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Research Article

CLINICAL STUDY TO EVALUATE EFFECT OF *MUSTADI KWATH* IN *MADHUMEHA*

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ABSTRACT

The dissertation is entitled "Clinical study to evaluate the effect of *Mustadi kwath* in *Madhumeha.* Diabetes mellitus has become a dreadful disease in the era. It is also described in Ayurvedic text in terms of *Madhumeha.* Diabetes Mellitus is a group of metabolic disease in which there are high blood sugar levels over a prolonged period, this high blood sugar produces the symptoms of frequent urination, increased thirst, and increased hunger. Untreated, diabetes can cause many complications. Sedentary lifestyle, lack of exercise, improper medication and urbanization precipitates the disease. In the present study, *Mustadi kwath* (mentioned in *Bhaisjya Ratnawali*) was selected for clinical trial. The study comprises of 40 patients of *Madhumeha.* These patients were randomly selected on the basis of inclusion and exclusion criteria with detailed clinical history, physical examination and other desired investigation. The duration of study is of 90 days with 15 days follow up. After evaluating therapy it was observed that the '*Mustadi kwath'* provided better relief to the patients of *Madhumeha.*

KEYWORDS: *Madhumeha,* Diabetes Mellitus, *Mustadi kwath.*

INTRODUCTION

Diabetes mellitus is a group of metabolic disease 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, especially the eyes, kidneys, nerves, heart and blood vessels. Diabetes is worldwide in distribution and the incidence of both types of diabetes, i.e., Type 1 and Type 2 is rising. However, the prevalence of both varies considerably in different parts of the world and this is probably due to differences in genetic and environmental factors. The prevalence of both types in Britain is between 1% and 2% but almost 50% of cases of type 2 diabetes remain undetected. The great majority of cases seen worldwide have primary diabetes, and in Europe and North America the ratio of Type 2: Type 1 is approximately 7:3.[1]

According to the international Diabetes Federation there are currently 415 million people living with diabetes and the total is expected to rise to 640 million by 2040.[2]

There is a similar condition in Ayurveda, in which a person passes honey like (sweet) urine. And this is known as *Madhumeha*. *Madhumeha* is one among 20 types of *Prameha* (urological disorder) described in various Ayurvedic classics viz. *Charak Samhita Sushruta Samhita*, *Ashtanga Sangraha, Madhav Nidan*. Ancient seers have narrated that excess use of *Guru* (heavy to digest), *Snigdha* (unctuous), *Amla (*sour), and *Lavana* (salt), *Navanna* (food prepared from newly harvested grains), new wine, *Asya sukha* (sedentary lifestyle), *Atinidra* (excess sleep), *Avyayma* (lack of exercise), obtaining from *Samshodhana* (purification) therapy as the major causes of *Madhumeha*. All these factors (*Nidan)* leads to imbalance of *Doshas,* causes *Manda- Agni* and formation of *Amadosh* which increases *Kleda,* and also leads to *Margavaran*. Aggravated *Vata* brings *Kleda* and *Oja* to the *Basti* and ultimately produces profuse and turbid urination. This clinical presentation is termed as *Madhumeha* in Ayurved.[3]

Ayurveda is non-invasive, cost effective and safe form of treatment. It has been proved as an ideal approach which not only aims diseased person, but also promotes health of a person. So that he may live a healthy and blissful life. This holistic science also described definition of ideal therapy or treatment. It explains that it is not coherent treatment in which medicine modifies the disease only but gives rise to new complication. In Ayurveda classics '*Madhumeha* is described as '*Asadhya' Vyadi* and it cannot be cured totally but controlled definitely.[4]

AIM AND OBJECTIVE

To evaluate the effect of *Mustadi kwath* in *Madhumeha.*

MATERIALS AND METHODS

Study design- Randomized Sampling, Single blind.

Source of Data- 40 patients of *Madhumeha* were selected for study from O.P.D/I.P.D. unit of P.G department of Kayachikitsa, Uttarakhand Ayurveda University Gurukul Campus, Haridwar.

Sample size- 40

Duration of study- 90 days

Selection of drug- *Mustadi kwath*

Dose- 30ml BD before meal

Ingredients

Contents	Part used	Part
Musta	*Mool* (root)	1
Amalki	*Phal* (fruit)	1
Haritiki	*Phal* (fruit)	1
Vibhitak	*Phal* (fruit)	1
Indrayan	*Mool* (root)	1
Haridra	*Kand* (stem)	1
Devdaru	*Twak* (bark)	1
Murva	*Mool* (root)	1
Lodhra	*Twak* (bark)	1

Inclusion Criteria

- Fasting blood glucose level>110mg/dl-<350mg/dl
- Post prandial blood sugar level>140mg/dl-<450mg/dl
- Patients between the age group of 30-60 years

Exclusion Criteria

- Patients of type1 diabetes mellitus
- Age below 30years and above 60 year.
- Blood sugar- fasting blood sugar level>350mg/dl.
- Post Prandial blood sugar level>450mg/dl.
- Patients having complications.
- Patients suffering from any serious medical or surgical illness
- Personal matters

Criteria for Withdrawal

- Aggravation of complaints
- Inter current illness
- Any other difficulties

Subjective Parameters

- *Prabhuta mutrata*
- *Avila mutrata*
- *Atisudha*
- *Daurbalaya*
- *Pipasaadhikya*
- *Kar-padha daha*

Objective Parameters

- Blood sugar fasting
- Blood sugar post-prandial
- HbA1c
- Bodyweight
- B.M.I

Investigations

- Hb%, TLC, DLC, ESR
- Lipid profile
- LFT
- Urine examination
- Urine sugar
- Body weight
- BMI

Grading of Symptoms

1. ***Prabhuta mutrata*** **(Frequency of urine)**
   - Urination 3-5 times per day, no or rarely at night-0
   - Urination 6-8 times per day, and 1-2 times per night- 1
   - Urination 9-11 times per day, and 3-4 times per night- 2
   - Urination >11times per day, and > 4times per night- 3
2. ***Pipasa - adhika*** **(Polydipsia)**
   - Feeling of thirst 7-9 times/24 hours, consuming-0, 1.5-2.0 litre/24 hour
   - Feeling of thirst 9-11 times/24 hours, consuming-l, 2.0-2.50 litre/24 hours
   - Feeling of thirst 11-13 times/24 hours, consuming -2, 2.5-3.00 litre/24 hours
   - Feeling of thirst >13 times/24 hours, consuming -3, >3.00 litre/24 hours
3. ***Avila mutrata*** **(Turbidity in Urine)**
   - Crystal clear fluid- 0
   - Faintly cloudy or hazy with slight turbidity- 1
   - Turbidity clearly present and newsprint easily read- 2 through test tube
   - Newsprint not easily read through test tube-3
   - Newsprint cannot be visualized through test tube-4
4. ***Kshudha- adhika*** **(polyphagia)**
   - As usual/ routine- 0
   - Slightly increased (extra 1-2 meals)- 1
   - Moderately increased (extra 3-4 meals)- 2
   - Markedly increased (extra 5-6bmeals)- 3

5. *Daurbalya* (Weakness)

- No weakness in doing routine work and exercise- 0
- Mild weakness in doing routine work and exercise- 1
- Moderate weakness in doing routine work and exercise- 2
- Severe weakness in doing routine work and exercise- 3

6. Kara-pada daha

- No *Daha*- 0
- Mild *Kara- Pada daha* for short period- 1
- *Kara pada daha* continuous but bearable- 2
- *Kara pada daha* continuous, and unbearable-3

Statistical Analysis

Wilcoxon signed rank test was applied on subjective parameters. Paired t test was applied on the both objectives and biochemical parameters.

Thus, the obtained results were interpreted as;

p>0.05- Not significant

P<0.01 and <0.05- Significant

P<0.001 – Highly significant

OBSERVATIONS

Table 1.1: Shows Status of 40 patients of *Madhumeha*

Drug	Total registered	*Lama*	completed
Mustadi kwath	40	0	40

Table 1.2: Shows the effect of *Mustadi Kwath* in Subjective Parameters

Subjective Parameters	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Prabhut Mutrata	2.10	0.33	2.50	0.00	1.10	0.47	-5.246[a]	0.00000016	84.52	Sig
Pipasa Adhika	1.53	0.15	2.00	0.00	1.11	0.36	-4.879[a]	0.00000107	90.16	Sig
Avila Mutata	2.03	0.10	2.00	0.00	1.19	0.44	-5.215[a]	0.00000018	95.06	Sig
Kshudha Adhika	0.78	0.05	0.00	0.00	1.10	0.22	-3.573[a]	0.00035240	93.55	Sig
Daurbalya	1.70	0.53	2.00	0.00	1.18	0.60	-4.724[a]	0.00000231	69.12	Sig
Kara-Pada-Daha	0.73	0.25	1.00	0.00	0.82	0.54	-3.578[a]	0.00034662	65.52	Sig

Table 1.3: Shows the effect of *Mustadi Kwath* in Objective Parameters

Objective Parameters		Mean	N	SD	SE	t-Value	P-Value	Result
Body Weight	BT	69.55	40	8.47	1.34	1.677	0.102	NS
	AT	67.48	40	8.69	1.37			
BMI	BT	25.15	40	2.53	0.40	2.008	0.052	NS
	AT	24.35	40	2.88	0.46			
Blood Sugar Fasting	BT	179.76	40	58.67	9.28	9.178	0.000	Sig
	AT	111.22	40	25.52	4.03			
Post Prandial	BT	266.94	40	84.63	13.38	8.645	0.000	Sig
	AT	160.98	40	31.55	4.99			
HBAIC	BT	9.74	40	1.41	0.22	9.779	0.000	Sig
	AT	8.05	40	1.07	0.17			

Table 1.4: Shows the effect of *Mustadi Kwath* in Biochemical Parameters

Objective Parameters		Mean	N	SD	SE	t-Value	P-Value	Result
HB%	BT	14.32	40	1.63	0.26	1.752	0.088	NS
	AT	14.89	40	1.70	0.27			
TLC	BT	7566.50	40	1626.74	257.21	0.829	0.412	NS
	AT	7406.65	40	1566.25	247.65			

Neutrophill	BT	58.99	40	11.20	1.77	-0.679	0.501	NS
	AT	60.16	40	10.57	1.67			
Lymphocytes	BT	30.11	40	7.24	1.14	-0.815	0.420	NS
	AT	31.03	40	9.76	1.54			
Monocytes	BT	2.33	40	2.51	0.40	0.308	0.760	NS
	AT	2.25	40	2.07	0.33			
Basophils	BT	0.20	40	0.41	0.06	-1.000	0.323	NS
	AT	0.25	40	0.44	0.07			
Eosinophils	BT	2.95	39	1.26	0.20	-2.919	0.006	Sig
	AT	3.21	39	1.28	0.21			
E.S.R	BT	18.17	40	8.63	1.36	1.677	0.102	NS
	AT	16.65	40	6.01	0.95			

Objective Parameters		**Mean**	**N**	**SD**	**SE**	**t-Value**	**P-Value**	**Result**
Serum Cholesterol	BT	188.43	40	43.20	6.83	0.381	0.705	NS
	AT	186.26	40	39.22	6.20			
Serum Triglyceries	BT	134.24	40	91.32	14.44	-0.532	0.598	NS
	AT	137.61	40	81.77	12.93			
HDL Cholesterol	BT	50.97	40	14.71	2.33	2.008	0.052	NS
	AT	47.87	40	13.51	2.14			
VLDL	BT	27.02	40	18.19	2.88	-0.423	0.674	NS
	AT	27.52	40	16.51	2.61			
LDL Cholesterol	BT	116.78	40	25.20	3.98	-0.560	0.578	NS
	AT	118.42	40	25.53	4.04			
Total/HDL Cholesterol Ratio	BT	4.02	40	1.41	0.22	-1.108	0.275	NS
	AT	4.19	40	1.41	0.22			
LDL/HDL Cholesterol Ratio	BT	2.43	40	0.99	0.16	-2.004	0.052	NS
	AT	2.62	40	0.78	0.12			

Objective Parameters		**Mean**	**N**	**SD**	**SE**	**t-Value**	**P-Value**	**Result**
Serum Bilirubin	BT	0.70	40	0.37	0.06	-3.334	0.002	Sig
	AT	0.88	40	0.41	0.06			
Conjugated	BT	0.30	39	0.17	0.03	-2.358	0.024	Sig
	AT	0.35	39	0.16	0.03			
SGOT/AST	BT	25.09	40	7.36	1.16	0.586	0.561	NS
	AT	24.62	40	9.11	1.44			
SGPT/ALT	BT	24.32	40	8.76	1.38	0.026	0.979	NS
	AT	24.30	40	8.77	1.39			
Alkaline Phosphate	BT	108.82	40	34.27	5.42	1.814	0.077	NS
	AT	104.03	40	34.03	5.38			
Total Protein	BT	5.32	40	2.23	0.35	-1.375	0.177	NS

	AT	5.59	40	1.98	0.31			
Albumin	BT	3.07	40	1.30	0.20	-0.260	0.796	NS
	AT	3.10	40	1.20	0.19			
Globulin	BT	3.36	40	1.15	0.18	0.857	0.397	NS
	AT	3.23	40	1.27	0.20			

RESULT

Statistically significant result was obtained in subjective parameters i.e., *Prabhuta mutrata*, *Avila mutrata*, *Atishudha*, *Pipasaadhikya*, *Daurbalaya*, *Kar-pada daha*. Statistically significant result also obtained in objective parameters i.e., blood sugar fasting and post prandial sugar level, eosinophil, Serum Bilirubin level and conjugated. Other objective parameters were non-significant.

DISCUSSION

Any research work without discussion about its nature, utility and importance is said to be incomplete. Any hypothesis/principle, if to be proved, must be discussed thoroughly from all angles. Discussion improves the knowledge and discussion with the *Shastra,* become the base of establishment of the concept. The present study entitled "Clinical study to evaluate the effect of *Mustadi kwath* in *Madhumeha"* was done on 40 patients.

Conceptual

Premeha is *Kapha pradhan tridoshaja vyadi*. *Prameha* is considered most troublesome "*Anushangi Vyadi"* in Ayurveda and has been included in *Astha Mahagadas*. Ayurvedic *Acharyas* considered genetics and acquired factors responsible for manifestation of *Prameha.* Two types of pathogenesis have been described in the Ayurvedic classics one is *Aavaranjanya* and second is *Dhatu kshayajanya.* Both of these cause *Vata-prakopa* but different mechanism.

In *Aavaranjanya Madhumeha* due to excessive indulgence of *Guru*, *Snigdha*, *Amla*, *Lavana Ahara, Kapha* and *Pitta* get vitiated. Vitiated *Kapha* and *Pitta* block the nature pathway of *Vata*. Getting hindrances in free flow, *Vata* get intensification. Thus aggravated *Vata* vitiates the *Dushyas* like *Kapha, Meda, Mamsa* and brings *Oja* to the urinary bladder and along with other *Dushya* excrete *Oja* through urine.

In case of *Dhatu kshayajanya Madhumeha, Vata prakopakaahara –Vihara* leads to aggravation and vitiation of *Vata.* Therefore, in this type *Vata* becomes more harmful than the previous type. This aggravated *Vata* disturbs the normal metabolism of body and cause *Kshaya* of all vital *Dhatus*. In both these types *Aparaoja* is excreted through urine.

In pathogenesis of *Prameha Agnimandya* particularly *Dhatvagnmandya* plays important role. In *Premeha*, especially *Medo dhatvagnimandya* is observed. Derangement of *Agni* leads to *Ama* production at various levels. As a result, the process of *Dhatuposhana* and *Dhatu- utpatti* is hampered.

Diabetes mellitus is a clinical syndrome characterized by hyperglyceamia due to absolute or relative deficiency of insulin. Lack of insulin, whether absolute or relative, affects the metabolism of carbohydrate, fat, water and electrolyte. Two types of diabetes mellitus are observed in the people i.e., Type 1 and Type 2. In this Type 1, the process of beta – cell destruction occurs that may ultimately leads to diabetes mellitus. In this type insulin is required for survival to prevent the development of ketoacidosis, coma and death. Onset of symptoms is generally abrupt with polyuria, polydipsia and polyphagia. The Type 2 is characterized by disorder of insulin action and insulin secretion, either of which may be predominant feature. Patients of this type are generally obese and have mild onset of disease.

In the general survey of the patients the observation is as follow

In the current study, i.e., 32.5% of patients were aged 41-50 years. The incidence of type 2 D.M. may be indicated. It is more in the higher age group. Less physical activity and increased age could be the cause of this finding, while 25% or patients were of 51-60 and 61-70 ages. 65% of patients were male and 35% of patients were female. The incidence of DM in men and women is comparable in most age ranges. Modern studies indicate that males and female suffer similarly from the disease, but males are most vulnerable than females to the effects of indolence and obesity and regional fat deposition.

In this study maximum number of patients i.e., 42.5% patients were desk worker, followed by 35% were housewives. In this observation of occupation we found maximum patients belongs to desk worker, housewives, both are related to physical inactivity thereby leading a sedentary lifestyle which leads to a less energy expenditure than uptake. The present study reveals that vegetarian dietary habits were found more (70%) than mixed (30%). This data is in consistence with population characteristics of Haridwar.

Current study reveals that the frequency of patients in weight group of 71-80kg was the highest

47.5% followed by 30% of patients from 61-70 weight groups. This means most of the patients do not have physical activity and follow sedentary lifestyle.

Effect of Therapy

- Statistically significant result was found in subjective parameters like *Prabhut Mutrata Aavila- Mutrata, Atikshuda, Pipasaadhikiya, Daurbalya, Kara-pada daha* as, P-value for all parameters are less than 0.05.
- Statistically significant result was found in objective parameters like blood sugar fasting, postprandial blood sugar and HBALC as p- value for the parameters are less than 0.05.

In the present study, complete relief in 27.5%, marked improvement in 50%, moderate improvement in 22.5% was found

Probable mode of action of *Mustadi Kwath*

The *Mustadi Kwath* is *Tridosha Shamaka* especially *Kapha- Vata Shamaka* and also its contents have *Laghu, Ruksha, Tikshna* properties due to which it depletes the vitiated *Kapha* and *Vata doshas* which is dominant in the pathogenesis of *Madhumeha*.

CONCLUSION

Mahumeha is *Kapha-vata pradhan vyadi* which has symptoms similar to diabetes mellitus. *Mustadi kwath* had a significant result in *Madhumeha.* No adverse drug effects were observed at the end of trial, hence it is concluded that *Madhumeha* is effectively treated by Ayurvedic medicine.

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