

The Anti-Diabetic (Hypoglycaemic) Effect of Devadarvadi Kashaya- A Polyherbal Compound Drugs- A Pilot Study

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ABSTRACT

Diabetes mellitus is becoming fastest considerable disease in the world. India has being estimated with fastest growing population of Diabetics. In Ayurveda it is described as prameha, which can be managed conservatively with exercise, diet along with internal medication. Madhumeha (Diabetes mellitus) is a multi-factorial disease resulting from a gene environment interaction. Projection of disease prevalence and incidence rate in worldwide by WHO indicating the danger and graveness of this disease. In the present study, the initiation has been taken to collect and compiled all the related previous study about Madhumeha with current formulary devdarvadi kwath used therapeutically for the management of Madhumeha as a pilot project clinically. The diabetic patients were enrolled from the OPD of panchakarma and kaya-chikitsa department of Rajiv Lochan Ayurved Medical College and Hospital, Durg by considering the inclusion and exclusion criteria. The patients were supplied with the specific devdarvadi kwath without any other medications and observations were done once in a week for 60 days. After the completion of scheduled dosage form and regimen to the patients the ayurvedic symptoms which was scored according to their intensity, the blood serum biochemical changes are found to be statistically significant while comparing the result before and after the treatment. This outcome has encouraged us to further trial of this formulation with other established and evidence based standard anti-diabetic formulation of Ayurveda and then with modern allopathic medicines in future time.

Key Words: Madhumeha, Prameha, Diabetes mellitus, Devdarvadi kwath

INTRODUCTION

Globally, an estimated 422 million adults are living with diabetes mellitus, according to the latest 2016 data from the World Health Organization (WHO). Until recently, India had more diabetics than any other country in the world, according to the International Diabetes Foundation, although the country has now been surpassed in the top spot by China. Diabetes currently affects more than 62 million Indians, which is more than 7.1% of the adult population. The average age of onset is 42.5 years. Nearly 1 million Indians die

due to diabetes every year. According to a study carried out in the year 2013 by the Indian Council of Medical Research India has 62.4 million people with Diabetes, out of which (>90%) have Type 2 diabetes.

Madhumeha is the disease of having basically metabolic derangement and genetic predisposition related with each individual body constitution and systemic consideration. In Ayurveda Madhumeha has been described as one among the 20 types of Prameha & is a sub-type of Vatika Prameha in which patient passes excessive amounts of urine that tastes & looks like honey. [1,2]

Though it is a subtype of Vataja Prameha it has more prevalence in the society and may be compared to diabetes mellitus of the modern medical sciences. The disease in which the properties of urine is similar with that of Madhu i.e. of Kashaya and Madhura rasa, rooksa (dry) guna and honey like colour, is widely known as Madhumeha. [3] The main factors involved in the pathogenesis are Vata, Pitta, Kapha, Meda and Oja. [4] Therefore the treatment of this disease should be Tridosha shamaka chikitsa along with Brimhan-Karshana and Rasayana chikitsa. [5] Acharya Sushurt has narrated that all the Pramehas finally convert into Madhumeha, if not treated at the primary stage. [6] As per Charaka Urine of Madhumeha patient is Kashaya and Madhura rasa, Pandu varna and Ruksha in quality. [7] Gangadhar opines upon this that natural Madhura Rasa of Oja is replaced by “kashaya Rasa” in Basti. Chakrapni opines on assertion that vayu because of its prabhava converts madhura rasa of Oja into Kashaya rasa. [8] Debility, disorders of senses, loss of mental and physical strength etc. are created by loss of ojas. The polyuria and turbidity of urine is seen due to the excessive use of heavy, sweet and cold food which aggravates more kapha in the body. More fluid is required to eliminate the unwanted Ojas present in basti through

urine leading to trishnadhikya (Polydipsia). Resemblance of urine with honey is described by Sushruta, Ashtanga Sangraha, Ashtanga Hridaya and Madhava Nidana. [9-12] All the metabolic activities (Paka, Parinamana) are governed by Agni and its mandata leads to so many metabolic disorders and Madhumeha is one of them. In Madhumeha, Dhatvagnimandya is a major etiological component. It has been mentioned that Dhatvagnimandya leads to dhatu vriddhi and Dhatvagni – tikshnata causes Dhatukshaya. It probably occurs due to increased involvement of Vata with increased complexity of Dosha-dushya Sammurcchana and leads to Dhatukshaya. [13]

MATERIALS AND METHODOLOGY

Study design - The diabetic patients were enrolled in the study from OPD of panchakarma and kaya-chikitsa department by considering the inclusion criteria and exclusion criteria. The patients were supplied with the specific devdarvadi kwath without any other medications and observations were done once in a week for 60 days.

Preparation of medicine: Devdarvadi Kashaya-The medicine used for the study was taken from the text Bhaishjya Ratnawali of chapter sutika rogadhikar. [14]

Contents of Devdarvadi Kashaya:

Sl No	Drugs name	Latin name	Family	R/G/Vi/Ve	Part used	Concerned Karma according to samhitas
1	Devdaru [15-17]	Cedrus deodara	Pinaceae	Ti/LS/U/Kt	Kastha, kaanda (Stem)	Pramehanut
2	Vacha [15]	Acorus calamus	Araceae	Kt,Ti/LT/U/Kt	Moola (Root-Rhizome)	Mutravisodhani
3	Kustha	Saussurea lappa	Asteraceae	Ti,Kt,M/LRT/U/Kt	Moola	-
4	Pippali	Piper longum	Piperaceae	K/TLS/Anushna/M	Phala, Moola	Pramehaananti
5	Shunthi [17]	Zingiber officinalis	Zingiberaceae	K/LS/U/M	Moola kanda (Rhizome)	Bhedan
6	Chirayta	Swertia chirata	Gentianaceae	T/LRSara/S/Kt	Panchanga	Saarak
7	Katphal	Myrica esculanta	Myricaceae	Ks,Ti,Kt/LT/U/Kt	Twak (Stem bark)	Pramehahanti
8	Musta	Cyperus rotundus	Cyperaceae	Ti,k,kt/LR//Kt	Moola	-
9	Katuki [15]	Picrorrhiza kurroa	Scrophulariaceae	Ti/L,Ru/S/Kt	Moola (Rhizome)	Bhedaniya, Pramehanut
10	Dhanyak	Coriandrum sativum	Apiaceae	K,Ti,M,Kt/LS/U/M	phala	-
11	Haritaki [18,19]	Terminalia chebula	Combretaceae	Ks,Ma,kt,Ti,A/LR/U/M	Phala	Visramstrani, Pramehanasak
12	Kantkari [15]	Solanum surrattense	Solanaceae	Ti,Kt/LR/U/Kt	Moola	Medorog- nasak
13	Gokshru [15,17]	Tribulus terrestris	Zygophyllaceae	M/GS/U/M	Phala, Moola	Pramehanut
14	Brihati	Solanum torvum	Solanaceae	Kt,T/LRT/U/Kt	Moola	Medohar
15	Ativisha	Aconitum heterophyllum	Ranunculaceae	Kt,T/LR/U/Kt	Moola (Rhizome)	-
16	Guduchi [20,21]	Tinospora cordifolia	Menispermaceae	Ti,K/GS/U/M	Kaanda (Stem)	Pramehanut
17	Karkatsringi	Pistacia integerrima	Anacardiaceae	K,Ti/LR/U/Kt	Sringakar Kosha (Insect Gall)	-
18	Krishna jeerak	Carum carvi	Apiaceae	Kt/RL/U/Kt	Phala (Fruits)	-

Table No 1: Specific Ayurvedic Symptoms^[22-24] (Parameters) and its scoring:

Parameters	Nearer Medical terminology	Different Scoring of Parameters according to intensity			
		0	1	2	3
1. Malina danta	Tartar in teeth	No yellowish	Mild yellowish or pale	Moderate Yellowish	Dark yellowish
2. Hasta pada daha	Burning sensation of hands and feet	Very mild	Non-continuous and occasional	moderate and daily activity is not hampered	continuous, severe and unbearable
3. Deha chikkanata	Excess glossy/oily skin	Usage of soap in alternate days to remove oiliness	Usage of soap daily once in a day to remove oiliness	Usage of soap daily twice a day to remove oiliness	Usage of soap daily thrice a day to remove oiliness
4. Trishna	Excessive thirst	Within a day less than 200ml	Every 12 th hr and take approx. 400ml of water	Evry 6 th hour and approx. take 500 ml of water	Every 2 nd hour and approx. take 600ml or more water
5. Madhuryam asya	Feeling sweetness in mouth	No madhuryata	Madhuryata remains for 6hr	Madhuryata remains for 12hr	Madhuryata remains for 24hr
6. Prabhuta mutrata	Excessive urination	Less than 1000 ml per day	1000 to 1800ml of urine output per day	1800 to 2500ml of urine output /Day	More than 2.5ltr urine output / Day
7. Avila mutrata	Turbid urination	Clear urine	Pale yellow	Dark yellow	Brown
8. Madhu samana varna	Urine having colour of honey	Absence of madhu varna	Slightly madhu varna	Moderately madhu varna	Intensely madhu varna
9. Sweda adhikya	Excess perspiration	No perspiration or Less than 3hrs of continuous perspiration	Approx. 6hrs of perspiration / Day	Approx. 12hrs of perspiration / Day	Approx more than 12hrs of perspiration / Day
10. Anga gandha	foul body odour	3hrs After bath No smell perceived n felt	3hrs After bath smell not felt by himself but perceived when dress is changed	3hrs After bath self-perceived smell	3hrs after bath smell is perceived by others
11. Shithilangata	Flaccidity of muscles	Does the work by self interest	Does the work by self-interest but late process	Does the work slowly by other instructions	Does the work by complete unwillingly by others repetitive instructions
12. Swapna sukha	Desire for not willing to leave the bed	Desire for sleep or feeling Drowsy equal or less than 8hrs	Feeling sleepy or drowsy for 12hrs	Feeling sleepy or drowsy for 18hrs	Feeling sleepy or drowsy for 24hrs
13. Shukhasana	Desire for sedentary life	Can able to stand for a little while 10min	Able to stand and shows desire for sitting before 10mins	Always desiring for straight sitting posture	Always desire sitting posture with external support
13. Shitapriyatwa	Desire for cold food & environment	Comfortable in normal food and enviornmental changes	Needs air conditioning and environmental changes for 8hrs and rarely needs cold items	Needs air conditioning and environmental changes for 12hrs and frequently needs cold items	Always desirous for AC environment with cold food stuffs.
14. Gala talu shosha	Dryness of palate & throat	After consuming water can withstand for 4hrs and not felt dry lip	Rarely felt dryness of lip after drinking water or felt dry lip after 6hrs	Frequently felt dryness of	Always taking sip of water but lips are touched by tongue due to dryness
15. Kshudhadhikya	Polyphagia	Desire for taking food in 8 hrs	Desire for taking food in the interval of 6 hrs	Desire for taking food in the interval of 4 hrs	Desire for taking food in every 2hrs
16. Pipasa	Polydipsia	Taking water in the interval of 4hrs	Taking water in the interval of 3hrs	Taking water in every 2hrs	Taking water in every 1hr
17. Naktamutrata	Nocturia	Don't need to wake up at night	Need to wake up 2 times	Need to wake up for urination 4 times	Need to wake up for urination for more than 4 times

The drugs were collected under the supervision of Dravyagun department by proper identification and quality control. The drugs were made Yavkut churna (coarse powder) in the Rasa shastra department of Rajiv Lochan Ayurvedic Medical College. Ghrita bhrishta 500 mg of

sodhita hingu with 1gm of Saindhav lavan was to be added while administration.

Administration of drugs: ^[14] The patients were advised to take 5 gm of yavkut churna and add two glass of water in the night. In the morning it has to be boiled to one fourth. The prepared decoction was mixed with Ghrita bhrishta 500 mg of sodhita hingu

with 1gm of Saindhav lavan and to be taken by patients in the morning and evening in empty stomach.

Inclusive criteria:

Patient having classical signs and symptoms of the disease prameha according to Ayurveda as well as modern science are included.

Patient having F.B.S. level 125 to 250 mg/dl and P.P.B.S. level upto 300 mg/dl were selected for the study.

Patients are of age group 20-60 years and having no serious complications.

The patients having classical signs and symptoms of Madhumeha (Diabetes Mellitus type-2) have been selected randomly from O.P.D. & I.P.D. of RLAMCH irrespective of age, sex, caste, religion and occupation etc.

Exclusive criteria:

- 1) Patients below 20 yrs. of age.
- 2) Patients above 60 yrs. of age.
- 3) Patients of Type 1 D.M.
- 4) Patients of Type 2 D.M. taking insulin.

- 5) Patients of Gestational D.M.
- 6) Patients of Sahaja Madhumeha (hereditary)
- 7) Patients with severe diabetic complications like CVD, Nephropathy, Neuropathy, Retinopathy, Diabetic foot etc.
- 8) Patients complicated with cardiac problems.
- 9) Patients having other serious disease like carcinoma, AIDS etc.
- 10) Patients of D.M. in association of endocrinopathies like Acromegaly, Thyrotoxicosis, Hyperthyroidism, Pheochromocytoma, Cushing's syndrome etc.
- 11) Patients with genetic syndromes associated with D.M. like Down's syndrome, Klinefelter's syndrome, Turner's syndrome etc.
- 12) Diabetes due to side effect of drugs like Diuretics (Thiazide) etc.

OBSERVATION AND RESULT

Table No 2: The effect of test drug on various serum Biochemical Parameters: (NS-Not significant)

Sl No	Parameters	BT	AT	Mean of Difference	SD of Difference	SEM of Difference	P Value	P Summary Value
1	Blood Glucose FBS (mg/dl)	127.43	110.93	-16.50	5.94	1.08	<0.0001	****
2	Blood Glucose PPBS (mg/dl)	229.20	134.33	-99.83	49.18	8.97	<0.0001	****
3	Cholesterol (mg/dl)	252.33	226	-26.33	31.89	5.82	<0.0001	****
4	Triglycerides (mg/dl)	252.20	239.83	-12.37	7.29	1.33	<0.0001	****
5	HDL (mg/dl)	34.6	36.9	2.30	2.54	0.46	<0.0001	****
6	Blood Urea (mg/dl)	34.76	27.2	-7.56	4.32	0.78	<0.0001	****
7	Creatinine (mg/dl)	1.83	1.9	0.06	1.99	0.36	0.863	NS
8	SGPT (IU/L)	36.06	21.9	-14.17	5.79	1.05	<0.0001	****
9	SGOT (IU/L)	37.16	31.9	-12.37	7.29	1.33	<0.0001	****
10	Total Protein (g/dl)	8.15	8.13	-0.02	0.07	0.01	0.089	NS
11	Albumin (g/dl)	5.30	5.21	-0.09	0.07	0.01	<0.0001	****
12	Globulin (g/dl)	8.11	8.06	-0.05	0.06	0.01	<0.0001	****

Table No 3: Statistical data of Ayurvedic symptomatic parameters: (NS-Not significant, S-significant)

Parameters	Nearer Medical terminology	Mean of Diff.	SD of Diff.	SEM of Diff.	Sum of Signed Ranks (W)	P value	P value Summary
1.Malina danta	Tartar in teeth	-1.43	0.56	0.10	-465.0	<0.0001	****
2.Hasta pada daha	Burning sensation of hands and feet	-1.43	0.56	0.10	-465.0	<0.0001	****
3.Deha chikkanata	Excess glossy/ oily skin	-1.36	0.55	0.10	-465.0	<0.0001	****
4.Trishna	Excessive thirst	-1.33	0.54	0.09	-465.0	<0.0001	****
5.Madhuryam asya	Feeling sweetness in mouth	-1.50	0.62	0.11	-465.0	<0.0001	****
6.Prabhuta mutrata	Excessive urination (Polyuria)	-1.46	0.68	0.12	-465.0	<0.0001	****
7.Avila mutrata	Turbid urination	-1.46	0.63	0.12	-465.0	<0.0001	****
8.Mutra madhu samana varna	Urine having colour of honey	-1.36	0.66	0.12	-465.0	<0.0001	****

9.Sweda adhikya	Excess perspiration	-1.30	0.65	0.11	-465.0	<0.0001	****
10.Anga gandha	foul body odour	-1.30	0.74	0.13	-406.0	<0.0001	****
11.Shithilangata	Flaccidity of muscles	-1.36	0.55	0.10	-465.0	<0.0001	****
12.Swapna sukha	Desire for not willing to leave the bed	-1.50	0.68	0.12	351.0	<0.0001	t-test-NS But signed ranked test-S
13.Shukhasana	Desire for sedentary life	-1.27	0.78	0.13	-465.0	<0.0001	****
14.Shitapriyatwa	Desire for cold food & environment	-1.26	0.58	0.10	-465.0	<0.0001	****
15.Gala-talu shosha	Dryness of palate & throat	-1.45	0.68	0.11	-465.0	<0.0001	****
16.Kshudhadhikya	Polyphagia	-1.53	0.62	0.11	-465.0	<0.0001	****
17. Pipasa	Polydipsia	-1.46	0.68	0.12	-465.0	<0.0001	****
18.Naktamutrata	Nocturia	-1.53	0.62	0.12	-465.0	<0.0001	****

Table No: 4 (references of drugs under trials) [25]

Trial drug attempted (single herb / formulation/Bhasma/Kupipakwa Rasa)	Reference
Pramehaghna Ghanavati	Anubhuta*
Medohara Rasayana Vati	Sushruta Samhita, Chikitsa Sthana9/6
Nishakatakadi Yoga	Prakarana Sahasrayoga, Parishishta Kashaya, p. 275
Nyagrodhadi Ghanavati	Chakradatta, Prameha Chikitsa,35/27-31
Nisha-Amalaki Churna Kuberaksha	Ashtanga Samgraha, PramehaChikitsa, 14/13
Mamajjaka Ghanavati	Bhaishajya Samhita (pub published by Health Ministry Gujarat State, Ahmedabad), p. 493
Guduchi Satva	Nighnatu Ratnakar, 1st ed.,Part 2, p. 579
Guduchi Ghana	Siddha Yoga Sangraha, Jwaradhikara, p. 4
Medoghna Rasayana Vati	Sushruta Samhita, Chikitsa Sthana9/6
Triphaladi Vati	Chikitsa Chakradatta, Prameha, 35/24
Shilajitwadi Vati	Rasodhdhara tantra,prameha Chikitsa,p.78
Mehamudgara Vati	Bhaishajya Ratnawali 37/69-72
Nyagrodhadi Vati	Chakradatta, Prameha Chikitsa,35/27-31
Gokshuradi Guggulu	Sharangdhara Samhita, Madhyam Khand,7/84-87
Saptaranyadi Ghanavati	Anubhut*
Vatsakadi Ghanavati	Chikitsa Chakradatta, Prameha, 35/24
Saptavimshati Guggulu	Bhaishajya Ratnawali ,Bhagandara Adhikar,p-609;AFI part 1,5/11
Triphaladi Kwatha granules	Yoga Ratnakar,Prameha Chikitsa,verse 73, p-531
Asanadiyoga Vati	Ashtanga Hridaya, Prameha chikitsa 12/34-35
Shilajitwadi Vati	Siddha Yoga Sangraha, Jwaradhikara, p. 4
Vanga Bhasma	Rasamritam 3/88
Naga Bhasma	Rasa Tarangini 19/29-33
Laghu Malini Vasanta Rasa	Yogaratanakara Jwaradhikar ,p.245,AFI part 1, 20/46
Makaradhujja	Bhaishajya Ratnawali, vajikaran adhikara,verse114-123
Anubhuta;Experience based formulation traditionally practiced in folklore, having no classical references.	

DISCUSSION

Diabetes mellitus type 2 or adult onset diabetes can be correlated to apathynimithaja prameha where Sahaja prameha or Juvenile onset Diabetes is excluded. In this context the effect of many herbal drugs already tried in different institutions from time to time is shown in table no 4. The effect of Guduchi Ghana and Guduchi Satwa which is already tried in patients in previous studies as a single herbal drug formulary an important constituent of current polyherbal test drug. [26-28] Haritaki effect can be enumerated from the usage of Triphaladi vati and

triphaladi kwatha granules. [29,30] Another potent evidence based ayurvedic diuretic drug Gokshura is already used in the management of DM type 2 in the form of Gokshuradi Guggulu in previous studies. [31] The usage of mainly Devdaru, Vacha, kustha, pippali, Sunthi, katuki, Brihati, kantakari, Katphal, Ativisha, Karkatsringi, chirayata, Dhanyak, Krishna jeerak is being rationally analysed here. Improvement of Quality of Life is well marked after the consumption of scheduled drugs as advised to the patient due to their rejuvenating and antioxidant properties by eliminating the free radicals especially from the blood

vascular tissues. As per Seetha chandran [32] et al the states of diabetes can be differentiated into kaphaj (Prediabetic), Pittaj (Diabetic) and Vatika (complications of diabetes). He has also explained the appearance of sweet and viscid urine in patient might be due to either sampooranath sleshma samudbhava (over nourishment and aggravated kapha) or due to ksheena dhatu anilatmaka (tissue depletion with vata vitiation) which can be compared with NIDDM and IDDM respectively.

The compound formulation Devdarvadi kashaya is consisting of 18 herbal drugs as ingredients out of which *Devdaru*, *Pippali*, *Katphal*, *Katuki*, *Haritaki*, *Gokshura* and *Guduchi* which possesses Pramehahara properties as per Bhav Prakash Nighantu. [33] The above 7 drugs provide the vital pharmacological actions combating the symptoms of Prameha such as Kara pada daha, prabhuta mutrata, avila mutrata, nakta mutrata, kshudha-pipasadhikya which synchronizely termed as anti-diabetic activity i.e. both hypoglycemic along with antihyperglycemic activity. Most of the drug of this formulation is having Tikta-Katu-Kasaya rasa, Laghu-Ruksha-Tikshna guna, Ushna Veerya with both Katu and madhur vipaka. All these properties are helpful in alleviating the deranged dhatus which are main causes in the manifestation of Prameha such as Rasa, Rakta, Mamsa, meda, Lasika along with one mala ie Mutra. Again the herbal drug Vacha, Kustha and Katphal having katu tikta rasa with ushna veerya and katu vipak shows mutravisoridhini properties i.e. purification of urinary bladder and urinary constituents. Pippali and sunthi have katu rasa pradhan dravya with madhur vipaka while pippali is of anushna veerya sunthi is of ushna veerya. Pippali possesses pramehaghna properties while sunthi possesses bhedan properties. Both of these drugs are said to be enhance the bioavailability of other active molecules present in the studied compound drug. Both Chirayata and Musta having tikta rasa, sita veerya and katu vipak. While the sara guna

of chirayata here played a vital role of sarak to eliminate excessive kleda, lasika from micro tissues of the body and musta helps in pachan of toxic remnants i.e. ama in annavaha srotas as well as rasa and rakta vaha srotas.

By assessing the serum biochemical parameters it was seen that blood glucose level before and after treatment reduced and maintained significantly from the presented P value (<0.0001). Similarly PPBS level also reduced significantly. Along with this Cholesterol, Triglycerides, HDL, Blood urea level also decreased significantly in patients after usage of the prepared formulation Devdarvadi Kashaya. The significant gradient can be described as extremely significant for the said formulation. The creatinine level and the total protein level didn't show significant reduction before and after treatment in the present study.

While analysing the effect of medicine over ayurvedic symptoms of Prameha, the result was very encouraging as almost all the symptoms reduced significantly before and after the treatment and during the follow up period after 60 days. For assessing all these symptoms both paired Student 't' test and wilcoxon signed ranked test was applied, the result of which showed high significance before and after the treatment except one symptoms of Swapna sukha where t test result was not significant but the wilcoxon signed ranked test was significant.

CONCLUSION

The effect of Devdarvadi kashaya in the management of type 2 Diabetes mellitus have shown encouraging results which can further be compared with any of the established rasa ausadhi used for the long term treatment of diabetes and its associated generalized to specific complications. Again it was observed that the therapy is significantly effective and clinically safe as no adverse events and reactions were not reported during the course of studies. It was concluded that the usage of shamana

ausadhi in the form of devdarwadi kashaya is very important to alleviate the present symptoms in a stable manner for longer duration and period of time along with further helping it not to recur or aggravate the symptoms by the resistance of the body tissues to the drug usage. Hence the prepared formulation can be taken for the multicentric trials in larger population to precisely infer its therapeutic efficacy and safety.

Abbreviation

Su.ni. – Sushurut Nidan

As. ni - Ashtanga Sangraha Nidan

A.H Ni. - Ashtanga Hridaya Nidan

M. N. - Madhava Nidana

Conflict of interest: None

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