

A CLINICAL STUDY OF “PANCH SWARAS BHAVIT SHILAJIT” IN THE MANAGEMENT OF MADHUMEHA (DIABETES MELLITUS)

Viramgami Jasminkumar M

HOD & Assistant Prof.,

Department of Swasthavritta, Sheth J. P. Govt. Ayurved College, Bhavnagar, Gujarat, India

Email: drjmvgami@gmail.com

ABSTRACT

From ancient to modern times, the Management of *Madhumeha* (DM) has shifted from holistic to drug oriented approach. Until a few years ago, the holistic approach of *Ayurveda* was not much focused. *Ayurveda* has shown various kinds of classical drugs and preparations for the management of *Madhumeha* in various treatises. There are also various combinations and single drugs that are used for the management of *Madhumeha* for a long time in general public. This research work was planned to evaluate the effects and role of combination of such long used and socially accepted drugs in *Madhumeha*. A total of 20 patients were selected and divided into two groups. “*Panch Swaras bhavit Shilajit* Tablet” was used for the management of *madhumeha* in these patients. The study showed moderately significant results in most parameters in both the groups. However, further trials with increased number of patients are needed to support the current observations.

Keywords: Diabetes Mellitus, *Haritakyadi Yoga*, *Kostha shuddhi*, *Madhumeha*.

INTRODUCTION

Until the end of first decade of the 20th century, infectious diseases predominated. However with the help of antibiotics, the incidence of infectious disease started to wane. On the other hand diseases of civilization (urbanization) like high blood pressure, CHD, and cancer increased steadily. Diabetes is also such a constitutional disease and a byproduct of urbanization. Diabetes is a chronic disease that

occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces^[1]. Type 2 diabetes (formerly called non-insulin-dependent or adult-onset) results from the body’s ineffective use of insulin^[1]. Type 2 diabetes comprises the majority of people with diabetes around the world^[1], and is largely the result of excess body weight and physical in-

activity. Changing life style, lack of exercise, unbalanced diet and stress etc. have lead to the emergence of diabetes and made it very vulnerable disease. A condition believed to affect only the urban population, the scenario has changed.

Looking at its gravity, the World Health Organization (WHO) ^[1] has taken up a close vigilance and survey about this problem the world over. The WHO Global report on diabetes demonstrates the number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014 ^[2]. This rise is largely due to the rise in type 2 diabetes. Diabetes prevalence is rising more rapidly in middle and low income countries ^[1]. In year 2000, the five countries having the largest numbers of diabetics were India, China, United States, Pakistan & Japan. India has now been declared by W.H.O. as the diabetes capital of the world ^[3]. India had 69.2 million people living with diabetes (8.7%) as per the 2015 data. Of these, more than 36 million people are undiagnosed ^[4]. In 2013, there were 65.1 million people between 20 and 79 years of age with diabetes and this number was predicted to rise to 109 million by 2035. The growing epidemic of type 2 diabetes in India has been highlighted in several studies.

Diabetes Mellitus (DM) is often referred to as a "silent killer." Diabetes and its complications pose a major threat to public health resources throughout the world. Its complications can lead to heart attack, stroke, blindness, kidney failure and lower limb amputation. In 2012, an estimated 1.5 million deaths were directly caused by diabetes and another 2.2 million deaths were attributable to high blood glucose ^[1]. Adults with diabetes have a

2-3 fold increased risk of heart attacks and strokes ^[5]. Diabetic retinopathy is an important cause of blindness, and occurs as a result of long-term accumulated damage to the small blood vessels in the retina. 2.6% of global blindness can be attributed to diabetes ^[6]. Diabetes is among the leading causes of kidney failure ^[7]. "Beat Diabetes" was the slogan for the World Health Day, 2016 ^[8]. The theme of World Diabetes Day 2016 was "Eyes on Diabetes" with the focus on promoting the importance of screening to ensure early diagnosis of type 2 DM and treatment to reduce the risk of serious complications ^[9].

In spite of increasing prevalence all over the world, still scientists are struggling to search an effective and harmless remedy. The public health threat has always been treated by oral hypoglycaemic agents and insulin which are though helpful in relieving the symptoms; create side effects as well. As a non-invasive, safe and cost-effective form of treatment, *ayurveda* therefore proves an ideal medical option. So here in this research work, we have tried to find a safe and effective oral combination with comparatively nil side effects. In all the classical literature *Madhumeha* (a subtype of *vataja prameha*) has been described as *Asadhya vyadhi* ^[10-11]. It cannot be eliminated but can certainly be controlled. Our aim is to find out a drug which helps to manage the disease and to keep a control on it. Taking these facts into consideration, this study was undertaken to evaluate the effect of "Panch Swaras bhavit Shilajit Tablet" in the management of *Madhumeha* (DM).

MATERIALS AND METHODS:

Patients:

For the present study 20 diagnosed patients of *Madhumeha* (DM type 2) were selected randomly from the Outdoor Patient Department of Govt. Akhandanad Ayurved Hospital, Ahmedabad, Gujarat, India and were registered on the basis of signs and symptoms of *Madhumeha* as per *Ayurvedic* classics and modern medicine.

Inclusion criteria:

- Patients of either sex
- Patients showing classical signs and symptoms of *Madhumeha* included in the study as below:

Prabhuta Mutrata, *Avila Mutrata*^[12], *Pipasadhikya*^[13], *Kshudhadhikya*^[15], *Karapadatala Daha*^[16], *Karapadatala Suprata*^[14].

Criteria for diagnosis of DM by American Diabetic Association^[17]:

- Patients having Symptoms of diabetes plus Random blood sugar level 200 mg/dl or
- Fasting blood sugar (FBS) 126 mg/dl up to 375 mg/dl or
- Postprandial blood sugar (PPBS) 200 mg/dl up to 500 mg/dl.

Exclusion criteria:

- Patients of Type 1 DM (IDDM).
- Patients complicated with any cardiac problem.
- Patients suffering from any severe systemic disease.
- Diabetes due to endocrinopathies.
- Patients with certain genetic syndromes.

- Drug or chemical induced Diabetes.

Grouping: The registered 20 patients were divided into two groups:

Group-A:

Patients were given *Haritakyadi yoga*^[18] 10gm/day (3 days) at night for *kostha-shuddhi* with *usnodaka* (lukewarm water), followed by "Panch Swaras bhavit Shilajit Tablet". It was administered in a dose of 6 tab/day, in 2 divided doses; in the morning and evening on empty stomach (before food) for 8 weeks. (n= 10)

Group-B:

Patients were treated only with "Panch Swaras bhavit Shilajit Tablet". It was administered in a dose of 6 tab/day, in 2 divided doses; in the morning and evening on empty stomach (before food) for 8 weeks. (n= 10)

For the preparation of the "Panch Swaras bhavit Shilajit Tablet", 3 bhavanas of Panch swarasa, viz. *Amalaki*, *Haridra*, *Guduchi*, *Bilwapatra* and *Agnimanth* was given to *Shuddha Shilajit* and tablets of 500mg each were manufactured for administering to the patients.

Criteria for assessment:

- a) Objective parameters: FBS level, PPBS level, Fasting Urine Sugar, postprandial Urine Sugar
- b) Subjective parameters: Improvement in signs and symptoms of the disease on the basis of the symptom score. A detailed proforma was designed to assess the results. Specific symptom score was as follows:

Table 1: Sugar (mg/dl):

Grade	FBS	PPBS	Urine sugar
0	< 126	< 200	absent
1	126-150	201-225	+
2	151-175	226-250	++
3	176-200	251-275	+++
4	>200	>275	++++

Table 2: *Prabhuta mutrata* (Polyuria):

Grade	Frequency		Volume
	Day	Night	
0	3-4	0-1	Normal
1	5-7	1-2	Excessive
2	8-10	2-3	Excessive
3	>10	3-4	Excessive

Table 3: *Avila mutrata* (Turbidity of Urine):

Grade	Turbidity
0	Crystal clear fluid
1	Faintly cloudy or hazy with slight turbidity
2	Turbidity clearly present but news print can be read through the tube.
3	More turbidity & news print cannot be read

Table 4: *Kshudhadhikya* (Polyphagia):

Grade	Quantity
0	Normal
1	Slightly increased
2	Moderately increased
3	Markedly increased

Table 5: *Trishadhikya* (Polydipsia):

Grade	Feeling of Thirst
0	Normal
1	Increased but frequencies can be controlled
2	Increased with increased frequency [aprox. once in 2hr]
3	Very much increased with Very frequent intake

Table 6: *Karpadataladaha* (Burning sensation in hand & feet):

Grade	<i>Daha</i>
0	No <i>Daha</i>
1	<i>Daha</i> incontinous
2	<i>Daha</i> continuous but bearable
3	<i>Daha</i> continuous and severe

Table 7: Karapada suptata (Numbness in hand & feet):

Grade	Supti
0	No Supti
1	Suptata incontinuous
2	Suptata continuous but bearable
3	Suptata continuous and severe

Assessment of overall effect of therapy:

1. Control: Patients having FBS and PPBS levels within normal limit and 100% relief in sign and symptoms.
2. Marked Improvement: Blood Sugar level reduced more than 75 mg/dl and more than 75% relief in signs and symptoms.
3. Moderate Improvement: Blood Sugar level reduced in between 25 to 75 mg/dl and 50% relief in signs and symptoms.
4. Mild Improvement: Blood Sugar reduced less than 25 mg/dl and 25 % relief in sign and symptoms.
5. No Improvement: No reduction in Blood Sugar and less than 25% relief in sign & symptoms.

Statistical analysis:

The obtained information was analyzed statistically in terms of Mean Score (x), Standard Deviation (S.D.), Standard Error (S.E.). Paired t test was carried out at the level of 0.05, 0.01, 0.001 of P levels. The results were interpreted as,

- P<0.05 Improvement
- P<0.01 Significant improvement
- P<0.001 Highly significant improvement

Observations:

It was observed that the higher no. of patients were from Male sex (60%), Hindu community (75 %), Educated (85%) and Lower-middle (45%) or middle class (40%). All the patients were married. 80% were in the age group of

41-60 years. More than 1 year chronicity of the disease was found in 90% patients, among them 20% were chronic for more than 10 years. 95% were involved in light or household work. *Vishamashana* was observed in 45% patients. 50% belonged to *Vata-Kaphaj Prakriti* & 65% were having *Rajas prakriti*. Daysleeping was present in 85%, among them 60% were doing regular *Divaswap*. The food habits includes: *Madhura ahara*- 75%, *Guru ahara*- 65%, *Snigdha ahara*- 30%, Milk- 70%, *Dadhi*- 40%, *Mamsa*- 45%, Daysleep- 85%, *Vyayamavarjana*- 65%, *Asyasukha*- 75%.

Almost all the cardinal signs & symptoms of *Madhumeha* viz. *Prabhutmutrata*, *Avilmutrata*, *Trishadhikya*, *Kshudhadhikya*, *Karpadsupti* and *Karpadtaldaha* were found in all the patients. Associated signs & symptoms i.e. *Daurbalya* 100%, *Asya madhurya* in 75%, *Tandra* in 80%, *Klama* in 95%, *Shithilgatrata* in 50%, *Atisweda* in 45% and *Snigdha-gatrata* in 40% patients were found.

RESULTS:

Effect of therapies on subjective parameters:

The results in main signs & symptoms were highly significant in both the groups except in *Kshudhadhikya* and *Karapadatalasupti*. But better symptomatic relief was found in *Kostha-shuddhi purvak shaman* group. Statistically both groups showed highly significant results on *Prabhutamutrata*. But comparatively, the patients from Group-A achieve

higher percentage of relief than group-B. Both groups showed highly significant results on *Avilmutrata*. Group-A shows higher relief (71.42%) than Group-B (61.11%). In *Pipasadhikya* relief achieved by Group-A was 52.38% and 40% in Group-B. On *Kshudhadhikya* 30% relief was bestowed with Group-A while Group-B gain 14.28% relief. Here the results were insignificant. *Karapadasupti* was relieved by 56.25% in Group-A and 31.25% in Group-B. 75% relief was observed in *Karapadataladaha* in Group-A and 57.89% in Group-B.

Effect of therapies on objective parameters:

In Group-A, therapy provided statistically significant relief (P<0.05) in F.B.S. (22.19%) and

P.P.B.S. level (21.26%). In Group-B the results were F.B.S.-20.66% and P.P.B.S.-18.51%, which was highly significant but the achieved relief was better in group-A. In Group-A therapy provided statistically significant relief (P<0.05) in F.U.S. level (43.75%) and P.P.U.S. level (37.04%) statistically insignificant (P<0.01). In Group-B this results were F.U.S. - 36.00% and P.P.U.S. - 35.13% which shows higher percentage of relief in group A. Hb was increased from 10.85 to 11.95 in Group-A and 12.25 to 12.95 in Group-B. Initial Mean Score of ESR was 14.50 which reduced to 6.0 after treatment in group- A and in group-B it reduced from 10.5 to 8.

Table 2: Effect of therapy on cardinal symptoms of *Madhumeha* in group-A

Symptoms	n	BT	AT	%Relief	SD	SE	t	P
<i>Prabhuta Mutrata</i>	10	2.6	1.2	53.85	0.84	0.27	5.25	<0.001
<i>Avila Mutrata</i>	10	2.1	0.6	71.42	0.52	0.17	9.00	<0.001
<i>Pipasadhikya</i>	10	2.1	1.0	52.38	0.56	0.17	6.12	<0.001
<i>Kshudhadhikya</i>	10	1.0	0.7	30.00	0.48	0.15	1.96	>0.05
<i>Karapadatala Daha</i>	10	2.4	0.7	75.00	0.42	0.13	13.50	<0.001
<i>Karapadatala Suptata</i>	10	1.6	0.7	56.25	0.56	0.17	5.01	<0.001

Table 3: Effect of therapy on cardinal symptoms of *Madhumeha* in group-B

Symptoms	n	BT	AT	%Relief	SD	SE	t	P
<i>Prabhuta Mutrata</i>	10	2.1	1.2	42.85	0.31	0.10	9.00	<0.001
<i>Avila Mutrata</i>	10	1.8	0.7	61.11	0.56	0.18	6.12	<0.001
<i>Pipasadhikya</i>	10	2.0	1.2	40.00	0.42	0.13	6.00	<0.001
<i>Kshudhadhikya</i>	10	0.7	0.6	14.28	0.32	0.10	1.00	>0.05
<i>Karapadatala Daha</i>	10	1.9	0.8	57.89	0.31	0.11	11.00	<0.001
<i>Karapadatala Suptata</i>	10	1.6	0.7	56.25	0.56	0.17	5.01	<0.001

Table 4: Effect of therapy on biochemical parameters in group-A

Parameters	n	BT	AT	%Relief	SD	SE	t	P
F.B.S.	10	168.5	131.5	22.19	1.68	0.53	2.25	>0.05
P.P.B.S.	10	264.8	208.1	21.26	1.57	0.49	2.80	<0.05
F.U.S.	10	1.6	0.9	43.75	0.94	0.30	2.33	<0.05
P.P.U.S.	10	2.7	1.7	37.04	0.94	0.29	1.00	>0.05

Hb	10	10.85	11.95	10.13	-	-	-	-
ESR	10	14.50	6.00	58.60	-	-	-	-

Table 5: Effect of therapy on biochemical parameters in group-B

Parameters	n	BT	AT	%Relief	SD	SE	t	P
F.B.S.	10	168.5	131.5	22.19	1.68	0.53	2.25	>0.05
P.P.B.S.	10	279.7	227.9	18.51	1.07	0.33	4.70	<0.01
F.U.S.	10	2.5	1.6	36.00	0.73	0.23	3.85	<0.01
P.P.U.S.	10	3.7	2.4	35.13	0.82	0.26	4.99	<0.001
Hb	10	12.25	12.95	5.71	-	-	-	-
ESR	10	10.5	8.0	23.80	-	-	-	-

Overall effect of therapy:

In overall effect of therapy control over disease was found in 20% in group-A and 0% in group-B. Marked improvement was found in 10% in both groups. Moderate improvement

was observed in 50% in group-A and 70% in group-B. Mild improvement was in 10% patients in both groups while 10% patients in each group did not achieve any results.

Table 6: Overall effect of therapy

Results	Group-A		Group-B	
	Pts.	%	Pts.	%
Controlled	2	20	0	00
Marked Improvement	1	10	1	10
Moderate Improvement	5	50	7	70
Mild Improvement	1	10	1	10
No Response	1	10	1	10

DISCUSSION

On *Prabhutamutrata* both groups showed highly significant results. *Panch swaras bhavit Shilajit* due to its *Kaphavata-shamak* property, acts upon vitiated *Vata* and controls the *Prabhutamutrata*. *Haridra* which is having *Mutrasangrahaniya* property acts upon one of the *Prabhutamutrata*. *Kostha-shuddhi* expels morbid *dosha* along with fluid containing metabolic wastes. On *Avilmutrata* both groups showed highly significant results. Here *Haridra* is *Mutra-virajniya*. So the drugs work upon *Avilamutrata*. In *Pipasadhikya* relief achieved by Group A was 52.38% and 40.00%

in Group B. This symptom arises due to increased *Pitta* and *Rasa-dhatu-kshaya*. Most of the drugs of *shaman yoga* are *Pitta-shamak*, so subsides *Pipasadhikya*. *Karapadasupti* and *Karapadadaha* generally manifests as complications of diabetes due to chronicity. *Shilajit*, *Guduchi*, *Amalaki* acts as a *Rasayana* drugs which rejuvenate the body and helps in controlling the complications.

For Blood Sugar level, the results were significant. From this data we can say that *Shodhan* reduces the blood sugar by eliminating the morbid matter from the body. Due to *Pramehaghna* property of maximum ingredient of

trial drug, blood sugar was reduced. The *Pramehahara* property of the ingredients of trial drug helps in alleviating the hyperglycaemia.

Ushna virya & *Katu vipaka* and *Katu-Tiktarasa* predominance of the trial drug also help in reducing urine sugar level. In modern science, clinical & experimental studies depicts that *Bilvapatra*, *Guduchi*, *Shilajit* reduces blood glucose significantly. *Shilajit* and *Haridra* are also *Mutrashodhak* drugs. Hb was increased from 10.85 to 11.95 in Group A and 12.25 to 12.95 in Group B. This effect might be achieved by modulation of *Dhatu-poshana* (proper functioning of *dhatu*) and *Rasayana* effect of the treatment.

After assessing the above result it can be conclude that better results are achieved in *Kostha-shuddhi* purvak *shaman* group, though the overall effects are approximately same, not showing any vast difference.

The drug formulation has *Katu pradhana Tikta-Kashaya rasa*, *Ushna virya*, *Katu vipaka* and *Laghu-Ruksha guna* which help in eliminating vitiated *kapha*. It also corrects the vitiated *Meda*. Both *Meda* and *Kapha* are the main articles in the *Samprapti* of the disease. The drug formulation has *Kapha-vata shamak* (66.66%) & *Tridosh shamak* (33.33%) properties. Most drugs are *Pramehaghna* and doing *Rasayana* karma. So it works on *dhatu dushti* and pacifies the process of normal *dhatu-nirmana*. Formulation with ingredients possessing anti *Meda* & *Kapha* properties will be useful in disintegrating the pathophysiology of disease. *Rasayana* effect (immunomodulation and rejuvenation of body) is also useful in the treatment because complications like debility, fatigues etc. are very harmful.

CONCLUSION:

No side effects were observed during treatment. Though *Madhumeha* is described *asadhya*, and irreversible if once sets in, the complication of diabetes mellitus and side effects of the modern oral hypoglycaemic agents can be controlled or prevented with the best use of *ayurvedic* formulations. The present study was conducted with limited time, limited facilities and limited number of patients. A study of larger group of patients may help to understand the mode of action of the trail drug. If the patients have less chronicity and longer duration of treatment then perhaps better results could be achieved. Good results have been achieved by the help of *Kostha-shuddhi (aavasthiki-shodhan)* so a complete *shodhana* process might be very affirmative in achieving good control over this killer disease. In the future further studies might be carried out to reveal some more hidden facts and to find out a better remedy for this silent killer disease named *Madhumeha* (Diabetes mellitus).

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