

Clinical Evaluation of Shilajatu in Diabetes Mellitus

Research Article

Neha Lamba^{1*}, Piyush Chaudhary², Sharma YK³

1. Assistant Professor, Department of Kayachikitsa,
2. Assistant Professor, Department of Rasa Shastra, BK Ayu. Medical College, Daudhar, Moga, Punjab
3. Dean & Principal, RGGPGAC, Paprola

Abstract

The incidence of diabetes mellitus is increasing rapidly because of changes in dietetic habits and life style. Continuous research is being done by scientists of various fields in order to achieve an effective cure of the disease. A great deal of work has also been done by Ayurvedic research scholars on various herbal and mineral drugs to find an effective treatment for *Prameha*. *Shilajatu* is one such drug which has been described for the management of *Prameha* in Ayurveda texts. The present study was conducted to clinically assess the efficacy of *Shilajatu* in the management of *Prameha*. Twenty two diabetic patients were selected for the study. The results were assessed in terms of symptomatic relief on the basis of scoring system, laboratory investigations including fasting blood glucose, post prandial blood glucose, glycosylated Hb, urine sugar, and a Questionnaire on Quality of Life. Statistically highly significant improvement ($p < 0.001$) was observed on FBS and PPBS. Statistically significant improvement was observed on urine sugar and glycosylated haemoglobin with $p < 0.05$ and $p < 0.01$ respectively. In terms of subjective parameters also, highly significant improvement, with $p < 0.001$ was observed in *Shaithilya*, *Mukha Sosh*, *Sandhi Shoola*, *Prabhuta Mutrata*, *Pipasa* and *Kshudha*. Highly significant improvement was observed in quality of life statistically with $p < 0.001$. The study revealed that *Shilajatu* can be used as a drug in the management of *Prameha*.

Keywords: Diabetes, glycosylated hemoglobin, *Shilajatu*, *Prameha*, WHO-QOL-BREF

Introduction

Of the wide spectrum of disorders affecting people globally, Diabetes is growing in full pace and alarming the world as a non-infectious pandemic. The new estimates show an increasing trend towards younger people developing

diabetes, a trend that is very worrisome for future generations. If current demographic patterns continue, more than 592 million people will be affected with diabetes within a generation. Estimates of type 1 diabetes in young people also show unexplained and rapid increases in several regions along with the rise in type 2 diabetes in older populations. As per the WHO reports, 347 million people worldwide have diabetes. In 2004, an estimated 3.4 million people died from consequences of fasting high blood sugar. A similar number of deaths have been estimated for 2010.(1)

*Corresponding Author:

Neha Lamba

Assistant Professor,
Department of Kayachikitsa,
BK Ayu. Medical College, Daudhar
Moga, Punjab.

Mobile No: +91-9736333868

Email: nehafamilyfriends@gmail.com

The burden of diabetes is reflected not only in the increasing numbers of people with diabetes, but also in the growing number of premature deaths due to diabetes. In 2013, roughly half of all deaths due to diabetes in adults were in people under the age of 60, and in less-developed regions like sub-Saharan Africa, that proportion climbs to 75%. As life expectancy increases, while the infectious disease burden decreases and development drives rapid changes in lifestyles, it is the developing regions that will see the greatest changes in the burden of diabetes.(2)

When the resources of Modern medicine ends and the road to success seems far, attention is diverted to explore the Ayurvedic resources. Ayurveda is a rich treasure of safe materia medica which provides a promising field of drug research, especially in view of its vast treasury of drugs.

Shilajatu is one such drug the use of which has been widely advocated for *madumeha* (~Diabetes mellitus) in ancient texts.(3) *Shilajatu* can be used either alone or in combination with other herbo mineral formulations, after its proper purification process.(4) The complete evidence based data on the efficacy of *Shilajatu* as *madhumehahar* has certain lacunae. Also, no study has been conducted on *Shilajatu*, taking in to account its effect on the disease and the related Quality of Life. Hence, an attempt has been made to study the effect of *Shilajatu* in *madhumeha*, which has been reported to possess hypoglycaemic property.(5) Thus, the present study was planned to generate evidence based data regarding efficacy of *shilajatu* in diabetes mellitus.

Materials and Methods

Selection of subject:- 22 patients attending the OPD of the Institution's

Hospital were selected in the age group of 25 years to 70 years irrespective of race, caste and religion. It was an observational trial with Single group only.

Inclusion criterion:

Patients willing for the trial with Fasting Blood Sugar between 126mg/dl - 200 mg/dl and only uncomplicated cases of Type II Diabetes Mellitus were included in the trial.

Exclusion criterion:

Patients presenting with complications like severe renal disease, retinopathy, ischemic heart disease, severe hypertension and those suffering from type I Diabetes Mellitus were excluded from the trial.

Laboratory Analysis:

1. Blood examination:- fasting Blood Sugar, Post prandial blood sugar, HbA_{1c}, Hb% gm, TLC, DLC, ESR, S.urea, S. creatinine, Lipid profile
2. Urine Sugar

Method of Study

- I. IEC & Consent:-** Approval from the Institutional Ethics Committee (IEC) for the M.D./M.S. (Ayu.) Research Work was taken prior to begin with this study vide No. IEC/2013/355 dated 10-06-2013. Written & informed consent of the patients was taken before their registration for the study.
- II. Patient Information Sheet & CRF:-**All the patients were given an information sheet stating all the details of the study protocol, benefits of the trial & any expected side effects. A clinical Research proforma was prepared to note down all the details of the patients and their disease profile.
- III. Drug:-** The trial drug namely, Shuddha Shilajatu was procured from the Charak Govt. Ayurvedic Pharmacy, Paprola.

IV. Administration of Drug:- The trial drug *Shuddha Shilajatu* was given by oral route in the dose of 250 mg twice a day for 28 days with plain water.

V. Assessment:- Before and after treatment total two assessments were carried out. Objective criterion included laboratory investigations. Another criterion of assessment was based on the scoring of Questionnaire on Quality of Life, which included Physical Domain, Psychological Domain, Social Relationships Domain, Environment Domain. Assessment of subjective improvement in terms of *Prabhuta Mutrata* (polyuria), *Pipasa* (polydipsia), *Kshudha* (polyphagia), *Shaithilya* (numbness in hands and feet), *Karpada Daha* (burning sensation in hands and feet), *Pindikio Udveshtana* (calf tenderness), *Mukha Sosha* (dryness of mouth), *Sandhi Shoola* (pain in joints) was also done.

Statistical Analysis:- The obtained data was analyzed statistically and expressed in terms of mean, standard deviation (\pm SD) and standard error (\pm SE). Appropriate 't' test was applied to observe the significance of results obtained after treatment. The data was analysed using the "spss software" of statistics.

Observations

Of the total 22 subjects enrolled, 18 completed the study. Four patients did not turn up for the follow up and were considered drop out. Maximum number of patients 36.36% was in age group of 41-50 years, 54.54% were male patients, 59.09% were Graduates, 63.63% belonged to Middle class. 45.45% patients were in government service while 40.90% were housewives, 72.72% took mixed diet,

36.36% patients had BMI between 25-30 followed by 27.27% BMI between 20-24.9. of the total patients 45.45% were of *Vata Kaphaja Prakriti*, 27.27% each were of *Vata Pittaja* and *Pitta Kaphaja Prakriti*. 54.54% patients had diabetes mellitus for less than one year. In 50% cases a positive family history of diabetes was present. The Blood pressure of 40.90% patients was within normal limits, 36.36% of patients were pre hypertensive while 27.72% of patients reported to be stage-I hypertensive. 59.09% patients in the study reported to have increased appetite. In the present study, only 04.54% patients were taking strenuous physical activity, while 63.63% patients had mild physical activity. Among various signs and symptoms *Prabhuta Mutrata* (polyuria), *Pipasa* (polydipsia), *Shaithilya* (fatigue) and *Mukha Sosha* (dryness of mouth) each was observed in 72.72% patients, *Kshudha* (polyphagia) was observed in 50.00% patients, *Sandhi Shoola* (pain in joints) was observed in 31.81% patients, *Karpada Suptata* (numbness) was observed in 36.36%, *Karpada Daha* (burning sensation in hands & feet) was observed in three 13.63% patients, and *Pindikio Udveshtana* (calf tenderness) in 18.18% patients. (Table-1)

Results

The effect of therapy was assessed on the basis of observations of subjective symptoms, laboratory investigations and the questionnaire on quality of life (WHO-QOL-BREF).

The laboratory profile of the patients revealed that the trial drug namely, *shilajatu* was effective in lowering the mean fasting blood glucose levels with $p < 0.001$ which was highly significant statistically. The reduction in the mean post prandial blood glucose levels was also found to be highly significant statistically with $p < 0.001$. Similar effect was observed in mean urine sugar level with $p < 0.001$ which was statistically highly significant.

The mean score of Glycosylated Hemoglobin (HbA_{1c}) was also reduced significantly with $p < 0.01$ statistically. (Table 2)

Among the subjective symptoms of *Prameha*, statistical analysis revealed highly significant improvement statistically in *Prabhuta Mutrata*, *Pipasa* and *Kshudha* with $p < 0.001$. The drug was effective in improving the symptoms like *Shaithilya*, *Mukha Sosha* and *Sandhi Shoola*. The improvement was highly significant improvement statistically with $p < 0.001$. The mean score of *Karpada Daha* could not be calculated as only two patients had presented with this symptom hence p value could not be calculated. (Table 3)

A Questionnaire on Quality of Life (WHO-QOL-BREF) was given to each patient to assess the quality of Life, and its impact on their Physical, Psychological and social life and well-being. Statistical analysis (Table 4) showed highly significant improvement ($p < 0.001$) in their Physical and Psychological Domain. Environmental domain was another aspect that was analysed in the WHO-QOL-BREF. Highly significant score with $p < 0.001$ was observed on it. Social Relationships Domain was also analysed according to the questions as stated in the questionnaire and the result was found to be highly significant ($p < 0.001$). Based on this result, it could be inferred that the patients responded well to the treatment and there was a marked improvement in their Quality of Life. This part of the result also indicated that the treatment was effective in improving the psychological and social life and had a significant outcome on the well-being of the patients in relation to their surrounding environment.

Discussion

The present study was undertaken to evaluate the efficacy of *Shilajatu* in the management of type II Diabetes Mellitus.

The outcome of the study showed ample evidence of *shilajatu* acting as *Pramehahar* and showed significant results in reducing the symptoms of type II Diabetes Mellitus.

In Ayurvedic classics, *Kapha*, *Pitta* and *Vata* play important role in the pathogenesis of *Prameha*.⁽⁶⁾ In *Sushruta Samhita*, while describing the principle of management of *Prameha* it has been mentioned that the drugs which are *Tikta*, *Katu*, *Kashaya* in taste, *Sara* in property with *Katu Vipaka* and *Ushna Veerya* with *Soshaka* and *Chedana* actions should be selected for the treatment of *Prameha*.⁽⁷⁾ The drug used in the study, namely *Shilajatu* possesses these properties in addition to being '*dehadardhyakara*'⁽⁸⁾ i.e. it is able to improve consistency and quality of tissue elements, which counteracts the *shithilta* produced in the body due to *Prameha*. It also cause lyses of excess *Meda* and helps in its *anulomana*. However, its exact mechanism has not been fully understood, but it is proposed that *Shilajit* might have some direct effect on lipid profile. It is also proposed that humic acid, a constituent of *Shilajit* may show antiatherogenic effect by inhibiting the lipopolysaccharide induced expression of vascular cell adhesion molecule.⁽⁹⁾

Madhumeha manifests in the form of *Prabhuta* and *Avila Mutrata* which are the result of *Mutra-Vaha-Sroto-Dushti*. Moreover, *Shilajatu* has been stated to be useful in the treatment of diseases of *Basti (Mutravaha Srotasa)* and *Shukra*.⁽¹⁰⁾ Also the *tikta* and *katu* rasa enables *Shilajatu* to act effectively against the *madhumeha*. In reference to *Shilajita*, *Vagbhata* has mentioned that when all other treatments are ineffective to improve the condition of *madhumehi* patient, then *Shilajatu* must be used thus helping to improve condition of such patients.⁽¹¹⁾ The most important aspect in the management of *madhumeha* (diabetes) is the control of sugar levels in the blood and to minimize the

complications arising out of the disease, thus improving the quality of life of patients. The results obtained from this study also substantiate the earlier hypothesis of hypoglycemic effects of *Shilajatu*.(12) *Shilajatu* may be associated with correction of blood glucose level and lipid regulation in circulation. Experimental studies reveal that *Shilajatu* may be associated with phenomenon of reducing direct sugar and lipid from gut, thereby affecting the overall metabolic syndrome along with dyslipidemia.(13) It may have the potential of reducing cellular sensitivity towards circulating insulin and some potential of correcting dyslipidemia at hepatic level. However, at this level it is difficult to verify and can only be represented as hypothesis in view of results seen.

From this clinical study and the data generated from it, a hypothesis can be postulated that *Shilajatu* possesses potential hypoglycemic activity, though the success rate of the treatment needs to be verified by repeated experimental studies. The effect of the therapy on the Quality of Life was significant as assessed by WHO-QOL-BREF scoring (Table 5). The overall feeling of well being was improved in the patients as per WHO questionnaire. Newly diagnosed patients & those having FBS <200mg/dl can be advised the intake of *Shilajatu* along with life style modifications.

Conclusion

In the present study *Shilajatu* was evaluated for its efficacy in *prameha*. The drug showed potent *Pramehahar* effect which is evident from the reduction in fasting and post prandial blood glucose levels, glycosylated hemoglobin and improvement in subjective symptoms including the quality of life, psychological and social well-being. However, further research to elucidate its exact mechanism of action and studies over animal models to validate the claim are required.

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Table 1: Demographic Observations

Factor	Observation	No. of Patients (Percentage)
Age group	41-50 yrs	36.36%
Sex	Males	54.54%
Education	Graduates	59.09%
Socio-Economic Status	Middle class	63.63%
Occupation	Government Service	45.45%
	Housewives	40.90%
Dietary Habit	Mixed diet	72.72%
BMI	25-30	36.36%
	20-24.9	27.27%
Blood Pressure	Normal	40.90%
	Pre HTN	36.36%
	Stage-1	22.72%
Family History of Diabetes mellitus	Present	50%
Appetite	Increased	59.09%
Prakriti	Vata-Pitta	27.27%
	Pitta-Kapha	27.27%
	Kapha-Vata	45.45%
Physical Activity	Strenuous	04.54%
	Moderate	31.81%
	Mild	63.63%

Subjective symptoms	Prabhuta Mutrata	72.72%
	Pipasa	72.72%
	Kshudha	50.00%
	Shaithilya	72.72%
	Karpada Suptata	36.36%
	Karpada Daha	13.63%
	Pindiko Udveshtana	18.18%
	Mukha Sosha	72.72%
	Sandhi Shoola	31.81%

Table 2: Effect of Therapy on various objective criteria

S. no.	Criteria	n	Mean score		%age change	+ SD	+ SE	t	P
			BT	AT					
1.	FBS	18	157.89	111.67	29.27	30.89	7.28	6.35	<0.001
2.	PPBS	18	233.06	179.72	22.88	26.12	6.16	8.66	<0.001
3.	HbA ₁ C	18	7.37	7.05	4.36	0.36	0.08	3.75	<0.01
4.	Urine Sugar	03	1.67	00	100	0.57	0.33	5.00	<0.05

Table 3: Effect of Therapy on subjective parameters of Prameha

S. No	Criteria	n	Mean score		%age change	+ SD	+ SE	t	p
			BT	AT					
1.	Prabhuta Mutrata	14	1.57	0.57	63.69	0.39	0.11	9.54	<0.001
2.	Pipasa	16	1.71	0.64	62.57	0.62	0.17	6.51	<0.001
3.	Kshudha	12	1.83	0.75	59.01	0.29	0.08	13.00	<0.001
4.	Shaithilya	15	1.67	0.60	64.07	0.59	0.15	6.96	<0.001
5.	Karpada Suptata	05	1.80	1.00	44.44	0.45	0.20	4.00	<0.05
6.	Karpada Daha	02	1.50	0.50	66.66	-	-	-	-
7.	Pindiko Udveshtana	05	1.80	0.40	77.77	0.55	0.24	5.72	<0.05
8.	Mukha Sosha	13	1.69	0.77	54.61	0.64	0.18	5.20	<0.001
9.	Sandhi Shoola	06	1.83	0.67	63.93	0.41	0.17	7.00	<0.001

Table 4: Effect of therapy on WHO-QOL-BREF Score

S. No.	Criteria	Mean		%age Diff.	SD+	SE+	t	p
		BT	AT					
1	Physical Domain	79.33	102.22	28.85	11.21	2.64	8.66	<0.001
2	Psychological Domain	68.89	86.00	24.83	12.63	2.98	5.75	<0.001
3	Social Relationships Domain	40.44	45.78	13.18	3.36	0.79	6.73	<0.001

4	Environment Domain	112.44	119.78	6.52	6.76	1.59	4.60	<0.001
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Table 5: WHO-QOL-BREF SCORE

Score: 1- very poor; 2- poor; 3- neither poor nor good; ; 4- good; 5- very good											
S.No	Question	BT					AT				
1	How would you rate your quality of life?	1	2	3	4	5	1	2	3	4	5
Score: 1- very dissatisfied; 2-Dissatisfied; 3- neither Sat nor Dissat; ; 4-Sat; 5- very Sat.											
		BT					AT				
2.	How satisfied are you with your health?	1	2	3	4	5	1	2	3	4	5
Score: 1- not at all; 2- a little; 3- moderate amount; ; 4- very much; 5- extremely											
		BT					AT				
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5	1	2	3	4	5
4.	How much do you need any medical treatment to function in your daily life?										
5.	How much do you enjoy life?										
6.	To what extent do you feel your life to be meaningful?										
7.	How well are you able to concentrate										
8.	How safe do you feel in your daily life?										
9.	How healthy is your physical environment?										
Score: 1- not at all; 2- a little; 3- Moderately; ; 4- Mostly; 5- completely											
		BT					AT				
10.	Do you have enough energy for everyday life?	1	2	3	4	5	1	2	3	4	5
11.	Are you able to accept your bodily appearance?										
12.	Have you enough money to meet your needs?										
13.	How available to you is the information that you need in your day to day day?										
14.	To what extent do you have the opportunity for leisure activities?										
Score: 1- very poor; 2- poor; 3- neither poor nor good; ; 4- good; 5- very good											
		BT					AT				
15.	How well are you able to get around?	1	2	3	4	5	1	2	3	4	5
Score: 1- very dissatisfied; 2-Dissatisfied; 3- neither Sat nor Dissat; ; 4-Sat; 5- very Sat.											
		BT					AT				
16.	How satisfied are you with your sleep?	1	2	3	4	5	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?										
18.	How satisfied are you with your capacity for work?										
19.	How satisfied are you with yourself?										
20.	How satisfied are you with your personal relationship?										

21.	How satisfied are you with our sex life?													
22.	How satisfied are you with the support you get from your friends?													
23.	How satisfied are you with the conditions of your living place?													
24.	How satisfied are you with your access to health services?													
25.	How satisfied are you with your transport?													

Score: 1- very poor; 2- poor; 3- neither poor nor good; ; 4- good; 5- very good

		BT					AT				
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5	1	2	3	4	5

SCORING OF THE WHOQOL-BREF

The WHOQOL-BREF (Field Trial Version) produces four domain scores. There are also two items that are examined separately: question 1 asks about an individual’s overall perception of quality of life and question 2 asks about an individual’s overall perception of his or her health. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100, and subsequently transformed to a 0-100 scale, using the formula above. (WHOQOL user Manual, Appendix 10). A method for the manual calculation of individual scores is below:

- Physical domain**= ((6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18)x4.
- Psychological domain**= (Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26))x4.
- Social Relationships domain**= (Q20 + Q21 + Q22)x4.
- Environment domain**= (Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25)x4.

Where more than 20% of data are missing from an assessment, the assessment should be discarded. Where up to two items are missing, the mean of other items in the domain is substituted.
