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A COMPARATIVE STUDY OF EFFICACY OF *BHUDHATRAYADIYOG* AND METFORMIN IN THE MANAGEMENT OF *MADHUMEHA* W.S.R TO TYPE-2 DIABETES MELLITUS

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ABSTRACT

Diabetes Mellitus is becoming fastest considerable diseases in the World. India has being estimated with fastest growing population of Diabetics. Diabetes Mellitus is a metabolic disorder of carbohydrate, fat, & protein characterized by hyperglycemia with or without glycosuria. It is associated with long-term potentially catastrophic effects on almost all systems of the body. Diabetes mellitus is one of the leading causes of morbidity and mortality. Recent survey conducted by World Health Organization (W.H.O.) has revealed that the Indian diabetic population is 35 million and is estimated to touch 57.2 million by the year 2025 and 79.4 million by the year 2030. The modern management of Diabetes inspite of many advances still remains unsatisfactory. Drug intolerance, hypersensitivity and resistance to insulin, the danger of acute and chronic complications, the fear of hypoglycemic episodes with Sulphonyl Ureas makes it all more important to search out safe, effective and cheaper remedies. So, I have planned to study the efficacy of Bhudhatrayadiyog in Madhumeha (DM type-2). Other details will be described in full paper.

KEYWORDS: Diabetes Mellitus, Prameha, Madhumeha, Bhudhtrayadiyog, Metformin.

INTRODUCTION

Ayurveda is an ancient Indian system of medicine that has been continuously practiced for over 5000 years. Prevention and promotion of health as well as the treatment of diseases are the vital aspects that have been discussed in all the Ayurvedic Samhitas. Emphasis has been laid on the enhancement of natural immunity to prevent illness. Ayurveda follows a comprehensive approach to healthy living. Treatment of various types of physical, mental and spiritual illnesses have been described in a comprehensive individualistic and holistic manner by treating physical, mental and spiritual aspects.

Madhumeha can be correlated with Diabetes mellitus in modern science. *Madhumeha* is also called as a ***'Mahagada'*** (major disorder).

Diabetes Mellitus is a metabolic disorder of carbohydrate, fat, & protein characterized by hyperglycemia with or without glycosuria. It is associated with long-term potentially catastrophic effects on almost all systems of the body. These can manifest as minor annoyances at first but then insidiously destroy the cellular components of a given body part, organ, or entire system. DM is aggressively progressive and the prognosis is poor unless definite measures are taken to control the disease. At present, there is no known cure for DM and even with proper medical management; prognosis may still be poor due to irreversible major impairments or severe disabilities. It is most often treated with diet and exercise, typically in conjunction with oral hypoglycemic drugs (OHD's). Controlling the disease is paramount because there is no cure and the complications are so critical and hazardous. Oral hypoglycemic agents and insulin used for the treatment of diabetes mellitus by the allopathic system of medicine have numerous side effects. Ayurveda because of its holistic approach not only aims to achieve strict glycemic control but also treat the root cause of the disease.

Diabetes mellitus is one of the leading causes of morbidity and mortality. Recent survey conducted by World Health Organization (W.H.O.) has revealed that the Indian diabetic population is 35 million and is estimated to touch 57.2 million by the year 2025 and 79.4 million by the year 2030.

National urban diabetes study (NUDS) conducted recently in big cities of India has estimated the prevalence rate of diabetes mellitus in the adult

population as 12.1% and the prevalence rate of Impaired glucose tolerance (IGT), a pre-diabetic condition as 14%.

The above-mentioned figures point towards the alarming situation, which suggests that the incidence of diabetes mellitus is increasing among the general population. The top three countries for number of persons with diabetes are India, China and United States of America. India has now been declared by WHO as the Diabetes capital of the world.

Today, the mankind is living in an era of evolutionary explosion with greatest stress and strain than any time in the past. Technical and economical development has totally changed the lifestyle. Stress and strain leads to a large number of diseases including Madhumeha. Stress causes excess of circulating hormones (i.e glucagon) which leads to inappropriate elevation of blood glucose.

Conventional modern medicine provides a number of choices for controlling the blood sugar level in the patients of diabetes mellitus type-2. However, with the prolonged treatment, doses of the drugs often needs to be increased to control the blood sugar level; at the time there are limitations as regards to the side effects and a time comes when patient has to be switched over to insulin. Such patients become cases of insulin dependent diabetes mellitus. The modern management of Diabetes inspite of many advances still remains unsatisfactory. Drug intolerance, hypersensitivity and resistance to insulin, the danger of acute and chronic complications, the fear of hypoglycemic episodes with Sulphonyl Ureas makes it all more important to search out safe, effective and cheaper remedies. Ayurvedic classics have many references on herbal and herbo-mineral preparations, which can be safely used in controlling the blood sugar level of the patients of diabetes mellitus and also to delay or reduce the complications of the same highly increasing prevalence of Diabetes Mellitus.

Ayurveda accepts this disease as *Yapya* (Very difficult to cure) but effectively checks the ongoing pathogenesis of the disease. While studying this disease, we noticed the treatment advised by Acharya *Yogratnakar* in *Prameha Prakarana* ***Bhudhatrayadiyog*** – A combination of *Bhumyamalaki Swaras* with *Maricha Churna* is used as it acts on various factors in the *Samprapti* of *Madhumeha*. *Bhumyamalaki* is an Appetizer, Digestive, Hepatoprotective, Hypoglycemic, Laxative and Carminative. Maricha is Antioxidant, Hepatoprotective and Lipolytic. A combination of both these drugs has excellent results in the management of *Madhumeha*. It not only reduces the symptoms but also helps to check the pathology of the disease. Successful results encouraged to select this topic for research work.

This research work is just a prototype study in the pathway of solution of *Madhumeha* or Diabetes Mellitus. The trial has been made in the present study to make some new dimensions of treating *Madhumeha*. Present research work entitled **"A Comparative Study of Efficacy of *Bhudhatrayadiyog* and Metformin in the Management of *Madhumeha* W.S.R To Type-2 Diabetes Mellitus"** has been carried out and comparative assessment of results as improvement in subjective and objective criteria is done with the help of statistical methods.

In this research study total 60 patients with signs and symptoms of *Madhumeha* fulfilling inclusion and exclusion criteria were selected. They are divided into two groups of 30 each. Group A was treated with *Bhudhatryadiyog* and Group B was treated with Metformin. All the patients were treated for a period of 6 months.

MATERIALS AND METHODS

Material used
Bhumyamalaki Swaras
Maricha churna

Method of Preparation of Trial Drug Bhudhatrayadiyog
Preparation of trial drug is done in two stapes.

1) Identification & Collection of raw Drugs

- ***Bhumyamalaki***

Bhumyamalaki was identified by using its *Gundharma* in Classical text and collected from the Botanical Garden of the institute. Standardization of drug was done in an authorized pharmaceutical laboratory.

- ***Maricha Churna***

Maricha also were identified by using its *Gunadharma* in Classical text and then collected, from local Market.

2) Preparation of trial drug: (*Bhudhatrayadiyog*)
Ingredients
1. *Bhumyamalaki swaras* – 20ml
2. *Maricha* – 20 in number (approx 1gm powder)

Procedure
20ml of *Bhumyamalaki swaras* and *Churna* of 20 *Maricha* were taken and thoroughly mixed with each other till the mixture becomes homogenous. The mixture formed finally is in the form of '*Swaras*'.

Administration of *Bhudhatrayadiyog*
Freshly prepared *Bhudhatryadiyog* i.e 20ml of *Bhumyamalaki swaras* and *Churna* of 20 *Maricha* was given to the patient with lukewarm water in two divided doses (morning and evening).

Clinical Study
1. Research Study Centre
Total 60 patients fulfilling the criteria and attending *Kayachikitsa* OPD or IPD of the concerned institutional hospital were selected for research study.

2. Medium of Dissertation
Medium of dissertation is in English Language.

3. Sample Size
60 patients excluding dropped out were recruited after satisfying inclusion and exclusion criteria and divided in two groups to get data of 30 patients in each group.

4. Inclusion Criteria
- Patients of *madhumeha* diagnosed according to classical features like *prabhootmutrata, avilmutrata*, etc.
- Age: 16 years to 60 years
- Sex: Either sex
- Plasma sugar level between :
  Fasting - 110mg/dl to 200mg/dl
  Postprandial - 140mg/dl to 300mg/dl
- Recently diagnosed (<6 months) and old cases of type-2 DM not taking any other anti-hypoglycemic drugs.

5. Exclusion Criteria
- Patients suffering from IDDM (Insulin dependent diabetes mellitus)
- Patients suffering from Juvenile Diabetes or Gestational diabetes.
- Patients with complications of diabetes like diabetic ketoacidosis, diabetic coma, diabetic retinopathy, diabetic neuropathy and diabetic nephropathy.
- Patients suffering from other systemic diseases.
- Patients suffering from any current acute illness.
- Patients having congenital physiological anomalies, surgical interventions, any trauma.

6. Investigations
i) Blood sugar levels – Fasting and Postprandial
ii) Urine Sugar - Fasting and Postprandial are taken as major objective criteria.
iii) HbA1C (If required) Other routine investigations are done wherever necessary to rule out exclusion criteria of present study such as CBC, Thyroid profile, ECG etc.

7. Withdrawal
- Life threatening illness
- Adverse events
- Noncompliance to the study

Subjects were withdrawn from present study in above situation.

8. Randomization
As per lottery method of randomization, 60 patients were randomly divided in two groups –

Group A
30 patients of this group were treated by trial drug.
Yog – *Bhudhatrayadiyog*

Duration – 6 months

Matra – 20ml *Bhumyamalaki Swaras* with *Churna* of 20 *Maricha* in two divided doses (morning & evening) with lukewarm water

Route of administration – Oral

Group B
30 patients of this group were treated with METFORMIN

Yog – Metformin

Duration – 6 months

Matra – 500mg OD

Route of administration – Oral

9. Follow Up Study
Follow up of the study were carried out on 7^{th} day, 15^{th} day, 1 month, 2 months, 3 months, 6 months

12. Safety Assessment
All the ingredients used in the trial drug are in human use since thousands of years, hence they are considered safe.

13. Subject Confidentiality
The identity of subject was kept confidential except the study persons, Guide and ethical committee members. The data generated and recorded from trial was also kept confidential and in coded form.
(The ICF and CRF are attached in the Appendix)

14. Informed Consent
A well informed written consent of all patients, included in the study, had taken before starting treatment.

15. Case Record Form (C.R.F)
A detailed case taking form was specially designed according to protocol of the study encompassing all the aspects of the disease.

16. Assessement of the Therapy
Assessment was done on the basis of improvement in signs & symptoms.
Patient was assessed with subjective and objective parameters before & after the treatment and percentage relief obtained along with statistical evaluation.

- **Subjective Criteria**

1) *Prabhoota Mutrata* (Polyuria)
2) *Pipasa* (Polydypsea)
3) *Bahu ashee* (Increased Appetite)
4) *Alasya*
5) *Kara-pada-tala-daha/Supti*

- **Objective Criteria**

1) *Avila Mutrata* (Turbidity of urine)
2) *Mutra Madhurya* (Glycosuria)

3) FBS (mg/dl)
4) PPBS (mg/dl)

RESULT

Effect of therapy according to relief in Patients' score
Table 1: Relieved score and % relief in Patients' score.

Sr No	Group A				Sr No	Group B			
	B.T.	A.T.	Relieved	Relief %		B.T.	A.T.	Relieved	Relief %
1	9	6	3	33.33	**1**	8	2	6	75
2	10	8	2	20	**2**	11	2	9	81.81
3	13	8	5	38.46	**3**	11	4	7	63.64
4	12	8	4	33.33	**4**	8	3	5	62.5
5	9	5	4	44.44	**5**	11	6	5	45.45
6	10	8	2	20	**6**	9	3	6	66.67
7	8	5	3	37.5	**7**	6	2	4	66.67
8	14	13	1	7.14	**8**	14	7	7	50
9	9	6	3	33.33	**9**	16	9	7	43.75
10	9	7	2	22.22	**10**	9	3	6	66.67
11	13	6	7	53.85	**11**	8	1	7	87.5
12	10	8	2	20	**12**	9	3	6	66.67
13	14	10	4	28.57	**13**	10	4	6	60
14	13	6	7	53.85	**14**	11	7	4	36.36
15	5	3	2	40	**15**	9	3	6	66.67
16	7	4	3	42.86	**16**	8	1	7	87.5
17	9	8	1	11.11	**17**	9	3	6	66.67
18	11	8	3	27.27	**18**	10	2	8	80
19	14	9	5	35.71	**19**	12	3	9	75
20	12	6	6	50	**20**	10	5	5	50
21	11	5	6	54.55	**21**	7	3	4	57.14
22	9	6	3	33.33	**22**	8	2	6	75
23	11	7	4	36.36	**23**	12	6	6	50
24	11	9	2	18.18	**24**	14	4	10	71.43
25	7	5	2	28.57	**25**	8	0	8	100
26	5	3	2	40	**26**	7	4	3	42.86
27	11	8	3	27.27	**27**	10	2	8	80
28	10	7	3	30	**28**	11	5	6	54.55
29	14	8	6	42.86	**29**	10	2	8	80
30	14	9	5	35.71	**30**	9	4	5	55.56

The relieved symptom score and percent relief are mentioned in the Table No.1. This relief is calculated according to BT and AT total score of patients in each patient of both groups.

Effect of therapy according to relief in Symptoms' score
Table 2: Relieved score and %relief in Symptoms' score in Group A.

Sr. No.	Symptoms (Group A)	B.T.	A.T.	Relieved	% Relief
1	***Prabhut mutrata***	64	48	16	25
2	***Ati pipasa***	57	36	21	36.84
3	***Bahu ashee***	53	35	18	33.96
4	***Alasya***	53	37	16	30.19
5	***Kar pad daha***	42	27	15	35.71
6	***Kar pad supti***	45	26	19	42.22

Table 3: Relieved score and %relief in Symptoms score in Group B.

Sr. No.	Symptoms (Group B)	B.T.	A.T.	Relieved	% Relief
1	***Prabhut mutrata***	70	20	50	71.43

2	***Ati pipasa***	60	23	37	61.67
3	***Bahu ashee***	57	22	35	61.40
4	***Alasya***	56	21	35	62.5
5	***Kar pad daha***	26	9	17	65.38
6	***Kar pad supti***	26	10	16	61.54

The relieved symptom score and percent relief are mentioned in the Table No.2 and Table No.3. This relief is calculated according to BT and AT total symptom score of each symptom in both groups.

Total Effect of the Therapy

Table 4: Effect of therapy according to Patient's score.

Sr. No.	Cure	Criteria	No of patients	
			Group A	Group B
1	**Good Cure**	**75% - 100%**	0	10
2	**Moderate Cure**	**50% - 74%**	4	17
3	**Mild Cure**	**25% - 49%**	19	3
4	**Poor Cure**	**00% - 24%**	7	0

Among 30 patients of Group A, 4 patients have shown Moderate cure, 19 patients have shown Mild cure and 7 patients have shown Poor cure.

Among 30 patients of Group B, 10 patients have shown Good cure, 17 patients have shown Moderate cure and 3 patients have shown Mild cure.

It shows that Group B (i.e. Metformin) has shown overall good effect than Group B (i.e. *Bhudhatryadiyog*) to reduce score of patients.

According to Symptoms' score

Table 5: Effect of therapy according to Symptoms' score.

Sr. No.	Cure	Criteria	Group A		Group B	
			Symptoms	No	Symptoms	No
1	**Good Cure**	**75% - 100%**	---	**0**	---	**0**
2	**Moderate Cure**	**50% - 74%**	---	**0**	*Prabhuta mutrata, Ati pipasa, Bahu ashee, Alasya, Daha, Supti*	**6**
3	**Mild Cure**	**25% - 49%**	*Prabhuta mutrata, Ati pipasa, Bahu ashee, Alasya, Daha, Supti*	**6**	---	**0**
4	**Poor Cure**	**00% - 24%**	---	**1**	---	**0**

Among 4 symptoms of *Madhumeha* in Group A, all symptoms have shown Mild cure. Whether among 4 symptoms of *Madhumeha* in Group B, all symptoms have shown Moderate cure.

It shows that Group B (i.e. Metformin) has shown overall good effect than Group B (i.e. *Bhudhatryadiyog*) to reduce score of symptoms.

DISCUSSION

Discussion on Drug

As per Charakacharya some dravya acts through its Rasa, some acts through its Vipaka, Veerya, Guna and some through its Prabhava. The probable mode of action of the drug is better understood with the correlation with its diseases Sampraptibhanga, Doshashamak and Dhatu vruddhikara properties.

Bhumyamalaki have Tikta-kashaya-Madhura Rasa, Sheeta Virya, Madhura Vipaka and Laghu-Ruksha Guna. Maricha have Katu Rasa, Ushna Virya, Katu Vipaka and Laghu-Ruksha-Tikshna Guna.

Probable Mode of Action of Bhudhatrayadiyog

Samprapti Ghatak of *Prameha* are

1) *Durbalagni (Mandagni*)
2) Vitiated *Kapha Dosha*
3) Involvement of 7 *Dushya's* like *Meda*, *Lasika*, etc.
4) *Hetu's* of *Prameha* like *Atimadhur, Guru, Snigdha Ahara, Atinidra, Sukhasana* also vitiates the *Kapha dosha*.

Hence, *dravya* (medicines) having properties opposite to these are used for *Sampraptibhanga* of *Prameha*. *Bhudhatryadiyog* (*Bhumyamalaki* & *Maricha*) is having '*Katu-Tikta' Rasa*, which is known for its '*Kleda-shoshana', Medoghana* and *Lekhana karyas*. *Bhumyamalaki* having '*Tikta' Rasa* will do absorption i.e. *Shoshana of Kleda, Meda, Vasa, Majja, Pitta* and *Kapha*.

Due to *Tikshana, Ushna* and *Deepan Guna*, it works as a '*Agnideepan' Dravya* and helps in relieving *Agnimandya*. *Ayurveda* has described *Agnimandya* as the root cause of all the *Vyadhi's* (Diseases) in the body, hence *Agnideepan* is very must for *Sampraptibhanga*.

Bhudhatryadiyog has *Ruksha, Laghu*, and *Tikshna Guna* which in turn reduces *Guruta* and *Picchilata* of *Kapha* and *Meda Dhatu*. This action helps in *Kapha Shamana* and *Sampraptibhanga* of *Prameha*. In addition, 'Predominant *Madhur Vipaka*' plays a role in rejuvenation by *Rasayan karma*, nourishes *Dhatu's* and increases *Deha Bala.*

Due to *Tikta, Katu* and *Ushna Guna*, it expels the *Kaphadi Dosha* from *Srotas*. Thus, removes the obstructive vitiated *Dosha* from each and every *Srotas* of the body.

Overall, properties of *Bhudhatryadiyog* have a very important role in *Sampraptibhanga* of *Prameha*. It possesses qualities opposite to *Meda Dhatu* and *Tikshna* (most potent) in nature, predominant for increasing the ability of *Jatharagni*. This will increase the strength of *Pachakagni* leading to metabolism of *Meda* by *Lekhana* (scraping) action because of which *Prasarana* of *Meda* will be restricted.

CONCLUSION

After clinical trials, data collection – presentation and data analysis in the dissertation work **"A Comparative Study of Efficacy of *Bhudhatrayadiyog* And Metformin in the Management of *Madhumeha* W.S.R To Type-2 Diabetes Mellitus"**, here is time to conclude few inferences found from the study.

1. *Madhumeha* can be correlated with Diabetes Mellitus.
2. Prevalence of *Madhumeha* is increasing day by day.
3. Addiction to the pleasure of sedentary habits, sleep, curd, soup of the meat of domestic and aquatic animals and animal inhabiting marshy lands, milk preparations, freshly harvested food articles, freshly prepared alcoholic drinks, preparations of jaggery and all kapha-aggravating factors are responsible for *Madhumeha*.
4. *Madhumeha* is mostly prevalent in middle aged people (approximately 35 to 60).
5. Job holders, Housewives and Labors are found more prone to *Madhumeha*.
6. *Samprapti Ghatak* observed were

***Dosha* –** *Vata, Pitta, Kapha (Tridosha*)
***Dushya* –** *Meda, Rakta, Shukra, Vasa, Lasika, Majja, Rasa, Ojas, Mamsa.*
***Strotas* –** *Medovaha, Mutravaha, Udakavaha, Mamsavaha*
***Avastha* –** *Chirkari*

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9. Control group has shown overall good improvement in *Madhumeha* than Trial group.
10. Metformin effectively reduced the symptoms *Prabhuta Mutrata, Bahu Ashee* and *Alasya* in *Madhumeha* ($p<0.0001$).
11. *Bhudhatryadiyog* and Metformin are almost equally effective to reduce *Ati pipasa* in *Madhumeha*. Mean scores ($p=0.0264$) of both groups suggest that Metformin has better efficacy than *Bhudhatryadiyog*, but this difference is not greater than expected by chance.
12. *Bhudhatryadiyog* and Metformin are almost equally effective to reduce *Kar-pad-tal daha* in *Madhumeha*. Mean scores ($p=0.927$) of both groups suggest that *Bhudhatryadiyog* has better efficacy than Metformin, but this difference is not greater than expected by chance.
13. *Bhudhatryadiyog* and *Metformin* are almost equally effective to reduce *Kar-pad-tal supti* in *Madhumeha.* Mean scores ($p=0.360$) of both groups suggest that *Bhudhatryadiyog* has better efficacy than Metformin, but this difference is not greater than expected by chance.
14. Metformin is more effective than *Bhudhatryadiyog* to reduce Urine turbidity in *Madhumeha* ($p=0.0051$).

15. *Bhudhatryadiyog* and Metformin are almost equally effective to reduce USL fasting in *Madhumeha*. Mean score (p=0.730) of both groups suggest that Metformin has better efficacy than *Bhudhatryadiyog*, but this difference is not greater than expected by chance.
16. *Bhudhatryadiyog* and Metformin are almost equally effective to reduce USL-PP in *Madhumeha*. Mean score (p=0.214) of both groups suggest that Metformin has better efficacy than *Bhudhatryadiyog*, but this difference is not greater than expected by chance.
17. *Bhudhatryadiyog* and Metformin are almost equally effective to reduce BSL fasting in *Madhumeha*. Mean score (p=0.0338) of both groups suggest that Metformin has better efficacy than *Bhudhatryadiyog*, but this difference is not greater than expected by chance.
18. *Bhudhatryadiyog* and Metformin are almost equally effective to reduce BSL-PP in *Madhumeha*. Mean score (p=0.783) of both groups suggest that *Bhudhatryadiyog* has better efficacy than Metformin, but this difference is not greater than expected by chance.
19. Overall, by *Bhudhatryadiyog* 4 patients had moderate relief, 19 patients had mild relief and 7 patients had poor relief while by Metformin 10 patients had Good relief, 17 patients had moderate relief, 3 patients had mild relief and 0 patients had poor relief.
20. *Bhudhatryadiyog* is effective, safe, cost effective therapy to treat *Madhumeha* and prevents development of complications of *Madhumeha*.
21. No complications or adverse drug effects were observed during the study with both of the drugs.
22. *Madhumeha* (Diabetes Mellitus) can be treated effectively by *Ayurveda* along with hypoglycemic drugs to prevent complication of Diabetes.