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A CLINICAL STUDY ON HARIDRA (*CURCUMA LONGA LINN.*), DARUHARIDRA (*BERBERIS ARISTATA DC.*) AND AMALAKI (*EMBLICA OFFICINALIS GAERTN.*) IN MADHUMEHA (DM TYPE 2)

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ABSTRACT

Ayurveda was practiced and preached for the betterment of human beings. Its primary aim was attainment of sustainable health while patients were treated by using natural products. The present clinical study was done with an aim to evaluate the Effect of Haridra *(Curcuma longa Linn.)* and Daruharidra *(Berberis aristata DC.)* processed with Amalaki *(Emblica officinalis Gaertn.)* swarasa in Madhumeha (DM Type 2). According to Ayurveda, Madhumeha is defined as the disease in which patient voids urine similar to Madhu (honey) in taste and colour. Diabetes mellitus is a syndrome, characterized by hyperglycemia resulting from defects in insulin secretion, insulin resistance or both. In India, the prevalence of Type 2 DM between age group 20-79 years is 91.3 million in year 2011 and expected data in 2030 is 101.2 million according to International Diabetes Federation. Present study consists of 60 registered cases of Type 2 DM which is divided in 3 groups i.e. Group A, B and C having 20 cases in each. Out of these, 10 cases did not follow the treatment thus the present study population includes only 50 patients. Group A was treated with trial drug, group B was treated with tablet Gliclazide and group C was treated with both the trial drug and Gliclazide. In group C, significant statistical and clinical changes were observed in reduction of Fasting Blood Sugar followed by group 'A' and 'B'. Effect on Post Prandial Blood Sugar was highly significant in group 'A' followed by group 'C' and 'B'. There was statistically significant reduction in HbA1c in group C. Lastly it is concluded that this trial drug is an effective therapeutic medicine for management of *Madhumeha* (Type 2 D.M).

KEYWORDS: *Haridra, Daruharidra, Amalaki, Madhumeha, Ayurveda, Diabetes*.

INTRODUCTION

According to *Ayurveda*, *Madhumeha* is defined as the disease in which patient voids urine similar to *Madhu* in taste and colour. In *Ayurvedic* classics, *Madhumeha* is described independentaly (S.Ci.13 *Madhumeha Chikitsa*).[1] Considering the severity of the disease and its prognosis, *Ayurvedic* scholars have referred *Madhumeha* as "*Maharoga*" or "*Mahagada*" i.e. a disease which has grave and serious clinical manifestations with possibility of occurrence of serious complications and at times with fatal prognosis (C. In. 9/8-9).[2] *Madhumeha* is the disease having metabolic derangement and genetic inclination related with each constituent of the body having systemic concern. To understand its etiology, pathophysiology, complications and management, it is necessary to put emphasis on the disease *Prameha* as *Madhumeha* which is a subtype of *Vataja Prameha*.[3] *Sushruta* has narrated the term *Kshaudrameha* in place of *Madhumeha* means in which patient voids urine similar to *Kshaudra* or *Madhu* i.e. of *Kashaya* and *Madhura* taste and *Ruksha* texture and honey like colour.[4] Further he narrated that when any of the *Prameha* was not properly treated or neglected that would be converted into *Madhumeha*.[5] Diabetes mellitus Type 2 is a syndrome, characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. The chronic hyperglycemia of diabetes is associated with long term damage, dysfunction and failure of various organs and systems in the body like diabetic retinopathy, neuropathy and nephropathy and so on, so it is necessary to use such drugs which cure the Diabetes along with its complications. The most important demographic change to diabetes prevalence across the world appears to be the increase in the proportion of people >65 years. By the 2030, it is estimated that the number of people with diabetes >64 age will be >82 million in developing countries and >48 million in developed countries.[6]

So we are carrying out a study about *Haridra (Curcuma longa Linn.), Daruharidra (Berberis aristata DC.)* and *Amalaki (Emblica officinalis Gaertn.)* belongs to family Scitaminae, Berberidaceae and Euphorbiaceae respectively. These plants are containing *Pramehaghna* (antidiabetic) properties by its *Rasa, Guna, Vipaka, Virya*. In *Charak Samhita, Haridra* is included in *Lekhaniya mahakashaya (C.Su 4/3), Arshoghna mahakashaya (C.Su 4/12), Kushthaghna mahakashaya (C.Su 4/13), Kandughna mahakashaya (C.Su 4/14), Vishaghna mahakashaya (C.Su 4/16), Tiktaskandha (C.Vi 8/143)* and *Shirovirechana dravya(C.Su 2/5)*; *Daruharidra*, is included in *Lekhaniya Mahakashaya (C.Su 4/3), Arshoghna Mahakashaya (C.Su 4/12), Kandughna Mahakashaya (C.Su 4/14), Tiktaskandha (C.Vi 8/143)* and *Shirovirechana (C.Su 2/5)*; and *Amalaki* included in *Kushthhaghna mahakashaya (C.Su 4/13), Virechanopaga mahakashaya (C.Su 4/24), Kasahara mahakashaya (C.Su 4/36), Jwarahara mahakashaya (C.Su 4/39), Vayasthapana Mahakashaya (C.Su 4/50)* and *Amlaskandha (C.Vi 8/140)*.[7] It is also described in *Sushruta Samhita, Ashtanga Samgraha, Ashtanga Hridaya* and most of the *Nighantus*.

AIM AND OBJECTIVES

The Clinical evaluation of *Haridra (Curcuma longa Linn.), Daruharidra (Berberis aristata DC.)* and *Amalaki (Emblica officinalis Gaertn.)* powder in management of *Madhumeha*.

MATERIAL AND METHOD

A) Collection and Identification of Drug

The drugs, *Haridra Kanda (Curcuma longa* Linn.) and *Amalaki Phala (Emblica officinalis* Gaertn.) were purchased from the vicinity of Varanasi (Mohanlal Rajnish shop, Goladeenanath, Varanasi) and *Daruharidra mula* (*Berberis aristata* DC.) was collected from the hilly area of Barot, Himanchal Pradesh. Botanical identification of these drugs was confirmed by supervisor.

B) Powder Dose, Duration of Treatment and Follow up

According to *Sharangdhara Samhita* (Sha. S. Madh. 6/1) the general dose of *Churna* (powder) has been described as 1 *Karsha* i.e. approx. 12 gm. An average dosage of *Churna* (12 gm) in two divided dose per day was fixed for an average adult individual. The dosage of every patient was calculated with this ratio. It was given just before meal. The dosage of Gliclazide 160 mg daily in two divided dose was also given just before meal. The patient was treated in 3 follow ups, at every 1 month interval and the total duration of treatment was up to 3 months.

C) Selection of Patients

Present study consists of 60 cases of *Madhumeha* (DM Type 2) randomly selected from the O.P.D. of Department of Dravyaguna and Endocrinology, Sir Sundarlal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi. Out of these, 10 cases did not follow the treatment thus the present study population includes only 50 patients. Some of these cases were already known as diabetics while other cases were diagnosed for the first time when they visited with other complaints. All the cases were registered as O.P.D. cases.

D) Inclusion Criteria

All the patients were examined clinically for sign and symptoms of type 2 Diabetes mellitus for e.g. polyuria, polyphagia, polydypsia, weakness, numbness of limbs, tingling and burning sensation in sole and palm, cramps in legs and weight loss over few months etc. However new diagnostic criteria given by WHO was adopted as anchoring diagnostic criteria.

1. Patients having classical symptoms of diabetes with Random Plasma Glucose $\geq$ 11.1 mmol/dl ($\geq$200 mg/dl).
2. Increased Fasting Blood Glucose >7.0mmol/dl ($\geq$ 126 mg/dl), more than two occasions in different days.
3. Increased Post-Prandial Glucose >11.1mmol/dl ($\geq$ 200 mg/dl) during an oral glucose tolerance test.

A patient filling any two of the above this criterion was confirmed having diabetes.

E) Exclusion Criteria

1. Patients having type 1 DM.
2. Super infection, severe complications of Diabetes (Nephropathy, Cardiomyopathy, Retinopathy and Neuropathy etc.), any other chronic diseases like Tuberculosis, Rheumatic Heart disease, Rheumatoid arthritis etc.
3. Patients of type 2 DM taking insulin were also not included in the study.

F) Grouping and distribution of patients

Registered 50 patients were divided into 3 groups i.e. Group A, B and C-

- Group A with trial drug (*Haridra, Daruharidra* and *Amalaki)*.
- Group B with standard
- drug (Gliclazide).
- Group C was treated with trial drug and standard drug.

Parameter of Assessments

a) Criteria to assess the effect of trial drug

All the selected patients were advised to come for follow up at every 1 month interval up to 3 months. Assessment was done under subjective and objective parameters-

i) Subjective Assessment

Subjective Assessment depends completely upon symptomatology and grade depends on symptoms told by patient. In each follow up, patients were assessed for the subjective improvement i.e. polyuria, polydypsia,

polyphagia, nocturia, weakness, loss of weight and other complications.

This clinical symptomalogy was divided into four grades (0-3) and changes in gradations of each symptom were assessed. The clinical grade was decided as follows.

Table 1: Scale of Symptoms of Cases

Symptoms	Score	Grade	Grading Criteria of Symptoms
Polyuria	0	Absent	Normal frequency of 1-4 times in a day, 0-2 times at night and normal volume.
	1	Mild	Frequency 5-7 times/day, 3-5 times/night with normal volume.
	2	Moderate	Frequency 8-10 times/day, 3-5 times/night with excessive volume.
	3	Severe	Frequency > 10 times/day, > 8 times/night and with excessive volume.
Polydypsia	0	Absent	Normal 1.5-3 L/day
	1	Mild	Increased but controlled; 3-4 L/day
	2	Moderate	Increased but uncontrolled ;4.5 L/day
	3	Severe	Very much increased ; > 5 L/day
Polyphagia	0	Normal	Main meal 2, light breakfast 1/day
	1	Mild	Main meal – 2 light breakfast 2-3/day
	2	Moderate	Main meal 2, but light breakfast 3-5/day
	3	Severe	Main meal 2 or 3 light breakfast > 5/days
Weakness	0	Absent	No feeling of weakness
	1	Mild	Mild feeling of weakness
	2	Moderate	Routine activities disturbed
	3	Severe	Severe weakness leads to bed ridden.
Loss of weight	0	Absent	0-2Kg /year
	1	Mild	2-4Kg / year
	2	Moderate	4-6Kg/year
	3	Severe	>6 kg/year
Other Complications			
Cramps in legs	0	Absent	No Cramps
	1	Mild	Cramps after walking 1 km.
	2	Moderate	Cramps after waling some distance.
	3	Severe	Inability to walk even up to ½ km.
Tingling and burning sensation	0	Absent	No tingling and burning sensation.
	1	Mild	Sensation of burning and tingling in palm and soles of mild degree.
	2	Moderate	Sensations like crawling of ants all over the body and burning that hamper patient's routine work.
	3	Severe	Loss of sensation

ii) Objective Assessment

This was done as per W.H.O. guideline:

- Fasting Blood Sugar was done in each follow up.
- Post Prandial Blood Sugar was done in each follow up.
- HbA1c was done before and after completion of the treatment.
- Regular checkup of body weight in each follow up.

RESULTS AND DISCUSSION

The observation and results have been made in the present work on the basis of demographic, constitutional and clinical profile of 60 patients having Type 2 Diabetes Mellitus. Out of 60 patients, 10 patients did not follow the whole treatment [Table 2].

Table – 2:

Group	No. of registered patients	No. of patients completed the follow-up	Drug
A	20	14	Trial drug
B	20	20	Standard drug
C	20	16	Trial drug and standard drug.
Total	**60**	**50**	

Data Analysis

Majority of the cases belongs to the age group of 46-55 yrs. (30%), among these most of the cases were Male (68%), Married (90%), Hindu (70%), belonging middle class (74%) and live in Rural area (70%). Maximum patients belong to graduated group (26%), having mixed diet (78%) and good digestive power (54%). High prevalence of disease in service class (28%), No addiction (19%) with normal bowel habit (62%) and duration of illness was 0-3 yrs (36%). Maximum cases were reported with No family history of type 2 DM (70%) and moderately active (44%).

Some of the important criteria are explained in the Table 3-6.

Table – 3: Showing incidence of age in total cases and in entire groups:

Age group	Total cases n=50		Group A n=16		Group B n=20		Group C n=14		χ^2
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	
35-45	13	26.0	3	18.8	6	30.0	4	28.6	1.018 P = 0.985 P > 0.05
46-55	15	30.0	5	31.2	6	30.0	4	28.6	
56-65	12	24.0	4	25.0	5	25.0	3	21.4	
66-75	10	20.0	4	25.0	3	15.0	3	21.4	
Total	**50**	**100**	**16**	**100**	**20**	**100**	**14**	**100**	

Table – 4: Showing Incidence of sex in total cases and in entire groups:

Sex	Total case n = 50		Group A n = 16		Group B n = 20		Group C n = 14		χ^2
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	1.771
Male	34	68.0	9	56.2	14	70.0	11	78.6	P = 0.413
Female	14	32.0	7	43.8	6	30.0	3	21.4	P > 0.05
Total	**50**	**100**	**16**	**100**	**20**	**100**	**14**	**100**	

Table – 5: Showing Incidence of family history in total cases and entire groups:

Family history	Total case n = 50		Group A n = 16		Group B n = 20		Group C n = 14		χ^2
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	2.168 P=0.338 P> 0.05
Non-significant	35	70.0	9	56.2	15	75.0	11	78.6	
Significant	15	30.0	7	43.8	5	25.0	3	21.4	
Total	50	100	16	100	20	100	14	100	

Table – 6: Showing Incidence of Total duration of illness in total cases and in entire groups:

Duration of Illness	Total case n = 50		Group A n = 16		Group B n = 20		Group C n = 14		χ^2
	No	%	No	%	No	%	No	%	
0-3 years	18	36.0	7	43.8	6	30.0	5	35.7	0.939
4-6 years	16	32.0	4	25.0	7	35.0	5	35.7	P=0.019
>6 year	16	32.0	5	31.2	7	35.0	4	28.6	P>0.05
Total	**50**	**100**	**16**	**100**	**20**	**100**	**14**	**100**	

Effect of treatment

As per paired t- test all the 3 groups (group A, B and C) shows statistically significant results in above mentioned subjective and objective parameters. Some of the important criteria are explained in the Table 7-13.

Table – 7: Showing distribution of patients having polyuria at initial and different follow-ups in entire groups:

Polyuria	Score	BT		F1		F2		F3		Within the group comparison Friedman test
		No	%	No	%	No	%	No	%	
Group A n = 16	0	0	0.0	0	0.0	0	0.0	1	6.2	χ^2 **=34.333** P<0.001
	1	3	18.8	3	18.8	8	50.0	14	87.5	
	2	8	50.0	10	62.5	8	50.0	1	6.2	
	3	5	31.2	3	18.8	0	0.0	0	0.0	
Group B n = 20	0	0	0	0	0.0	0	0.0	1	5.0	χ^2 **=12.798** P<0.001
	1	3	15.0	4	20.0	7	35.0	7	35.0	
	2	9	45.0	11	55.0	11	55.0	9	45.0	
	3	8	40.0	5	25.0	2	10.0	3	0.0	
Group C n = 14	0	0	0	1	7.1	6	42.9	10	71.4	χ^2 **=35.035** P<0.001
	1	1	7.1	6	42.9	7	50.0	4	28.6	
	2	8	57.1	7	50.0	1	7.1	0	0.0	
	3	5	35.7	0	0.0	0	0.0	0	0.0	
Between the group comparison (χ^2)		**χ^2=1.175 P =0.882**		**χ^2=8.244 P =0.221**		**χ^2 = 24.346 P =0.000**		**χ^2 = 39.979 P =0.000**		

#BT- before treatment; F1, F2, F3- follow up 1, 2, 3 respectively.

Table – 8: Showing distribution of patients having polydypsia at initial and different follow-ups in entire groups:

Polydypsia	Score	BT		F1		F2		F3		Within the group comparison Friedman test
		No	%	No	%	No	%	No	%	
Group A n = 16	0	1	6.2	7	43.8	9	56.0	12	75.0	χ^2 **=32.359** P<0.001
	1	10	62.5	6	37.5	7	43.8	4	25.0	
	2	5	31.2	3	18.8	0	0.0	0	0.0	
	3	0	0.0	0	0.0	0	0.0	0	0.0	
Group B n = 20	0	2	10.0	7	35.0	5	25.0	4	20.05.0	χ^2 **=2.926** P =0.403
	1	13	65.0	9	45.0	11	55.0	13	15.0	
	2	4	20.0	3	15.0	4	20.0	3	0	
	3	1	5.0	1	5.0	0	0	0	0	
Group C n = 14	0	2	14.3	6	42.9	10	71.4	11	78.6	χ^2 **=24.316** P<0.001
	1	6	42.9	5	35.7	4	28.6	3	21.4	
	2	6	42.9	3	21.4	0	0.0	0	0	
	3	0	0.0	0	0.0	0	0.0	0	0	
Between the group comparison (χ^2)		**χ^2 = 4.207 P=0.649**		**χ^2 = 2.121 P=0.908**		**χ^2=11.340 P=0.023**		**χ^2 =16.886 P=0.002**		

Table– 9: Showing distribution of patients having polyphagia at initial and different follow-ups in entire groups:

Polyphagia	Score	BT		F1		F2		F3		Within the group comparison Friedman test
		No	%	No	%	No	%	No	%	
Group A n = 16	0	0	0.0	1	6.2	1	6.2	3	18.8	χ^2 =37.697 P<0.001
	1	3	18.8	2	12.5	12	75.0	13	81.2	
	2	8	50.0	13	81.2	3	18.8	0	0.0	
	3	5	31.2	0	0.0	0	0.0	0	0.0	
Group B n = 20	0	0	0.0	0	0.0	0	0.0	3	15.0	χ^2 =17.301 P<0.001
	1	3	15.0	5	25.0	7	35.0	8	40.0	
	2	11	55.0	12	60.0	11	55.0	9	45.0	
	3	6	30.0	3	15.0	2	10.0	0	0.0	
Group C n = 14	0	0	0.0	1	7.1	5	35.7	11	78.6	χ^2 =35.638 P<0.001
	1	4	28.6	6	42.9	8	57.1	2	14.3	
	2	7	50.0	6	42.9	1	7.1	1	7.1	
	3	3	21.4	1	7.1	0	0.0	0	0	
Between the group comparison (χ^2)		χ^2 = 2.002 P= 0.465		χ^2 = 8.322 P= 0.215		χ^2= 2.351 P=0.001		χ^2 =29.545 P=0.000		

Table – 10: Showing distribution of patients having loss of weight at initial and different follow-ups in entire groups:

Loss of weight	Score	BT		F1		F2		F3		Within the group comparison Friedman test
		No	%	No	%	No	%	No	%	
Group A n = 16	0	1	6.2	7	43.8	14	87.5	16	100.0	χ^2 =37.904 P<0.001
	1	6	37.5	7	43.8	2	12.5	0	0.0	
	2	8	50.0	2	12.5	0	0.0	0	0.0	
	3	1	6.2	0	0.0	0	0.0	0	0	
Group B n = 20	0	3	15	7	35.0	12	60.0	12	60.0	χ^2 =21.183 P<0.001
	1	12	60.0	9	45.0	7	35.0	8	40.0	
	2	4	20	4	20.0	1	5.0	0	0.0	
	3	1	5.0	0	0.0	0	0.0	0	0.0	
Group C n = 14	0	3	21.4	8	57.1	13	92.9	12	85.7	χ^2 =22.478 P<0.001
	1	8	57.1	6	42.9	1	7.1	2	14.3	
	2	3	21.4	0	0.0	0	0.0	0	0	
	3	0	0.0	0	0.0	0	0.0	0	0	
Between the group comparison (χ^2)		χ^2 = 6.172 P=0.404		χ^2 =3.677 P=0.451		χ^2=6.769 P=0.149		χ^2 =9.286 P=0.010		

Table – 11: Showing effect of treatment on FBS

(FBS) Fasting Blood Sugar	BT Mean ± S.D.	AT Mean ± S.D.			Within the group comparison paired 't' value BT - F3
		F1	F2	F3	
Group A	209.24 ± 51.24	127.34 ± 16.61	112.44 ± 17.02	103.61 ± 14.32	105.62 ± 51.740 t=8.166 P<0.001
Group B	195.88 ± 54.89	173.30 ± 56.24	157.17 ± 47.99	134.78 ± 25.94	61.100 ± 42.774 t=6.388 P<0.001
Group C	245.45 ± 50.46	134.11 ± 8.28	111.37 ± 7.32	103.00 ± 12.42	14.245 ± 48.84 t=10.912 P<0.001
Between the group comparison one way ANOVA	F=3.762 P=0.031	F=8.053 P=0.001	F=11.822 P=0.000	F=15.617 P<0.001	
POST HOC TEST					
A Vs B	P=1.000	P=0.002	P<0.001	P<0.001	
A Vs C	P=0.198	P=0.198	P=1.000	P=1.000	
B Vs C	P=0.028	P=0.012	P=0.001	P<0.001	

Table –12: Showing improvement in Post Prandial Blood Sugar in entire groups-

(FBS) Fasting Blood Sugar	BT Mean ± S.D.	AT Mean ± S.D.			Within the group comparison paired 't' test value BT - F3
		F1	F2	F3	
Group A	342.94 ± 35.10	182.67 ± 35.10	169.16 ± 21.57	152.17 ± 19.57	190.76 ± 43.49 t=17.545 p<0.001
Group B	318.58 ± 51.96	257.34 ± 38.48	220.94 ± 35.58	206.33 ± 35.58	112.25 ± 55.897 t=8.981 P<0.001
Group C	336.85 ± 42.53	218.36 ± 29.72	178.23 ± 24.03	171.29 ± 22.43	165.56 ± 39.185 t=15.809 p<0.001
Between the group comparison one way ANOVA on difference of BT and F3	F=1.462 P=0.242	F=20.183 P<0.001	F=16.916 P<0.001	F=21.950 P<0.001	
POST HOC TEST **A Vs B** **A Vs C** **B Vs C**	 P=0.332 P=1.000 P=0.739	 P<0.001 P=0.024 P=0.008	 P<0.001 P=1.000 P<0.001	 P<0.001 P=0.125 P=0.001	

Table –13: Showing effect of treatment on HbA1C

HbA1c	BT Mean ± S.D.	AT Mean ± S.D.	Within the group comparison paired 't' test value BT - F3
Group A	9.58 ± 0.852	6.74 ± 0.348	2.837 ± 0.916 t=12.385 P<0.001
Group B	8.91 ± 0.858	7.33 ± 0.550	1.580 ± 0.691 t=10.215 P<0.001
Group C	9.36 ± 0.970	6.65 ± 0.332	2.714 ± 0.856 t=11.870 P<0.001
Between the group comparison one way ANOVA on difference of BT and F3	F=2.688 P=0.078	F=12.585 P<0.001	
POST HOC TEST **A Vs B** **A Vs C** **B Vs C**	 P=0.087 P=1.000 P=0.448	 P=0.001 P=1.000 P<0.001	

Group 'A' showed significant relief in polyuria(6.20%), polydypsia (75.00%), polyphagia (18.80%), weakness (68.75%), loss of weight (100%), cramps in legs (93.00%), tingling and burning sensation (50.00%) and improvement in numbness (100%).

Group 'B' showed significant result in polyuria (5.00%), polydypsia (20.00%), polyphagia (15.00%), weakness (65.00%), loss of weight (60.00%), cramps in legs (60.00%), tingling and burning sensation (15.00%) and improvement in numbness (60.00%).

Group 'C' showed significant relief in polyuria (71.4%), polydypsia (78.6%), polyphagia (78.6%), weakness (78.5%), loss of weight (85.7%), cramps in legs (85.7%), tingling and burning sensation (78.6%) and improvement in numbness (92.9%).

In *Charak Samhita* use of *Haridra* is indicated in *Kushtha* (Skin diseases), *Prameha* (diabetes mellitus), *Arsha* (piles), *Grahani* (Gastrointestinal diseases), *Kamala* (jaundice), *Pandu* (anaemia), *Hikka* and *Swasa* (Respiratory diseases), *Visha* (Poisons) etc; *Daruharidra* is indicated in *Krimi roga* (worm infestation), *Prameha* (diabetes mellitus, *Kushtha* (skin diseases), *Arsha* (piles), *Pandu* (anaemia), *Kamala* (jaundice), *Atisar* (diarrhoea), *Vrana* (Wound), *Mukharoga* (mouth diseases), *Ajirna* (indigestion) etc and *Amalaki* is indicated in *Atisthoulya* (Obesity), *Vayasthapana* (anti-aging), *Krimi* (Worm infestation), *Rasayana* (Rejuvenating agent), *Vajikarana*

(Aphrodisiac), *Jwara* (fever), *Prameha* (diabetes mellitus), *Kushtha* (skin diseases), *Unmada* (psychosis), *Udara roga* (Stomach disorder), *Arsha* (piles), *Kamala* (jaundice), *Pandu* (anaemia), *Hikka* (Respiratory diseases), *Netra roga* (Eye disorder) etc.[7]

In *Sushruta Samhita* use of *Haridra* is indicated in *Jalauka Avacharana* (leech therapy), *Kushtha* (skin diseases), *Prameha* (Diabetes mellitus), *Dushtavrana* (chronic wound) *Gandamala* (goiter), *Vrana ropana* (wound healing), *Netra roga* (Eye diseases), *Timira* (cataract), *Kasa* (respiratory diseases) etc; *Daruharidra* is indicated in *Krimi* (worm infestation), *Kushtha* (skin disorder), *Bhagandara* (fistula-in-ano), *Jwara* (fever), *Kamala* (jaundice), *Atisara* (diarrhoea) etc; *Amalaki* is indicated in *Vrana* (wound), *Vatarakta* (gaut), *Arsha* (piles), *Kushtha* (skin diseases), *Prameha* (diabetes mellitus), *Kasa-shwasa* (respiratory diseases), *Jwara* (fever), *Pandu* (aneamia), *Mutradosha* (Urinary disorders) etc.[8]

Charak has described two type of treatment for *Pramehi* (i.e. *krisha* and *sthula*); for *krisha* and *durbala pramehi* he has narrated *brinhana* (nourishment of body) *chikitsa* and *samshodhana* (purificatory procedures) *chikitsa* for *sthula* (obese) and *balwana* (strong) *Pramehi.*[9]

WHO recommendations about hypoglycemic agents of plant origin used in traditional medicines are important.[10]

The improvement in symptoms of *Bahumutrata* (polyuria) was found statistically highly significant after treatment in entire groups. This shows that test drugs containing *Daruharidra* and *Amalaki* are effective in polyuria because of its *Kasaya* rasa which is *Stambhana* (absorbing property) and also reduces *Shariragata Kleda* (body fluid). This result shows that trial drug proved better synergistically with Gliclazide (OHG).

Reduction in polydypsia was observed statistically highly significant in group C followed by group A this may be due to *Tikta rasa* of trial drug which is claimed to be *Trishnashamak* (decreases thirst). Improvement in polyphagia was statistically highly significant in group C. With respect to weakness, response of treatment was found more pronounced synergistically with test drug and Gliclazide (OHG). Reduction in loss of weight was statistically significant in group A while it was less significant in group B. Considering cramps on walking of test drug was more profound in comparison to Gliclazide. Relief in this symptom observed with test drug, this may be due to its *Vatakaphashamaka* property. Regarding tingling and burning sensation as well as numbness the treatment with test drug was found synergistically significant.

In group C, statistically significant changes were observed in reduction of Fasting Blood Sugar followed by group 'A' and 'B'. Effect on Post Prandial Blood Sugar was highly significant in group A. Results show that trial drug proved better synergistically with Gliclazide (OHG). It lowers the Blood Sugar level might be due to its *Katu, Tikta rasa* and *Katu vipaka* which pacify *Kapha* and *Meda. The Kapha* and *Meda* are the causative factors to increase *Madhuratva (sweetness)*. It may have acarbose like action to which causes reduction in glucose absorption. Reduction in HbA1c was statistically significant in group C. Overall the observations were found more effective in group C where the test drug was continued with the modern drug. It was more significant due to its synergistic action.

CONCLUSION

With above facts we can say that factors involved in *Madhumeha* (type 2 DM) are *Meda* and *Kapha*, vitiation of *Vata* and *Dhatukshaya* mainly. Trial drugs *Haridra, Daruharidra* and *Amalaki* have *Tikta*, and *Katu rasa* which alleviate *Meda* and *Kapha* which are main etiological factors involved in pathogenesis of *Madhumeha*. Being *Ushna virya* it pacifies *Vata* and by virtue of *Kashaya rasa* it reduces *Shariragata Kleda*. This seems that it acts by *Guna Prabhava*. Improvement in physical strength observed in the test subjects can be explained by its Kasaya property, this benefit may be due to *Dravya Prabhava*. So we may infer that the drug acted by both *Gunaprabhava* and *Dravyaprabhava*.

The aforesaid evidences and experiences give positive output that powder of the *Haridra, Daruharidra* and *Amalaki* are very effective for treatment of *Madhumeha* (Type 2 DM), which needs a large number of data to communicate that these drugs are effective in *Madhumeha*.

REFERENCES

1. Sushuruta Samhita of Sushuruta with Nibandhasangraha commentary of Sri Dalhanacharya and Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana, by Vaidya Jadavji Trikamji Acharya, Introduction by Prof. P.V. Sharma; Published by Chaukhambha Orientalia, Varanasi; Reprint edition 2009; Chikitsa Sthana 13; p.456.
2. Charak Samhita of Agnivesha, revised by Charak and Dridhabala with introduction by Vaidya Samrata Sri Satya Narayana Shastri with Vidyotini Hindi Commentary; by Pt. Kashinath Shastri and Dr. Gorakhnath Chaturvedi; Published by Chaukhambha Bharati Academy, Varanasi; Reprint edition 2011; part-I; Indriya Sthana 9/8-9; p.1004.
3. Charak Samhita of Agnivesha, revised by Charak and Dridhabala with introduction by Vaidya Samrata Sri Satya Narayana Shastri with Vidyotini Hindi Commentary; by Pt. Kashinath Shastri and Dr. Gorakhnath Chaturvedi; Published by Chaukhambha Bharati Academy, Varanasi; Reprint edition 2011; part-I; Nidana Sthana 4/39; p.638.
4. Sushuruta Samhita of Sushuruta with Nibandhasangraha commentary of Sri

Dalhanacharya and Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana, by Vaidya Jadavji Trikamji Acharya, Introduction by Prof. P.V. Sharma; Published by Chaukhambha Orientalia, Varanasi; Reprint edition 2009; Nidana Sthana 6/12; p.291.

5. Sushuruta Samhita of Sushuruta with Nibandhasangraha commentary of Sri Dalhanacharya and Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana, by Vaidya Jadavji Trikamji Acharya, Introduction by Prof. P.V. Sharma; Published by Chaukhambha Orientalia, Varanasi; Reprint edition 2009; Chikitsa Sthana 6/27; p.294.
6. Harrison's Principle of Internal Medicine. Vol. 2 ed. Chapter 333, (Diagnostic criteria for Diabetese Mellitus). U.S.A.: Mc Graw-Hill Medical Publishing House; 2005; p-2111.
7. Charak Samhita of Agnivesha, revised by Charak and Dridhabala with introduction by Vaidya Samrata Sri Satya Narayana Shastri with Vidyotini Hindi Commentary; by Pt. Kashinath Shastri and Dr. Gorakhnath Chaturvedi; Published by Chaukhambha Bharati Academy, Varanasi; Reprint edition 2011; part-I & II.
8. Sushuruta Samhita of Sushuruta with Nibandhasangraha commentary of Sri Dalhanacharya and Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana, by Vaidya Jadavji Trikamji Acharya, Introduction by Prof. P.V. Sharma; Published by Chaukhambha Orientalia, Varanasi; Reprint edition 2009.
9. Charak Samhita of Agnivesha, revised by Charak and Dridhabala with introduction by Vaidya Samrata Sri Satya Narayana Shastri with Vidyotini Hindi Commentary; by Pt. Kashinath Shastri and Dr. Gorakhnath Chaturvedi; Published by Chaukhambha Bharati Academy, Varanasi; Reprint edition 2011; part-II; Chikitsa Sthana 6/15; p.235.
10. Divya Jyithi, IJPRBS, 2013; 2(4): 39-47.