Original Article

A comparative study of *Shilajatu* and *Asanadi Ghana Vati* in the management of *Madhumeha* w.s.r. to type-2 diabetes mellitus

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Abstract

Introduction: Diabetes mellitus is becoming an alarming problem for society nowadays causing impediment in normal life. Diabetes and its complications impose a major burden upon health-care facilities. **Materials and Methods:** In this study, 90 patients of *Madhumeha* (type-2 diabetes mellitus) were registered and randomly divided into two groups. Out of 90 registered patients, 80 patients completed the treatment. In Group A, cap. *Shilajatu* (500 mg twice daily) was given for 3 months and in Group B, *Asanadi Ghana Vati* (2 *Vati* twice daily) was given for 3 months. **Aim:** An attempt was made to evaluate and compare the efficacy of *Shilajatu* and *Asanadi Ghana Vati* in the management of type-2 diabetes mellitus. The efficacy of therapy was assessed on the basis of improvement in sign and symptoms of diabetes mellitus, blood sugar level, and glycosylated hemoglobin **Results:** Statistically significant improvement was observed in sign and symptoms as well as on blood sugar level in both groups after the completion of treatment. **Conclusion:** *Shilajatu* and *Asanadi Ghana Vati* seem to be effective and completely safe for the management of *Madhumeha* (type-2 diabetes mellitus).

Keywords: *Asanadi Ghana Vati*, diabetes mellitus, *Madhumeha, Shilajatu*

Introduction

Diabetes mellitus is a syndrome characterized by disordered metabolism and hyperglycemia either due to the deficiency of insulin secretion or due to the combination of insulin resistance and inadequate insulin secretion. Type-1 diabetes is due to the destruction of pancreatic islet beta cells predominantly by an autoimmune process and these patients are prone to ketoacidosis. Type-2 diabetes is the more prevalent form and results from insulin resistance with a defect in compensatory insulin secretion. Many patients with type-2 diabetes have an insidious onset of hyperglycemia and remain asymptomatic for longer period. Hence, many individuals with type-2 diabetes mellitus have complications at the time of presentation. Diabetes is now the leading cause of blindness, neuropathy, end-stage renal disease, and nontraumatic leg amputation. In addition, morbidity and mortality due to adverse cardiac events and stroke are also very common in diabetes.

Currently, a number of antidiabetic agents such as oral hypoglycemic agents and various insulin preparations are available for the management of diabetes, but their long-term applications cause various adverse effects. Therefore, the search for effective and safer drugs to manage hyperglycemia is one of the important areas of research. In Ayurveda, many plants and plant-based medications have been advocated for the management of diabetes since time immemorial. In the present study, the classical herbomineral drug, *Shilajatu* (*Asphaltum punjabinum*) and *Asanadi Gana Dravya*, has been selected for the management of *Madhumeha* (type-2 diabetes mellitus). In Ayurvedic classics, *Shilajatu* is described as *Naimittika Rasayana* for *Prameha*. *Asanadi Gana* has been described in *Ashtanga Samgraha*[1] and *Ashtanga Hridaya*[2] for the treatment of *Shwitra*, *Kushtha*, *Kaphaja-Vikara*, *Krimi*, *Panduroga*, *Prameha*, *and Medodosha.* The ingredients of

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Asanadi Gana are *Asana* (*Pterocarpus marsupium* Roxb.), *Tinisha* (*Ougeinia oojeinensis* Roxb.), *Bhojpatra* (*Betula utilis* D. Don.), *Shwetawaha* (*Terminalia arjuna* Roxb.), *Prakirya* (*Holoptelea integrifolia* Planch.), *Khadira* (*Acacia catechu* Wild), *Kadara* (*Acacia suma* Ham), *Bhandi* (*Albizia lebbeck* Benth.), *Shimshapa* (*Dalbergia sissoo* Roxb.), *Meshashringi* (*Gymnema sylvestre* R. Br.), the three *Hima*, i.e. *Shweta Chandana* (*Santalum album* Linn.), *Raktachandana* (*Pterocarpus santalinus* Linn.), and *Daruharidra* (*Berberis aristata* DC.), *Tala* (*Borassus flabellifer* Linn.), *Palasha* (*Butea monosperma* Lam.), *Agaru* (*Aquillaria agallocha* Roxb.), *Shaka* (*Tectona grandis* Linn.), *Shala* (*Shorea robusta* Gaertn.), *Dhava* (*Anogeissus latifolia* Wall.), *Kramuka* (*Areca catechu* Linn.), *Indrayava* (*Holarrhena antidysenterica* Linn.), *Chagakarna* (*Vateria indica* Linn), and *Ashwakarna* (*Dipterocarpus alatus*).

The present study was carried out to assess the efficacy of *Shilajatu* and *Asanadi Ghana Vati* in the management of *Madhumeha* (type-2 diabetes mellitus) and compare the effect of *Shilajatu* and *Asanadi Ghana Vati* in the management of *Madhumeha*.

Materials and Methods

Ninety patients with classical signs and symptoms of *Madhumeha* (type-2 diabetes mellitus) were selected from the OPD and IPD of Department of Kayachikitsa, IMS Banaras Hindu University. The research protocol was approved by the Institutional Ethical committee (No. Dean/2012-13/125).

A proforma including classical signs and symptoms of diabetes mellitus and *Srotodusti Lakshana* was made for assessing all the patients. The patients were properly interrogated and examined on the basis of proforma, and laboratory investigations were carried out for diagnosis.

Inclusion criteria

1. Fasting plasma glucose ≥126 mg/dL up to 250 mg/dl
2. 2-h plasma glucose ≥200 mg/dl and up to 350 mg/dl during an oral glucose tolerance test
3. Symptoms of diabetes plus random blood glucose ≥200 mg/dl and up to 350 mg/dl
4. Patients in between 30 and 80 years
5. Patients having complication of diabetic neuropathy.

Exclusion criteria

1. Patients of type-1 diabetes mellitus cases
2. Cases with severe diabetic complications such as cardiac disease, nephropathy, and foot ulcer
3. Patients with chronic diseases such as tuberculosis, bronchial asthma, chronic renal failure, HIV, and hepatitis
4. Patient below 30 years and above 80 years
5. Patients on corticosteroid therapy.

Plan of study

Ninety patients having classical signs and symptoms of *Madhumeha* (type-2 diabetes mellitus) were selected for the study on the basis of inclusion and exclusion criteria and investigations done. Out of 90 registered patients, 80 patients could complete the study and 10 patients discontinued the treatment. 80 patients of the study were randomly divided into two groups:

- Group A: 40 cases of type-2 diabetes mellitus were advised to take cap. *Shilajatu,* 1BD (each cap. 500 mg) for 3 months (divided into three follow-ups, each of 1 month interval)
- Group B: 40 cases of type-2 diabetes mellitus were advised to take *Asanadi Ghana Vati,* 2 BD (each *Vati* 500 mg) for 3 months (divided into three follow-ups, each of 1 month interval).

Investigation

Following investigations were carried out to assess the efficacy of trial drugs (cap. *Shilajatu* and *Asanadi Ghana vati*) and to find any other systemic disease:

- Fasting blood sugar (FBS) and postprandial blood sugar (PPBS)
- Glycosylated hemoglobin % ($HbA1_c$)
- Lipid profile, blood urea, and serum creatinine.

Criteria for assessment

Assessment was done on the basis of improvement in the clinical symptoms (polyuria, polydipsia, polyphagia, weakness, burning sensation and numbness, joint pain, cramps, weight loss, loss of libido) with the help of suitable scoring method (0–3). Under the objective parameters, biochemical investigations (FBS, PPBS, glycosylated hemoglobin, lipid profile) have been done.

The data of all the patients were assessed statistically by using paired *t*-test in both groups. For inter-group comparison, unpaired *t*-test was used.

Criteria for assessment of overall improvement in symptoms

To determine overall improvement based on all the symptoms, a criteria was defined. Number of symptoms absent at 3rd follow-up as compared to before treatment (in percentage) was used to define it as overall criteria for improvement as below:

1.	Complete improvement	100%
2.	Marked improvement	75% to <100%
3.	Moderate improvement	50% to <75%
4.	Mild improvement	1 to <50%
5.	No improvement	0%.

Observations and Results

In this study, maximum cases (36.66%) were from the age group of 51–60 years, 63.33% were males, 77.78% were Hindus, 42.22% were graduates, 43.33% were servicemen, and 93.33% were married. Maximum cases (71.11%) were from middle socioeconomic group, 75.55% were from

urban community, and 55.56% were belonging to mixed dietary habit. About 53.34% patients had negative family history and 46.67% were not having any addiction. Nearly, 55.56% were having *Kaphapittaja Prakriti* and 62.22% were having *Rajasika Manas Prakriti*. In the study, maximum chronicity was >1–3 years (25.55%). Among the chief complaints of *Prameha*, 83.75% patients had generalized weakness, 81.12% patients had burning sensation and numbness, 78.75% patients had polyuria, 76.25% patients had polydipsia, 73.75% patients had polyphagia, 51.25% patients had joint pain, 43.75% patients had loss of libido, 38.75% patients had cramps on walking, and 30.0% patients had weight loss.

In Group A, 79.62% of the patients had symptomatic relief in case of polyuria, 74.48% relief in polyphagia, 80.76% relief in polydipsia, 79.23% relief in generalized weakness, 75.79% relief in burning sensation and numbness, 83.33% relief in joint pain, 85.45% relief in cramps, 86.84% relief in weight loss, and 92.85% relief in loss of libido. The relief was statistically highly significant in all the symptoms.

Group B provided 69.03% improvement in polyuria, 70.34% in polyphagia, 77.44% in polydipsia, 75.48% in generalized weakness, 76.47% in burning sensation and numbness, 87.50% in joint pain, 94.33% in cramps, 91.89% in weight loss, and 79.31% in loss of libido [Table 1].

Overall effect of therapy

In Group A, 15% of the cases had complete improvement in the symptoms and 30% cases had marked improvement. Patients with moderate improvement and mild improvement were 40% and 12.5%, respectively. In Group B, 10% of the cases had complete improvement in the symptoms and 30% cases had marked improvement. Patients with moderate improvement and mild improvement were 35% and 25%, respectively [Table 2].

FBS and PPBS reduced by 24.01% and 20.23%, respectively, in Group A, which was statistically highly significant ($P < 0.001$). In Group B, reduction in FBS and PPBS was 26.03% and 19.29%, respectively, which was also statistically highly significant ($P < 0.001$) [Table 3 and Figure 1]. Statistically significant reduction was found in glycosylated hemoglobin percentage in both groups.

Discussion

In the etiopathogenesis of *Madhumeha*, all the three *Doshas* and ten *Dushyas* get vitiated but *Vata Dosha* and *Oja* (essence

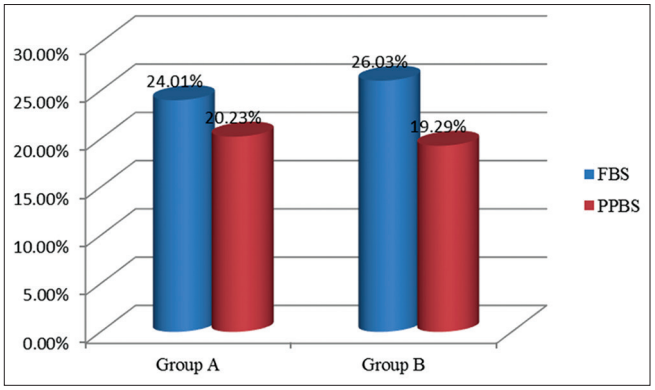

Figure 1: Mean percentage fall in blood sugar levels after completion of treatment

Table 1: Effect of trial drugs on symptoms of diabetes mellitus

Clinical symptoms	Group A					Group B				
	BT	AT	Percentage relief	*t*	*P*	BT	AT	Percentage relief	*t*	*P*
Polyuria	1.57	0.32	79.62	7.66	<0.001	1.55	0.48	69.03	7.20	<0.001
Polyphagia	1.45	0.37	74.48	6.20	<0.001	1.18	0.35	70.34	5.97	<0.001
Polydipsia	1.30	0.25	80.76	6.56	<0.001	1.33	0.30	77.44	6.65	<0.001
Weakness	1.83	0.38	79.23	9.03	<0.001	1.55	0.38	75.48	7.55	<0.001
Burning*	1.57	0.38	75.79	7.45	<0.001	1.70	0.40	76.47	8.51	<0.001
Joint pain	0.78	0.13	83.33	4.60	<0.001	0.80	0.10	87.50	4.85	<0.001
Cramps	0.55	0.08	85.45	4.00	<0.001	0.53	0.03	94.33	4.21	<0.001
Weight loss	0.38	0.05	86.84	3.91	<0.001	0.37	0.03	91.89	3.82	<0.001
Loss of libido	0.70	0.05	92.85	4.75	<0.001	0.58	0.12	79.31	3.49	<0.01

*Burning sensation or numbness. BT: Before treatment, AT: After treatment

Table 2: Overall effect of therapy on the symptoms of diabetes mellitus

Category	Group A, number of patients (%)	Group B, number of patients (%)
Complete improvement	6 (5.0)	4 (10.0)
Marked improvement	12 (30.0)	12 (30.0)
Moderate improvement	16 (40.0)	14 (35.0)
Mild improvement	5 (12.5)	10 (25.0)
Unchanged	1 (2.5)	-

Table 3: Effect of trial drugs on blood sugar level in patients of diabetes

Blood sugar	Group A					Group B				
	BT	AT	Percentage relief	*t*	*P*	BT	AT	Percentage relief	*t*	*P*
FBS	166.58	126.57	24.01	19.67	<0.001	170.45	126.08	26.03	25.37	<0.001
PPBS	274.50	218.95	20.23	20.27	<0.001	272.30	219.77	19.29	52.57	<0.001
HbA1c%	7.82	7.16	8.44	9.80	<0.001	7.61	6.89	9.46	28.66	<0.001

FBS: Fasting blood sugar, HbA1c: Glycosylated hemoglobin, PPBS: Postprandial blood sugar, AT: After treatment, BT: Before treatment

of all the *Dhatus*) are the main factors. Vitiation of *Vata* may occur either due to *Dhatukshaya* or due to *Avarana* of *Vata* by the *Doshas* (*Kapha*, *Pitta*, *Meda*, and *Mamsa*).[3] Hence, in its management, such drugs are to be selected which can maintain the normal state of *Agni* and removes the *Avarana* of *Vata* along with *Rasayana* property.

Shilajatu is having *Tikta*, *Katu*, and *Kashaya Rasa*, *Katu Vipaka*, *Ushna Virya*, *Rechaka*, *Shoshana*, and *Chedana* properties.[4] It has *Rasayana*, *Vrishya*, and *Pramehagna* property also. *Shilajatu* acts on *Agni* (maintain the excellent status of *Agni*) and *Srotas* (removes the blockage of microchannels leading to better perfusion of tissue) by *Katu Vipaka* and *Ushna Virya*. It reduces quantity of *Kapha*, *Meda*, and *Kleda* by its properties. Moreover, the *Rasayana* property of *Shilajatu* nourishes the body, helps to keep the body tissue in healthy state, and improves the metabolism at each and every level of *Dhatu*. In various pharmacological studies, it has been seen that *Shilajatu* can prevent maturity onset diabetes mellitus[5] and is effective in controlling blood glucose level and lipid profile.[6]

In *Asanadi Ghana Vati*, most of the ingredients are having *Kashaya* and *Tikta Rasa*, *Laghu* and *Ruksha Guna*. All the drugs in this polyherbal compound are having *Katu Vipaka* and majority of the drugs possess of *Kapha-Pitta Shamaka* property. *Asanadi Ghana Vati* scrap out excessive *Kapha* and *Meda* from *Srotas* by *Kashaya* and *Tikta Rasa*. *Laghu* and *Ruksha Guna* absorb the excess *Kapha*, *Meda*, and *Kleda* and improve the consistency of tissue elements. *Katu Vipaka* enhances the *Agni* (normalizes the metabolic processes) and remove the *Avarana* (obstruction) of *Vata*. Moreover, in various pharmacological studies, it has been proved that almost all the drugs of *Asanadi Gana* have antidiabetic properties.[7]

Overall therapeutic effects of both test drugs (*Shilajatu* and *Asanadi Ghana Vati*) were found statistically significant in all the symptoms when compared with initial and follow up. On objective parameters, both drugs showed significant decrease in FBS, PPBS and glycosylated hemoglobin.

Conclusion

Although both groups showed significant relief in all the symptoms, *Shilajatu* provided overall more relief than *Asanadi Ghana Vati*. The reduction in FBS level was found slightly more by *Asanadi Ghana Vati* while the reduction in PPBS level was found slightly more by *Shilajatu.* Moreover, any adverse effects were not reported during the clinical trial of 3 months. Hence, the present trial drugs (*Shilajatu* and *Asanadi Ghana Vati*) seem to be effective and completely safe for the management of *Madhumeha* (type-2 diabetes mellitus).

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Nil.

Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

मधुमेह की चिकित्सा में शिलाजतु एवं असनादि घन वटी का तुलनात्मक अध्ययन

वंदना गुप्ता, बिपिन बिहारी केशरी, एस. के. तिवारी, के. एच. एच. व्ही. एस. एस. नरसिम्हा

मधुमेह वर्तमान काल में समाज के लिए एक चिंताजनक समस्या के रूप में स्थापित हो रहा है तथा सामान्य जीवन व्यवस्था में बाधक रूप है। मधुमेह एवं तत्जन्य उपद्रव स्वास्थ्य संबंधी सेवा पर बोझ रूप है। प्रस्तुत अध्ययन में ९० मधुमेह रोगियों को पंजीकृत किया गया, जिस में ८० मधुमेह रोगियों ने चिकित्सा क्रम पूर्ण किया। इन रोगियों को दो वर्गों में विभाजित किया गया। वर्ग अ में ४० रोगियों को कैप्सूल शिलाजतु (५००मि. ग्रा. दिन में दो बार) तथा वर्ग ब में ४० रोगियों को असनादि घनवटी (१ ग्राम, २ वटी दिन में दो बार) ३ माह तक दिया गया। दोनों वर्गों के औषधियों का प्रभाव, मधुमेह के मुख्य लक्षणों में सुधार एवं रक्तगत शर्करा और अन्य जैव रसायनिक घटकों में सुधार पर निश्चित किया गया । सांख्यिकीय दृष्टि से इस परीक्षण में, मधुमेह के लक्षणों एवं रक्तगत शर्करा के प्रमाण में अच्छा लाभ मिला।