPBS

3) Effect of Trial Drug on Glycosylated Hemoglobin (HbA1c):

Mean Glycosylated Hemoglobin (HbA1c) before treatment was 8.76 which decreased by 7.03 and SD from 1.72 to 0.59. Z=9.10, P<0.001; hence the result is statistically highly significant. It implies that the effect of the trial drug on Glycosylated Hemoglobin (HbA1c) after 90 days i.e. after treatment is highly significant. (Table 4, Figure 3).

Table 4 Effect of Trial Drug on Glycosylated Hemoglobin (HbA1c)

N	Mean		SD		SE	Z value	P value	Remarks
84	BT	AT	BT	AT	19	9.10	P<0.001	Highly significant
	8.76	7.03	1.72	.59				

CONCLUSION

It can be concluded that Haridradi Kashaya as mentioned in *Charak Samhita,Chikitsa Sthan*, Chapter 6,*sloka* 27 is effective in the management of Madhumeha and has got hypoglycemic effect. No untoward effect was noted during treatment and follow up period and patient satisfaction was also noted .Though this study is a preliminary study as a part of the educational research programme with limited number of patients in a fix stipulated time. In order to establish the hypoglycemic effect of this drug, a broad

spectrum clinical and experimental study is required with the application of new technology to establish its effect in view of modern and scientific approach.

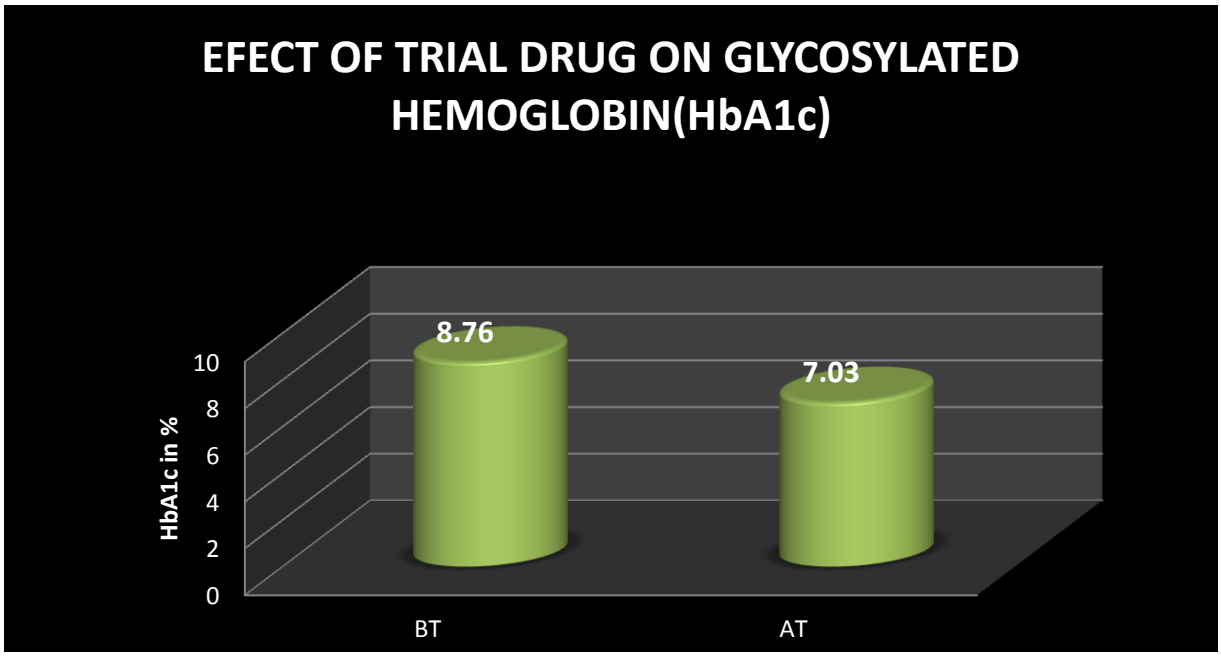

Fig 3 Effect of Trial Drug on Glycosylated Hemoglobin (HbA1c)

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