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Bhudhatryadi Yoga in *Madhumeha* (diabetes mellitus type 2): An open label single arm clinical study

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ABSTRACT

Background: Diabetes mellitus is a metabolic disorder characterized by persistent hyperglycemia either due to less production of insulin or resistance of insulin receptors. Globally 463 million individuals are affected by type 2 diabetes & 77 million belong to India. India is deemed as the world's capital of diabetes. It can be correlated to *Madhumeha. Bhudhatryadi Yoga* is mentioned for the treatment of *Prameha*. *Bhudhatryadi Yoga* has *Tikta Rasa, Laghu-Ruksha Guna, Sheeta Veerya. Katu Rasa* of *Maricha* is *Deepana* and *Pachana*. It does *Kleda Shoshana*, *Meda Shoshana* and *Kapha Harana*. It removes *Sroto Rodha* and thereby helps in alleviating *Kapha Prakopa.* The effect of methanol extract of aerial parts of *Bhumyamlaki* has α–amylase & α–glucosidase enzyme inhibitory properties. α –amylase & α – glucosidase aid the production of glucose from the catabolism of starches and oligosaccharides. **Methods:** 28 registered subjects, 23 completed the course of intervention. They were administered with *Bhudhatryadi Yoga* orally 12 gm per day (6 gm twice daily before food) with *Anupana* of lukewarm water for a period of 30 days. Blood and urine glucose test was done on 1^{ST,} 7TH and 30th from the day one of study initiation. For Statistical analysis subjective parameters were assessed by Cochran's Q test followed by McNemar test and objective parameters were assessed by Repeated Measures Anova and Paired T Test. **Results:** There was statistically significant improvement observed in the signs and Symptoms of *Madhumeha* with blood and urine glucose levels. ($p<0.05$). **Interpretation and Conclusion:** *Bhudhatryadi Yoga* is effective in management of *Madhumeha.*

Key words: *Madhumeha, Diabetes Mellitus, Bhudhatryadi Yoga, Ayurveda.*

INTRODUCTION

Diabetes is a major health issue; nearly half a billion people are living with diabetes worldwide. It is one of the fastest growing global health emergencies of 21st century. In 2019 it is estimated that 463 million people have diabetes and this number will reach 578 million by 2030 and 700 million by 2045.[1] Diabetes mellitus is one of the most common systemic disease and it occurs when pancreas does not produce enough insulin or when the body cannot effectively use that insulin.[2] Type 2 diabetes is the most common type of diabetes, accounting around 90 % of all diabetes worldwide. India is deemed as the world's capital of diabetes.[3]

Prameha when left untreated leads to Madhumeha. It is also known as *Ojomeha*. *Madhumeha* arises either by *Dhatukshaya* or *Avarana*.[4] *Atisevana* of *Guru, Snigdha Guna, Amla , Lavana rasa , Naveena Annapana, Ati Nidra, Avyayama* lead to *Dushti* of *Kapha, Pitta, Meda, Mamsa* thereby causing obstruction to *Vata*. This obstructed *Vata* expels *Oja* through *Basti* causing *Madhumeha*. It produces *Lakshana* like *Prabhootamutrata,Madhurasyata, Kshudhadhikya, Pipaasaadhikya, Kara-Padadaha, Kara-Padasuptata, Mukha-Talu-Kantashosha, Alasya, Atisweda, Dourgandhya*.[5] Diabetes mellitus clinically presents with polyuria, polydipsia, polyphagia,

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paresthesia. The symptoms of Diabetes Mellitus are found to be similar with of *Madhumeha. Bhudhatryadi Yoga* is mentioned in the treatment of *Prameha*.[6] It has two ingredients, *Bhudhatri* and *Maricha*. *Bhudhatri* has *Tikta, Kashaya Rasa, Sheeta Veerya & Pitta Kapha Hara* properties[7] *Maricha* has *Katu Rasa, Ushna Veerya, Deepana & Kapha Vata Hara* properties.[8] Hexane extract of *Bhudhatri* is found to have α-amylase inhibitory properties which shows hypoglycemic effect by inhibiting starch converts into glucose.[9] Piperine, one of the phytoconstituent is found to have antidiabetic action.[10]

Material and Methods

Source of data

Outpatient department of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan

Method of collection of data

Screening: Subjects were screened using screening form and recruited subject's data was collected using specially prepared case report form (CRF) by incorporating subjective, objective parameters of *Madhumeha* (Diabetes mellitus Type 2)

Diagnostic Criteria

Among screened subjects, *Madhumeha* (diabetes mellitus) was diagnosed on the basis of Signs and symptoms of *Madhumeha* like *Prabhootamutrata, Kshudhadhikya Pipaasaadhikya, Kara-Padadaha, Kara-Padasuptata, Mukha-Talu-Kantashosha* , ADA (American Diabetes Association) diagnostic criteria of diabetes was taken into consideration.

Inclusion Criteria

Fresh cases or diagnosed cases of Diabetes mellitus Type -2 on Ayurveda treatment,

Subjects of either gender of age between 30-70yrs, Type II Diabetes mellitus with Fasting Blood glucose: >126mg/dl, or Post Prandial, Blood glucose >200mg/dl or HbA1c >6.5[11] Subjects who were willing to participate in study and ready to sign the informed consent were taken into study.

Exclusion Criteria

subjects with other systemic conditions like cardiac illness, impaired kidney and hepatic function, carcinoma, AIDS, Lactating and pregnant women, Subjects with Diabetes mellitus Type 2 on Insulin, History of uncontrolled Diabetes were excluded.

Ethical clearance and CTRI registration

Ethics clearance certificate was obtained from Institutional Ethics Committee.

Trial was registered on www.ctri.gov.in (12/2019/029702 dated 13th December ,2019)

Study design

The study was an open label, single arm, prospective clinical trial in madhumeha (diabetes mellitus) (n=23) selected using convenience (non random) sampling technique with pre and post design conducted in tertiary Ayurveda hospital attached to Ayurveda medical college located in district headquarters in southern India.

Dosage and Drug Administration

Drug: *Bhudhatryadi yoga*

Dosage: 6gm BD

Route of administration: Oral

Time of administration: BD Before food

Anupana: *Ushna jala*

Duration: 30 days

Observation

In the present study total 50 subjects were screened, out of which 28 subjects were registered for the study, among them 23 subjects completed the study. Among 28 subjects maximum (n=10) were from the age group of 51-60 years and predominance of Females (n=15). 14 subjects were from middle class group and majority of them (n=19) had sedentary life style. Diet wise distribution showed maximum (n=21) had non veg diet. Considerable number of subjects (n=20) were not doing *Vyayama* (Exercise), maximum number of subjects (n=15) had family history.

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RESULTS

23 subjects were administered with *Bhudhatryadi yoga* in a dose of 6gm BD Before food along with *Ushna Jala* for a period of one month

Mc nemar test was run on subjective parameters and has shown significant improvement in symptoms like *Praboota Mootrata , Kshudadikya, Karapada Daha*. Results are placed at

Paired t Test was run on objective parameters like FBS, PPBS, FUS and PPUS and has shown significant improvements.

DISCUSSION

Effect of *Bhudhatryadi* Yoga on *Prabhootamootrata*

There was statistically significant improvement in *Prabhootamootrata* after treatment with p value <.05. *Prabhuta Mootrata* is *Mootravahasrotas, Medovahasrotasvikriti Lakshana*. It can be understood as increase in *Kapha, Abadhamedas, Kledamsha. Bhudhatryadi Yoga* has *Tikta-Kashaya Rasa* and *Rukshaguna* which are *Kledo-Upashoshaka* and helps in pacifying this symptom.

Effect of on *Trishnadhikya* and *Mukhatalushosha*

There was statistically significant improvement in *Trishnaadhikya* after treatment with p value <.05. *Bhudhatryadi Yoga* showed significant result in *Udakavhasrotasdusti* due to its *Tikta, Madhura, Kashaya Rasa* and *Trishnanigrahana* property of *Bhumyamlaki*.

Effect of on *Kshudhadhikya*

There was statistically significant improvement in the *Kshudhaadhikya* after treatment with p value <.05. *Kshudhaadhikya* occurs due to *Avarana* of *Abadhamedas* over *Koshtaagni* which causes vitiation of *Vata* and leads to *Kshudhaadhikya*. *Maricha* has *Katu Rasa, Ushnaveerya*, *Deepana Pachana* and *Srotoshodhaka* properties which acts at level of *Dhatwaagni*, leads to proper formation of rasa dhatu and removes the *Avarna* of *Abadhamedas* at level of *Koshtaagni* and thus specify the symptom.

Effect of *Bhudhatryadi Yoga* on Biochemical parameters

Effect of *Bhudhatryadi Yoga* in Fasting blood sugar

A repeated measures ANOVA determined that FBS mean scores were statistically significant with $p < 0.05$. Post hoc tests using the Bonferroni correction 0.016 revealed that treatment elicited decrease in Fasting Blood Glucose from 1st day – 30th day of treatment.

Effect of *Bhudhatryadi* yoga in Post prandial blood glucose

A repeated measure ANOVA determined that PPBS mean scores were statistically significant with $p < 0.05$. Post hoc tests using the Bonferroni correction 0.016 revealed that treatment elicited decrease in Fasting Blood Glucose between 1st day -7th day, 7th – 30th day and 1st day – 30th day with p <.016.

Result on Fasting Urine Glucose

There was statistically significant difference in FUS with Friedman's test at $p < 0.05$. Post hoc with Wilcoxon signed rank test showed there was statistically significant difference in FUS between 1st day -7th day, 7th – 30th day and 1st day – 30th day with p <.016.

Result on Post Prandial Urine Glucose

There was statistically significant difference in PPUS with Friedman's test at $p< 0.05$. Post hoc with Wilcoxon signed rank test showed there was statistically significant difference in PPUS between before treatment and after treatment with p<0.016.

Discussion on Probable Mode of Action of Drug

Bhudhatri has *Tikta, Kashaya, Laghu, Ruksha Guna* acts as *Pitta-KaphaShamaka, Grahi, Kleda-Medoupashoshaka. Sheetha Virya, Madhura Vipaka* of *Bhudhatri* is *Kapha-Pithashamaka. Maricha* is *Katu Rasa Pradhana* which has *Deepana- Pachana,* property. *Katu Rasa* has *Sneha-Meda-Kledaupashoshana* property. *Katu Rasa* also causes *Srotoshodhanam*. Hexane extract of *Bhudhatri* has α–amylase & α–glucosidase inhibitory properties. α–amylase & α–glucosidase aid the production of glucose from the catabolism of starches and

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oligosaccharides.[12] Phytoconstituent of Maricha, Piperine is found to have antidiabetic action.[13]

The present study showed significant reduction in both subjective and objective parameters of *Madhumeha*.

CONCLUSION

Bhudhatryadi Yoga in a dose of 6gm BD Before food along with *Ushna Jala* for a period of one month has shown better results in subjective parameters like *Praboota Mootrata, Kshudadikya, Trishna Adhikya* and *Karapada Daha* and also in objective parameters like FBS, PPBS, FUS and PPUS.

Table 1: Showing effect of *Bhudhatryadi yoga* on subjective parameters by applying Friedman's test

Parameter	Value		N	Cochran's Q	P value	Remark
	Present	Absent				
Prabhoota Mootrata BT	19	4	23	17.160	<.05	S
Prabhoota Mootrata 7TH day	17	6				
Prabhoota Mootrata 30th day	8	15				
Mukhatalukanthashosha BT	2	21				
Mukhatalukanthashosha 7th day	2	21	23	2.0	>.05	NS
Mukhatalukanthashosha 30th day	1	22				
Kshudha Adhikya BT	9	14				
Kshudha Adhikya 7TH day	6	17	23	10.57	<.05	S
Kshudha Adhikya 30 day	2	21				
Trishna Adhikya BT	8	15				
Trishna Adhikya 7th day	8	15	23	12.00	<.05	S
Trishna Adhikya 30th day	2	21				
Karapada Tala Daha BT	3	20				
Karapada Tala Daha 7th day	3	20	23	2	>.05	NS
Karapada Tala Daha	2	21				
Karapada Suptata BT	3	20				
Karapada Suptata 7th day	3	20	23	2	>.05	NS
Karapada Suptata 30th day	2	21				

Table 2: Pair wise comparison of PPBS at different interval of treatment

Pairs	P Value		Mean Difference	SE	95% Confidence interval for difference		Remark
					Lower bound	*Upper bound*	
BT	.053	7 Days	21.696	10.594	-.274	43.665	S
7 Days	.520	30 Days	3.739	5.725	-8.12807	15.61	NS
AT	040	30 Days	25.435	11.660	1.25410	49.61	S

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Table 3: Pair wise comparison of PPBS at different interval of treatment

Pairs	Days	Mean Difference	SE	P Value	95% Confidence interval for difference		Remark
					Lower bound	Upper bound	
BT	7 Days	47.95	13.1	.001	20.65	75.25	S
7 Days	30 Days	5.9565	6.6	.383	-7.9	19.8	NS
AT	30 Days	53.91	15.9	.003	20.79	87.03	S

Table 4: Wilcoxon Signed rank test showing effect of *Bhudhatryadi Yoga* on FUS

Intervals	N				Sum of Ranks	Z	P	Remarks
	NR	PR	T	Total				
BT - 7Th Day	7	0	16	23	28	-2.6	<0.016	S
7Th Day - 30TH Day	8	0	15	23	36	-2.8	<0.016	S
BT - 30Th Day	15	0	8	23	120	-3.8	<0.016	S

Table 5: Wilcoxon Signed rank test showing effect of *Bhudhatryadi Yoga* on PPUS

Intervals	N				Sum of Ranks	Z	P	Remarks
	NR	PR	T	Total				
BT-7TH Day	16	0	7	23	136	-4.0	<0.016	S
7TH Day – 30TH Day	4	0	19	23	10	-2.0	>0.016	NS
BT-30TH Day	19	0	4	23	190	-4.26	<0.016	s

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