

## A CLINICAL STUDY ON THE MANAGEMENT OF STHULA MADHUMEHA VIS-A-VIS TYPE II DIABETES MELLITUS WITH SPECIAL REFERENCE TO THE EFFECT OF HERBAL COMPOUND ON BLOOD SUGAR LEVEL

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### ABSTRACT

Prameha which is familiar to world as Diabetes Mellitus is now-a-days is a big health issue and receiving more attention. Various oral hypoglycaemic agents, insulin formulation, life style modification consisting diet management and regular exercise are basic regimen. In spite of these, world seeking for a safer and effective remedy. Resistance to the drugs, increasing side-effects, lack of effectiveness in complications and high cost of newer drugs are basic problems in modern science. Because of these problems, people are looking forward for a solution towards Ayurveda. As described in classical literature of Ayurveda, Madhumeha which is a type of Vataja Prameha, and it is said as *Asadhya* to treat due to its Mahatyayatvata property, but Charaka explained the treatment of Vatolbana Prameha, having more Kshinata of Kapha and Pitta Dosha as compared to Vitiated Vata Dosha. By implication one can apply specially mentioned Chikitsa for Vatolbana Madhumeha to Sthula Madhumeha also. As diabetes is a lifestyle disorder, along with medication, lifestyle modification also plays a key role in controlling it. Keeping this view in mind, it was thought that the effect of Apatarpana Chikitsa should be evaluated on the patients of Sthula Madhumeha. For that compound preparation namely "Daruharidradi Ghanvati" made of singly proven drugs Daruharidra, Meshashringi, Vijayasara, Mamajjaka, Jambubija and Methikabija was selected for the study in trial group and Tab Metformin was taken in control group.

Keywords: Diabetes Mellitus, *Sthula Madhumeha*, *Apatarpana*.

### INTRODUCTION

Prameha which is familiar to world as Diabetes Mellitus is now-a-days is a big health issue and receiving more attention. Diabetes Mellitus is a metabolic disorder. Park K.<sup>1</sup> (2012) termed it as 'Silent Killer' be-

cause disease is not responsible for death but its deadly complications such as diabetic nephropathy, retinopathy, and neuropathy are bringing person near to the death. Various oral hypoglycaemic agents, insulin formulation, life style modification

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consisting diet management and regular exercise are basic management. In spite of these, world seeking for a safer and effective remedy. Resistance to the drugs, increasing side-effects, lack of effectiveness in complications and high cost of newer drugs are basic problems in modern science. Because of these problems, people are looking forward for a solution towards Ayurveda.

As described in classical literature of Ayurveda, *Madhumeha* which is a type of Vataja Prameha, and it is said as Asadhya to treat due to its Mahatyayatvata property, still i am taking this topic for study because Charaka<sup>2</sup> explained the treatment of Vatolbana Prameha, having more Kshinata of Kapha and Pitta Dosha as compared to Vitiated Vata Dosha. By implication one can apply specially mentioned Chikitsa for Vatolbana Madhumeha to Sthula Madhumeha also.

Main treatment given is Shodhana for Sthula Madhumeha and if it is not possible then Shamana Chikitsa is also indicated. Shamana in the form of Apatarpana can be given. While going through the review of literature, it is observed that so many single drugs were studied as a anti-diabetic property effectively. Therefore, it was thought in mind that, combination of some of them must enhance effectiveness against this disease.

As diabetes is a lifestyle disorder, along with medication, lifestyle modification also plays a key role in controlling it. Keeping this view in mind, it was thought that the effect of Apatarpana Chikitsa<sup>3</sup> should be evaluated on the patients of Sthula Madhumeha. For that compound preparation namely "Daruharidradi Ghanvati" made of singly proven drugs Daruharidra<sup>4</sup>, Meshashringi<sup>5</sup>, Vijayasara<sup>6</sup>,

Mamajjaka<sup>7</sup>, Jambubija<sup>8</sup> and Methikabija<sup>9</sup> was selected for the study.

## AIMS AND OBJECTIVES

### Aims:

1. To evaluate the effect of herbal compound preparation (Ghanvati) of Daruharidra, Meshashringi, Vijayasara, Mamajjaka, Jambubija and Methikabija on Sthula Madhumeha.
2. To evaluate the effect of drug on various parameter such as blood sugar level, lipid profile, various symptoms score of Madhumeha.

### Objectives:

#### Primary:

1. To evaluate the effect of drug on various parameter such as blood sugar level, lipid profile, various symptoms score of Madhumeha.

#### Secondary:

2. To study Madhumeha in detail, from Ayurvedic perspective.
3. To study Madhumeha vis-a-vis Type II Diabetes Mellitus with modern point of view.

**MATERIALS AND METHODS:** 60 patients of Sthula Madhumeha were randomly selected. All the patients were examined on the basis of special proforma prepared on the basis of guidelines given in Ayurveda. Necessary investigations were performed, such as complete blood count, erythrocyte sedimentation rate, blood sugar level, urine routine examination, urine specific gravity, lipid profile etc. The Apatarpaka drug in the form of Daruharidradi Ghanavati was given to trial group patients and its results were compared with control group, by giving the patients Metformin tablets.

**CRITERIA OF DIAGNOSIS:** Diagnosis of Sthula Madhumeha was done particularly on the signs and symptoms of *Sthula*

*Madhumeha* described in Ayurvedic text as follow

<i>Mukha-Madhurya</i>	<i>Avilmutrata</i>	<i>Tandra</i>
<i>Kar-Pada Supti</i>	<i>Kshudhadhikya</i>	<i>Kshudhadhikya</i>
<i>Trishnadhikya</i>	<i>Anutsaha</i>	<i>Sakashta Maithuna</i>
<i>Karpada-Daha</i>	<i>Daurbalata</i>	<i>Mutradhikya</i>
<i>Alasya</i>	<i>Swedadhikya</i>	<i>Nidradhikya</i>
<i>Maladhikya</i>	<i>Nitamba-Stana-Ura Pradeshi</i>	<i>Medadhikya</i>

The routine blood examination such as haemoglobin percentage, total leucocyte count, differential leucocytes count, erythrocyte sedimentation rate, urine routine and microscopic were done to rule out other infections. Patients having fasting blood sugar level >125mg/dl and post prandial blood sugar level >200mg/dl were considered as diagnostic criteria (WHO:2013). To decide *Sthulata* in case of Diabetes Mellitus, BMI >23 were considered as described by Chamukuttan S. (2006).

#### **Inclusion Criteria:**

1. Newly detected patients fulfilling the criteria of diagnosis and having the signs and symptoms of *Sthula Madhumeha* (Diabetes mellitus).
2. Patients having fasting blood sugar level >125mg/dl and post prandial blood sugar level >200mg/dl and <300mg/dl (WHO: 2013).
3. Patients having BMI more than 23 (Chamukuttan S: 2006)
4. Patient willing and able to participate in the study.
5. Patients having age between 30 to 60 years.

#### **Exclusion Criteria:**

1. Patients not willing for trial.
2. Patients with postprandial blood sugar level >300mg/dl and fasting BSL >200 mg/dl.

3. Patients having insulin dependent diabetes mellitus and juvenile diabetes mellitus, Gestational diabetes mellitus.
4. Patients having BMI less than 23.
5. Patients having complications such as vasculopathy, nephropathy, retinopathy and neuropathy.
6. Patients having other systemic complications like malignancies or having hepatic/renal/cardiac problems.
7. Patients having poorly controlled blood pressure.
8. If any complication arises during treatment or if any patient discontinues the treatment, these were rejected.
9. Patients on prolonged medication (>6weeks) with corticosteroids, or any other drugs that may have an influence on the outcome of the study.
10. Patients who was currently participating in any other clinical trials (since last 6 months).
11. Patients having hemoglobin less than 9 gms%.
12. Pregnant and lactating patients were excluded.
13. Patients having surgical intervention and or having febrile illness during the course.

All of the above patients were not included in the study.

#### **Groups of Management:**

In this manner, total 60 patients, diagnosed as *Sthula Madhumeha* were included in this study. These 60 patients were further

divided into two groups having 30 patients in each namely control and trial group respectively, by applying lottery system as

mentioned earlier. Groups of management were as follows:

Table-1 Table showing Groups of Management into the study

Groups	Drug	Dose	Timing	Anupana	Duration
Trial Group	Daruharidradi Ghana Vati	500 mg	Before two major meals	Ushnodaka	Three months
Control Group	Metformin tablet	500 mg	Before two major meals	Drinking Water	Three months

Table-2 Table showing Properties of Each Content of Daruharidradi Ghanavati

Sn	Drug	Latin Name	Rasa	Virya	Vipaka	Doshghnata
1	Daruharidra	<i>Berberis Aristata</i>	Tikta,	Ushna	Katu	Pitta-
2	Vijaysara	<i>Pterocarpus Marsu-</i>	Katu, Tikta	Sheet	Katu	Pitta-
3	Meshshringi	<i>Gymnema Sylvestree</i>	Kashaya,	Ushna	Katu	Kapha-Vat-
4	Mamajjaka	<i>Enicostemma Litto-</i> <i>rale</i>	Tikta	Ushna	Katu	Kapha-Pit-
5	Jambubija	<i>Syzygium Cumini</i>	Kashaya, Madhura, Amla	Sheet	Katu	Kapha-Pit-
6	Methikabija	<i>Trigonella-foe-</i> <i>numgranum</i>	Katu	Ushna	Katu	Vat-
						Kaphshamak

Table-23 Table Showing Properties of Ghanavati of Daruharidradi Ghanavati

Sr.No.	Properties	Name	Percentage
<b>1</b>	<b>Rasa:</b>		
	Madhura	0	0%
	Amla	0	0%
	Lavana	0	0%
	Tikta	4	66.67%
	Katu	1	16.67%
	Kashaya	1	16.67%
<b>2</b>	<b>Virya</b>		
	Ushna	4	66.67%
	Shita	2	33.33%
<b>3</b>	<b>Vipaka :</b>		
	Madhura	0	0%
	Amla	0	0%
	Katu	6	100%
<b>4</b>	<b>Guna:</b>		
	Laghu	5	83.33%
	Ruksha	4	66.67%
	Snigdha	1	16.67%
	Katu	0	0%
<b>5</b>	<b>Doshaghata</b>		
	Kaphashamaka	5	83.33%
	Pittashamaka	4	66.67%
	Vatashamaka	2	33.33%

**Criteria of Assessment:** Patients of both groups were asked to come for follow-up every weekly and were assessed on the basis of following points:

6. Effect of herbal compound and tablet Metformin 500mg on signs and symptoms of Sthula Madhumeha.

7. Effect of therapy on specific gravity and urine sugar, fasting and post meal blood sugar level, lipid profile.

**OBSERVATIONS AND RESULTS**

In these series total 60 patients were included during study, so the observations and results are as follows:

Table-3

Table showing Effect of therapy on Physical Parameter–Urine by Paired t test

S N	Physical	Gr	Mean ± SD		Mean of diff. ± SD	Sed	‘t’	P
			BT	AT				
1	Quantity Of	T	2126.66±279.	1353.33±138.	773.33±254.	46.47	16.6	<0.000
		C	2033.33±170.	1340.00±130.	693.33±203.	37.06	18.7	<0.000
2	Specific Gravity	T	1.03±0.01	1.01±0.01	0.02±0.01	0.002		<0.000
		C	1.02±0.008	1.015±0.009	0.008±0.07	0.001		<0.000

Table-4 Table Showing Effect of Therapy by Wilcoxon-Signed-Rank Test on Urine Sugar

Sr.No	Urine Sugar	Group	% Re-lief	Total Sum of Ranks Diff.W	Mean of Diff.	S.D. (T+)	P
1	Fasting	TG	66.67%	55	0.1852	0.2461	>0.001
		CG	87.5%	28	0.1400	0.2291	>0.01
2	Post meal	TG	58.82%	55	0.1852	0.2461	>0.001
		CG	91.66%	45	0.2200	0.3253	>0.001

Table-5 Table Showing Effect of Therapy by Mann-Whitney Test on Urine Sugar

Sr.No.	Urine Sugar	Mean of Diff.± SD		U’	U Value	P
		Trial Group	Control Group			
1	Fasting	0.1852±0.2461	0.1400±0.2291	368	307	>0.1
2	Post meal	0.1852±0.2461	0.2200±0.3253	344	331	>0.1

Table-6 Showing Effect of therapy on Biochemical Parameters by Paired-t test:

SN	Physical Parameter	GP	Mean ± SD		Mean of diff. ± SD	Sed	‘t’	P
			BT	AT				
1	BSL-F	TG	153.7±22.04	102.4±12.64	51.3±13.67	2.5	20.55	<0.001
		CG	158.6±21.25	102.9±9.51	55.7±19.09	3.49	15.98	<0.001
2	BSL-PP	TG	255.8±32.9	145.5±14.39	110±30.06	5.49	20.11	<0.001
		CG	257.7±29.37	155.6±16.4	102.1±22.86	4.17	24.48	<0.001
3	Cholesterol	TG	203.8±36.44	180.4±22.95	23.34±17.5	3.2	7.31	<0.001
		CG	174.1±29.84	160.9±21.07	13.2±15.6	2.85	4.63	<0.001
4	HDL	TG	46.53±13.90	42.84±7.7	3.69±12.72	2.32	1.59	>0.1232
		CG	43.93±4.52	47.8±5.24	3.87±6.21	1.13	3.41	<0.0019
5	LDL	TG	125.7±31.48	107.9±22.83	17.8±13.78	2.52	7.07	<0.001
		CG	122.2±19.11	115.9±15.42	6.3±15.33	2.8	2.25	<0.0338
6	Triglycerides	TG	143.9±54.25	132.7±36.88	11.2±28.56	5.21	2.17	<0.0385
		CG	133.4±42.31	124.9±29.93	8.5±24.9	4.55	1.87	<0.0072
7	VLDL	TG	33.48±15.06	28.04±7.31	5.44±9.7	1.77	3.07	<0.001
		CG	29.0±8.2326±	26±8.84	3.0±5.91	1.08	2.78	<0.0094

Table-7 Comparison between Two Groups by Unpaired “t” test w.r.t. Biochemical parameters

SN	Parameter respective	Mean of diff. ± SD		Mean of diff. Bet Two Groups	Sed	‘t’	P
		Trial	Control				
1	BSL-F		55.7±19.09	4.4±4.29	3.49	1.03	0.3089
2	BSL-PP		102.1±22.86	8.3±6.89	4.17	0.56	0.798
3	Cholesterol	23.4±17.5	13.2±15.6	10.2±4.28	2.85	3.58	<0.02
4	HDL	----	---	----	----	----	----
5	LDL	----	----	----	----	----	----
6	Triglycerides	11.2±28.25	8.5±24.9	2.7±6.88	4.55	0.59	0.70
7	VLDL	---	-----	----	----	----	----

#### TOTAL EFFECT OF THERAPY

1. Completely controlled: Total control in cardinal signs and symptoms.
2. Moderately controlled: 50% or more average improvement
3. Markedly controlled: Improvement ranging in between 25 to 50%
4. Unchanged: Less than 25% improvement will be categorised as “Unchanged”

Table-8 Showing Comparison between 2 Group of Sthula Madhumeha WRT to Total Effect of Therapy by Chi Square Test

S.N.	Total Effect	Trial Group		Control Group		Total No. of
		Observed	No. of Pa-	Observed	No. of Pa-	
1	Completely Controlled	Observed	00	Observed	00	00
		Expected	00	Expected	00	
		Chi Sq. of	00	Chi Sq. of	00	
2	Moderately Controlled	Observed	00	Observed	00	00
		Expected	00	Expected	00	
		Chi Sq. of	00	Chi Sq. of	00	
3	Markedly Controlled	Observed	26	Observed	27	53
		Expected	26.5	Expected	26.5	
		Chi Sq. of	00.04	Chi Sq. of	0.04	
4	Unchanged	Observed	04	Observed	03	07
		Expected	3.5	Expected	3.5	
		Chi Sq. of	0.0	Chi Sq. of	0.0	
Total No. of Pa-			30		30	60

#### DISCUSSION

60 patients of Sthula Madhumeha were categorized into two groups i.e. Trial Group and Control Group, 30 in each group.

Out of 60 patients, 93.33% patients from age group Praudhavastha, only 40% patients had positive history for diabetes mellitus in their families. 76.67% patients had sedentary nature of work. All the patients were taking tea in excess quantity. 96.67% patients were complaining of Aalasya and Mutradhikya while no patient

was found complaining about Sakashta Maithuna. Significant decrease in all symptom scores, blood sugar level, urine sugar, total cholesterol, triglycerides level in both groups, were the main outcome of this study. Along with above outcome, there is more significant decrease in total cholesterol, triglycerides level in trial group than in control group. Only significant decrease in fasting blood sugar level was more in control group than trial group while post-meal blood sugar level was more reduced in trial group as that of con-

tol group. This reduction in total cholesterol, triglycerides level, very low density lipoproteins level might be because of Shoshana and Pachana of Meda by enhancing Meda-Dhatvagni due to Tikta Rasa (66.67%), Kashaya Rasa(16.67%), Ushna Virya(66.67%), Ruksha Guna(66.67%), Laghu Guna (83.33%) and Katu Vipaka(100%) of Daruharidradi Ghanavati. The concept of Medagni plays important role by increasing Medagni, metabolism might be enhanced so that Apachita, Abaddha Meda was reduced. As we go through the literature of Madhumeha, the disease is chronic in nature and it is said to be Asadhya. It means it runs throughout the life. To see the effect on blood sugar, basic concept of Ayurveda to treat the main deranged Dosha and Dushya for a prolonged period of time is important. In case of Madhumeha, they are not only Kapha and Meda, but Kleda and other Dhatu, are also important. To breakdown this scenario of Shat-Kriya-Kala, it is necessary to administer drug for prolonged period along with regular exercise and strict diet regimen of Pathya-Apathya. This holistic approach of Ayurveda might be fruitful. To sum up, Ayurvedic contention of treatment of Sthula Madhumeha is to reduce the aggravated Bahu Drava Kapha, Abaddha Meda and more Kleda. Daruharidradi Ghanavati is responsible to do that in this study. Effect of Daruharidradi Ghanavati can be augmented by advising Pathya- Apathya. All ayurvedic text expounded the role of Vyayama in Madhumeha. Some of them advised to walk, to dig wells on regular basis. It is very clear on the horizon of Ayurveda that Ayurvedic basic concepts are very much relevant to augment the effect of Daruharidradi Ghanavati.

## CONCLUSION

Madhumeha is described as one of the 'Ashtau Mahagada' as it is very difficult to treat because of its 'Anushangi' and 'Yapya' nature. There is Abaddhata of Meda, Bahu-Dravatva of Shleshma and Kledabahulya. In such scenario, Apatarpana is the best therapeutic modality for this disease.

Daruharidra, Meshashring, Vijayasara, Mamajjaka, Jambubija and Methikabija are proven drugs in management of Madhumeha and Bhavamishra has also suggested Pramehaghna properties of these drugs. Various animal as well as clinical trials had been done on these drugs regarding their hypoglycaemic activity.

In this study, Daruharidradi Ghanavati was prescribed only for 3 months. Response to all the symptoms, urine specific gravity, urine sugar level, Blood sugar level and lipid profile was seen in both groups. But blood sugar level was markedly reduced in control group as compared to trial group. Reductions in total cholesterol, triglycerides level were seen marginally more in trial group than control group as unpaired t test results were insignificant. This study revealed that, both drugs used while doing study i.e. Daruharidradi Ghanavati and Metformin were equally effective in controlling Diabetes Mellitus. But Daruharidradi Ghanavati is more effective in controlling post meal blood sugar level, total cholesterol and triglycerides level than Metformin.

Thus Ayurvedic contention of Apatarpana in the form of Ghanavati in Sthula Madhumeha may be established on the horizon of Ayurveda. Even in present status the prescription having Daruharidradi Ghanavati in Sthula Madhumeha will definitely improve the quality of life of the patients.

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