

CLINICAL TRIALS OF VATSAKADI GHANAVATI AND MADHUTAILIK BASTI IN MADHUMEHA

Surkar Sonam Vasant¹, Vaidya Minal S²

¹MD Final Year, ²HOD & Professor

Kayachikitsa Dept., Y.M.T. Ayurvedic Medical College Kharghar.

Navi Mumbai, Maharashtra, India

ABSTRACT

In the present scenario, sedentary life style and stressful mental conditions leads to the emergence of various life style disorders like obesity, diabetes mellitus etc. The prevalence of diabetes is about 62 million in 2013 which is increasing rapidly. Ayurveda is the first medical science that identified, diagnosed, and managed *madhumeha* while it is said that incurable much earlier by modern science. Ayurveda can give effective solutions to this burning problem due to its special treatment methods based on highly effective and safe herbomineral preparations. Therefore in present article the reassessment of *Madhutailik basti* and *Vatsakadi ghanavati* has been done to understand its efficacy on *Madhumeha* (diabetes mellitus).

Key words: *Madhumeha*, diabetes mellitus, *Madhutailik basti*, *vatsakadi ghanavati*.

INTRODUCTION

Diabetes Mellitus was known to Indian Civilization since Vedic period by name *Madhumeha* which literally means excessive urine with sweetness like honey. *Madhumeha* is included among “*Ashtamahagada Vyadhi*”¹ in *Charak samhita* which indicates the graveness of disease and on the other hand Diabetes Mellitus which is a syndrome of impaired carbohydrate, fat and protein metabolism caused by either lack of insulin secretion or decreased sensitivity of the tissue to insulin in the present scenario. Among the many dreadful conditions arising because of modern day life style, diabetes mellitus (DM) is a giant disease considered as one of the archenemies of humankind caused by improper diet. It is often referred as a “Silent Killer”. *Madhumeha* is fast emerging as one of the major killers of

present era.² Diabetes and its complications have major threat to public health resources throughout the world, if remained untreated can lead to various health complication and at times death.

India has been already recognized as a diabetic capital³ as every 10th person in India is diabetic and prevalence of diabetes is about 62 million in 2013 which is increasing rapidly. Throughout the world various health systems have been working to manage diabetes efficiently. Besides the miraculous achievements of modern medical science, humanity is passing through a horror of disease, drug phobia, drug related complications and side effects i.e. Hypoglycemia, weight gain, GI disturbance, disturbance in liver and kidney metabolism.

In such scenario the ancient Ayurvedic principle provide wide reference on herbal n herbo-mineral preparations which can be safely used orally for longer period⁴. There are large numbers of drugs made up of herbal and mineral origin mentioned in Ayurvedic texts, advised for the treatment of *Madhumeha*.

Aims and Objectives:

1. To study in detail about *Madhumeha* and diabetes mellitus as per respective texts.
2. To assess the efficacy of *Madhutailik basti* on *Madhumeha* (DM).
3. To evaluate the effect of *Vatsakadi ghanavati* on *Madhumeha* (DM).
4. To introduce an easily available and much effective drug for the patient of *Madhumeha*(DM).

Study design:

1. Sample size:- 45 patients (15 in each group).
2. Study duration: - 3 months.
3. Source of data: OPD and IPD of Kaychikitsa department, Y.M.T. Ayurvedic

Medical College, Kharghar, Navi Mumbai.

4. Type of study:- Open comparative type of study.

Materials and Methods:

Group 1: Patients were given *Madhutailik basti* then *Vatsakadi ghanavati*.

Group2: Patient were given *Vatsakadi ghanavati* and Tab. Metformin.

Group3: Patients were given *Vatsakadi ghanavati*.

Inclusive criteria:

1. Patients with K/C/O Type 2 DM.
2. Patient falling in age group within 25-65 yrs.
3. Patient with fasting blood sugar level 126-400 mg/dl and post prandial >200 mg/dl with presence of urine in sugar.
4. Patient with HbA1C value >6.5%.
5. Few sign and symptoms of *Madhumeha*.

Table No. 1 SYMPTOMS WITH GRADATION

Sr. No.	Symptom	Grade 0	Grade 1	Grade 2	Grade 3
1	<i>Prabhut mutrata</i>	1-4 times/day	5 – 7 times/day	8-10 times/day	>10 times/day
2	<i>Nakt mutrata</i>	0-2 times in night	3-4 times in night	5-6 times in night	> 6 times in night
3	<i>Pipasa vrudhi</i>	Normal 1.5-3 L/day	Increased but controlled 3-4 L/day	Increased but uncontrolled 4-5 L/day	increased but uncontrolled > 5 L/day
4	<i>Kshuddha vrudhi</i>	Main meal-2 light breakfast 1/day	Main meal-2 light breakfast 2-3 times/day	Main meal -2 light breakfast 3-5 times /day	Main meal 2-3 light breakfast >5 times/days
5	<i>Hast paad tal daah/ chimchimayan</i>	Absent	Occasional	Persistent but bearable	Persistent non bearable requires medicine

6	Swedatipravrutti	Absent	Excessive sweating on exertion	Excessive sweating on slight exertion	Excessive sweating on rest
7	Anutsaaha (fatigue)	No fatigue	Fatigue occurs after 1-2 hr work	Fatigue occurs after 30 min	Fatigue occurs after 10-15 min.

Exclusion criteria:

1. K/C/O Type 1 DM and Gestational diabetes.
2. K/C/O ketoacidosis, diabetic coma, acute infection, gangrene.
3. Patients on insulin and steroid therapy.
4. K/C/O of immunocompromised, tuberculosis, Ca patients.

Objective parameters:

1. Fasting and postprandial blood sugar.
2. HbA1C.
3. Presence of sugar in urine.

Study formulation:

According to textual reference as *Vatsakadi ghanavati* was prepared.

1. Contents of *Vatsakadi ghanavati*⁵-
 1. *Vatsaka beej* (Holarrhena antidysenterica)
 2. *Aamalaki* (Embllica officinalis)
 3. *Bibhitaki* (Terminalia bellirica)
 4. *Haritaki* (Terminalia chebula)
 5. *Musta* (Cyperus rotundus)
 6. *Daruharidra* (Berberis aristata)
 7. *Bijak* (Pterocarpus marsupium)

2. Contents of *Madhutailik Basti*⁶-

1. *Erandmool* (Ricinus communis)
2. *Madanphala* (Randia spinosa)
3. *Shatapushpa* (Anthem sowa)
4. *Saindhav* (Sodium chloride)
5. *Til tail* (Sesamum indicum)
6. *Madhu* (Honey).

Procedure:

1. Doses of drug:

Group 1: *Madhutailik basti*- for 8 days then *Vatsakadi ghanavati*- 500 mg TDS
 Group2: *Vatsakadi ghanavati*- 500 mg TDS and Tab. Metformin- 500mg BID
 Group3: *Vatsakadi ghanavati*- 500mg TDS

1. Anupan: Luke warm water

Observation:

There is reduction in symptoms after 3 month follow up in group-1 patients as compare to other two groups. At the end of 3 months the patient of group-1 shows significant improvement in the blood sugar level, urine sugar level and HbA1C value.

Table No.2: Showing reduction in blood sugar level (Fasting).

Sr. No.	Groups	Mean reduction	Difference	C.D.
1	G-1	79.20	36.09	
2	G-2	42.48		29.71
3	G-3	43.11	0.63	

As mean reduction in score of treatment group-1 is maximum, so it is most effective for reducing BSL (fasting) as compare to other groups.

Table No. 3: Showing reduction in blood sugar level (Postprandial).

Sr. No.	Groups	Mean reduction	Difference	C.D.
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1	G-1	98.48	35.48	
2	G-2	57.94		9.002
3	G-3	63	6.06	

As mean reduction in score of treatment group-1 is maximum, so it is most effective for reducing BSL (postprandial) as compare to other groups.

Table No.4: Showing reduction in HbA1C value.

Sr. No.	Groups	Mean reduction	Difference	C.D.
1	G-1	45.92	23.66	
2	G-2	20.93		21.61
3	G-3	22.26	1.33	

As mean reduction in score of treatment group-1 is maximum, so it is most effective for reducing HbA1c value as compare to other groups.

DISCUSSION

In *madhumeha Bahumutrata*, *hastapada-tal daha*, *Alasya* are seen due to *kleda* formation and *drav guna* of *kapha dosha* and the contents of *Vatsakadi ghanavati* having *katu, tikta, kashaya rasa, Ushna, Tikshna guna kledashoshak* and *kapha-vata shamak agni deepan-pachan* property due to which *dhatvagnimandya* might be avoided and excessive *kleda nirmiti* might be stop and formed *kleda* might be excreted by *mutral dravya*. All *dravyas* of *Vatsakadi ghanavati* having “*Pramehaghna*” means anti diabetic property. *Madhutailik basti* has been administered in *madhumeha* patients have got the result by virtue of its *rasayan* and *shodhan* qualities might have stimulated B cells to enhance the insulin property and increased peripheral resistance. It might have improved the specific immunity in the body and stopped the degeneration of B cells and give strength to the existing B cells to enhance the secretion of insulin production. Hence,

when it improves the immunity in the body it gives the resistance power to the whole body.

In this way the combination of *Vatsakadi ghanavati* and *Madhutailik basti* is more significant in subjectively means symptomatically as well as objectively than allopathic medication.

CONCLUSION

The clinical trials on *Madhutailik basti* and *Vatsakadi ghanavati* in *Madhumeha* (comparative study) can be concluded that individually all three treatment groups have shown encouraging result in reducing all the symptoms and blood investigations.

1. From the study, it can be concluded that Group-1 has significant & highly effective in reducing the symptoms as well as blood sugar levels.
2. It has concluded that Group-2 has moderately effective in reducing blood sugar levels.
3. The patients treated in Group-3 have got effect on symptoms and slight poor effect on blood sugar level.

Finally from the present clinical trial it can be concluded that group1 (Madhutailik basti)

with *vatsakadi ghanavati* has got most significant result than other two groups.

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CORRESPONDING AUTHOR

Dr. Surkar Sonam Vasanttrao

MD Final Year

Kayachikitsa Dept.

Y.M.T. Ayurvedic Medical College Kharghar, Navi Mumbai, Maharashtra, India

Email: sweetsonam028@gmail.com

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