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.¹ Evidently it is regarded as one among the eight Mahagadas². 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.³ 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 Anupan of 50 ml of Salsaradikwatha 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 santarpanottavikara. 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.\(^4\) 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\(^5\) 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 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 kwath\(^6\) 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/DMII (polyuria, polydipsia, and unexplained weight loss) plus casual plasma glucose concentration ≥200 mg/dl (11.1 mmol/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 ≥26 and ≥200 mg/dl or
3) Post Prandial Plasma Glucose Level ≤ 200 mg/dl and ≥50 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. Dourbalya
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. **Prabhootamutratra**
   - Normal-0
   - Mild increase in frequency-1
   - Moderate increase in the frequency-2
   - Severe increase in the frequency-3
2. **Pippasaadhiykya**
   - 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 karapadaha -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. 33.33% patients were males and 66.66% 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 *Kaphapittaparakruti* 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 *AvaraViyayama Shakti*.

Out of 15 patients taken for the study 100% patients had *Prabhootamutrata*, 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 *Prabhootamutrata* was reduced by 62.49%, *KshudhaAdhikya* by 81.5%, *PipasaAdhikya* by 75%, *Daurbalya* by 66.66%, *MukhataluShosha* by 75%, *KarapadaDaha* by 70%, *KarapadaSuptata* by 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.D. | S.E.M | “t” | p     |
| *Prabhootamutrata* | 2.133 (1.187)   | .800 (0.775)    | 1.333           | 0.976 | 0.252 | 5.292 | <0.001 |
| *Kshudhaadhiyaga*  | 1.800 (1.373)   | 0.333 (0.617)   | 1.467           | 1.302 | 0.336 | 4.363 | <0.001 |
| *Pipasaadhiyaga*  | 2.200 (0.941)   | 0.533 (0.834)   | 1.667           | 0.900 | 0.232 | 7.174 | <0.001 |
| *Daurbalya*       | 2.400           | 0.800           | 1.600           | 0.910 | 0.235 | 6.808 | <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**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean score</th>
<th>% Relief</th>
<th>Paired “t” Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT (±S.D)</td>
<td>AT (±S.D)</td>
<td>BT-AT  S.D.</td>
</tr>
<tr>
<td>FBS</td>
<td>155.53 (21.530)</td>
<td>112.60 (14.515)</td>
<td>42.933 18.972</td>
</tr>
<tr>
<td>PPBS</td>
<td>264.200 (33.605)</td>
<td>178.933 (40.844)</td>
<td>85.267 56.739</td>
</tr>
</tbody>
</table>

**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 *Santarpanotthavikara*. 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 vitiatiated 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 *MamsaDhatu* resulting into the *PramehaPidaika*. This circulating *Kapha* and *Medas* vitiates other *Dushya* such as Rakta, Mamsa, Meda, Majja, Shukra, Vasa, Oja, Lasika, Kledaand *Sweda*. This leads to the *Avarana* pathology in the *Basti* which finally results into the *Prabhoota AvilaMutrata*, 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 Shthoola-Pramehi and KrishnaPramehi. 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 NidanaParivarjana, 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 Shamanaline 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 ShamanaChikitsa 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 Pathyaare 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 as ajwara, atisara and pootimapsapadaka 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 β 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 ShilajatuLohaRasayana was taken for the study to see its effects in the disease Prameha. Various animal studies have already proven the efficacy of the ShilajatuLohaRasayana in the diabetic rats leading to the conclusion that ShilajatuLohaRasayana is having antidiabetic property. More to add, it’s clearly mentioned in classics that Shilajatu is more effective if administered with the suitable drugs advised in that particular disease, thus SalasaradiKwatha 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 SampraptiVighatana in the patients who were taken for the study? Due to the abnormal increase in Kleda and due to vitiation of the MutravahaSrotas, Prabhoottamutrata 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 Vataavriddhi 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 Jathragni. Atipipasaand Mukhatalushosha are the symptoms of Dushhti of the Kleda, Pitta Dosha and Udakavaha-Srotas 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 statistically significant reduction in the symptom scores of various subjective and objective parameters.

REFERENCES
4. Dr. M.S. Bhagel. Researches In Ayurveda, Jamnagar: Mridu Ayurvedic Publication And Sales;2005

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