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A CLINICAL STUDY OF SHILAJEET VATI IN PRAMEHA PURVARUPA (PRE-DIABETIC STATE)

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ABSTRACT

Introduction- The incidence of *Prameha* is increasing rapidly because of changes in dietetic habits and lifestyle. If the *Prameha Purvarupa* (Pre-diabetic) clinical features are treated by formulation *Shilajeet* is recommended in Ayurvedic Classics, proven efficacious and widely practised in the management of *Prameha* (Diabetes). **Materials and methods-** 30 patients from OPD and IPD of *Govt. Ayurvedic College & Hospital, Balangir*, fulfilling the **Subjective** and **Objective Parameters** were registered for the clinical trial. After diagnosis, they were under trial with *Ayurvedic* formulation *Shilajeet Vati* treated in a dose of 2 *Vati* (500mg each) twice daily empty stomach, for a period of 30 days with *Ushna Jala*. The assessment of subjective and objective parameters was evaluated on the 10th, 20th and 30th day from the day of initiation of trial up to 30 days in order to find the efficacy of the trial by statistical paired 't' test. **Observation and results-** The average percentage of improvement in subjective parameter *Prabhuta Mutrata* (quantity) 71.43%, *Prabhuta Mutrata* (frequency) 77.78%, *Pipasa* (increased thirst) 72.73%, *Kshudha* (excessive appetite) 72.22%, *Kara-pada Daha* (burning sensation in hand and feet) 73.81%,

Kara-pada Suptata (numbness of hand and feet) 80%, *Sweda Pravritti* (excessive sweating) 83.33%, *Mukha Shosha* (dry mouth) 79.17%, *Mukha Madhurya* (sweetness in mouth) 77.78%, *Sheeta Priyata* (liking for cold things) 80% and *Madhura Shukla Mutrata* (sweetness in urine) 100% and in objective Parameter fasting plasma glucose 68.89%, postprandial glucose 81.11%, HbA1c 73.33%. It has been observed that the trial drug patients are highly significant ($p<0.001$) to reduce both Subjective and Objective parameters after 30 days of treatment. **Discussion and Conclusion-** *Prameha* is a ***Kapha Pradhana Tridoshaja Vyadhi*** in which *Meda* is a *Pradhana Dushya.* The drug showed a potent *Pramehahar* effect which is evident from the reduction in the Subjective Parameter of *Prameha* and objective parameter of the levels of FBS, PPBS and HbA1c in patients. No side effect was noticed during the clinical study of *Shilajeet Vati.*

Keywords: *Prameha,* Diabetes, *Shilajeet Vati.*

INTRODUCTION

In *Ayurveda*, *Prameha* is described as a set of complex clinical disorders characterized by excessive urination (both in frequency and quantity), and turbidity[1]. The nature of the turbidity may vary depending upon the body reacts to the doshas[2]. Nowadays the disease *Prameha* has evolved as a life complicating disorder. *Prameha* is a *Tridoshajanya Vikara* due to the simultaneous vitiation of all the three *Doshas*[3]. *Ayurveda* describes 20 types of *Prameha* as different clinicopathological conditions produced out of specific *Doshas* and *Dushyas*, showing gross urinary characteristics and clinical manifestations. The fractional changes in *Dushyas* namely *Meda, Mamsa, Kleda, Shukara, Shonita, Vasa, Majja, Lasika, Rasa* and *Oja,* in association with three morbid *Doshas* manifests different subtypes of *Prameha*[4]. Shilajeet is one such drug the use of which has been advocated for *Prameha* in ancient texts[5]. So, for better and safe treatment *Ayurvedic* preparation *Shilajeet Vati* are selected for the present research protocol in *Prameha.*

AIM AND OBJECTIVE OF THE STUDY

1. To study the efficacy *of Shilajeet vati* in the management of *Prameha.*
2. To find out a suitable herbal drug for the treatment of *Prameha.*
3. To correlate *Prameha* in modern parlance.

MATERIALS AND METHODS

Selection of Patients

A total of 30 patients had been selected by special proforma covering demography along with both Subjective and Objective parameters from OPD and IPD of Govt. *Ayurvedic College and Hospital, Balangir and Saradeshweri Govt. Ayurvedic Hospital Balangir.* The consent of patients was also taken before the clinical trial.

Inclusion Criteria

Patients aged between 30-65 years of both sexes. Patients having symptoms of *Prabhuta Mutrata* (frequency of micturition), *Pipasa* (increased thirst), *Kshudha* (excessive appetite), *Kara-pada Daha* (burning sensation in hand and feet), *Kara-pada Suptata* (numbness of handand feet), *Sweda Pravritti* (excessive sweating), *Mukha Shosha* (dry mouth), *Mukha Madhurya* (sweetness in mouth), *Sheeta Priyata* (liking for cold things) *Madhura Shukla Mutrata* (sweetness in urine). Patients having FBS (100-125mg%), PPBS (140-200mg%) and HbA1c (5.7-6.4mg/dl) were selected for this study.

Exclusion Criteria

Patients age <30 years and >65 years, fasting plasma glucose > 125mg, oral glucose tolerance > 200mg%**,** HbA1c 6.5% or more, having complications of diabetes like ketoacidosis, nephropathy, neuropathy, retinopathy, and diabetic wounds, chronic, contagious infection diseasesuch as active tuberculosis, hepatitis B or C, or HIV**,** Pregnant and lactating females, active metabolic or gastrointestinal disease that may interfere with nutrient absorption, metabolism, excretion, excluding diabetes, Type-1 diabetes mellitus and Type-2 diabetes mellitus.

Criteria for Investigations

Hb%, TLC, DLC, Urine (Routine and Microscopic), Fasting blood sugar (FBS), Postprandial blood sugar (PPBS), HbA1c were investigated initially and follow up periods.

Selection of Drug

Shilajeet Vati had been taken for the clinical trial. The drug was identified by the experts of Dept. of *Dravyaguna and Rasashastra and Bhisajya Kalpana* which were approved by DRC and IEC of College and Sambalpur University. Medicines were prepared as per GMP certified method in Mini Pharmacy of College under the supervision of experts of *Rasashastra and Bhisajya Kalpana.*

Method of preparation of Shilajeet Vati

Good quality and given proportion of *Shilajeet* was added to prepared *Triphala Kwatha* and then filtered with a cotton cloth. The final filtrate *Shilajeet* was taken in a stainless-steel vessel (kadhai) placed over a mild fire, boiled, and reduced to a thicker consistency. Vati of 500mg was made with the help of *Goghrita* and dried packed as per recommended dose.

Administration of Drug

The trial drug *Shuddha Shilajeet* was given by oral route in the dose of 2 vati (500mg each) twice daily empty stomach, for a period of 30 days with *Ushna Jala*.

Table 1: Showing the pharmacodynamics of drug of Shilajeet Vati

Name	Rasa	Guna	Veerya	Vipaka	Doshakarmata	Quantity
Shilajeet	*Tikta Lavana*	*SheetaGuru Snigdha*	*Sheeta*	*Katu*	*Tridoshashamaka*	950gm
Triphala Kwatha						
Haritaki	*Kasaya, Madhura, Amla, Katu, Tikta (Pancharas)*	*Laghu, Ruksha*	*Ushna*	*Madhura*	*Tridoshashamaka*	315gm
Bibhitaki	*Kasaya*	*Ruksha, Laghu*	*Ushna*	*Madhura*	*Tridoshashamaka*	315gm
Amalaki	*Amlapradhana Lavana Varjita Pancharasa*	*Guru, Laghu, Sheeta*	*Sheeta*	*Madhura*	*Tridoshashamaka*	315gm

Assessment Criteria: The Subjective parameters and Objective parameters as per Inclusion Criteria were assessed by the grading score from 0 to 3 according to the severity of disease and favourable shift to back. Both parameter follow-ups were taken on the 10^{th}, 20^{th} and 30^{th} day of medication. The overall assessments were done considering the percentage relief of both parameters and statistical evaluation.

OBSERVATION AND RESULT

Within the aforesaid period, the demography (Table No.-02) based on Age-Sex-Religion etc. along with the incidence of *Dashvidha Pariksha* (Table No.-03) were observed and assessed.

Table 2: Demography Incidence of Registered Patients. (n=30)

Criteria	Maximum Percentage	Category
Age	53.33%	40-50 years
Sex	53.33%	Male
Religion	100%	Hindu
Education status	73.33%	Literate
Occupation	53.33%	Service
Socio- Economical status	73.33%	Middle class
Marital status	100%	Married
Dietary habit	80%	Mixed diet
Habit / Addiction	70%	Taking tea

Mode of onset	100%	Gradual
History of past illness	60%	No past history
Family history	60%	Absent
Sleeping habit	66.66%	Less sleep
Urination	60%	More
Bowel habit	53.33%	Normal

Table 3: Incidence of *Dashavidha- Pariksha* of Registered Patients. (n=30)

Criteria	**Maximum Percentage**	**Category**
Prakriti	43.33%	*Vatakapha*
Vikriti	50%	*Madhyama- vastha*
Sara	63.33%	*Madhyama-sara*
Samhanan	53.33%	*Madhyama*
Pramana	86.67%	*Madhyama sharira*
Satwa	50%	*Madhyama*
Satmya	53.33%	*Madhyama*
Ahara Shakti	70%	*Madhyama Ahara Shakti*
Vyayama Shakti	63.33%	*Hinabala Vyayama Shakti*
Vaya	60%	*Madhyamavastha*

The Subjective and Objective Parameters of research patients were observed during the clinical study. The percentage of improvement was also observed and assessed after the clinical trial. (Table No.-04)

Table 4: Showing the observation of total patients as per disease and percentage of Improvement (n=30) (f- Frequency, %- Percentage)

Symptoms	Frequency	Percentage	Percentage of Improvement
Subjective Parameter			
Prabhuta Mutrata (Quantity)	7	46.67	71.43
Prabhuta Mutrata (Frequency)	6	40	77.78
Pipasa (Increased thirst)	11	73.33	72.73
Kshudha (Excessive appetite)	9	60	72.22
Kar-pada Daha (Burning sensation in hand and feet)	7	46.67	73.81
Kar-pada Suptata (Numbness in hand and feet)	4	26.67	80
Sweda Pravriti (Excessive Sweating)	7	46.67	83.33
Mukha Shosha (Dry mouth)	8	53.33	79.17
Mukha Madhurya (Sweetness in mouth)	6	40	77.78
Sheeta Priyata (Liking for cold things)	5	33.33	80
Madhura Shukla Mutrata (Sweetness and whitish in urine)	3	20	100
Objective Parameter			
FBS	30	100	68.89
PPBS	30	100	81.11
HbA1c	30	100	73.33

After observation of subjective and Objective Parameters, the statistical analysis of parameters was assessed with help of statistical methods. (Table No.-05)

Table 5: Showing the Statistical Analysis of Subjective Parameter and ObjectiveParameter. (n=30)

Symptoms	Mean ± SD		value	p-value
	Before treatment	After treatment		
Subjective parameter				
PrabhutaMutrata (Quantity)	2.14 ± 0.69	0.71 ± 0.76	7.07	<0.001
Prabhuta Mutrata (Frequency)	2.50 ± 0.84	0.67 ± 0.82	5.97	< 0.005
Pipasa	2.09 ± 0.70	0.55 ± 0.52	7.46	< 0.001
Kshudha	2.11 ± 0.78	0.67 ± 0.71	5.96	< 0.05
Kara-padaDaha	1.86 ± 0.69	0.57 ± 0.53	6.97	< 0.001
Kar-pada Suptata	1.50 ± 0.58	0 ± 0.00	5.20	< 0.05
Sweda Pravriti	1.86 ± 0.69	0.43 ± 0.79	7.07	< 0.001
Mukha Shosha	2.00 ± 0.76	0.50 ± 0.53	7.94	< 0.001
Mukha Madhurya	1.83 ± 0.75	0.33 ± 0.52	4.39	< 0.01
Sheeta Priyata	1.60 ± 0.55	0.40 ± 0.55	6.00	< 0.005
Madhura ShuklaMutrata	1.33 ± 0.58	0.0 ± 0.0	4.00	<0.05
Objective Parameters				
FBS	2.87 ± 0.35	0.93 ± 0.70	12.61	< 0.05
PPBS	2.20 ± 0.68	0.47 ± 0.64	9.54	< 0.05
HbA1c	1.80 ± 0.68	0.60 ± 0.74	8.29	< 0.05

S. D= standard deviation, t= test of significance, p=probability; <0.05= significant at 5% level, <0.01 =significant at 1% level, <0.005= significant at 0.5%, <0.001 = Highly significant at 0.1% level

DISCUSSION

The present study was undertaken to interpret the efficacy of *Shilajeet Vati* in the management of *Prameha.*

Regarding demographic incidence it has been observed that (Table No.-02) males of middle age group, educated residing in urban areas, middle class, married, mixed diet, addiction of taking tea and having more urination and less sleep were prone to *Prameha*. Individual *Dashavidha- Pariksha* was covered and observed that (Table No.-03) *the Vata-Kapha* patients having *Madhyama – Sara- Samhanan- Pramana- Satwa- Satmya- Ahara Shakti and Hinabala Vyayama Shakti* were manifested with *Prameha*.

The effect of therapy was assessed on the basis of observations of subjective and objective parameters which was significant (p<0.05) statistically after 30 days. (Table No.-04 and 05). The outcome of the study showed ample evidence of *Shilajeet Vati* acting as *Pramehahar* and showed a significant result in reducing the symptoms. *Shilajeet* has *Tikta, Katu,* and *Kashaya Rasa, Katu Vipaka, Ushna Virya*, *Rechaka*, *Shoshana* and *Chedana* properties. It has *Rasayana*, *Vrishya* and*Pramehaghna* properties also. The selected *Rasayana* drug showed better improvement on subjective and objective parameters. The *Ayurveda* inspired a holistic approach to have a unique response promoting *Agni* (bio fire) and *Ojas* (immune strength) status leading to good health and wellness. So, *Shilajeet* has *Lavana Rasa* which acts on *Agni* and maintains the excellent status of *Agni. Katu Vipaka* and *Ushna Virya* acts on *Srotas* and remove theblockage of microchannels leading to better perfusion of tissue. It reduces the quantity of *Kapha, Meda* and *Kleda* by its properties which are the *Dushyas* in *Prameha. Rasayana* property of *Shilajeet* nourishes the body, helps to keep the body tissue in a healthy state and improves the metabolism at each and every level of *Dhatu.* It can also function as an antioxidant to improve the body's immunity and memory, anti-

inflammatory, and energy booster. Due to *Rechaka* property, it acts as a diuretic to remove excess fluid from the body. **(**Table No.-1)

CONCLUSION

In the present study, *Shilajeet* was evaluated for its efficacy in *Prameha Purvarupa (Pre-diabetic Condition)*. The drug showed a potent *Pramehahar* effect which is evident from the reduction in fasting and postprandial blood glucose levels, glycosylated haemoglobin and improvement in subjective parameters including the quality of life, psychological and social well-being. So, the study revealed that *Shilajeet Vati* can be used as a drug in the management of *Prameha Purvarupa*. The present study was carried out with certain limitations like fewer samples. Forthcoming researchers may pursue further study in large sample size over a period of longer duration. No side effect was noticed during the clinical trial.

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