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Clinical study to evaluate the efficacy of *Madhutailika Basti* in the management of *Madhumeha* w.s.r. to Diabetes Mellitus

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A B S T R A C T

Madhumeha 'Richman's disease', since Vedic period, is familiar to mankind. *Madhumeha* is a disease in which *Mutra* (urine) of the patient attains similar property like those of *Madhu* (Honey). It is also explained that, when the other *Prameha* are left untreated, this lead to the condition called *Madhumeha.* So *Madhumeha* can also be considered as an advanced condition or stage of *Prameha*. Diabetes Mellitus is a chronic disorder of carbohydrate metabolism, marked by hyperglycemia and glycosuria and resulting from inadequate production or use of insulin. In present study the reassessment of *Madhutailika Basti* has been done to understand its efficacy in Diabetes mellitus. *Madhutailika Basti,* contains *Madhu, Erandamool Kwatha, Til Taila, Shatapushpa Kalka, Saindhava Lavana*. The improvement was calculated by subjective parameters like *Prabhutavil Mutrata* (polyurea), *Kshudha Vruddhi* (polyphasia), *Pippasa Vruddhi* (polydipsia), *Dourbalya* (general weaknesss), *Paridaha* (burning sensation), *Kandu* (itching), *Bhrama* (vertigo), *Anidra* (insomnia), *Nakta Mutra Pravrutti* (urination during night), *Hast Pada Chimchimaya* (tingling) to score clinical outcome. Here statistical analysis was done with the help of Mann-Whitney test which shows some promising results, i.e. $p < 0.0001$. These results show a window of opportunity to treat *Madhumeha* with Ayurvedic perspective to provide better life to the patients.

Key words: *Diabetes mellitus, Madhumeha, Prameha, Madhutalika Basti.*

INTRODUCTION

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. A consequence of this is chronic hyperglycaemia (that is elevated levels of plasma glucose) with disturbances of carbohydrate, fat and protein metabolism. Long-term complications of diabetes mellitus include retinopathy, nephropathy and neuropathy. The risk of cardiovascular disease is increased.[1]

Madhumeha 'Richman's disease', since Vedic period, is familiar to mankind. *Madhumeha* is a disease in which *Mutra* (Urine) of the patient attains similar property like those of *Madhu* (Honey). It is also explained that, when the other *Prameha* are left untreated, this lead to the condition called *Madhumeha.* So *Madhumeha* can also be considered as an advanced condition or stage of *Prameha*.[2]

According to recent study, India will be Diabetes Capital of the world in the near future. This disease of sugar is becoming a great national catastrophe with the current incidence rate of 3% It is very clear that at the end of 2025 A.D. it may find more than 75% diabetes patients in the developing countries. Among them maximum are in India. According to statistics

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from the International Diabetes Federation (IDF), India has more diabetics than any other nation of the world. Current estimates peg the diabetics in the country at about 62 million, an increase of over 10 million from 2011 when estimate suggested that about 50.8 million people in the country were suffering from the disease. The disease has already reached endemic proportions in the country, consider this. By the year 2030, over 100 million people in India are likely to suffer from diabetes, say researchers. 8% Maharashtra suffer from diabetes.

OBJECTIVE OF THE STUDY

To evaluate clinical Efficacy of *Madhutalika Basti* in the management of *Madhumeha* w.s.r. to Diabetes Mellitus

MATERIALS AND METHODS

Materials

Madhutailika Basti[3]

Ingredients

- *Madhu (Honey) - 4 Pala -* 160 gms

- *Erandamool Kwatha (Ricinus communics) - 8 Pala* - 320 ml

- *Til Taila (Sesamum Indicum) - 4 Pala -* 160 ml

- *Satapushpa Kalka (Anethum sowa) - 3 Karsha -* 30 gms

- *Saindhava Lavana - 1 Karsha -* 10 gms

SOP of preparation of *Madhutailika Basti*

Initially 100gms of *Madhu* and 5gms of *Saindhava Lavana* are taken in the *Khalva Yantra* and tricurated to form a homogenous mixture. Preparation is continued until *Lavana* is completely dissolved. Then 100ml of *Tila Taila* is added and again mixed for specific time period. Here oil layer should become minute globules, mixture should become homogeneous. It is followed by adding of 10gms of *Shatapushpa Kalka.* Mixing is done so that *Kalka* particles remain uniformly distributed and do not settle down at the base of the vessel. At last 320ml of *Erandamula Kwatha* is added, mixing is continued

until it properly mixes with oil globules. Homogeneity of final mixture is assessed with certain features under the heading *Suyojitha Niruha Lakshana*. Finally quantity of 530ml *Basti* formulation is measured.[4]

Methods

1. **Research Place:** Dept of Kayachikitsa, OPD/IPD of DY Patil School of Ayurveda.

2. **Sample Size:** 30 patients

3. **Type of Study:** Single Arm Open Clinical Study

Posology

Sample size	30 patients
Medicine	*Madhutailika Basti*
Dose	530 ml
Duration	8 days
Kala	*Prataha (Abhakata)*
Type of Basti	*Niruhavata*
Parihara Kala	16 days

Criteria for Selection of Patients

Inclusion Criteria

- The patients for this study will be selected randomly irrespective of their sex, religion, etc.

- Age between 30 to 70 years.

- Patients with clinical positive history of type 2 diabetes mellitus.

- Blood Sugar level (Fasting 126- 150 mg/dl, Post Prandial 200-250 mg/dl), HbA1c - 6.5 to 7

The patients will be diagnosed clinically with the help of following signs and symptoms.

1. *Prabhutavil Mutrata* (Polyurea)

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2. *Kshudha Vruddhi* (Polyphasia)

3. *Pippasa Vruddhi* (Polydipsia)

4. *Dourbalya* (General Weakness)

5. *Paridaha* (burning sensation)

6. *Kandu* (Itching)

7. *Bhrama* (Vertigo)

8. *Anidra* (Insomnia)

9. *Nakta Mutra Pravrutti* (urination during night)

10. *Hast Pada Chimchimayan* (Tingling)

11. *Suptata* (Numbness)[5]

Exclusion Criteria

- The cases with complications like diabetic gangrene, carbuncles, diabetic coma, retinopathy, IDDM will be excluded from present clinical trials.

- Any major diseases like Koch's, IHD, and AIDS etc. associated with diabetes mellitus.

- Thyroid dysfunction, Patients on Corticosteroid Therapy.

Method of data collection

- CRF will be prepared with details of history, physical examination, pathological investigations.

- The general condition of the patient, severity of symptoms before starting of the treatment will be recorded properly.

- The parameter of signs and symptoms investigations was analyzed statistically by applying Mann Whitney test.

Investigations

- CBC ESR

- BSL - Fasting & PP, HbA1c

- Lipid Profile

- Urine R/M

- ECG

CRITERIA FOR ASSESSMENT

Subjective Parameters

Symptom	Normal	Mild	Moderate	Severe
Weakness	Perform normal activities	Feels weak on long walking	Feels on performing general activities	Unable to perform general activities
Burning sensation	No burning sensation	Occasional	Regular burning sensation	Persistent
Vertigo	No	Occasional	Unable to work properly	Persistent
Insomnia	6 hrs	6-4 hrs	4-2hrs	>2hrs
Tingling numbness	No	Occasional	At palm and feet	persistent
Itching	No Itching	Itching with skin rashes over limbs	Itching with skin rashes on body	Persistent itching
Polyurea	Freq 3-4 times	5-8 times	9-12 times	>12 times
Polyphagia	Eating 2 times per day	3-4 times	5-6 times	>7 times
Polydipsia	Freq 3-4 times	5-8 times	9-12 times	>12 times

Objective Parameters

1. WHO recommendations for the diagnostic criteria for Diabetes Mellitus and intermediate hyperglycemia

	Impaired fasting glucose	Impaired glucose tolerance	Diabetes mellitus
Fasting plasma glucose	110-125 mg/dl	<126 mg/ dl	> or = 126 mg/dl

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2 hour plasma glucose	140 mg /dl	140 -199 mg/dl	> or = 200 mg/dl

2. HBA1C > or = 6.5 %

OBSERVATIONS AND RESULTS

Statistical analysis was done with the help of Mann-Whitney test, following results were found.

1. Patients between age group of 41-50 years are prone to Diabetes Mellitus in this study.

2. Patients having *Hastapada Daha* have 54.64% improvement

3. Patients with *Hastapada Chimchimayan* have 51.81% improvement

4. Patients having *Dourbalya* have 50% improvement

5. Patients having polyurea has 51.02% improvement

6. Patients having polyphagia have 46.29 % improvement

7. Patients having polydipsia have 48.54 % improvement
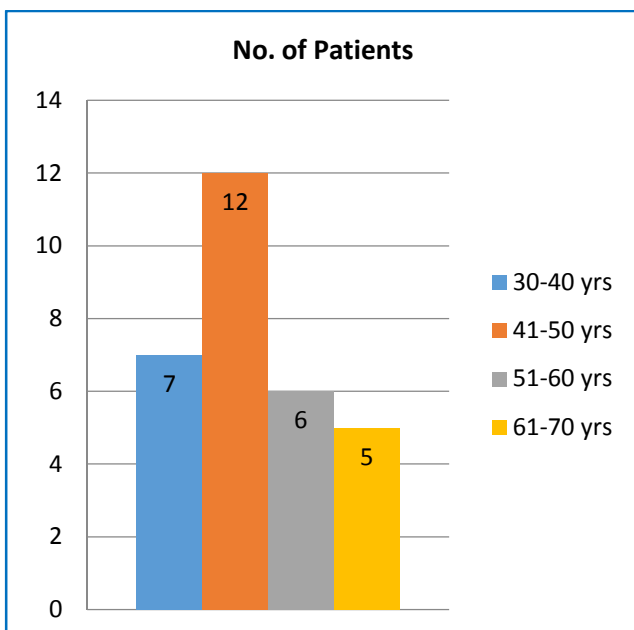
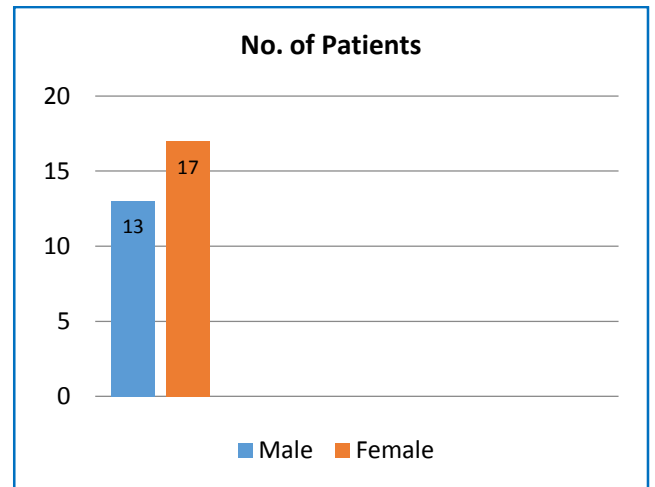**Figure 1: Age wise distribution**

Figure 2: Sex wise distribution

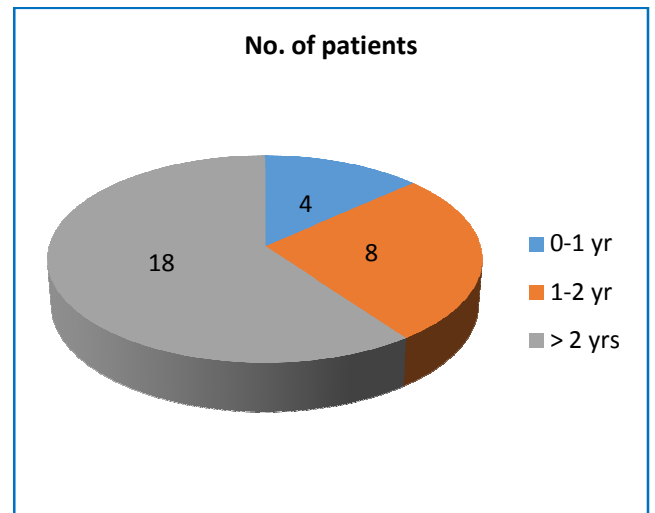
Figure 3: Chronicity wise distribution

Table 1: Effect of therapy on subjective and objective parameters

Symptoms	Mean		SD	P	U	% Improvement
	BT	AT				
Polyurea	1.96	0.96	0.49	<0.0001	92.5	51.02
Polyphagia	2.16	1.16	0.46	<0.0001	86.5	46.29
Polydipsia	2.06	1.06	0.0821	<0.0001	80	48.54
Weakness	0.02	1	0.083	<0.0001	81	50

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Investigation	Mean		SD	P	U	% Improvement
Burning Sensation	1.83	0.83	0.069	<0.0001	62.5	54.64
Tingling Numbness	1.93	0.93	0.002	<0.0001	80	51.81
Investigation	BT	AT	SD	P	U	% Improvement
BSL FASTING	140.5	128.5	-	0.0002	193.5	8.49
BSL -PP	221.86	198.86	-	< 0.0001	63	9.98
HbA1c	6.66	6.51	-	0.0009	226	2.25

DISCUSSION

Maximum number of patients (40%) belonged to the age group of 41-50 years, which shows its predominance in the middle age group. In this study, numbers of the female patients were (56.66%) as compared to male (43.33%). Patients with chronicity less than 1 year were 13.33%, between 1 to 2 years were 26.66% and more than 2 years were 60%. Highly significant results (P<0.001) were obtained in all the cardinal symptoms Polyurea (51.00%), Polyphagia (46.29%), Polydipsia (48.54%), Weakness (50%), Burning Sensation (54.64%), Tingling Sensation (51.81%), BSL F (8.49%), BSL PP (9.98%), HbA1c (2.255%).

Ayurveda is first medical science that identified diagnosed and managed *Madhumeha* while claiming it is incurable, it can give effective solutiton to this burning problem due to its special treatment methods, which are based on highly effective and safe Herbo mineral drug preparation. Ayurveda is based on the *Dosha and Dushyas* involved (i.e. *Samprapti*).

Madhutailka Basti maintains the equilibrium of the body tissue with *Hridya* and prevents exhaustion or *Dhatupaka* to prevent loss of *Ojas,* and nourishes all *Dhatu* tissue including *Mansa-Majja* and *Shukra* and

enhances more strength to the *Dhatus* at the cellular levels and increase the proper cellular.[6]

It produces the following changes

1. Cure the vitiated or aggravated *Dosha* (elimination of circulatory waste products)

2. Increases digestive capacity (altered metabolism - *Agni Sanrakshan*)

3. Purification of *Koshtha* and remove the constipation *(Koshthashudi)* Strengthen the host defence mechanism without increasing circulatory levels of sugar, facts and metabolities.

4. Enhances the function of all *Agni Sthula* and *Sukshmaagni (Aama Pachana)*

5. Production of better *Dhatus* and *Upadhatus* (immonomodulatory action - *Dhatusanrakshana*)

6. Enhances strength of body (adaptogenic activity)

7. Proper functioning of nervous tissues (improvement of micro circulation by modulation of macrophage function - *Strotoshodhana*)

8. Increases the resistance of body (*Dhatuvardhana* - maintain tissue regeneration)[7]

CONCLUSION

The present treatment modality viz. *Madhutailka Basti* is found to be effective clinically as well as statistically in the treatment of Diabetes Mellitus. Also, it gives significant results in blood sugar level and HbA1c which is used for diagnosis of DM. By combating *Kapha* and *Vata Dosha* and *Ama* (the chief pathological factors), it lead to *Samprapti Vighatana* of *Madhumeha* and hence, highly significant results were achieved in all the cardinal symptoms. Due to limitation of number of cases and duration of the trial, there is a need to conduct further study in this regard on larger sample and for a longer duration to improve this preliminary study.

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