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An Open Label Clinical Study to Evaluate the Therapeutic Effect of *Abhrakabhasmadi Yoga* in *Madhumeha* W.S.R to Type II Diabetes Mellitus

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ABSTRACT
Madhumeha , one of the *ashtamahagadas*, is a *santarpanottha vikara*, and may be due to *avarana* or *swavardhaka hetus* and is chronic in nature. All types of *prameha* when neglected in the initial phase leads to *madhumeha***.** Based on the symptoms of *Madhumeha*, it can be understood as Diabetes Mellitus. Diabetes mellitus is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, in particular the blood vessels and nerves. **Objective:** to evaluate the therapeutic effect of *abhrakabhasmadi yoga* in *madhumeha.* **Methodology:** open label clinical study with pre and post-test design. 20 patients diagnosed with *madhumeha* (type 2 diabetes mellitus) were taken for the study from Sri Dharmasthala Manjunatheshwara Ayurveda Hospital,Udupi, Karnataka. Intervention included administering 5gms *abhrakabhasmadi* yoga in the morning with *madhu* before food for 28 days. the parameters were assessed before and after treatment. **Results**: Results were statistically analysed using paired t test and Wilcoxon sign rank test and were statistically significant. **Conclusion:**The study revealed positive outcomes and proved that the formulation was successful in reducing FBS, PPBS, FUS, PPUS and symptoms of *madhumeha.*

Key words: *madhumeha*; diabetes mellitus; *abhrakabhasmadi yoga*

INTRODUCTION

Madhumeha is a *santarpanottha vikara* and the *samprapthi* may be due to *avarana* or *swavardhaka hetus*[1]. It is also included in *ashtamahagadas*[2]. As the disease is chronic in nature it is also addressed as p*rameho anushanginam*[3]. It involves all the three *dosha* and ten *dushya* that includes *meda, rakta, shukra, ambu, vasa, lasika, majja, rasa, ojas* and *mamsa*[4]. The result of *aparipakva kapha* formed due to indulgence of etiological factors with *meda* proceed downward through the *mutravaha srotas* and gets settled at *basti mukha* leading to *prabhoota mutrata, avila mutrata* etc symptoms. All types of *prameha* when neglected in the initial phase leads to *madhumeha*[5.] Based on the symptoms of *Madhumeha*, it can be understood as Diabetes Mellitus.

Diabetes mellitus is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, in particular the blood vessels and nerves[6].

Diabetes is a growing challenge in India with estimated 8.7% diabetic population in the age group of 20 and 70 years. The rising prevalence of diabetes is driven by a combination of factors – rapid urbanization, sedentary lifestyles, unhealthy diets, and increasing life expectancy[7]. India currently represents 49% of the world's diabetes burden, with an estimated 72 million cases in 2017. With a pre diabetes prevalence of 10.3% among adults, people with diabetes in India are likely to more than double in the next decade[8].
The ultimate aim is, a good control and management of *Madhumeha* and thus reducing the risk of the development of complications.
There are many studies done to evaluate the efficacy of ayurvedic formulations in *prameha/madhumeha* showing positive results. However, study of formulations with both herbal and mineral origin drugs can be done to get best outcome owing to their independent attributes as well as their synergetic action, hence this study is taken up.

MATERIALS AND METHODS

Objective of the study:

To evaluate the therapeutic effect of *abhrakabhasmadi yoga* in *madhumeha* w.s.r to type 2 diabetes mellitus.

Design:

Study Type: Interventional, Estimated enrolment: 20 participants, Allocation: Non Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Single Group Assignment, Primary Purpose: Treatment, Masking: Open Label.

Setting:

Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi.

Participants:

From August 2020 to January 2021, 20 patients with fasting Plasma Glucose ≥126 mg/dl (7.0 mmol/l), two-hour plasma glucose ≥ 200mg/dl7, with or without the association of symptoms of *Madhumeha* like *Prabhootamutra, Avila mutrata, kshut* and *pipasa adhikya* were taken up for the study.

Diagnostic criteria[9]:

1. Fasting Plasma Glucose ≥126 mg/dl (7.0mmol/l). Fasting is defined as no caloric intake for at least 8-10 Hours.
2. Two - hour plasma glucose ≥ 200mg/dl, with or without the association of Symptoms of *Madhumeha* like *prabhootamutra, Avila mutrata, kshut, pipasa adhikya* etc.

Inclusion criteria:

1) Patients fulfilling the diagnostic criteria

2) Patients between the age group of 30 to 70 years of either sex.

3) Fasting Plasma Glucose Level ranging from 126mg/dl to 200 mg/dl or Post Prandial Plasma Glucose level ranging from 200 to 350mg/dl.

4) Patients who are already on other anti-diabetic drugs after discontinuing the treatment and after the washout period of one week.

5) Both participant and caregiver are willing and able to provide informed consent.

Exclusion criteria:

1) Type 1 DM.

2) Diabetic Cardiomyopathy, Neuropathy, Nephropathy, Retinopathy, and Diabetic ketoacidosis

3) CNS disorders e.g. Encephalopathy.

4) Any major concomitant illness or hospitalization for MI, Cardiovascular disease, CKD, Gastrointestinal disease (especially - Chronic Intestinal disease, IBD, Intestinal Ulceration) carcinoma, HIV, TB etc.

5) Pregnant & Lactating women.

6) Had participated in any clinical trial within 3 months of screening.

Intervention:

Patients were administered 5gm of *Abhrakabhasmadi yoga*[10] in the morning, 30 mins before food with *madhu* for 28 days and followed up on 14th and 56th day. The total duration of study was 56 days.

Assessment criteria:

Objective and Subjective criteria were scored by standard method and were assessed before, and after treatment on 0th and 28th days. Follow up done on 14th and 56th day.

Statistical analysis:

Results were statistically analysed using paired t test and Wilcoxon sign rank test for objective and subjective parameters respectively.

Primary outcome/objective parameters:

- Fasting Plasma Glucose Level
- Post Prandial Plasma Glucose Level
- Fasting urine sugar level
- Post Prandial urine sugar level

Secondary outcome/ subjective parameters:

- *Atibhubuksha.*
- *AtiMutrapravritti.*
- *AtiTrishna.*
- *Dourbalya*
- *Mukhatalushosha*
- *Kara padadaha*
- *Kara padasuptata*
- *Shithilangata*

Results:

The overall percentage of improvement in FBS was 13.79%, was 18.11% in PPBS, 36.428% in FUS, and 38.554% improvement in PPUS. There was significant reduction in symptoms with the overall percentage of improvement in *atimutrata* of 41.463%, 35.555%, in *atibubuksha*, 44.117% in *atitrusha*, 52.941% in *mukatalushosha*, 33.333% in *karapadadaha*, 39.13% in *karapadasuptata*, 33.333% in *daurbalya* and 40% improvement in *shithilangatha.*

Effect of treatment in objective parameters are shown in table no. 1 and subjective parameters are shown in table no.2

Overall effect of the treatment:

There was moderate remission in 50% of patients, mild remission in 25% of patients, good remission in 20% of patients and excellent remission in 5% of patients i.e 10, 5, 4 and 1 patient(s) respectively. Overall effect of treatment is shown in table no. 3

Table no. 1 Effect of treatment on objective parameters

Criteria	Time	Mean	± SD	±SE	Difference in mean	% improvement	paired t test	
							t value	P value
FBS 92 - 270 N = 20	**BT**	162.4	27.683	6.190	22.4	13.793 %	t = 2.589	P= 0.018
	AT	140	40.057	8.957				
PPBS 114 – 429 N = 20	**BT**	264.200	46.248	10.341	47.850	18.11 %	t = 2.892	P = 0.009
	AT	216.350	73.461	16.426				
FUS 0.0– 1.1 N = 7	**BT**	0.280	0.423	0.0945	0.102	36.428%	t = 2.553	P = 0.019
	AT	0.177	0.310	0.0693				

Table no. 2 Effect of treatment on subjective parameters

Range	time	Mean Median	± SD	±SE	Difference in mean	% improvement	W.S.R.T*	
							z value	P value
Atibubuksha 0 – 3 N = 17	**BT**	2.2503	1.070	0.239	0.800	35.555%	3.418	P = <0.001
	AT	1.4502	0.887	0.198				
Atimutrata 0 – 3 N = 18	**BT**	2.0502	0.759	0.170	0.850	41.463%	3.900	P = <0.001
	AT	1.2001	0.696	0.156				
Atitrusha 0 – 3 N = 17	**BT**	1.7002	0.923	0.206	0.750	44.117%	3.419	P = <0.001
	AT	0.9501	0.759	0.170				
Dourbalya 0 – 3 N = 11	**BT**	1.0501	1.050	0.235	0.350	33.333%	2.070	P = 0.063
	AT	0.7000	0.923	0.206				
Mukatalu shosha 0 – 2 N = 13	**BT**	0.8501	0.745	0.167	0.450	52.941%	2.714	P = 0.008
	AT	0.4000	0.503	0.112				
Karapada	**BT**	1.2001	1.152	0.258	0.400	33.333%	2.828	P = 0.008

daha 0 – 3 N = 12	**AT**	0.800 1	0.768	0.172				
Karapada suptata 0 - 2 N = 12	**BT**	1.150 2	0.988	0.221	0.450	39.130%	2.714	P = 0.004
	AT	0.700 0	0.801	0.179				
Shitilangata 0 – 3 N = 11	**BT**	1.000 1	1.076	0.241	0.400	40%	2.530	P = 0.008
	AT	0.600 0	0.821	0.184				
*** Wilcoxon signed rank test**								

Table no. 3 Overall effect of treatment

Remission	No. of patients	Percentage
Mild	5	25%
Moderate	10	50%
Good	4	20%
Excellent	1	5%

DISCUSSION:

Abhrakabhasmadi yoga is explained in *prameha roga adhikara* in *Yogaratanakara* and consists of *haritaki, vibhitaki, amalaka, hardira* and *abhraka bhasma*. All the 5 drugs, individually are *Pramehagna* as explained in the *samhithas* and various research studies[11-13] have proved their hypogycemic effect in diabetes.

Haritaki, Amalaki and *Vibhitaki* have *balya, rasayana* and *dhatuvardhaka* property, thus helps in rejuvenation of the cells and rectifying the *khavaigunya* in the *rogadhisthaana*. They are *tridoshahara* and help in rectifying *dosha dushti* and thus helps in *samprapti vighatana*. The *chakshushya* property of these 3 drugs may also benefit in preventing diabetic retinopathy. The *kaphahara* and *medohara* property of all the drugs, help in *kaphameda harana* and thus helps in removing *margavarana* in the *avaranaja* variety. *Hareetaki, vibhitaki* and *haridra* have *ruksha guna* thus is *kapha, medohara* helping in the *samprapti vightana*. *Hareetaki, vibhitaki* and *haridra* have *ushna virya* and thus helps in *vata kaphaharana* and reversal of *samprapti*. The *trishna nigraha karma* of *haritaki* is beneficial in managing *atitrusha* and *mukhatalushosha. Vibhitaki* has *dhatuvardaka* and *mutradoshagna* action. The *dahaprashamana karma* of *amalaka* is benficial in reducing *karapadadaha* and also *trushna*. Individual drugs of *triphala* contain glycosides, polyphenols, menthol, sorbitol alkaloids, terpenoids, flavonoids, carotenoids etc and these are all frequently implicated to possess potential as antidiabetic and antioxidants. Ellagic acid in *amalaki* exerts antidiabetic activity though the action on beta cells of pancreas that stimulates insulin secretion and decreases glucose intolerance. Its important constituents including gallic acid, gallotanin, ellagic acid and corilagin possess antidiabetic effects through their antioxidant and free radical scavenging peoperties. It has also been reported to prevent/reduce hyperglycemia, cardiac complications, diabetic nephropathy, neuropathy, cataractogenesis and protein wasting.

Haridra has *rasayana* and *balya* property necessary for the rectification of the *khavaigunya* in the disease. *Haridra* has a *tridoshashamaka* effect useful in all varieties of *Prameha*. *Haridra* also has a *mutrasangrahaniya* quality. *Haridra* is considered to be the best *agrya dravya* in *prameha*. Active ingredient

curcumin is said to be responsible for antidiabetic action, and this may be due to its potent ability to suppress oxidative stress and inflammation. It shows a beneficial role on the diabetes induced endothelial dysfunction and induces a down – regulation of nuclear factor – kappa B- a micro inflammatory molecule leading to pro-inflammatory states hypothesized to contribute to diabetes. Curcumin possesses a protective role against advanced glycation as well as collagen crosslinking and through this way, mitigates advanced glycation end products – induced complications of diabetes. Curcumin also reduces blood glucose and the levels of glycosylated haemoglobin through regulation of polyol pathway.

The presence of major and minor elements like Fe, Al, Si, Mg, Ca in *abhraka bhasma* may balance the minerals in the body which are very essential for diabetic patient, which are excreted through improper metabolism and excessive urination. The electrolytes like Ca, Mg present in *abhraka bhasma*, are very much essential to the diabetics. *Guru snigdha* properties of *abhraka bhasma* along with its *rasayana* effect helps in normalcy of *dhatus*. It may have synergetic effect with other drugs in the formulation and also it may mimic the action of insulin in *prameha*, because most of the formulations used in treatment of *prameha* have *abhraka* as one of the ingredients. *Abhraka* may cause regeneration of islet of langherhans and induce secretion of insulin from pancreas.

Conclusion:

It can be concluded with statistical evidence that the formulation *abhrakabhasmadi yoga* that was selected for the study to evaluate the therapeutic effect in *madhumeha*/ type 2 diabetes mellitus proved very efficient in reducing plasma glucose levels and symptoms of *madhumeha*.

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