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TO STUDY EFFICACY OF HARITAKYADI KWATH IN MADHUMEHA WITH SPECIAL REFERENCE TO TYPE II DIABETES MELLITUS

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ABSTRACT

This study was carried out to find out the antidiabetic effect of Haritakyadi kwath in type 2 diabetes patients. The study was performed in two different groups for a period of 90 days One group received metformin 500mg and other received Metformin 500mg plus Haritakyadi kwath. Fasting blood glucose level(FBG) and Post prandial blood glucose level(PPBG) Were estimated at the time of enrolment in the study and then after 30 days and 90 days. The drop in HbA1c was more in tn the group which received Metformin plus Haritakyadi kwath. All of the patients were observed for hypoglycemic episodes at every visit from Day 1 to day 90. Thus from the results we can conclude that Haritakyadi kwath can be used as as adjuvant in type 2 Diabetes Melitus Patients.

KEYWORDS: Type II Diabetes Mellitus, Madhumeha, Prameha, Haritakyadi Kwath.

INTRODUCTION

Diabetes Mellitus is Metabolic cum Vascular Syndrome of Multiple Aetiology Characterized by Chronic Hyper-glycaemia with Disturbances of Carbohydrate, Fat and Protein Metabolism Resulting from Defects in insulin secretion, insulin action.[1] Inspite of Tremendous Advancements of Modern System of Medicine i.e OAD(Oral Anti Diabetic Drugs) and Insulin Therapy; till date, An Ideal Drug which can control Hyperglycaemia without any adverse effects is still not yet Available and Still Scientists are struggling to search an Effective and Harmless Therapy.

So there is need for effective, safe, potent medicine/drug which controls hyperglycaemia and does overall improvement in signs and symptoms related to Diabetes (NIDDM) and has no adverse effect.

AIM AND OBJECTIVE

1. To study description of Prameha Nidana, Lakshana & Chikitsa are explained in Bruhatrayis & Laghutrayis.
2. To study description of NIDDM (Non Insulin Dependent Diabetes Mellitus) is explained in all most all the Modern text books of medicine like API Text book of Medicine, Davidson's Principles of Internal Medicine and Harrison's Textbook of Internal Medicine.
3. To study description of Haritakyadi Kwath in Prameha Chikitsa is explained in Charak Samhita.

MATERIAL AND METHOD

Diabetes mellitus (DM) is not a single disease but it is a metabolic-cum-vascular syndrome of multiple aetiologies characterise by chronic hyperglycaemia with distribution of carbohydrates, fats, protein metabolism resulting from defect in insulin secretion or insulin action or both.

Prameha (Diabetes) in *Ayurveda*. *Prameha* is elaborately described and discussed with their types, symptom and management by specific formulations as well as life styles. It is surprising that ancient scholars had prime focus to treat disease along with management of complications and thus use multi ingredient therapy for *Madhumeha* (Diabetes mellitus).

Haritakyadi kwath is basically described as *Ayurvedic kwath* dosage form (decoction) in *Charak Chikitsasthan Pramehaadhyaya* (*Kaphaj Prameha*), and here it was called as *Madhumeha* when administered with honey (as supporting liquid for administration).

Ingredients of *Haritakyadi Kwath*

Haritakyadi Kwath is *Ayurvedic* formulation, recommended to administer in decoction form. It has four ingredients *Lodhra* bark (*Symplocos racemosa* Roxb.), *Musta* rhizome (*Cyperus rotundus* L.), *Katphala* bark (*Myrica esculenta*) and *Haritaki* fruit pulp (*Terminalia chebula* Retz.). These ingredients are made into *yavakut* (coarse powder) and were taken in equal quantity for preparation of decoction. All the ingredients are still available to the human

being easily and naturally, so this formulation may be a cost effective formulation within reach of common people.

Ayurvedic properties of Haritakyadi Kwath ingredients

Ingredients that are present in *Haritakyadi kwath* were used having *katu, tikta* and *kashaya rasa* mainly that along with *ushna veerya*, responsible for *kapha* and *vata shamak*. *Laghu* and *Ruksha* property is responsible for reducing obesity and clear *strotas* and also subside *kapha* and *vata*. *Sheeta veerya* is responsible for *pitta shamak* along with *Kashaya rasa* and help in balancing metabolism. All the properties are assimilated in the formulation in such a way to control *kapha* and *vata* and *pitta dosha*. *Haritakydi kwath* ingredients are having all properties that may be utilized for approaching toward equilibrium of *tridosha*. Its *Katu, Kashaya.*

Ayurvedic properties of Ingredients of Haritakyadi Kwath				
Property	*Lodhra*	*Haritaki*	*Musta*	*Katphala*
Rasa	*Kashaya*	*Kashaya pradhana, Panch rasa*	*Katu, Tikta, Kashaya*	*Katu, Tikta, Kashaya*
Guna	*Laghu, Ruksha*	*Laghu, Ruksha*	*Laghu, Ruksha*	*Laghu, Tikshna*
Veerya	*Sheeta*	*Ushna*	*Sheeta*	*Ushna*
Vipaka	*Katu*	*Madhur*	*Katu*	*Katu*
Karma	*Kapha-Pitta Shamak*	*Tridoshashamak*	*Kapha-Pitta Shamak*	*Kapha-vata shamak*

Sr. no.	**Ingredients**	**Antidiabetic Potential**
1	Lodhra	1. Hexane extract of *Symplocos* sp. leaves has potential of antidiabetic property to treat type 2 diabetes. 2. The ethanolic extract of leaves showed hypoglycemic activity. 3. Bark has antidiabetic potential along with insulin like effect on peripheral tissues.
2.	Haritaki	1. Ethanolic extract of fruit have antidiabetic potential. *2. T. chebula* fruit extract significantly reduced the blood glucose. 3. Ethanolic extract of fruit having the pharmacological action against the diabetic condition, even though the mechanism of the action is unknown.
3	Musta	1. The ethanolic extract of *Cyperus rotundus* showed the significant decrease in serum glucose level in both oral glucose tolerance test and alloxan induced diabetic rats. 2. hydro-ethanol extract of *musta* has been reported for antidiabetic effect. *3. C. rotundus* extract has a hypoglycemic or anti-diabetic effect by

		inhibiting intestinal glucose absorption and promoting glucose consumption.
4	Katphala	1. Methanolic extractof *Myrica esculenta* leaves showed dose-dependent antidiabetic activity by significant decrease in blood glucose level. 2. Antidiabetic action reported.

Study Population

The patients who visited Dhanvantari Hospital Ashta were included in the study A total 60 patients were selected for the study. A randomised control trial conducted In the hospital This study was carried in a semi urban population the study included 30 type of type 2 diabetic cases who received only Metformin500 mg tablet and 30 of type 2 diabetic cases received Metformin 500mg tablet plus Haritakyadi kwath.

The baseline Examinations were carried out in the population. A total of 60 patient with type 2 diabetes mellitus were included in the study.

Ethical Clearance

Protocol was duly submitted to institutional Human ethics committee and approval was taken before starting the study. The study was performed under the supervision of the physicians. All the procedure was informed to the patient in his native language and informed consent was taken from them.

Diagnosis

Type 2 Diabetes mellitus was diagnosed according to American Diabetes Association (ADA) criteria 2000 by demonstrating any one of the following.

Fasting plasma glucose ≥ 7.0 mmol/L (126mg/dL). Plasma glucose ≥11.1mmolL(200mg/dL) two hours after a meal. Symptoms of hyperglycemia and causal plasma glucose ≥11.1mmol/L(200mg/dL.).

Glycosylated haemoglobin (HbA1c) ≥6.5%.

Inclusion Criteria

1. Willing to give consent to participate in the study.

Age group limit- 30 to 70 years

2. Sex- Both Male and female (Irrespective of religion, education socioeconomic and marital status).

3. Type of Disease-Apathyanimittaja Prameha (Diabetes Mellitus type 2 NIDDM).
4. Fasting Blood sugar range- 126 to 250 mg/dl.
5. Post Prandial Blood sugar range-200 to 325 mg/dl

Exclusion Criteria

1. Patient not willing to participate in the study or not in position to give consent.
2. Patients of IDDM (Insulin Dependent Diabetes Mellitus)(DM Type 1).
3. Patients below 25 years of age & above 70 years of age.
4. Patients with Blood Sugar Level – FBS > 250 mg/dl PPBS > 325 mg/dl.
5. Patients with Gestational Diabetes.
6. Patients with severe complications (Chronic)[Micro & Macro-Vascular complications]

Criteria of assessment

Both the subjective and objective parameters are taken into consideration to assess the severity of disease.

1. Subjective Criteria[5,14]

1. Prabhutmutrata(Polyuria)
2. Avilmutrata(Turbidity)
3. Kshudhadhikya(Polyphagia)
4. Trishnadhikya(Polydipsia)
5. Pindiko-udveshtan(Cramps)
6. Dourbalya(Weakness)

Objective Criteria[5]

Sr. No.	Objective Parameters	Range
1	Fasting Blood sugar	126 to 250 mg/dl
2	Post Prandial Blood sugar	200 to 325mg/dl
3	HbA1C	≥6.5%≥mmol/L
4.	Urine sugar	Before and after therapy

Assessment of the condition will be done based on detailed Performa adopting standard scoring methods of subjective & objective parameters & will be analyzed statistically.

Severity Assessment Scales

Severity grade points

Highly severe(++++) G4

Severe(+++)G3

Moderate(++)G2

Mild(+)G1

No signs/symptoms(-) G0

Gradation criteria of Assessment

Prabhutmutrata

No polyuria

6-9 times per day 0-2 times per night

9-12 times per day, 2-4 times per night

More than 12 times per day, more than 4 times per night

Avilmutrata

No Turbidity

Faintly cloudy or smoky(turbidity barely visible)

Turbidity clearly present but newsprint easily read through test tube

News print not easily read through test tube

News print cannot be seen through test tube

Kshudhadikya

No Polyphagia

Slightly increased (1-2 meals)

Moderately increased(3-4 meals)

Markedly increased(5-6 meals)

Pindiko-Udvesthan(Cramps)

No Cramps

Cramps after walking more than 1km

Cramps after walking

Cramps after walking ½ km

Inability in walking even ½ km

Trishnadhikya

No Polydipsia

Feeling of thirst 9 -11times/24 hours either /or Intake of water 7-9 times/24 hours with quantity 2-2.50 litre/24 hours.

Feeling of thirst 11-13 times/24 hours either /or Intake of water 9-11 times/24 hours with quantity 2.50-3.0 litre/24 hours.

Feeling of thirst >13 times/24 hours either /orIntake of water >11 times/24 hours with quantity >3.0 litre/24 hours.

Dourbalya(Weakness)

No Weaknes

Can do moderate exercise with hesitancy

Cannot do mild exercise too

Fasting Blood Sugar (mg/dL)	**Post prandial Blood Sugar(mg/dL)**
0: <126	0:<200
1: 150- 175	1:200-225
2:176-200	2:226-250
3:201-225	3:251-300
4: 226-250	4:301-325

Statistical Analysis

Statistical analysis was done on statistical package for social sciences (SPSS Chicago, Version 15). Unpaired students T test was done. The control group is compared with the trial group Data were expressed as mean ± standard deviation the results were rationally analysed. P< 0.05 was considered statistically significant.

OBSERVATION AND RESULTS

Effect of Haritakyadi Kwath on Fasting Blood glucose Level: The group which received Metformin showed a sustained drop in mean Fasting blood glucose level when compared between day 1 to day 90 on the day 1 it was 174.35gm/dl which dropped significantly to 114.50 gm/dl on 90th day. The group which received Metformin plus Haritakyadi Kwath also showed a sustained drop in the fasting mean blood glucose level when compared between day 1 to day 90. On day 1 it was 171.53gm/dl which dropped significantly to 103.50gm/dl on day 90. The drop in the Fasting mean blood glucose level obtained by Metformin plus Haritakyadi kwath. was more than Metformin when used alone. The mean Fasting blood glucose fall percentage in Metformin group when compared between day 1st to day 30 was

15.48% which further increased when the treatment was continued for 90 days and was 34.32%. The mean fasting blood glucose fall percentage in the Metformin plus Haritakyadi kwath group when compared between day 1st to day 30 was 21.75% which further increased when the treatment was continued for 90 days and was 39.66%.

Effect of Haritakyadi Kwath on Post prandial blood glucose level

The group which received Metformin showed a sustained drop in the mean post prandial blood glucose levels when compared between day 1 to day 90. On day 1 it was 247.31gm/dl which dropped significantly to 152.02 gm/dl on 90th day. The group which received Metformin plus Haritakyadi kwath also showed a sustained drop in the post prandial mean blood glucose level when compared between day 1 to day 90. On day 1 it was 254.13 gm/dl which dropped significantly to 143.12 gm/dl on day 90.

The drop in the post prandial mean blood glucose level obtained by Metformin plus Haritakyadi kwath. was more than Metformin when used alone. The mean post prandial blood glucose fall percentage in Metformin group when compared between day 1st to day 30 was 19.87% which further increased when the treatment was continued for 90 days and was 38.53%. The mean Post prandial blood glucose fall percentage in the Metformin plus Haritakyadi kwath group when compared between day 1st to day 30 was 28.29% which further increased when the treatment was continued for 90 days and was 43.68%.

Mean values of Fasting and Post Prandial blood glucose levels and standard deviation in different group.

	Parameters	Day 1	Day 30	Day 90
Metformin	FBG	174.35±54.26	147.36±31.91	114.50±16.87
	PPBG	247.31±59.01	198.16±35.70	152.02±33.61
Metformin + Haritakyadi Kwath	FBG	171.53±52.15	134.22±26.91	103.50±14.74
	PPBG	254.13± 60.21	182.23 ± 31.62	143.12 ±27.43

Results were expressed in Mean± SD;

P<0.05 when FBS of metformin group compared between Day1 and Day90

P<0.05 when PPBS of metformin group compared between Day 11 and Day90

P<0.05 when FBS of Metformin+ Haritakydi kwath group compared between Day1 and Day 90.

P<0.05 when PPBS of Metformin+ Haritakydi kwath group compared between Day1 and Day 90.

Comparison of percentage reduction in Fasting and Post prandial blood glucose levels In case of Metformin group and group receiving Metformin plus Haritakyadi kwath.

	Parameters	Day 30	Day 90
Metformin	FBG	15.48%	34.32%
	PPBG	19.87%	38.53%
Metformin + Haritakyadi Kwath	FBG	21.75%	39.66%
	PPBG	28.29%	43.68%

Results were expressed in Mean± SD;

P<0.05 when FBS of metformin group compared between Day1 and Day 90

P<0.05 when PPBS of metformin group compared between Day 1 and Day 90

P<0.05 when FBS of Metformin+ Haritakydi kwath group compared between Day1 and Day 90.

P<0.05 when PPBS of Metformin+ Haritakydi kwath group compared between Day1 and Day 90.

Effect of Haritakyadi Kwath on glycosylated Haemoglobin (HbA1c)

The group which received Metformin showed a significant drop in the Glycosylated Haemoglobin (HbA1c) levels when compared between day 1 to day 90. On day 1 it was 7.62, which dropped significantly to 5.31 on day 90th day. The group which received Metformin plus Haritakyadi kwath also showed a significant drop in Glycosylated Haemoglobin (HbA1c) level when compared between day 1 to day 90. On day 1 it was 7.76 Which dropped significantly to 4.98 on day 90.

Comparison of HbA1c levels in case of Metformin group and group receiving Haritakyadi kwath plus Metformin

Drop	Day 1	Day 90	Percentage
Metformin	7.62±0.68	5.31±0.55	30.31
Metformin + Haritakyadi Kwath	7.76±0.73	4.98±0.39	35.82

Results were expressed in Mean± SD;

P<0.05 when HbA1c of metformin group compared between Day1 and Day 90

P<0.05 when HbA1c of Metformin+ Haritakydi kwath group compared between Day1 and Day 90.

DISCUSSION

In the present study, the combination of Metformin plus Haritakyadi kwath was found more effective in lowering both fasting and post prandial blood glucose levels in the patients of type 2 diabetes mellitus than who consumed only oral hypoglycemic agents Assesment of blood glucose levels was performed on the 1st day, 30th day and at the end of therapy (90th day). The current study additionally evaluated chane in HbA1c levels. The add on therapy of metformin plus Haritakyadi kwath showed a significant drop in Glycosylated Haemoglobin (HbA1c) level when compare between day1 to day90 and was found more effective than the the group which received only Metformin.

CONCLUSION

Diabetes is grasping the human population in accelerated manner due to disturbance in lifestyle, mind status and genome. Diabetic complications are needed to be addressed with more emphasis along with controlling the blood sugar level. So management of *Prameha* in ancient era has been highlighted here with selecting *Haritakyadi Kwath* mention in *Charak Samhita* for treatment of Kaphaja Prameha (*Madhumeha). Haritakyadi Kwath* has been selected to analyses ancient Since different ingredients of Haritakyadi kwath separately reported for many of pharmacological action that may be utilized in management of diabetes and its complications. So *Haritakyadi Kwath* may be considered as all rounder medicine for management of DM.

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