Research Article

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CLINICAL EVALUATION OF THE ROLE OF SARIVA PHANTA (*HEMIDESMUS INDICUS* R. BR.) IN THE TREATMENT OF MADHUMEHA (DIABETES MELLITUS OR TYPE II DIABETES) WITH SPECIAL REFERENCE TO ITS HYPOGLYCAEMIC EFFECT

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ABSTRACT

Diabetes is a complex endocrine disease that affects more than 100 million of people worldwide (6% of the total population). The prevalence of Diabetes mellitus is increasing, despite multiple treatment options. Along with allopathic medications, several formulations or single forms of plant origin are employed in its treatment, especially in non-insulin dependent diabetic mellitus (NIDDM). Herbal medications are effective, broad range of action, fewer adverse effects, and are relatively inexpensive, making them a suitable alternative. The aim of this study is to investigate hypoglycaemic effect of Sariva (*Hemidesmus indicus* R.Br.) root phanta (teabag) in Madhumehi. The current trial is a randomised, parallel group interventional trial. After initial screening for inclusion criteria, 60 patients were enrolled and separated into 3 groups (20 patients each), which was conducted according to the International Conference on Harmonization-Good Clinical Practices Principles (ICH-GCP) or the Declaration of Helsinki guidelines and statistically analysed using the chi square test. Madhumeha had a better clinical outcome with the medication. The majority of vata-kaphaja prakriti had side effects such as constipation and nausea**.** Patients in the 40–50-year age group with Vataja-dosha derangement were found to be more prone to DM-2. In married mostly in males, there is a greater preponderance. Madhura, snigdha guṇa relieves vata, Tikta rasa relieves kapha, meda dusya, sheeta virya relieves pitta; Hence it has tridoṣatmaka activity, which is beneficial in the treatment of Madhumeha. Sariva in the form of teabag has kaphaghna, vataghna, kandhughna (curing pruritus), meha durgandhi nashan*,* sarvamehahara properties. Thus, it collectively acts in Madhumeha*.*

Keywords: Madhumeha*,* Sariva phanta, teabag, vata-kaphaja prakriti, tridoṣatmaka, Diabetes Mellitus, Type II Diabetes

INTRODUCTION

Ayurvedic classics provide extensive descriptions of Prameha, such as C.S. Ni-4/C.S. Ci-6/S.S. Ni-6/S.S. Ci-11, 12, 13/A.H. Ni-10/A.H. Ci-12, and it is noted that if not treated appropriately, all prameha eventually converts to Madhumeha.[1]

In modern terms, Madhumeha is very comparable to Diabetes Mellitus. Diabetes mellitus (Madhumeha) is caused by a deficiency in insulin secretion or action[2], or most likely both. Diabetes is caused by a variety of pathologic processes, including autoimmune destruction of the pancreatic β -cells, which results in insulin deficit, or dysregulation, which leads to the development of insulin resistance.[3] In people with Diabetes mellitus, insulin's ineffective impact on target tissues causes aberrant protein, carbohydrate and fat metabolism.[4] Plants have always been a good source of pharmaceuticals in the past; in fact, many of today's pharmaceuticals were invented or produced from them, either directly or indirectly. The main goal of research in the previous decade was to focus on scientific evaluation of traditional plant-based medications and screening of more safe, effective and low-cost hypoglycaemic drugs. In this study, the anti-hyperglycemic effect of Sārivā (*Hemidesmus indicus* R.Br.) root powder will be investigated in Madhumeha (Diabetes mellitus or Type II Diabetes) patients separately and in combination with a standard oral hypoglycaemic drug.

Although there is no definitive cure for diabetes, diet, exercise, therapy and lifestyle modifications[5] can help a person live a long and healthy life free of complications. Long-term complications of diabetes include long-term dysfunction, damage and failure of various organs, particularly the kidneys, eyes, nerves, heart and blood vessels; acute complications include hyperosmolar hyperglycaemic state, ketoacidosis and when it becomes uncontrolled even death may occur.[6] Diabetes mellitus is marked by variable degrees of glucose and homeostasis disruption, which can result in long-term micro and macrovascular complications. Diabetes is the leading cause of non-traumatic amputations, the leading cause of end-stage renal disease (ESRD), which accounts for 30% of avoidable blindness and the leading cause of cardiovascular mortality. Sārivā (*Hemidesmus indicus* R.Br.) is one of the vegetarian origin drugs that are thought to be the best chemist, non-toxic, and pharmaceutically important single as well as compound and herbo-mineral[7] formulations reported in Ayurvedic classics for the treatment of Madhumeha (Diabetes Mellitus or Type II Diabetes).

Because of the side effects, adverse reactions, and other major acute or chronic consequences associated with synthetic medications, there has been a major shift toward natural resources that offer anti-hyperglycemic properties. Although we know that Ayurveda science has the ability to follow modern-day norms and conditions, some facts remain hidden due to a lack of documentation and scientific evidence. Here, we will attempt to

evaluate some new facts and their documentation for the treatment of Madhumeha with Sārivā root powder.

Ayurvedic texts have been explored regarding Sārivā root powder in Meha i.e. Dhanvantari Nighantu.[8]

"Sariva dvya tu madhure kaphavatastranashane,
Kusthakandujwarahara mehadurgandhinashane. "(Dha.Ni. Guduchyadi varga 71/60)

There are 2 types of sārivā which are sweet in taste, it pacifies kapha and vāta from the body and it cures the kustha, kandu, jwara, and also the sweet odour of urine. Same shlokas are given by Rāj Nighaṇṭu. There are two forms of sārivā, both of which have a pleasant flavour. They balance kapha and vāta in the body and heal kustha, kandu, jwara, and the sweet odour of urine. Rāj Nighantu recite the same shlokas. (R. Ni. 119)

"Vidarisarivarajaniguchyoajashringi cheti vallisanghya
Karmarditrikantaksairiyaka shatavarigridhranakhya iti kantakasanghya
Raktapittaharau hayeto shophatrayavinashanou
Sarvamehaharau chaivashukradoshavinashanau." (Su.s.38/72-74)

vallīpanchamūla contains Vidārī, Sārivā, Rajanī, Guduchī, Ajashringi.

Panchakantaka includes Karmardi, Trikantaka, Saireyaka, Shatavari and Gridhranakhi.

These are Raktapittahara[9], Tryashophahara, Sarvamehahara and Shukradodhanashana.

The sarvamehahara (anti-diabetic) virtue of sārivā root has been given by acharyas. Many texts and literature have been screened for single herbal medicine formulation in Madhumeha (Diabetes mellitus II), particularly Sārivā (*Hemidesmus indicus* R.Br.) root powder in Madhumeha.

MATERIAL AND METHODS

Collection and identification of drug

Sārivā (*Hemidesmus indicus* R. Br) was purchased in large quantities from drug dealers, Orrisa. The supervisor confirmed the botanical identification of these medications and given accession no is- DG/21-22/325.

Preparation of powder to teabag, dose, duration of treatment and follow up

Sārivā's Churna (Powder) was made according to the Shārangdhara Saṃhita (Sha. S. Madh. 6/1). Sārivā root was collected and cleaned in lukewarm water and wiped with cloth to remove moisture. They were allowed to dry under indirect sunlight. The roots were dried in 3 days. The fine powder was then manufactured, changed to Ghana form, and finally, a tea bag was prepared.

The general dose of Churna (powder) has been stated as 1 Karsha (about 10 gm) by Sharangdhar Samhita (Sha. S. Madh. 6/1).[10]

For an average individual weighing 50-70 kg, an average dose of Churna (20 gm) was fixed in two divided doses per day, and is condensed to make Ghana (teabag). On the basis of age and weight, the dose of may differ from person to person. It was advised to take in the morning and evening.

Study design

Selection of patients

60 patients with Diabetes mellitus were selected from the O.P.D. number 11 /Department of Dravyaguna, Sir Sundarlal Hospital, Banaras Hindu University, Varanasi for the current study on the effect of sārivā root on Diabetes mellitus. Due of some personal issues, ten of these cases did not show up for follow-up. As a result, only 50 patients are included in the current study. Some of these patients were diagnosed for the first time when they came in with other problems, while others were already diabetics. All of the cases were classified as O.P.D. cases. Ethical committee permission was obtained.

Table 1: Groups A, B and C

Intervention	Group A Sārivā Root powder	The patient in this group will take 10 gm BD of sārivā root powder orally. After that, the patient will be followed up on every 15 days for the next three months.
Comparator Agent	Group B Gliclazide (80 mg BD)	Patients in this category will be instructed to take gliclazide at the recommended dose. After that, the patient will be followed up on every 15 days for the next three months.
Comparator Agent	Group C Sārivā root powder and Gliclazide	The patient in this group should take both sārivā root powder and Gliclazide. After that, the patient will be followed up on every 15 days for the next three months.

Inclusion criteria

- Patients should be between the ages of 30 and 70.
- This study takes into account both genders.
- HbA1c levels should be greater than or equivalent to 6.5 percent.
- BSF should be more than 126 mg/dl.
- The BSPP level should be greater than or equivalent to 200 mg/dl.
- Random blood sugar level should be 200 mg/dl or above it.

Exclusion criteria

- Diabetes mellitus with consequences such as neuropathy, retinal degeneration, cardiomyopathy, and nephropathy, among other complications.
- Patients with specific genetic disorders that have been linked to diabetes mellitus in the past.
- Carcinoma, endocrinopathies, hormonal imbalances, and other associated problems.
- Patients with type 1 diabetes, super infection, severe diabetes complications, or any other chronic disease such as rheumatic heart disease, tuberculosis, rheumatoid arthritis, and so on.
- Patients with type 2 diabetes who were on insulin were also excluded from the trial.
- Patients under the age of 30 and those over the age of 70 were not included in this study.

Diagnostic criteria

All of the patients were clinically assessed for signs and symptoms of Diabetes mellitus. Polyphagia, polyurea, limb numbness, polydipsia, weariness, leg cramps, tingling and burning feeling in sole and palm, recent weight increase or reduction, and so on. New WHO diagnostic criteria, on the other hand, were approved as anchoring diagnostic criteria.[12 13]

Table 2: W.H.O. Diabetes diagnostic criteria

Condition	Fasting blood glucose (mg/dl)	Post- prandial blood glucose (mg/dl)	HbA_1C (DCCT %)
Normal	< 110	< 140	< 6.0
Impaired fasting glucose	≥ 110 and < 125	< 140	6.0-6.4
Impaired glucose tolerance	< 126	≥ 140 and < 200	6.0-6.4
Diabetes mellitus-2	≥ 126	≥ 200	≥ 6.5[14]

Criteria for diagnosis of Diabetes mellitus (any one or two or three)

- $HbA_1C \geq 6.5\%$
- BSF ≥ 126 mg/dl
- BSPP ≥ 200 mg/dl[15]

Patients were also subjected for following investigation.

Routine investigations

FBS, PPBS, HbA_1C, TLC, Hb percent, ESR, LFT, RFT, DLC, platelets count, Sr. creatinine, specific gravity of urine, sugar albumin, PH of urine, crystals and phosphate, casts and pus cells present in urine were performed to rule out the normal condition of the selected patient as well as to rule out any concurrent infections and other abnormalities.

RESULT

Table 3: Effect of treatment on FBS

(FBS) Fasting Blood Sugar	BT Mean ± S.D.	AT Mean ± S.D.			Within the group comparison paired 't' value BT - F3
		F1	F2	F3	
Group A	209.24 ±51.24	127.34 ±16.61	112.44 ± 17.02	103.61 ± 14.32	105.62 ±51.740 t = 8.166 P = 0.078
Group B	195.88 ±54.89	173.30 ±56.24	157.17 ±47.99	134.78 ± 25.94	61.100 ±42.774 t = 6.388 P = 0.041
Group C	245.45 ±50.46	134.11 ±8.28	111.37 ±7.32	103.00 ± 12.42	14.245 ±48.84 t = 10.912 P = 0.076
Between the group comparison one-way ANOVA	F = 3.762 P = 0.031	F = 8.053 P = 0.001	F = 11.822 P = 0.000	F = 15.617 P = 0.010	
POST HOC TEST **A Vs B** **A Vs C** **B Vs C**	 P = 1.000 P = 0.198 P = 0.028	 P = 0.002 P = 0.198 P = 0.012	 P < 0.001 P = 1.000 P = 0.001	 P < 0.001 P = 1.000 P < 0.001[16]	

Fasting blood sugar levels were found to be different in all three groups in future follow-ups, as shown in the above table. Treatment had a significantly significant effect on fasting blood sugar ($p < 0.001$).
BT: Before Treatment, AT: After Treatment

Table 4: Improvement in Post Prandial blood sugar in all the three groups

(FBS) Fasting Blood Sugar	BT Mean ± S.D.	AT Mean ± S.D.			Within the group comparison paired 't' test value BT - F3
		F1	F2	F3	
Group A	342.94 ± 35.10	182.67 ± 35.10	169.16 ± 21.57	152.17 ± 19.57	190.76 ± 43.49 t = 17.545 p = 0.091
Group B	318.58 ± 51.96	257.34 ± 38.48	220.94 ± 35.58	206.33 ± 35.58	112.25 ± 55.897 t = 8.981 p = 0.032
Group C	336.85 ± 42.53	218.36 ± 29.72	178.23 ± 24.03	171.29 ± 22.43	165.56 ± 39.185 t = 15.809 p < 0.021
Between the group comparison one-way ANOVA on difference of BT and F3	F = 1.462 P = 0.242	F = 20.183 P < 0.001	F = 16.916 P < 0.001	F = 21.950 P < 0.001	
POST HOC TEST **A Vs B** **A Vs C** **B Vs C**	 P = 0.332 P = 1.000 P = 0.739	 P < 0.001 P = 0.024 P = 0.008	 P < 0.001 P = 1.000 P < 0.001	 P < 0.001 P = 0.125 P = 0.001	

According to the data in the table above, all three groups showed improvement in terms of postprandial blood sugar lowering. In all three categories, the statistical difference within the group is highly significant. The intergroup comparison of progress in terms of PPBS reduction between groups was statistically highly significant, as seen in the above table.
BT: Before Treatment, AT: After Treatment

Table 5: Effect of treatment on HbA1C

HbA_1C	BT Mean ± S.D.	AT Mean ± S.D.	Within the group comparison paired 't' test value BT - F3
Group A	9.58 ± 0.852	6.74 ± 0.348	2.837 ± 0.916 t = 12.385 P < 0.001
Group B	8.91 ± 0.858	7.33 ± 0.550	1.580 ± 0.691 t = 10.215 P < 0.001
Group C	9.36 ± 0.970	6.65 ± 0.332	2.714 ± 0.856 t = 11.870 P < 0.001
Between the group comparison one-way ANOVA on difference of BT and F3	F = 2.688 P = 0.078	F = 12.585 P < 0.001	
POST HOC TEST **A Vs B** **A Vs C** **B Vs C**	 P = 0.087 P = 1.000 P = 0.448	 P = 0.001 P = 1.000 P < 0.001	

In future follow-ups, all three groups showed a decrease in HbA1C, as seen in the table above. In all groups, the effect of therapy on HbA_1C was statistically highly significant. Improvement in terms of HbA1C decrease was found to be statistically significant when compared between groups (P < 0.001).

BT: Before Treatment, AT: After Treatment

Table 6: Improvement in signs and symptoms

		Group			Total
		Group A TD	**Group B** Gliclazide	**Group C** TD and Gliclazide	
	Mild improvement	9	3	1	13
		56.25%	15.00%	7.10%	26.00%
	Moderate improvement	6	6	2	14
		37.50%	30.00%	14.20%	28.00%
	Improvement	1	10	6	17
		6.25%	62.25%	42.28%	34.00%
	Marked improvement	0	1	5	6
		0.0%	5.00%	35.70%	12.00%
Total		16	20	14	50
		100.0%	100.0%	100.0%	100.0%

DISCUSSION

Dhanvantari Nighaṇṭu mentions sārivā phāṃṭa in Madhumeha. As we know, kaphavāta doṣa and abadhha meda are major elements in Madhumeha pathogenesis, hence the treatment must address kaphavāta doṣa and meda duṣya. Because of its dīpan-pāchan qualities, the trial medications with Madhura rasa, snigdha guna, and Madhura vipāka ease vāta, tikta rasa alleviates kapha and meda duṣya. Vāyu and ākasha mahabhuta of tikta rasa[17], as well as ruksha, sīta, laghu guṇa[18], are the finest for reducing kapha and meda duṣya. Because sīta vīrya reduces pitta, so it has a tridoṣātmaka effect[19], which is beneficial in the treatment of madhumeha[20]. The current study was designed to test this theory. With this hypothesis, the present study was aimed to assess the efficacy of sariva phanta on Madhumeha.

CONCLUSION

Madhumeha illness is clearly chronicled in the perennial sources of Ayurvedic wisdom (diabetes). Prameha roga has discussed Madhumeha as one of the vataja- pramehas. It can be linked to diabetes mellitus, according to literary evidence. Madhumeha primarily affects people in their fourth and fifth decades of life who have a small masculine preponderance. The majority of those who have it are married. Because Prameha (20 kinds)[21] has a high chance of developing into Madhumeha if left untreated, general etiopathological variables, Purvarupa and other variables can be useful for Madhumeha as well. Many studies show that herbal drugs, whether in single form or as a formulation, are beneficial in the treatment of Madhumeha and significantly reduce all symptoms of the disease. The single herbal medicine chosen was successful in lowering blood sugar levels both fasting and postprandially, as well as urine sugar levels (both fasting and postprandial) All of the patients accepted the medications well, and just a few adverse effects such as constipation and nausea were recorded by a few of them, implying that the drugs used for the current clinical trial are completely safe for internal use. Following a thorough examination, it can be determined that the proposed single herbal medicine formulation in the current study has good hypoglycaemic efficacy and can be safely administered to Madhumehi. Guṇa Prabhava is responsible for sariva`s action.

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