

## A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF SHILAJATU LOHA RASAYANA IN PRAMEHA / DMII

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### ABSTRACT

*Prameha* is a disease known to mankind since Vedic period. It is always caused by severe morbidity of *Dosha* afflicting the different body elements. In the literature it is said that, collectively 10 *Dushya* are involved in the pathogenesis of *Prameha*.<sup>1</sup>Evidently it is regarded as one among the eight *Mahagadas*<sup>2</sup>. Sedentary life style is the leading cause of the illness. *Prameha* if not treated well, can lead to many complications which are more troublesome and even may prove fatal. Also it is worth mentioning here that due to change in life style, rapid increase in the incidence of *Prameha* is recorded in India as revealed by survey studies. The disease affects more than 62 million Indians, which is more than 7.1% of India's adult population. An estimate shows that nearly 1 million Indians die due to Diabetes Mellitus every year.<sup>3</sup>Considering this, the present study has been carried out to establish a treatment protocol to provide maximum outcome to the society. Selected patients were treated with oral administration of *ShilajatuLohaRasayana* for 21 days with the *Anupana* of 50 ml of *Salsaaradikwatha* thrice a day. Results showed that *ShilajatuLohaRasayana* is effective in the remission of the symptoms of *Prameha* and in reducing the blood sugar levels as evidenced by statistically significant reduction in the symptom scores of various subjective and objective parameters.

**Keywords:** *Prameha*, *ShilajatuLohaRasayana*, DMII

### INTRODUCTION

In this era of technical development, people have moved from the traditional way of life style to the modernized way of living. This advancement has not only awarded them the luxuries but also the high level of mental stress and unhealthy way of living. Consumption of the diet rich in the fat and high calories in combination with lack of exercise characterizes the modernized living. This unique life style has resulted in the increase of

various types of disorders and is collectively known as *santarpanothavikara*. *Prameha* is one among such disorder which is regarded as diabetes mellitus in modern parlance. The disease is more dreadful because it affects every part or rather say every cell of the body and the disease has become common in the all the groups of society.

Needless to say, a good control and effective management of *Prameha* should

be the ultimate aim and this reduces the risk of the development of complications. More than 300 clinical studies are carried out exploring the therapeutic effect of *Shodhana*; *Shamana* as well as *Rasayana* in the patients suffering from the *Prameha*.<sup>4</sup> Out of these nearly 280 works are related to the efficacy of the different herbal and herbo-mineral formulations. Few studies are also carried out related to the efficacy of folklore medicines. The combined effect of the *Shodhana* and *Shamana* was studied in about 20 clinical studies. Also the number of the total clinical studies exploring the effect of *Rasayanachikitsa* did not cross single digit. Though the *Rasayanachikitsa* is more important in chronic and lingering disease this area is left unexplored at large. Hence this study is intended to evaluate the therapeutic effect of *Shilajatu Loha Rasayana*<sup>5</sup> in patients suffering from *Prameha*.

### OBJECTIVES

1. To evaluate the therapeutic effect of *Shilajatu Loha Rasayana* in the remission of the symptoms of *Prameha*.
2. To evaluate the therapeutic effect of *Shilajatu Loha Rasayana* in reducing the blood sugar levels.

### MATERIALS AND METHODS

#### STUDY DESIGN

Open clinical study with pre-test and post-test design.

#### SOURCE OF DATA

15 patients diagnosed as *Prameha*/DMII fulfilling the diagnostic/inclusion and exclusion criteria were taken for study from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka.

#### DRUG

The cellulose capsules each containing 500 mg of *Shilajatuchoorna* and 500 mg of *Lohabhasma*, *Salsaaradi kwa-*

*tha*<sup>6</sup> and *Erandataila* were obtained from SDM Ayurveda Pharmacy Udyavara, Udupi.

### METHOD OF COLLECTION OF DATA

A special proforma was prepared incorporating all the clinical manifestations and assessment criteria including laboratory investigation findings of the *Prameha*/DMII. Complete data including detailed clinical history and complete physical examination were collected from all the selected patients as per this proforma.

#### Diagnostic criteria:

Patients fulfilling the any one of the following criteria:

1. Symptoms of *Prameha* /Diabetes Mellitus (polyuria, polydipsia, and unexplained weight loss) plus casual plasma glucose concentration 200 mg/dl (11.1mmol/l). Casual is defined as any time of day without regard to time since last meal.
2. Fasting Plasma Glucose 126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 hour.

#### Inclusion Criteria:

- 1) Patients fulfilling the diagnostic criteria
- 2) Type-2 Diabetes mellitus not taking any anti Diabetic drug
- 3) Patient already on medication has stopped the same for 7 days.
- 4) Patients between the age group of 30 to 70 years
- 5) Fasting Plasma Glucose Level 200 mg/dl or
- 6) Post Prandial Plasma Glucose level 350 mg/dl or
- 7) Glycated hemoglobin > 7% and <10%

#### Exclusion Criteria:

- 1) Age below 30 and above 70 years.
- 2) Fasting Plasma Glucose Level 126 and 200 mg/dl or

- 3) Post Prandial Plasma Glucose Level 200 mg/dl and 350 mg/dl or
- 4) Glycated hemoglobin 7% and 10%
- 5) Patients with complications of diabetes mellitus
- 6) Malignant and accelerated hypertensive
- 7) CVS disorder (CAD)
- 8) Pregnant woman and planning to be pregnant within six months
- 9) Lactating mother
- 10) Secondary Diabetes mellitus
- 11) CNS disorder e.g. encephalopathy
- 12) Patients suffering from DMI

#### Assessment Criteria

Assessment was done on the basis of subjective and objective criteria before, and after the treatment.

#### Subjective Parameters: Signs & symptoms of Prameha

1. *Prabhootamootra*
2. *Kshudaadhikya*
3. *Pippasaadhikya*
4. *Daurbalya*
5. *Mukhatalushosha*
6. *Kara padadaha*
7. *Kara padasuptata*
8. *Shareerabharahani*
9. *Shithilangata*

The details of the scores adopted for the signs and symptoms in present study were as follows

#### GRADINGS

##### 1. *Prabhootamutrata*

- Normal-0
- Mild increase in frequency-1
- Moderate increase in the frequency-2
- Severe increase in the frequency-3

##### 2. *Pippasaadhikya*

- Normal-0
- Mild increase in thirst-1
- Moderate increase in thirst-2
- Severe increase in thirst-3

##### 3. *Kshudaadhikya*

- Normal-0

- Mild increase in hunger-1
- Moderate increase in hunger -2
- Severe increase in hunger-3

##### 4. *Karapadadaha*

- Normal (No karapadadaha)-0
- Mild increase in karapada daha-1
- Moderate increase in karapadadaha -2
- Severe increase in karapadadaha -3

##### 5. *Karapadasupti*

- Normal (No karapadasupti)-0
- Mild karapada supti-1
- Moderate karapadasupti-2
- Severe karapadasupti-3

##### 6. *Daurbalya*

- Normal (No Daurbalya)-0
- Mild -1
- Moderate -2
- Severe -3

##### 7. *Mukhatalushosha*

- Normal (No mukhatalushosha)-0
- Mild -1
- Moderate -2
- Severe -3

##### 8. *Shithilangata*

- Normal-0
- Mild -1
- Moderate -2
- Severe -3

#### Objective Parameters

It includes estimation of Fasting Plasma Glucose Level and Post Prandial Plasma Glucose Level before and at the end of the therapy.

#### INTERVENTION

Day 1: 20 ml of *ErandaTaila* was given in the morning in empty stomach for the purpose of achieving *KoshtaShodhana*

Day 2 to 22: 3 g of *ShilajatuLohaRasayana* was administered orally in three divided doses before food with the Anupana of 50 ml of *Salasaradi Kwatha*.

Patients were advised to take their diet as described in patient information sheet and

do brisk walking/jogging or light exercise for half an hour daily during the course of the treatment.

Follow up Period: 21 days.

Duration of study: 43 days

### INVESTIGATIONS

- 1) Haemogram
- 2) Fasting Plasma Glucose Level
- 3) Post Prandial Plasma Glucose Level
- 4) Glycated hemoglobin
- 5) Lipid profile
- 6) Blood urea
- 7) Serum creatinine

### OBSERVATIONS

Among the 15 patients taken for the study 53.33% of the patients belonged to the age group of 51-60 years. 33.3% patients were males and 66.6% were females. 100% of the patients belonged to Hindu religion. Majority of patients comprising 46.66% in this study had completed their Higher Secondary School education; 100% of patients were married. Majority of the patient belonged to upper middle class i.e. 66.66%. 86.66% of the patients had the dietary habit of taking mixed diet.

Among the 15 patients 53.33% of the patients had the habit of day sleep. Out of the 15 patients, maximum of 73.33% of the patients had sound sleep. Majority of

patients belonged to *Kaphapittaprakruti* i.e. 46.66%, 53.33% of patients had *PravaraAbhyavaharana Shakti* similar number of the patients had *PravaraJarana Shakti*. Out of the 15 patients 53.33% of the patients had *AvaraVyayama Shakti*.

Out of 15 patients taken for the study 100% patients had *Prabhoota-mutrata*, 66.66% of the patients had *Kshudha Adhikya*, 93% patients had *PipasaAdhikya*, 86% of the patients had *Daurbalya*, *MukhataluShosha* was found in 93% of the patients, 86% of the patients had *KarapadaDaha*, *KarapadaSuptata* was seen in the 73.33% of the patients, *Shithilangata* was seen in the 100% of the patients and 40% of the patients were having history of *Shareerabhara Hani*.

### RESULTS

#### Effect of the treatment on the subjective parameters

The study proved that *Prabhoota-Mutrata* was reduced by 62.49%, *KshudhaAdhikyaby* 81.5%, *Pipasaadhikya* by 75%, *Daurbalya* by 66.66%, *MukhataluShoshaby* 75%, *KarapadaDahaby* 70%, *KarapadaSuptataby* 73% and *Shithilangata* by 70%. There was no effect on the *shareerabhara*.

**TABLE No.1-EFFECT OF SHILAJATU LOHA RASAYNA ON SUBJECTIVE PARAMETERS**

Parameters	Mean score			% Relief	Paired "t" Test			
	BT (±S.D)	AT (±S.D)	BT-AT		S.D.	S.E.M	"t"	p
<i>PrabhootaMutrata</i>	2.133 (1.187)	.800 (0.775)	1.333	62.49%	0.976	0.252	5.292	<0.001
<i>Kshudhaadhikya</i>	1.800 (1.373)	0.333 (0.617)	1.467	81.5%	1.302	0.336	4.363	<0.001
<i>Pipasaadhikya</i>	2.200 (0.941)	0.533 (.834)	1.667	75%	0.900	0.232	7.174	<0.001
<i>Daurbalya</i>	2.400	0.800	1.600	66.66%	0.910	0.235	6.808	<0.001

	(1.056)	(.862)						
<b>MukhataluShosha</b>	2.200 (0.941)	0.533 (.834)	1.667	75%	0.900	0.232	7.174	<0.001
<b>Karapadadaha</b>	1.600 (1.056)	0.467 (0.915)	1.133	70%	0.915	0.236	4.795	<0.001
<b>Karapadasuptata</b>	1.533 (1.187)	0.400 (0.828)	1.133	73%	1.060	0.274	4.141	<0.001
<b>Shithilangata</b>	2.733 (0.458)	0.800 (0.862)	1.933	70%	0.704	0.182	10.64	<0.001

**Effect of the treatment on the objective parameters**

FBS was reduced by 27.60%, and PPBS was reduced 32.29%.

**TABLE No.2-EFFECT OF SHILAJATU LOHA RASAYNA ON OBJECTIVE PARAMETERS**

Parameters	Mean score			% Re-lief	Paired “t” Test			
	BT (±S.D)	AT (±S.D)	BT-AT		S.D.	S.E.M	“t”	P
<b>FBS</b>	155.53 (21.530)	112.60 (14.515)	42.933	27.60	18.972	4.898	8.765	<0.001
<b>PPBS</b>	264.200 (33.605)	178.933 (40.844)	85.267	32.29	56.739	14.650	5.820	<0.001

**DISCUSSION**

In developing countries like India rising living standards paired with life style changes and faulty food habits have helped in furious spread of various diseases which are known as the *Santarpanothavikara*. This disease has emerged as the new pandemic which seems to be a formidable challenge to the world. Ample description of the *Prameha* can be found in the *Samhita* and *Sangrahagrantha* starting from its etiology till the treatment of the disease which includes its types, pathogenesis, prognosis and treatment including diet regimens. Literature specified that *Prameha* is a disease entity which occurs due to the *Santarpana* factor i.e. the one which brings positive energy balance in the body and also due to the hereditary factor. *Santarpana* factors e.g. excessive intake of *dugdha*, *Dadhi*, *Guda*, *Navanna*, *Madhura*, *Lavana Rasa*, sleeping at the

day time, no physical activities lead to the vitiation of the *Kapha* and more to add *Prameha* is such a disease whose seeds may be sown genetically but it is nourished and developed because of the faulty life style and food habits.

Due to vitiation of the *Kapha*, *Medadhatu* also gets vitiated because it shares similar qualities as that of the *kapha*. In due course of time, collection of the *Kapha* and *medas* (*tanumadhuryata*) in the *Rasa Dhatu* takes place. Both *Kapha* and *Medas* along with the *Rasa* start circulating in the body and later on may vitiate the *Mamsa Dhatu* resulting into the *Prameha Pidaka*. This circulating *Kapha* and *Medas* vitiates other *Dushya* such as *Rakta*, *Mamsa*, *Meda*, *Majja*, *Shukra*, *Vasa*, *Oja*, *Lasika*, *Kle* and *Sweda*. This leads to the *Avarana* pathology in the *Basti* which finally results into the *Prabhoota Avila Mutrata*, which is the cardinal symptom of the disease

*Prameha*. *Kaphaja Prameha* progresses into *Pittaja* and finally all the types of the *Prameha* get converted into the *Madhumeha*. Unctuousness of the body, excessive thirst, numbness in the hands and feet, dryness of the mouth, excessive hunger are few among the premonitory symptoms of *Prameha* due to vitiation of the various *Dosha* and *Dushya*.

Literature mentions 20 types of the *Prameha* which are categorized as 10 *Kaphaja*, 6 *Pittaja* and 4 *Vataja Prameha*. Based upon the physical strength of the patient it is again classified into *Sthoola Pramehi* and *Krishna Pramehi*. *Prameha* being a chronic lingering disease is considered as *Yapya*, which means that disease is best controlled rather than complete cure. Among all the *Prameha* its *kaphaja* variety of *Prameha*, that is easy to treat.

Among treatment first priority is given to the *Nidana Parivarjana*, if patient is obese various type of the *Shodhana* are mentioned as *Vamana*, *Virechana* and even few *Basti* are also mentioned. But it is better to avoid *basti* in *Pramehi* as this procedure is contraindicated in the *Prameha*. *Shodhana* is followed by the *Shamana* line of the treatment where various drugs formulations e.g. *Nishaamalaki* etc are mentioned. If the person is lean and thin it's better to go for *Santarpana* line of the treatment followed by *Shamana Chikitsa* and *Shodhana* treatment should be avoided in such patients. Physical exercise, brisk walking and outdoor game activities are also advisable in the *Pramehi*. Various types of the *Pathya* are also advised for a *Pramehi* where *Yavais* told as the best *Pathya*. Altogether, if a *Pramehi* follows *Shodhana*, *Shamana*, *Pathya* and keeps him engaged in the physical activities disease can be kept under well control, otherwise he may develop various complications of the

*Pramehasuch asjwara, atisara* and *pooti-mamsapidaka* etc.

In parallel science type 2 diabetes mellitus is a group of metabolic disorder involving carbohydrate, lipid and protein metabolism characterized by chronic hyperglycaemia, as a result of defect in insulin secretion from beta-cells of pancreas or peripheral action of the insulin (insulin resistance or both). Hyperglycemia develops due to factors like peripheral resistance to action of insulin, Increased hepatic glucose output, Impaired pancreatic cell secretion of insulin. Type 2 diabetes mellitus patients are usually obese and incidences of type 2 diabetes mellitus can be seen in all the age groups with more prevalence in the adult age group. With increase in the incidences and in the complications need of the hour is to provide safe and better management in the disease *Prameha*. Henceforth the study was carried out with the intention to provide best treatment and *Shilajatu Loha Rasayanawas* taken for the study to see its effects in the disease *Prameha*. Various animal studies have already proven the efficacy of the *Shilajatu Loha Rasayanain* the diabetic rats leading to the conclusion that *Shilajatu Loha Rasayanais* having antidiabetic property. More to add, its clearly mentioned in classics that *Shilajatu* is more effective if administered with the suitable drugs advised in that particular disease, thus *Salasaradi Kwatha* as *Anupana* was selected for the study as it is indicated in the *Prameha*.

After the treatment definite relief from the signs and symptoms of *Prameha* was seen, which is indicative of the *Samprapti Vighatana* in the patients who were taken for the study? Due to the abnormal increase in *Kleda* and due to vitiation of the *Mutravaha Srotas*, *Prabhootamutrata* was found as a symptom in *Prameha*, in pre-

sent study this symptom was reduced after the treatment this proves that treatment given was very much effective to bring about the normalcy of the *Kleda* and *Mutravahasrotas*. *Atikshudha* is a symptom due to the vitiation of *Kapha* and *Medas* leading to *Avarana* of *Vata*. Because of this *Vatavridhi* takes place which leads to the increase in the *Jatharagni*, after the treatment maximum number of the patients got relieved of this particular symptom which indicates that medication given was effective in bringing the normalcy of the affected *Dosha*, *Dushya*, *Kapha*, *Vata*, *Medas* and as well as of *Jatharagni*. *Atipipasa* and *Mukhatalushosha* are the symptoms of *Dushti* of the *Kleda*, *Pitta Dosha* and *UdakavahaSrotas* significant reduction was seen in this symptom too, indicating the effectiveness of the treatment to bring about normalcy of the *Kleda*, *Pitta* and *Udakavahasrotas*. *Avarana* of *Vata* by *Medas* and *Kapha* leads to the symptoms of *KarapadaDaha* and *KarapadaSuptata*, which were also reduced after the treatment indicating its efficacy to bring *Vata*, *Kapha* and *Medas* to the normal state. Patients also found relief from the *Daurbalya* which indicates the abnormality of *Medas* was brought to the normalcy.

### CONCLUSION

*Shilajatu Loha Rasayana* is very much effective in the remission of the symptoms of the *Prameha* and also in reducing the blood sugar levels as evidenced by statisti-

cally significant reduction in the symptom scores of various subjective and objective parameters.

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