ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

AN OPEN CLINICAL STUDY EVALUATING THE EFFECT OF *SHILAJITHU LOHA RASAYANA* ON AFFLICTION OF *BASTI MARMA* (DIABETIC NEPHROPATHY) IN PATIENTS WITH *PRAMEHA*

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ABSTRACT

Objectives of the study include answer to the research question or to the hypothesis framed. Present study was conducted to evaluate the therapeutic effect of *Shilajithu loha rasayana* in reducing the affliction of *Basti marma* in patients with *Prameha*/diabetic nephropathy, also to evaluate the therapeutic effect of *Shilajithu loha rasayana* in reducing the blood sugar level in patients suffering from affliction of *Basti marma* in *Prameha*/diabetic nephropathy. **Design:** Study Type: Interventional, Estimated enrolment: 30 participants, Allocation: Non-Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Single Group Assignment, Primary Purpose: Treatment, Masking: Open Label. **Participants:** From October 2019 to January 2020, 30 patients of affliction of *Basthi marma* in *Prameha*/ diabetic nephropathy having symptoms of diabetic nephropathy (microalbuminuria, reduced eGFR, raised cystatin-c) with a minimum of 5yrs history of diabetes are taken up for the study. **Intervention:** *Kosta shodhana* on day 1: 20ml of *Eranda taila* added with equal amount of *Shunthi kashaya* is orally administered during early morning in empty stomach. Day 2 to 22: *Shilajithu loha rasayana* is orally administered half an hour before breakfast, in a dose of 12g with warm water. Patient was advised diabetic diet and to do brisk walking/jogging or light exercise for 45 minutes daily during the course of treatment. **Results:** *Shilajithu loha rasayana* was successful in improving renal functions by increasing the glomerular filtration rate and reducing cystatin-c in patients also was successful in reducing fasting blood sugar and symptoms of *Prameha* which was justified statistically with p value <0.001. **Conclusion:** *Shilajithu loha rasayana* was successful in increasing the renal function and reducing symptoms of *Prameha*.

KEYWORDS: *Prameha, Shilajithu loha rasayana, Basthi marma abhigata*.

INTRODUCTION

Indian culture and diversity has given lot of valuable treatise which throws light on various aspects for the human population to follow. All the ancient medical texts not only give importance on knowledge of disease and its treatment but also a detailed explanation on rules and regulation to lead a healthy life. In the present era of modernization people have deviated from traditional lifestyle to the modernized way of leaving. Though this change gave luxurious living in the society but along with this, the level of mental stress and unhealthy diet and activities also increased.

The modern way of living is characterized by intake of diet that are rich in fats and high calorie or the combination of both, along with lack of physical activities. This unique change has increased the incidence of disease in the society and are collectively called as *Santarpana vikara* or metabolic syndrome in conventional system[1]. *Prameha* is one such disorder that is explained in texts which can be matched with the symptomatology of diabetes mellitus. The disease is considered as one among *Mahagada* because it affects each and every cell in the body. The incidence of diabetes has been increasing with the sedentary life style in the society.

Prameha is a disorder known to mankind since ages, it is caused by the vitiation of morbid *Dosha* effecting the 10 body elements[2]. It's an established fact that with the change in lifestyle and sedentary lifestyle there is a rapid increase in the incidence of *Prameha* in India. India is one among the top 3rd countries with maximum cases of diabetes along with china and United States[3]. *Prameha* when not treated well can lead to various serious complications that may even prove fatal. One among such complications is *Basthi marma abhigata. Basthi* is the seat for all *Mootravaha srotas vikara* and

Prameha for a certain period if not controlled can lead to affliction of *Basthi marma*[4].

The same can be matched with diabetic nephropathy. Prolonged uncontrolled blood sugar can damage nephrons leading to nephropathy. Diabetic nephropathy can present with micro-albuminuria initially and at a long run accounts for major cause for death in end stage renal disease. Early diagnosis and early treatment along with proper glycaemic control is the key to success in such cases[5]. *Shodhana* and *Shamana* are the two folds of treatment that is common to all diseases. There are certain groups of drug that acts on *Prameha* by controlling the glycaemic control on other hand certain group of drug acts on *Mootravaha srotas* and prevents nephron damage. Apart from these a special group of drugs that acts on *Prameha* as well as *Mootravaha srotas* is mentioned in texts.

Nearly 300 works done related to the efficacy of herbal and herbomineral drugs in *Prameha*, many more on effect of *Shodhana* and *Shamana* in *Prameha*. Few more on the efficacy of folklore medicine. Also the total number of studies on *Mootravaha srotas* is very less. *Rasayana* is one unique way of treating chronic illness and the study on *Rasayana* in *Prameha* did not cross single digit and this area has a huge scope for further studies.

MATERIALS AND METHODOLOGY

Objectives of the Study

This study entitled An open clinical study evaluating the effect of *Shilajithu loha rasayana* on affliction of *Basti marma* (diabetic nephropathy) in patients with *Prameha* is aimed to fulfill the following objectives

- Evaluating the therapeutic effect of *Shilajithu loha Rasayana* in reducing the affliction of *Basti marma* in patients with *Prameha*/diabetic nephropathy
- Evaluating the therapeutic effect of *Shilajithu loha rasayana* in reducing the blood sugar level in patients suffering from affliction of *Basti marma* in *Prameha*/ diabetic nephropathy.

Source of Data

Subjects with affliction of *Basti marma* due to *Prameha*/diabetic nephropathy will be selected for the study from OPD & IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. The *Shilajithu loha rasayana* required for the study will be procured from the Sri Dharmasthala Manjunatheshwara Ayurveda pharmacy, Udupi.

Method of Collection of Data

A minimum of 30 Patients suffering from affliction of *Basti marma* in due to *Prameha*/ diabetic nephropathy will be screened under strict diagnostic, inclusion and exclusion criteria and will be selected for the study. These patients are invited to participate in the study after signing the informed consent and then registered for the clinical trial. As per the intervention protocol these subjects will be given *Shilajithu loha rasayana* for the stipulated period. Patients are advised to undergo standard dietary management and therapeutic exercise for diabetes. The primary and secondary outcome measures are assessed before and after the medication.

Diagnostic Criteria[6]

- Clinical diagnosis of *Prameha* based on history of premonitory and cardinal symptoms.
- Diagnosis of type 2 diabetes mellitus fulfilling at least 1 of the following criteria.
- Subjects taking on anti-diabetics and / or insulin
- Documented evidence in the medical history of fasting glucose >/= 180mg /dl.
- Documented evidence in the medical history of HbA1c >/=6.5%.
- Diagnosis of diabetic nephropathy fulfilling at least 1 of the following criteria
- Urinary albumin-to-creatinine ratio (UACR) of >/=300mg/g (>/= 34mg/mmol).
- EGFR>/=30mL/min/1.73m^2 but<90mL/min/1.73m^2.

Inclusion Criteria

- Subjects with Type 2 diabetes mellitus and diabetic nephropathy.
- Well controlled blood sugar level (HbA1c≤7.5%) at screening.
- Serum creatinine ≤ 1.4 mg/dL at Screening.
- Sitting blood pressure of <=170/100 mm Hg at screening.
- Ages Eligible for Study: 40 Years to 70 Years.
- Males and non pregnant non lactating females.
- Able and willing to give written informed consent.

Exclusion Criteria

- Subjects with type 1 diabetes mellitus.
- Diabetes mellitus resulting from pancreatic disorder.
- Secondary diabetes mellitus (Cushing's syndrome, steroidogenic diabetes).
- Subjects who have history of acute kidney injury.
- History of non-diabetic renal disease, including renal artery stenosis.
- Patients who have undergone haemodialysis at any time.
- severe uncontrolled hypertension (sitting diastolic blood pressure > 115 and/or sitting systolic blood pressure> 220 mm Hg).
- Persons addicted to alcohol.

Parameters and its Gradations

***Kshudha* (Appetite)**

0 –normal limits
1- 2 main meals, light breakfast 2-3 / day
2- 2 main meals, light breakfast 3-5 / day
3- 2 main meals, light breakfast > 5 / day

Atitrishna

Quantity of water intake polydipsia

0- Intake of water 5-7 times / 24 hours with quantity 1.5-2.5 litres / 24 hours
1- Intake of water 7-9 times / 24 hours with quantity 2.5-3.0 litres / 24 hours
2- Intake of water 9-11 times / 24 hours with quantity 3.0 – 3.5 litres / 24 hours
3- Intake of water >11 times / 24 hours with quantity >3.5 litres / 24 hours

***Kara-pada-tala-daha/ supti* (Neuropathy)**

0- No daha
1- Kara pada tala daha is not continuous
2- Kara pada tala daha continuous but not severe
3- Kara pada tala daha continuous and severe

***Daurbalya* (Debility)**

0- Can do routine exercise / work
1- Can do moderate exercise with difficulty
2- Can do mild exercise only, with difficulty
3- Cannot too mild exercise

Prabhoota mootrata

Quantity of urine (in litre)

0- 1.5 to 2.00
1- 2.00 to 2.50
2- 2.50 to 3.00
3- 3.00 onwards

Frequency of Urine

0 - 3 To 6 Times per Day, Rarely At Night
1 - 6 to 9 Times per Day, 0-2 Times Per Night
2 – 9 To 12 Times Per Day, 2-4 Times per Night
3- More Than 12 Times per Day, More Than 4 Times per Night

Avila Mootrata

It will be measured using turbidimetry analysis method

Design of the study

Study Type: Interventional.
Estimated enrolment: 30 participants.
Allocation: Non-Randomized.
Endpoint Classification: Efficacy Study.
Intervention Model: Single Group Assignment.
Primary Purpose: Treatment.
Masking: Open Label.

Intervention[7]

Kosta shodhana day 1:20ml of *Eranda taila* with equal quantity of *Shunthi kasaya* administered orally during early morning in empty stomach.

Day 2-day 22: *Shilajithu loha rasayana* is orally administered half an hour before breakfast in a dose of 12 grams with hot water.

Duration of study: 22 days of intervention and 30 days of follow up period.

Follow up: 30 Days after treatment.

Assessment Criteria

Primary Outcome Measures

- Change from baseline in urinary Cystatin C at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)
- Change from baseline in eGFR Calculated Using Cystatin C at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)
- Change from baseline in Fasting blood sugar (FBS) at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)
- Change from baseline in Glycosylated haemoglobin (A1C) at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)

Secondary outcome measure:

- Change from baseline in Urine albumin-to-creatinine ratio (UACR) at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)
- Change from baseline in Systolic Blood Pressure and Diastolic Blood Pressure) at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)
- Change from baseline in the severity score of clinical symptoms of *Prameha* at completion of course of *Shilajithu loha rasayana* (Time Frame: day 1 and day 22)

Subjective parameters: signs and symptoms of *Prameha*

1. *Kshuda* (appetite)
2. *Atitrishna*
3. *Kara-pada-daha/ supti* (neuropathy)
4. *Dourbalya* (debility)
5. *Prabhuta mootrata*
6. Frequency of Urine
7. *Avila Mootrata*

OBSERVATION

In the present study total 30 patients of *Prameha* were registered and allocated into single group. The observations of the study were made under following headings: Demographic description, Observations on personal history, Observation on

family history, Observation on general examination, Observation on *Dashavida pariksha*.

Among 30 patients, maximum number of patients, 47% were between the age group of 61- 70, followed by 46% of patients between 51-60 and 7% of patients between 41-50 age group. 59% were males and 41% were females. 90% of patients were Hindu, 7% of patients were Christians and 3% of patients were Muslim. 28 patients in the study were married and 2 patients were widow. 44% patients completed graduation, 30% patients completed primary education, 13% patients completed high school and 13% patients were illiterate. 44% were having desk work as their profession, 30% were homemakers, and 13% had their occupation as labour 13% had their occupation as field work. Total of 60% patients belonged to middle class and 40% of patients belonged to lower middle class. There were no patients belonging to upper class, upper middle class, and lower class. 80% of patients adopted mixed diet and 20% of patient had vegetarian diet. 70% patients had sound sleep were as 30% of patients had disturbed sleep. 64% of patients had *Madhyama Kosta*, 25% with *Krura Kosta* and 11% with *Mridu Kosta*. 60% of the patients had a family history of diabetes. And 40% did not have history of diabetes in family members. 67% of patients were on oral hypoglycaemic agents, 20% patients on Ayurvedic medications, and 13% patients on insulin.

RESULT

30 patients in the age group of 40-70years having the symptoms of *Prameha*/ diabetes mellitus, and diagnosed to have *Basthi marma abhigata* due to *Prameha* / diabetic nephropathy with the symptoms like polydipsia, polyuria, unexplained weight loss, history of plasma glucose more than 180mg/dl and on screening raised cystatin-c and eGFR more than 30 less than 90 and HBA1C less than 7.5% was taken for the study and after willing to give a written consent was included for the study. The study was designed to evaluate the parameters related to diabetes and diabetic nephropathy and cardinal symptoms of *Prameha* before and after the treatment. With this background patient was administered 20ml of *Eranda taila* along with 20ml of *Shunthi kashaya* on day 1 for *Kosta shodhana*. From day 2 to day 22 patients were administered *Shilajithu loha rasayana* 12g in capsule form (each capsule of 1gm each) empty stomach half an hour before breakfast with warm water.

The mean score of cystatin-c before the treatment was 1.196 (±0.0181) and after 21 days of intervention it reduced to 1.037 (±0.0181) recording an improvement of 13.294% on laboratory values, which was statistically significant with p=<0.001. This proves that *Shilajithu loha rasayana* was very much effective in reducing cystatin-c in patients.

Table 1: Effect of Treatment on Cystatin-c

Criteria	Time	Mean	± SD	±SE	Difference in mean	% improvement	Paired T Test	
							t value	P value
1.530 - 0.708	BT	1.196	0.0989	0.0181	0.159	13.294%	t = 9.210	P = <0.001
	AT	1.037	0.135	0.0181				

The mean score of estimated glomerular filtration rate before the treatment was 62.912 (±1.500) and that after 21 days of intervention was increased to 89.193 (±0.954) recording improvement of 42.1% on laboratory values, which was statistically significant with p=<0.001. This again proves that the formulation *Shilajithu loha rasayana* was very much effective in increasing the estimated glomerular filtration rate thus improving the kidney function.

Table 2: Effect of Treatment on Estimated Glomerular Filtration Rate

Criteria (Range)	Time	Mean	± SD	±SE	Difference in mean	% improvement	Paired t test	
							t value	P value
120-231	**BT**	174.167	25.093	4.581	32.233	18.50%	15.515	P = <0.001
	AT	141.933	19.138	3.494				

The mean score of fasting blood sugar before the treatment was 174.167 (±4.581) and was reduced to 141.933 (±3.494) after treatment with a recording of 18.50% on laboratory values, which was statistically significant with p=<0.001. Thus proving the efficacy of *Shilajithu loha rasayana* in reducing the plasma sugar levels.

Table 3: Effect of Treatment on Fasting Blood Sugar

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	Paired t test	
							t value	P value
120-231	**BT**	174.167	25.093	4.581	32.233	18.50%	15.515	P= <0.001
	AT	141.933	19.138	3.494				

The mean score of glycosylated haemoglobin (HBA1C) before the treatment was 7.313 (±0.0893) and that after intervention was 7.163 (±0.0780) with a recording of 2.05% in laboratory values, which was statistically significant with p=<0.001. This proves on a whole that *Shilajithu rasayana* has a very good anti-diabetic property.

Table 4: Effect of Treatment on Glycosylated Haemoglobin

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	Paired t test	
							t value	P value
7.9-6.4	**BT**	7.313	0.489	0.0893	0.150	2.05%	6.289	P = <0.001
	AT	7.163	0.427	0.0780				

The mean score of urine albumin to creatinine ratio before the treatment was 85.186 (±4.100) and that after the intervention was reduced to 64.541 (±3.556) recording 24.23% of improvement in laboratory values, which was statistically significant with p=<0.001. This proved that *Shilajithu loha rasayana* was effective in improving the renal function.

Table 5: Effect of Treatment on Urine Albumin to Creatinine Ratio

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	Paired t test	
							t value	P value
7.9-6.4	**BT**	85.186	22.456	4.100	20.645	24.23%	15.921	P = <0.001
	AT	64.541	19.478	3.556				

The mean score of systolic blood pressure before the treatment was 140.333 (±1.477) and after the intervention was reduced to 132.667 (±1.433) with 5.46% of improvement in the reading, which was statistically significant with p=<0.001. This proved that *Shilajithu loha rasayana* by improving the renal function proved efficacious in reducing the systolic blood pressure.

Table 6: Effect of Treatment on Systolic Blood Pressure

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	Paired t test	
							t value	P value
150-120	**BT**	140.333	8.087	1.477	7.667	5.46%	4.678	P = <0.001
	AT	132.667	7.849	1.433				

The mean score of grading of *Praboothа mootrata* before the treatment was 1.367 (±0.112) and was reduced to 0.667 (±0.0875) after the intervention with a recording of 51.02% of improvement, which was statistically significant with p=<0.001. The efficacy of *Shilajithu loha rasayana* in reducing the cardinal symptom of *Prameha* was proved beneficial.

Table 7: Effect of Treatment on *Prabhoota mootrata*.

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
	AT	0.667	0.479	0.0875				

The mean score of grading of Avila mootrata before the treatment was 1.067 (±0.135) and was reduced to 0.367 (±0.102) after the treatment with 65.60% of improvement in the scoring which was statistically significant with p=<0.001. Hence *Shilajithu loha rasayana* was successful in reducing *Avila mootrata* in patients with *Prameha*.

Table 8: Effect of Treatment on *Avila mootrata*

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
4-0	**BT**	1.067	0.740	0.135	0.7	65.60%	4.001	P = <0.001
	AT	0.367	0.556	0.102				

The mean score of grading of *Kshuda* before the treatment was 0.767 (±0.0785) and was reduced to 0.400 (±0.0910) with 47.84% of improvement in the symptom which was statistically significant with p=0.017. Hence *Shilajithu loha rasayana* was successful in reducing *Kshuda* in patients with *Prameha*.

Table 9: Effect of Treatment on *Kshuda*

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
4-0	**BT**	0.767	0.430	0.0785	0.367	47.84%	2.668	P = 0.017
	AT	0.400	0.498	0.0910				

The mean score of grading of *Dourbalya* before the treatment was 1.467 (±0.0926) and was reduced to 0.800 (±0.0743) after the treatment with a marked improvement of 45.4% in the symptom which was statistically significant with p=<0.001. Hence *Shilajithu loha rasayana* was successful in reducing *Dourbalya* in patients with *Prameha*.

Table 10: Effect of Treatment on *Dourbalya*

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
4-0	**BT**	1.467	0.507	0.0926	0.667	45.4%	4.264	P = <0.001
	AT	0.800	0.407	0.0743				

The mean score of grading of *Kara pada daha* before the treatment was 1.433 (±0.177) and was reduced to 0.800 (±0.121) after the treatment with the marked improvement of 44.17% in the symptom, which was statistically significant with p=<0.001. Hence *Shilajithu loha rasayana* was successful in reducing *Kara pada daha* in patients with *Prameha*.

Table 11: Effect of Treatment on *Kara pada daha*

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
4-0	**BT**	1.433	0.971	0.177	0.633	44.17%	3.788	P = <0.001
	AT	0.800	0.664	0.121				

The mean score of grading of *Trishna* before the treatment was 0.533 (±0.0926) and was reduced to 0.200 (±0.0743) after the treatment with the marked improvement of 62.4% in symptom, which was statistically significant with p=0.002. Hence *Shilajithu loha rasayana* was successful in reducing *Trishna* in patients with *Prameha*.

Table 12: Effect of Treatment on *Trishna*

Criteria (Range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
4-0	**BT**	0.533	0.507	0.0926	0.333	62.4%	3.162	P = 0.002
	AT	0.200	0.407	0.0743				

The mean score of grading of frequency of urine before the treatment was 0.467 (±0.0926) and after the intervention was reduced to 0.167 (±0.0692) recording improvement of 64.3% in the symptom, which was statistically significant with p=0.004. Hence *Shilajithu loha rasayana* was successful in reducing frequency of urine in patients with *Prameha*.

Table 13: Effect of treatment on frequency of urine

Criteria (range)	time	Mean	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							Z value	P value
4-0	**BT**	0.467	0.507	0.0926	0.3	64.3%	3.000	P = 0.004
	AT	0.167	0.379	0.0692				

DISCUSSION

Excessive consumption of fatty food with lack of physical exercise leads to group of disease that includes *Prameha*, *Hridroga*, and *Gulma*, *Vataraktha* and *Shonitha dusti*. These diseases are collectively known as *Santarpana janya vikara*. And in conventional system these are put under the heading of metabolic disorders. Out of these metabolic disorders *Prameha* is one among the dreadful disease that has been causing problem to mankind. Diabetes is parallel term that is mentioned in conventional system. Developing countries like India the disease *Prameha* is a real challenge in preventing and controlling it. According to recent studies the incidence of diabetes in developing counties like India has rapidly increased due to sedentary lifestyle and lack of physical activities.

The combination of morbid *Medas* and *Kapha* travels all over the body vitiating other two *Dosha* and 10 body elements with either of two consequences. The *Kapha* and *Medas* vitiates *Mamsa dhatu* leading to *Prameha pidaka* or the *Kapha* and *Medas* vitiates *Kleda* leading vitiation of fluid in the body. This vitiated fluid along with the other vitiated elements gets lodged in *Basthi*. The vitiated *Kleda* is then converted into *Mutra* and is thrown out of the body. Initially *Prameha* starts with predominance of *Kapha dosha* and then ends with the predominance of *Vata dosha.* Though *Prameha* is *Medas srotas vikara* the symptoms and signs exhibited by the disease is related to *Mootravaha srotas*. This is because the seat that the disease takes place is *Basthi*. Change in

quality and quantity are the symptoms of individual types of *Prameha*.

When this pathogenesis continues for a certain time this damages *Basthi marma* and results in various complication. Text states when there is severe damage to *Basthi* person will die immediately but when there is minimal damage that will lead to a serious illness with this base there will be damage that will lead to symptoms like *Shotha* in the body and this stage of disease is called as *Basthi marma Abhighata* due to *Prameha*. There are two lines of thoughts, first group states that the morbid *Kapha* and *Medas* vitiates the *Sharira kleda*, lodges in *Basthi* produces *Prameha*. When untreated properly this will further aggravate to the predominance of *Pitta* and then end up with *Vata dosha*. In a long run when this is left untreated this will lead to affliction of *Basthi marma* and produce symptoms like *Shotha*. So the first school claims *Basthi marma abhigata* as a complication of *Vataja prameha*. The second school claims that the vitiated *Kapha medas* and other elements gets lodged in *Basthi* and on a long run this itself will afflict the *Basthi marma* leading to *Basthi marma abhighata*. Though both the explanation holds a valid justification it's difficult to identify which pathogenesis is more accurate.

On the contrary the disease *Prameha* can be matched with diabetes mellitus in conventional system. Pancreas is a very important organ in the body that is responsible for digestion and glucose homeostasis. This endocrine gland secrets insulin and this is associated with sugar metabolism and carbohydrate metabolism. Absolute or relative deficiency is the main cause for diabetes which is characterised by abnormalities of carbohydrate, protein and fat metabolism. Diagnosis of diabetes mellitus is mainly based on plasma glucose level. Polyuria, polydipsia, polyphagia are the main symptoms that are seen. Uncontrolled hyper-glycaemia for a certain time acts as a risk factor for all major organ damage and thus can lead to serious complications. Among those complications renal damage due to diabetes is quite more common. This complication remains asymptomatic at the initial stage, and when it is symptomatic it will be in end stage.

Diabetic nephropathy or diabetic kidney disease is one of the major microvascular complications. And it accounts for major cause for deaths in end stage renal disease. The disease develops as a result of nephron damage due to prolonged hyperglycaemia. Due to this there will be expansion of mesangium leading to a permanent nodule formation named Kimmelstel-Wilson nodules. The disease is initially diagnosed by chance or on screening for complications of diabetes. It initially starts with microalbuminuria. Diagnosis of the disease at this stage is by checking cystatin-c, estimated glomerular filtration rate and urine albumin to creatinine ratio. Apart from micro-albuminuria patient can present with fatigue, secondary hypertension and edema. If further left untreated or if uncontrolled plasma sugar continues, the nephron further gets damaged and thus leading to irreversible changes of diabetic kidney disease.

The study was screened in 90 diabetic patients and out of which 30 patients who were fit under the inclusion criteria was taken up for the study. The disease of *Mootravaha srotas* can be broadly classified into two categories with two different presentations. One group with less production of urine collectively called as *Mutraghata* and another group opposite to it and justified by the name *Prameha*. When the disease *Prameha* is left untreated then it is an open invitation for all the complications to occur. On long run the disease *Prameha* as a complication can lead to *Mutraghata*.

There are studies were the efficacy of herbal drugs or herbomineral drugs on *Prameha* was carried out. On the contrary there were a few studies that were taken to evaluate the efficacy of herbal or herbomineral drug on *Mutraghata*. But this study is unique of its kind where the efficacy of the drug is evaluated in both *Prameha* and its complication as *Basthi marma Abhigata* which if left untreated will develop *Mutraghata*. The selection of drug was the important step in the study because the selected drug should not only act on plasma glucose but also should effectively act on renal parameters. Text says *Shilajithu loha rasayana* as one of the best drug that can combat both renal function as well as plasma glucose. So on this ground the study was conducted. The study included primary outcome measures and secondary outcome measures which included both diabetic parameters and renal parameters. Diabetic parameters include fasting blood sugar, glycosylated haemoglobin and symptoms of *Prameha* mentioned in classical text. Cystatin-c, estimated glomerular filtration rate, urine albumin to creatinine ratio and systolic blood pressure are renal parameters.

When the overall symptoms of *Prameha* were observed there was a remarkable positive change in all the symptoms of *Prameha*. *Prameha* is a disorder where there in the initial stage there will vitiation of *Kapha* and *Medas* further adding on the 10 body elements that gets lodged in *Basthi* producing *Prameha* in the form of excessive urination. Though *Prameha* is *Medas vikara* the disease seat is in *Basthi* which is seat of *Mutra vaha srotas*, as well as a *Sadhya pranahara marma*. So in turn along with the *Medas*

even urinary system gets hampered. This vitiated *Mutra* gives various associated illness which need aggressive care. On the long run this effects the *Marma* and produces set of symptoms like *Shotha* that are different from *Prameha*. On other hand diabetes is a condition with increased plasma glucose leading to damage of nephrons on the long run and is named as diabetic nephropathy or diabetic kidney disease where the symptoms are quite different from that of mother disease.

- Reducing symptoms of *Prameha* like *Prabhuta Avila mootrata*, *Kara pada daha*, *Dourbalya, Kshuda, Atitrishna.*
- Reducing the complication of *Basthi marma abhighata* in terms of *Shotha*.
- On conventional system, reducing the plasma blood glucose.
- Also reducing the symptoms of diabetic kidney disease and improving renal functions.

Treating this type of condition might require many combinations of drugs. Where some drugs act on *Mootravaha srotas* and some drugs act on plasma glucose. There are very few formulations that acts on all the above said criteria. For a formulation to be stated as successful in *Basthi marma abhigata* in *Prameha* it should reduce the symptoms of *Prameha*, it should reduce the symptoms of *Basthi marma Abhigata* in *Prameha* and on contrary it should also reduce the plasma glucose and renal function. The combination that perfectly matches the indication is *Shilajithu loha rasayana*. In the study the drug proved to reduce the plasma glucose, increase the renal function by improving the glomerular filtration rate and reducing cystatin-c, also reducing the symptoms of *Prameha* thus proving the drug to be a drug of choice in *Basthi marma abhigata* in *Prameha*/diabetic nephropathy.

CONCLUSION

From the above data it proves that the drug *Shilajithu loha rasayana* that was selected for the study of affliction of *Basthi marma* in patients with *Prameha* proved very efficacious in reducing the plasma glucose level at the same time improving the renal function parameter with statistical evidence.

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Cite this article as:
Chinmaya, Aniruddha saralaya, Shrinivasa Acharya. G. An Open Clinical Study Evaluating The Effect Of Shilajithu Loha Rasayana on Affliction of Basti Marma (Diabetic Nephropathy) In Patients With Prameha. International Journal of Ayurveda and Pharma Research. 2020;8(9):27-34.

Source of support: Nil, Conflict of interest: None Declared

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