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A Clinical Study of Efficacy of 'Ushtra Dugdha' along with Lifestyle Modification in the Management of Madhumeha W.S.R. to Diabetes Mellitus (Type 2)

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ABSTRACT

This clinical trial was carried out with Ushtra Dugdha along with diet and lifestyle modification in the management of Madhumeha (diabetes mellitus type 2). The present study was conducted in 3 groups. In Group A- Ushtra Dugdha, Group B- Diet and lifestyle modification and Group C- both are given. Total 48 patients were registered for present study, in which 45 patients completed and 3 patients were dropouts. At the end of trial, it was observed that Ushtra Dugdha along with diet and lifestyle modification provided better results in comparison with other groups.

Keywords: *Prameha, Madhumeha, Ayurveda, Diabetes Mellitus, lifestyle disorders, Endocrine, Metabolic syndrome.*

INTRODUCTION

The disease *Madhumeha* is the subtype of *Vatika Prameha* [1]. All types of *Prameha* if not treated timely eventually develop into *Madhumeha* [2].

Acharya Vagbhatta classified *Madhumeha* as *Avaranajanya Madhumeha* and *Dhatukshayajanya Madhumeha.* The factors which provoke the *Vata* directly cause *Apatarpanajanya Madhumeha* while the factors which provoke *Kapha* and *Pitta* cause *Santarpanajanya Madhumeha*. In *Ayurvedic* literature, *Apathyanimittaja Prameha* (*Acharya Sushruta), Sthoola Pramehi (Acharya Charaka),* and *Avaranajanya Madhumeha* have been linked to Type-2 Diabetes Mellitus.

Diabetes is a disease known from the dawn of civilization and now it is a growing public health problem throughout the world. The late Arthur Koestler suggested the term "Coca-colonization" [3] as a means to describe the impact of western societies on traditional socio-cultural habits and way of life in developing countries. Furthermore, Drewnowski and Popkin have proposed "The concept of nutritional transition and impact of globalization on human diet" [4].

Previously the studies were conducted on Ushtra Dugdha for pre diabetic and Type 1 diabetes [5]. Studies have proved that active participation of the patients in the form of diet and lifestyle changes can result in less expense for the management of diabetes and ensure good glycemic control also [6]. we were therefore interested in determining the effect of *Ushtra Dugdha* along with diet and lifestyle modification in the management of *Madhumeha* (diabetes mellitus type 2).

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Table 1: Study Design

Study type	Interventional (clinical trial)
Purpose	Treatment
Masking	Open label
Timing	Prospective
End points	Efficacy and safety
No of groups	3
Treatment period	45 days

MATERIAL & METHODS

Total 45 clinically diagnosed and confirmed patients of Madhumeha (type 2 Diabetes Mellitus) of either sex in between the age group of 18-70 attending the O.P.D. of P.G. Department of *Kayachikitsa* in DSRRAU, Jodhpur were selected for the study. Patients having Type I DM, Age below 18 and above 70 years, Patients of type II DM who are on Insulin therapy, DM with complications and Uncontrolled DM were excluded from the trial. During the course of trial if any serious condition or any adverse effects occur which require urgent treatment and Patient, he/she want to withdraw from the clinical trial were in withdrawal criteria.

A) Administration & Dose of drugs

The study was divided into 3 groups.

Group A – 15 well diagnosed and confirmed patients of Diabetes Mellitus type 2 were administrated *Ushtra Dugdha* in the dose of 250 ml twice a day on empty stomach for 45 days.

Group B - 15 well diagnosed and confirmed patients of Diabetes Mellitus type 2 were advised for diet and lifestyle modification but here in this group the selected patients were already taking modern medicines as per their routine treatment.

Group C – 15 well diagnosed and confirmed patients of Diabetes Mellitus type 2 were administrated *Ushtra Dugdha* in the dose of 250 ml twice a day on empty stomach for 45 days along with diet and lifestyle modification.

In group B and C, the patients were provided proper diet and lifestyle modification guidance planned according to the classics.

TRIAL DRUGS

1. ***Ushtra Dugdha (*Camel Milk)**

   ***Ayurvedic* Perspective of Camel Milk**

   "औष्ट्रमीषत् कटु क्षारं लवणं मधुरं गुरु ॥१४३॥
   विकाशि विशदं तीक्ष्णं दीपनं च विशोधनम्।
   रूक्षोष्णं भेदनं वातश्लेष्मघ्नं मेहशूलजित् ।।१४४॥ कैयदेवनिघण्टु - द्रववर्ग)

2. **Lifestyle Modification**

Ayurvedic Diet and lifestyle modification for *Madhumeha* or Type 2 Diabetes Mellitus

A diabetic meal plan matches calories from foods to individual physical activity and insulin levels. WHO recommends intake of whole grain foods, with a minimum consumption of 5-10 portions of fruits and vegetables per day.[7&8]

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Table 2: The recommended diet for *Madhumehi* or Type 2 DM [9]

Diet	Which one should intake
Cereals	*Yava* (Hordeum vulgare - Barley), Old Wheat (*Godooma*), old rice (*Purana Shali*)
Pulses	*Mudga* (Vigna Radiata- Greengram), *Chanaka* (Cicer arietinum Linn. – Bengal gram), Kulattha (Dolichos biflorus), Adhaki (Cajanus cajan - Pigeon pea), and others.
Vegetables	Bitter vegetables (*Tikta Shaka*) e.g. *Karela* (Momordica charantia - Bitter gourd), *Methi* (Trigonella foenum-graecum - Fenugreek), *Patola* (Trichosanthes dioica, Vietnamese gourd), *Rasona* (Allium sativum Linn. – Garlic), *Udumbara* (Ficus racemosa - Cluster Fig Tree- *Gular*), *Haridra* (Curcuma longa -*Haldi*) *etc*.
Fruits	*Jambu* (Syzygium cumini - Black berry/*Jamuna*), *Amalaki* (Emblica officinalis- Indian gooseberry/*Amla*), *Kapitta* (Limonia acidissima - Wood Apple) , *Talphala* (Borassus flabellifer -Asian Palmyra palm), *Utpala* (Nymphaea Stellata), *Parushaka* (Grewia asiatica-*Phalsa*) *etc*.
Liquor	*Saarodak* (*Vijaysaar* –Pterocarpus marsupium decoction), *Triphla* decoction
Oils	Mustard oil (*Sarshapa Taila*), *Ingudi* (Balanites aegyptiaca), *Ghrita*

***Apathya Ahara* (contraindicated Diet)**

Rajamasha (Vigna unguiculata), Potato, Sweet potato, *Rakta Vrintaka*, Ripened Mango (Mangifera indica), Banana (Musa acuminata), Custard apple (*Sitaphala* / Annona reticulata), Jackfruit (Artocarpus heterophyllus), *Chikoo* (Manilkara zapota), Fresh Dates (Phoenix dactylifera), Paneer, Cheese, Junk foods, Aerated drinks, Carbonated Deep fried, Pastry foods, Foods prepared from *Maida* / Refined, Hydrogenated oil Sugar, sweets, cakes, jam, jelly, Narcotics, Jaggery, sugar, salty snacks, Fruit juices, Soft drinks, *Soviraka*, *Sura* (alcohol), *Asava* (fermented medications), *Dugdh* (buffalo's milk), Oil, *Ghee*, *Ikshuvikara* (food prepared with sugarcane) , *Dadhi* (curd), *Sarbata* (sugar containing syrups) etc.

Table 3: Lifestyle modification (*Pathya Vihara* for Diabetics)

S. N.	**Lifestyle**	***Dravya***	**Duration**	**Frequency**	**Remark**
1.	Waking up early in morning		4.00 am to 6.00 am	Daily	
2.	*Gandusha / Kavala Dharana*	Oil / Decoctions/ *Sukhoshna Jala*	3-5 minutes	Daily	
3.	*Ushna Jala Pana*	Water kept in copper vessel / *Sarodaka*		Daily around ½ to 1 liter	
4.	*Vyayama* / Yoga/ *Chankramana*		20- 60 minutes	Daily	Yoga in morning & *Chankramana* in evening
5.	*Padabhyanga*	*Tila Taila* or any other medicated oil	5 minutes	Thrice a week	
6.	*Shirobhyanga*	Suitable medicated oil	5 minutes	Twice a week	
7.	*Udvartana*	*Triphala Churna/ Yava Churna*	30 minutes	Thrice a week	
8.	Bathing	*Sukhoshna Jala*		Daily	

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9.	*Prabhata Bhojana*			Daily	
10.	*Madhyahna Bhojana*			Daily	
11.	*Ratri Bhojana*			Daily	Avoid eating late in the night
12.	Lukewarm water		as per necessity	Daily	
13.	Going to bed at night			1 hour after food	

Yoga Advice

1) *Acharya Sushuruta* has recommended walking of 100 *yojan* in 100 days. (1 yojan is = 7.5 km). So, patients will be advised to brisk walk 7.5 km / day or as per capacity.
2) Patients can choose either walk or Yoga practice (yoga advised according to the Ministry of Ayush's common yoga protocol.)
3) To prevent to hypoglycaemia, patients are advised to take a light breakfast (before ½ an hour) before starting yoga and exercises.

While selecting various practices for the individuals, considering their age, gender, severity of illness, capacity, presence of complications, status of the *Dosha* etc.

Apathya Vihar: Day sleep, Suppression of natural urges, night awaking, and stress etc.

Clinical Assessment

Subjective Criteria - All the patients registered for clinical trial were asked for any changes in their clinical signs & symptoms

Special symptom of *Madhumeha* (DM) which was looked in to includes-

1) *Prabhuta Mutrata* (Polyuria) frequency of urine
2) *Pipasa* (Polydipsia) feeling of thirst
3) *Kshudha* (Appetite)
4) *Avil mutrata* (Turbid urine)
5) *Tandra* (Drowsiness)
6) *Kara-Pada-Tala-Daha / Supti* (Burning sensation/Numbness in palm and soles)
7) *Alasaya / Utsahahani* (General Debility)
8) *Panduvarna Mutra* (Yellowish-white urine)
9) *Pindiko-udveshtan* (Cramps in calf muscles)
10) *Mutramadhurya* (Glycosuria)

(B) Objective Assessment: - Following investigations were assessed for objective assessment:

Laboratory Investigation

- Blood Sugar levels - Fasting Blood Sugar (F.B.S.)
- Postprandial Blood Sugar (P.P.B.S.)
- HbA1c (optional)
- LFT
- RFT (Renal Function Test)
- Urine Test: - Routine & Microscopic Examination

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CRITERIA FOR ASSESSMENT OF OVERALL EFFECT OF THERAPY

Two phases were used to measure the overall outcome of the therapy.

- By comparing how signs and symptoms improved before and after therapy.
- By comparing F.B.S and P.P.B.S. before and after treatment.

Assessment of relief in signs and symptoms were done on the following scoring pattern.

Grade	Assessment	Criteria for Signs and Symptoms
1	Marked improvement	76% and above relief in signs and symptoms
2	Moderate improvement	51-75% relief in signs and symptoms
3	Mild improvement	Up to 25-50 % relief in signs and symptoms
4	No improvement	< 25% relief in signs and symptoms

RESULT

For comparison among three groups we have used Kruskal Wallis Test (Non-Parametric ANOVA) and observe that there was significant difference observed in Group A, Group B and Group C for *Prabhutmutrata, Tandra, Kara-pada-tala-daha / Supti and Pindiko-udveshtan.*

Table 4: Showing the overall outcome of Therapy on Subjective parameters in each group

S.no.	Variable	% Relief		
		Group A	Group B	Group C
1.	*Prabhutamutrata* (polyurea)	61.54	50.00	58.33
2.	*Pipasa* (polydypsia)	40.74	56.52	53.13
3.	*Kshudha* (polyphagia)	42.86	38.46	46.15
4.	*Avilamutrata*	37.50	33.33	40.00
5.	*Tandra*	50.00	55.00	62.07
6.	*Kara-pada-tala-daha/supti*	60.00	57.14	64.52
7.	*Alasaya/ utsahahani*	41.18	44.44	56.00
8.	*Panduvarnamutra*	29.03	33.33	38.46
9.	*Pindiko-udveshtan*	57.69	54.55	63.89
10.	*Mutramadhurya*	53.33	46.67	57.14
11.	**Average**	**47.38**	**46.94**	**53.96**

In the study, average percentage improvement was maximum in Group C (53.96%) and minimum relief in Group B (46.94%). So from this data it is clear that in *Madhumeha* (DM Type 2), combined therapy (*Ushtra Dugdha* along with lifestyle modification) is more effective than individual *Ushtra Dugdha* and lifestyle modification.

Outcome of therapy on Objective parameters (Paired‘t’ Test)

Table 5: Outcome on Fasting BSL

Fasting BSL		Mean	N	SD	SE	t-Value	P-Value	% Change	Result
Group A	BT	126.13	15	17.32	4.47	3.673	0.003	8.19	VS
	AT	115.80	15	12.70	3.28				
Group B	BT	127.53	15	13.00	3.36	3.361	0.005	5.33	VS

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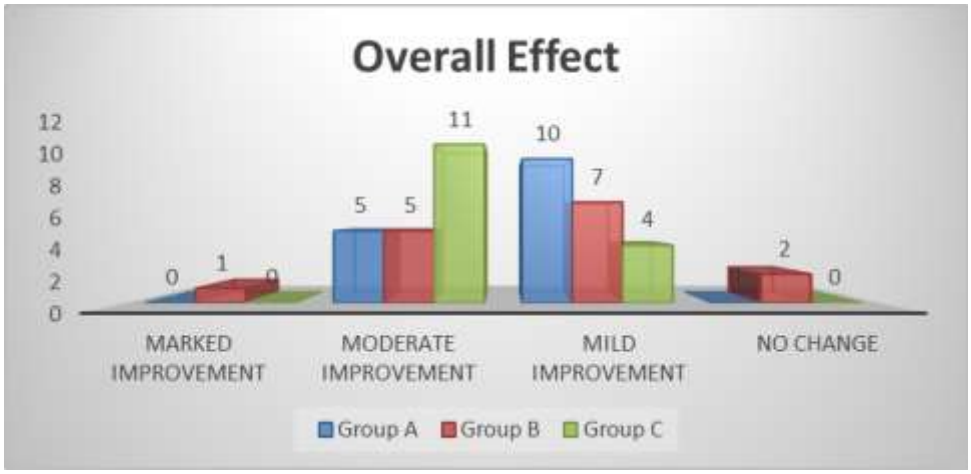
	AT	120.73	15	10.65	2.75				
Group C	BT	128.59	15	8.28	2.14	11.913	0.0001	12.49	ES
	AT	112.53	15	6.99	1.80				
	AT	112.53	15	6.99	1.80				

Table 6: Overall Outcome of Therapy

Overall Effect	Group A		Group B		Group C	
	N	%	N	%	N	%
Marked Improvement	0	0.00	1	6.67	0	0.00
Moderate Improvement	5	33.33	5	33.33	11	73.33
Mild Improvement	10	66.67	7	46.67	4	26.67
No Change	0	0.00	2	13.33	0	0.00
TOTAL	15	100.00	15	100.00	15	100.00



Graph 1: Showing the overall outcome of Therapy

OBSERVATION

In the present study out of 48 patients, 58.33% of the patients were Males and 41.67% of the patients were Females. Positive family history for DM (31.25%) showed genetic background of the disease. In the present study, Majority of patients had urban habitat (47.92%) followed by rural habitat (29.17%) and semi-urban habitat (22.92%). 64.58% were doing less exercise, while 18.75% doing moderate exercise and 16.67 were doing adequate exercise. Stress related previous history was present in 70.83% patients while in 29.17% patients no previous history of stress was observed. Maximum patients were having *Kapha Vata Prakriti*. *Samhanana* was *Madhyam* in maximum (66.67%) patients. *Samhanana Pariksha* was done on the basis of BMI. Patients having BMI (18.5 to 24.9) (29.17%) were considered as *Pravara Samhanana*, BMI <18.5 (4.17% of patients) were considered as *Avara Samhanana* and BMI >25 (66.67% of patients) were considered as *Madhyama Samhanana*. High BMI is a strong risk factor for Diabetes. Majority of the patients had *Madhyama Satva* (60.42%) which indicates that they were more prone to be psychologically disturbed with stress; tension *etc*.

DISCUSSION

Substantial evidence now exists to suggest that diabetes and other NCDs are strongly associated with increasing unplanned urbanization, patient's unhealthy lifestyle choices,

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reduced physical activity, obesity *etc* [10, 11]. It has been estimated that if the primary risk factors were eliminated, 80% of the cases of heart disease, stroke and type 2 diabetes and 40% of cancers could be prevented.

In *Ushtra Dugdha,* the dominance of *Laghu* and *Ruksha Guna* helps to reduce *Bahu-Abaddha Meda. Ushna Veerya* has *Kapha-Vata Shamaka, Deepana, Pachana,* properties. So it is useful in *Samprapti Vighatana* (Breaks the pathogenesis) of *Madhumeha.*

- Insulin of camel milk has unique properties thus act as regulatory and Immuno modulatory function on cells. Camel milk contains a large concentration of insulin 150 U/ml. Additionally, Camel milk insulin does not form coagulum in the acids environment of the stomach like insulin of other mammals. Furthermore, the insulin of camel is contained within micelles and protected from proteolysis in the upper gastrointestinal tract; it is encapsulated in nanoparticles that facilitate its absorption and easy passing to the bloodstream; itis again plausible that the antioxidant action of camel milk prevents metabolic syndrome, including hyperglycemia, hyperlipidaemia, and insulin resistance. (Ajamaluddin M, Abdulrahman A, Ewa S, Jerzy J. 2012. A study of the anti-diabetic agents of camel milk. Int J Mol Med. 30:585–592.)
- Biochemical studies also revealed the components of camel milk insulin like protein, lactoferrin and Immunoglobulins are responsible for camel milk as anti-diabetic. In parallel, epidemiological surveys stating low prevalence of diabetes in communities consuming camel milk clearly indicates its hopeful role in maintaining hyperglycemia.

Active participation of the patients in the form of lifestyle changes can result in less expense for the management of diabetes and ensure good glycemic control also.[12] Each person needs individualized treatment. Insulin or oral hypoglycemic agents are only prescribed for Type 2 diabetics if diet and exercise alone fail to lower the glycemic level.

High fat (total and saturated) and meat intake were associated with a higher risk of type 2 diabetes. High fat or oil intake is reported to decrease the favorable high-density lipoprotein (HDL) cholesterol levels in the blood and may adversely affect the lipid profile.[13&14] This supports *Ayurvedic* claims on the role of fatty items, marshy animals, aquatic animals (which are heavy with fats) and milk items in diabetes. These dietary irregularities further contribute to disturb the carbohydrate and lipid metabolism and result in *Madhumeha* in susceptible individuals.

Ayurveda suggests increased intake of fiber rich green vegetables and cereals *(Patola, Tanduleyakam, Vastukam, Yava,* etc.). *Yava* (barley) is high in fiber content (4 g in 100 g) and is highly recommended in diabetic diets in different forms. In a primary clinical trial in normal subjects, blood sugar pattern was recorded after giving different types of food such as wheat *chapati*, barley *chapati*, bajra *chapati*, maize *chapati*, gram *chapati* and rice with *Patola* curry separately. Three blood samples were taken at hourly intervals. The maximum rise was recorded in rice, followed by wheat while the minimum rise in the case of *Yava* which surpasses all cereals and pulses. Thus barley proved to be the best diet for patients with *Prameha*.[15]

Fruits, vegetables, and spices are micronutrient rich; influence various systems in the body with diverse metabolic and physiological functions, and enable elderly diabetics to be fit and

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active. They provide nutritional substances like dietary fiber, vitamins, minerals, phytonutrients such as flavonoids (antioxidants), saponins, polyphenols (antioxidants), carotenoids (vitamin A-like compounds), isothiocyanates (sulphur-containing compounds) and so on, which are essential to ensure a balanced diet. Avoid fruits with high GI like Banana, Chikoo, Grapes, and Mango etc. but Orange, *Jambu, Aamlaki* and Apple Guava etc. can be advised.

A number of condiments and spices advocated in *Ayurveda* including pepper, asafetida, fenugreek seeds, cumin seeds, curry leaves, Ocimum, rock salt, turmeric, cinnamon, mustard, garlic, onion, ginger and coriander are reported to possess potential antidiabetic substances and have been ascribed hypoglycemic activities, both experimentally and clinically.

A study reported that a daily brisk walk of 7.5 km (brisk is walking with speed of at least 5 km/hr) for 100 days can reverse the Glucose Tolerance Test to normal.[16,17] Exercise improves insulin sensitivity and glucose absorption, transport and uptake are increased in perfused skeletal muscle, which reduces the insulin requirement. Exercising also increases blood flow through distal muscle groups increasing oxygenation to tissues in the feet and hands. In Ayurveda, *Krisha Pramehi* are suggested not to do high intensity exercises and advised to protect their strength. Similarly in type 1 diabetes, there are risks of hypoglycemia during or after high exercises or of worsening metabolic control if insulin deficiency is present; therefore, well planned exercise regimens are suggested for them.[18]

Need of Society Awareness and Self-Care Strategies for Diabetics

Community awareness is required to improve knowledge and attitudes about the role of physical activity, nutrition, and healthy eating behavior in disease prevention. Self-care coping strategies in patients with diabetes are needed and these would be more achievable if they are well aware and advised to follow suitable dietary and lifestyle recommendations mentioned in Ayurveda.

CONCLUSION

Ushtra Dugdha along with lifestyle modification showed significant results in subjective parameters like *Prabhuta Mutrata, Tandra, Kara-pada-supti-daha* etc as well as in HbA1C, FBS and PP2BS. The plus point observed in this research is absence of any hazardous effect, which is really a great benefit to the patients and is of vital importance in view of the global acceptance of *Ayurveda*.

Disorderly lifestyle plays an important role in the development of type 2 diabetes. Effective health education in terms of change in dietary edibles and patterns, physical exertion according to daily caloric intake, environmental factors, and detection of genetic background has shown promising results in the primary prevention of type 2 diabetes and promotion of health of diabetic subjects. Dietary and lifestyle plans should be made in accordance with the day-to-day requirement of an individual. Maintaining physical well being, mental tranquility and sanctity is equally crucial.

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