



Title: Clinical efficacy of *shodhanottara shamana chikitsa* in type ii diabetes mellitus – an exploratory study

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Abstract:

Background: Diabetes Mellitus (DM) is a group of metabolic diseases characterised by hyperglycaemia resulting from defects in insulin secretion, insulin action or both. There is no permanent correction of DM in modern science. OHAs are not adequate because the dosage keeps on increasing and sometimes patients get shifted to insulin. DM comes under the umbrella of 'Prameha' which is included under *Ashtau Mahagada*. It is cited as *Santarpanotha vyadhi* which requires *shodhanottara shaman chikitsa*.

Objectives: to evaluate clinical efficacy of *shodhanottara shaman chikitsa* in type II Diabetes Mellitus

Methodology: An exploratory interventional clinical study in which 5 patients suffering from type II diabetes mellitus (chronicity not more than one year) having Blood Sugar Levels – Fasting >150 and PP >250, HBA1C > 8 were selected for the study. After baseline investigations and clinical examination, the study subjects were given *Mahatiktaka Ghrita* in escalating dose of 20, 30 and 40 ml for three days for *snehana* followed by *AragvadhaKapilaVati* or *AbhayadiModaka* depending on *koshtha* on fourth day. This *shodhana* was repeated every fortnight for three months. After first cycle of *shodhana, shamanachikitsa*, i. e. *Vasantakusumakara Rasa* 125mg and *Dhatrinisha Choorna* (500+250mg) were given. Study subjects were advised to follow specific diet regimen and exercises like *Suryanamaskara*. During this period Blood Sugar Levels were monitored and accordingly dosage of OHAs was adjusted.

Results: *Shodhanottara shaman chikitsa* was found to be effective in lowering Blood Sugar Levels as well as HBA1C levels. Significant improvement was observed in specific symptoms such as polyphagia, polydypsia, *hastapadataladaha*, polyuria and debility after three months of treatment. It reduced the OHA dependency of type II diabetic patients.

Conclusion: *Shodhanottara shaman chikitsa* has significant role in management of DM as well as in reduction of OHA dependency of type II diabetic patients.

Keyword: *Shodhanottara shaman chikitsa*, type II Diabetes Mellitus

Introduction:

Diabetes Mellitus recognized as global health hazard has long been a concern of World Health Organization. Changing environs, urbanization and altered life styles inducing immense stress and altered immune functions, has resulted in increasing the incidence of Diabetes mellitus by leaps and bounds. The Global burden due to diabetes is mostly contributed by type 2 diabetes which constitutes 80% to 95% of the total diabetic population. Diabetes mellitus is a major public health challenge of the twenty-first century. The explosive increase in the prevalence of Diabetes seen in the last three decades poses huge clinical and economic burden in many countries.

The estimates by the International Diabetes Federation (IDF) show that 285 million adults (20 years to 79 years) were affected by the disorder in 2010. Epidemiological trends indicate that without proper control and prevention, its prevalence will increase further to 438 million in 2030.^[1] Also according to Wild et.al^[2] the prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. Diabetes mellitus is fast gaining the status of a potential epidemic in India with

more than 62 million diabetic individuals currently diagnosed with the disease^[3,4] Diabetes mellitus, a chronic debilitating disease, is associated with increased mortality and a high risk of developing neurological, retinal, renal and cardiac complications leading to premature disability and death.

Diabetes mellitus is a metabolic disorder of multiple aetiologies characterized by hyperglycaemia and disturbances of carbohydrates, fat and protein metabolism resulting from absolute or relative deficiencies in insulin action and or insulin secretion^[5]. The malady results in increased glucose concentration in the blood which in turn hampers all most every systems and organ, in particular the nerves and blood vessels.

There is no permanent correction of DM in modern science. OHAs are not adequate because the dosage keeps on increasing and sometimes patients get shifted to insulin. The symptom complex Diabetes mellitus as known in modern medicine appears to have very strong co-relation and similarity to the *Prameha Vyadhi* described in Ayurvedic literature. A review of ancient literature indicates that Diabetes was fairly well conceived as an entity even in olden days. DM comes under the umbrella of '*Prameha*' which is included under *Ashtau Mahagada*.^[6] If



Prameha is not restricted in the stage of *Poorvarupa*, it progresses to advanced stage and depending on the predominance of *doshas*, it is classified into 20 types.^[7] From the *Prameha* pathogenesis it appears that all the three *Doshas* especially *Kapha Dosh* causes a progressive loss of *Dhatus* such as *Meda*, *Rakta*, *Shukra*, *Ambu*, *Vasa*, *Lasika*, *Majja*, *Rasa*, *Oja*, *Mamnsa* through the *Mutravaha strotasa*.^[8] There is an associated *Dhatushaithilya* and *Dhatuksharan* followed by gross *Dhatukshaya* with the depletion of *Ojas*. It is cited as *Santarpanothavyadhi* in which *Sthula Pramehi*, i. e. obese diabetics require *shodhanottara shaman chikitsa*.^[9]

The present study was planned to assess the effects of *shodhana chikitsa* i. e. *Virechana* followed by *shaman chikitsa* with specific diet regimen and exercise in patients suffering from DM type II.

Materials and Methods:

Type of study - An exploratory interventional clinical study

For the present study, 05 diagnosed patients of *Prameha* (DM type 2) from the Outdoor Patient Department of SMBT Ayurveda Mahavidyalaya, Nashik were registered on the basis of signs and symptoms of *Prameha* as per Ayurvedic classics and modern medicine.

Inclusion criteria

- Patients of either sex in the age group of 40-65 years
- Obese/overweight patients (BMI > 25 kg/m²)
- Patients showing classical signs and symptoms of *Prameha* (DM type 2) (chronicity not more than one year) as below were included in the study.

Prabhuta Mutrata (Polyuria), Frequency of urine^[10], *Pipasaadhikya* (Polydypsia)^[11] *Bahavashi-Kshudha-Adhika* (Polyphagia)^[12], *Daurbalya* (Weakness) and *Karpadataladaha* (Burning sensation in hand & feet)^[13]

Criteria for diagnosis of DM by American Diabetic Association:

1. Patients having random blood sugar level >200 mg/dl or
2. Fasting blood sugar (FBS) >150 mg/dl up to 375 mg/dl or
3. Postprandial blood sugar (PPBS) > 250 mg/dl up to 500 mg/dl.

Exclusion criteria:

- Patients with juvenile diabetes
- Patients less than 40 years and more than 65 years
- Emergency cases in DM
- Patients having insulin dependent DM (IDDM) and receiving insulin (type 1)
- Excessive blood glucose: FBS > 375 mg/dl and PPBS > 500 mg/dl
- Chronic complications (microvascular and macrovascular).

Plan of treatment:



After baseline investigations and clinical examination, the study subjects were given *Mahatiktaka Ghrita*^[14] in escalating dose of 20, 30 and 40 ml for three days for *snehana* followed by *Aragvadha Kapila Vati*^[15] or *Abhayadi Modaka*^[16] depending on *koshtha* on fourth day. This *shodhana* was repeated every fortnight for three months. After first cycle of *shodhana*, *shamanachikitsa*, i. e. *Vasantakusumakara Rasa*^[17] 125mg and *Dhatrinisha Choorna*^[18] (500+250mg) were given.

Study subjects were advised to follow specific diet regimen and exercises like *Suryanamaskara*. During this period Blood Sugar Levels were monitored and accordingly dosage of OHAs was adjusted.

Criteria for assessment:

- 1) Objective criteria: Blood Sugar Levels – Fasting and Post Prandial, HBA1C
- 2) Subjective criteria:

Sr. No.	Subjective parameters	Description Scoring
1	<i>PrabhutaMutrata (Polyuria)</i>	
	1.50-2.00 l/24 h	0
	>2.00-2.50 l/24 h	1
	>2.50-3.00 l/24 h	2
	>3.00 l/24 h	3
2	Frequency of urine	
	3-5 times per day, nil or rarely at night	0
	6-8 times per day, 1-2 times per night	1
	9-11 times per day, 3-4 times per night	2
	>11 times per day, >4 times per night	3
3	<i>Pipasaadhikya (Polydypsia)</i>	
	Feeling of thirst 7-9 times/24 h, either/or intake of water 5-7 times/24 h with quantity 1.5-2.0 l/24 h	0
	Feeling of thirst 9-11 times/24 h, either/or intake of water 7-9 times/24 h with quantity 2.0-2.50 l/24 h	1
	Feeling of thirst 11-13 times/24 h, either/or intake of water 9-11 times/24 h with quantity 2.50-3.00 l/24 h	2
	Feeling of thirst >13 times/24 h, either/or intake of water >11 times/24 h with quantity >3.00 l/24 h	3
4	<i>Bahavashi-Kshudha-Adhika (Polyphagia)</i>	
	As usual/routine	0
	Slightly increased (1-2 meals)	1
	Moderately increased (3-4 meals)	2
	Markedly increased (5-6 meals)	3
5	<i>Daurbalya (Weakness)</i>	

	Can do routine exercise/work	0
	Can do moderate exercise with hesitancy	1
	Can do mild exercise only, with difficulty	2
	Cannot do even mild exercise	3
6	Karpadataladaha (Burning sensation in hand & feet)	
	No burning sensation	0
	burning sensation not continuous	1
	burning sensation continuous but bearable	2
	burning sensation continuous and severe	3

Statistical analysis:

The study data generated and collected was put to statistical analysis to reach to the final results and conclusions. The data obtained in the studies were subjected to tests of significance.

- 1) Paired t test for objective parameters such as Blood Sugar Levels – Fasting and Post Prandial, HBA1C for comparison between baseline and on completion of treatment (90 days)
- 2) Wilcoxon's signed rank test for subjective parameters such as *Prabhuta Mutrata* (Polyuria),

Frequency of urine, *Pipasaadhikya* (Polydypsia), *Bahavashi-Kshudha-Adhika* (Polyphagia), *Daurbalya* (Weakness) and *Karpadataladaha* (Burning sensation in hand & feet) for comparison between baseline and on completion of treatment (90 days)

P value < 0.05 was considered significant and results were expressed as Mean ± SD.

Results:

All 5 patients completed the clinical trial. The procedure and drugs had good acceptance and did not show adverse effects.

Statistical Analysis of Biochemical Parameters of Patients of DM Type II

Paired t test

Sr. No.	Physical Parameters in their respective units	Mean ± SD		Mean of Difference ± SD	S.E.	t29	p
		BT	AT				
1.	BSL – F	195.20 ± 42.06	102.40 ± 9.84	92.80 ± 44.15	19.74	4.7	< 0.05 Significant
2.	BSL - PP	315.20 ± 83.16	135.80 ± 13.33	179.40 ± 95.80	42.84	4.19	< 0.05 Significant
3.	HBA1C	9.44 ± 0.86	6.70 ± 0.46	2.74 ± 0.88	0.39	6.97	< 0.05 Significant

Symptoms of Patients of DM Type II: Statistical test (Wilcoxon-matched-pairs signed-ranks test) was not applicable to the generated data as the sample size was very less.

Sr. No.	Symptom	BT	AT	Difference	% Relief
1	<i>Prabhuta Mutrata</i> (Polyuria)	12	2	10	83.33
2	Frequency of urine	12	3	9	75.00
3	<i>Pipasaadhikya</i> (Polydypsia)	11	2	9	81.82
4	<i>Bhavashi-Kshudha-Adhika</i> (Polyphagia)	13	3	10	76.92
5	<i>Daurbalya</i> (Weakness)	13	4	9	69.23
6	<i>Karpadataladaha</i> (Burning sensation in hand & feet)	12	1	11	91.67

Shodhanottarashamana chikitsa was found to be effective in lowering Blood Sugar Levels as well as HBA1C levels. Significant improvement was observed in specific symptoms such as *Prabhuta Mutrata* (Polyuria), Frequency of urine, *Pipasaadhikya* (Polydypsia), *Bhavashi-Kshudha-Adhika* (Polyphagia), *Daurbalya* (Weakness) and *Karpadataladaha* (Burning sensation in hand & feet) after three months of treatment. It reduced the OHA dependency of type II diabetic patients.

Discussions:

Prameha known to mankind since Vedic era has been dealt in details in Ayurvedic texts. *Prameha* mentioned in the ancient texts fully coincides with Diabetes mellitus of modern era. Diabetes mellitus is a

metabolic symptom complex disorder, which has affected every corner of the world. Being a major health hazard with varied etiology Diabetes is usually associated with a variety of irreversible complications. As a result in developing countries like India Diabetes has great impact on the economy. The wide spectrum of complications and unsatisfactory modern means to tackle them, make it all the more important for the researchers. Development of complications is an inevitable truth of this disease. The duration of Diabetes is a big determinant in the occurrence of complications like Diabetic Neuropathy, Diabetic Retinopathy and Diabetic Nephropathy. *Ayurvedic* drugs have come a long way in the management of various dreaded conditions; hence to the modern



medicine with a western impact, Ayurveda has always given a new direction with a ray of hope.

Acharya Sushruta has described the general pathogenesis of *Prameha*. He details that *pramehajanakaharvihar* i.e. aetiological factors vitiate the *aparipakva (Ama)*, *Vata*, *Pitta* and *Kapha* along with *dhatu*s especially *medadhātu*^[19]. These excited and vitiated *Doshas* and *Dhatu*s reach *basti* via *Mutravahastrotas*, remains near the *bastimukh* for some time and cause various types of *Prameha*. *Sushruta* has not described the pathogenesis of different types of *Prameha*, which indicates that different types of *Ahar* and *Vihar* help in making the *Dushyas* vulnerable to be excited by the vitiated *Doshas*.

According to plan of treatment given by *Charakacharya*, *Shodhana chikitsa* is to be administered in obese/overweight diabetics.^[20] *Mahatiktaka Ghrita* was given in escalating dose for 3 days for oleation. *Mahatiktaka ghrita* is useful in *ashtau mahagada* therefore it has played significant role in treatment of *prameha*. *Swedana* was not given to the patients as it is contra-indicated in *Pramehi* because *Dhatushaithilya*. Properly oleated patients were given *Virechana* with *Abhayadi Modak* or *Aragvadha Kapila vati* according to *koshtha*. *Kleda* plays significant role in patho-physiology of

Prameha which gets expelled out by *virechana chikitsa*. *Mrudu virechana* was given to avoid depletion of strength as well as aggravation of *vatadosha*. Light diet was advised for one day after *virechana*.

The possible mechanism of the action of *Vasant Kusumakar Ras* is possibly by the combined effects of each of the ingredients of the drug. The drug itself is a potent anti-diabetic (*Mehaghna*) agent. Each individual ingredient is said to have this property as well. All the ingredients have a property of acting at the level of the *dhatu*s, imparting them strength, preventing their *shaithilya* and also their *ksharan* through the urinary system. All ingredients possess a *Rasayana* property, thus restoring the lost strength and replenishing the lost *dhatu*s. *Vasant Kusumakar Ras* being a *Swarna kalpa* has all the added benefits of any *Swarna kalpa*. *Swarna bhasma* has a special quality of improving the *Rasa raktasancharan* in *Shira Pradesh* thus enriching the *indriyas* and inturn improving the sensory and motor functions^[20]. The unique property of *Swarna bhasma* mentioned about pacifying the aggravated *vayu*, nourishing (*pushti*), the *ksheenvayu* and maintaining the *samavastha* of *prakrutvayu* can be supposed to normalize the neuropathic symptoms of *Prameha* patients^[21]. It is



strongly believed that the presence of Swarna bhasma may potentiate the action of the drug. Ingredients like Swarna, Rajat, Loha, Praval and Mauktik have beneficial effect on the nerves. Ingredients like Swarna, Rajat, Abhrak, Praval, Mauktik, Naga and Vang aact directly on the symptoms of neuropathy and thus relieve them. Also Bhavana dravyas like Cow's milk, Sugarcane juice, Kamal Pushpa, Usheerswaras, etc are said to be good for the neuropathic symptoms related to Pitta dosha. The ingredient Vangabhasma is especially useful in mutravahastratodushti and it also improves the strength of indriyas and nourishes the body [22]. Thus Vasant Kusumakar Ras is beneficial in the dhatushaithilya, dhatukshya, dhatuksharan and ojudushtiavastha of diabetics. Thus from the vast treatise of Ayurveda keeping all the Ayurvedic principles in mind in the management of Prameha and its upadravas, Vasant Kusumakar Ras becomes a good candidate for being the drug of choice in Diabetics.

Dhatri-nisha is the best drug for the treatment of Prameha according to Vagbhatachaya. [23] Dhatri is used as a pramehaghna dravya while Haridra deserves Dipan and Pachan properties which might have the digestive process in the patients by correcting

Dhatvagnimandya. Dhatri-nisha shows Kleda reducing effect. Bahu drava Shleshma is the doshavishesha and Kleda is one of the dushyavishesha in Samprapti of prameda; thus Dhatri-nisha properties directly affect both the dosha and the dushyavishesha and hence effectively counteract the Samprapti. The antioxidant property, Rasayana effect and immunomodulatory property of Haridra and Dhatri might have helped in controlling the disease.

Shodhanottara shaman chikitsa has significant role in management of DM as well as in reduction of OHA dependency of type II diabetic patients.

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Cite article:

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Ayurlog: National Journal of Research in Ayurved Science- 2018; (6)(4): 1-10