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Research Article

A COMPARATIVE CLINICAL STUDY TO DETERMINE THE EFFICACY OF *BHUDHATRAYADI YOGA* AND METFORMIN IN THE MANAGEMENT OF *MADHUMEHA* W.S.R. TO TYPE II DIABETES MELLITUS

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ABSTRACT

Prameha is a chronic disease that is described in all the classics of *Ayurveda*. *Madhumeha* is categorised as a subtype of *Vataja Prameha. Vata Dosha* is mainly vitiated in *Madhumeha*. The patient passes large quantity of urine which is *Kashaya* (astringent), *Madhura* (sweet), *Pandu* (pale) and *Ruksha* (dry). *Madhumeha* is the final stage of all the *Prameha* when left untreated for long time which becomes difficult to treat. In modern medicine signs and symptoms of *Madhumeha* resembles Type II Diabetes Mellitus. Diabetes is a metabolic disease and is characterised by increase in blood glucose levels, deficiency of insulin or resistance to insulin uptake. 40 patients were selected from the IPD and OPD of Kayachikitsa Department of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Himachal Pradesh. 20 patients were managed with *Bhudhatrayadi Yoga* and 20 patients were managed with Tablet Metformin. *Bhudhatrayadi Yoga* showed moderate improvement in subjective parameters of *Madhumeha* in the study.

INTRODUCTION

Diabetes Mellitus is a metabolic disorder of multiple aetiology, characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. Long-term effects of Diabetes include organ deterioration, malfunction, and ultimately failure of organ. Chronic complications include the progressive development of retinopathy with potential blindness, nephropathy, diabetic foot ulcers, charcot joints and autonomic dysfunctions.[1] Diabetes is one of the top ten leading causes of death. India stands on the top of the world to have the largest number of Diabetic patients. 10.5% of adults (20–79 years) have diabetes, according to the IDF Diabetes Atlas (2021) and nearly half are completely ignorant that they have the disease.

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According to IDF predictions, 783 million adults, or one in eight, would have diabetes by 2045, a 46% rise.[2] Diabetes is a common condition, and its prevalence is increasing dramatically, the global public health is rapidly getting worse because of Diabetes and its complications. There is evidence of an epidemiological transition, with a higher prevalence of diabetes in low socioeconomic groups in the urban areas of the more economically developed states. The spread of diabetes to economically weak sections of society is a matter of great concern.[3] The global increase in diabetes is predicted because of population aging and because of increasing trends towards obesity, unhealthy diets and sedentary lifestyles.

Madhumeha is the sub-type of *Vataja Prameha* and is among one of the *Astamahagada* (eight difficult diseases to treat). The two main aetiological factors of *Madhumeha* described in *Charaka Samhita* are *Santarpana Janya (Avaranajanya/Apathya Nimitaja)* and *Aptarpana Janya (Sahaja/*hereditary). In *Madhumeha Bahudrava Shaleshma*, *Prakupit Pitta* along with *Vata Dosha* vitiates *Meda, Mansa, Vasa, Majja, Lasika* and ultimately carries *Oja* (essence of all the *Dhatu*) to *Basti* and through *Basti* essence of *Dhatus* are expelled out of the body. Another

pathological process where *Dhatvagnimandaya* hampers the *Dhatu Poshana* is an important step in the *Samprapti* of *Madhumeha. Dhatukshyajanya Madhumeha (Sahaja Prameha)* can be correlated with type I diabetes mellitus in modern medicine.

AIMS AND OBJECTIVES

- To evaluate the effect of an Ayurvedic formulation '*Bhudhatrayadi Yoga'* in the management of *Madhumeha* w.s.r. to Type II Diabetes Mellitus.
- To compare the efficacy of *Bhudhatrayadi Yoga* with Tablet Metformin in the management of *Madhumeha* w.s.r. to Type II Diabetes Mellitus.
- To evaluate the clinical safety and side effects of *Bhudhatrayadi Yoga.*

MATERIAL AND METHODS

Selection of the Patient

The patients were selected from the OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Dist. Kangra (H.P). 44 patients were selected randomly out of which 4 patients didn't come for follow up and were dropped from the study. 40 patients were divided into two groups 20 in each group.

Study Design

Study type - Randomised clinical trial
Blinding - Single blind
Timing - Prospective
Number of patients - 40 (20 in each group)
Number of Groups - 2
Duration of trial - 12 weeks
Follow up - After every 4 weeks

Diagnostic Criteria

The patients were diagnosed on the basis of:

1) Clinical signs and symptoms as described in classical texts.
2) Clinical signs and symptoms as described in modern literature.

Blood Sugar Levels

- Fasting (F.B.S.) >126 mg/dl
- Post prandial (PPBS) >200 mg/dl.
- HbA1c > 6.5%

Inclusion Criteria

1. Patients willing to participate in the trial.
2. Patients between the age group of 30-65 yrs were selected for the study.
3. Patients who presented with signs and symptoms of *Madhumeha* as described in classical texts and fulfilled the diagnostic criteria.
4. Patients having Blood sugar levels of
   F.B.S. - 150 to 250 mg/dl
   P.P.B.S. - 200- 350 mg/dl
   HbA1c - 6.5% to 8%

Exclusion Criteria

1. Patients below the age of 30yrs and above the age of 65yrs.
2. Patients with Type I and gestational diabetes.
3. Patients who had complications of diabetes like nephropathy, renal disease, retinopathy or cardiac disease.
4. Patients suffering from other major illness like CA or P.T.B. or any other condition were considered unfit for enrolment in the trial.

Grouping of Patients

40 patients were selected randomly and were divided into two groups (Group-I, Group-II) 20 in each group. Patients of Group I were managed with *Bhudhatrayadi Yoga*, Patients of Group II were managed with Tablet Metformin.

Trial drugs

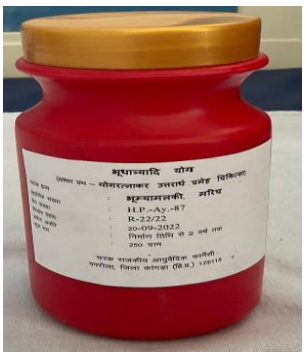
1. ***Bhudhatrayadi Yoga***
   Drug Dosage: 6g twice a day
   Route of administration: Oral
   ***Anupana*:** Lukewarm water
2. **Tablet Metformin**
   Drug Dosage: 1000 mg once a day
   Route of administration: Oral
   Anupana: Water

Table 1: Trial Drug Composition

S.No.	Ingredients	Botanical Name	Family Name	Part used	Part
1.	*Bhoomayamlaki*	*Phyllanthus niruri* (Linn.)	Phyllanthaceae	Whole part	11gm
2.	*Maricha*	*Piper nigrum* (Linn.)	Piperaceae	Fruit	20 in no. (approx. 1gm)

Maricha

Bhoomyamlaki (Panchanga)



Prepared Drug (*Bhudhatrayadi Yoga*)

Criteria of Assessment

Subjective Criteria

1. Patients were assessed on the basis of various clinical features described in Ayurvedic and modern literature.
2. The scoring/grading system was adopted for the assessment of subjective parameters.

Grading

Table 2: *Prabhuta Mutrata* (Polyuria)

Prabhuta Mutrata	**Grade**
3-5 times per day, rarely at night	0
6-8 times per day, 0-2 times at night	1
9-11 times per day, 3-4 times at night	2
>11 times per day, >4 times at night	3

Table 2.1: *Avila Mutrata* (Discoloured/turbid urine)

Avila Mutrata	**Grade**
Crystal Clear fluid	0
Faintly cloudy or smoky (turbidity barely visible)	1
Turbidity clearly present	2
Highly turbid	3

Table 2.2: *Pipasa- Adhikya* (Increased Thirst)

Pipasa- Adhikya	**Grade**
Normal thirst	0
Feeling of moderate thirst (>9-11 times/24 hrs.) & relieved by drinking water	1
Feeling of excess thirst (>11-13 times/24 hrs.) not relieved by drinking water	2
Feeling of severe thirst (>13 times/24 hrs.) not relieved by drinking water	3

Table 2.3: *Kshuda-adhikya* (Increased Appetite); (1 meal= about 350gm diet)

Kshuda-Adhikya	**Grade**
As usual/Routine	0
Slightly Increased (1 meal extra with routine diet)	1
Moderately Increased (2 meals extra with routine diet)	2
Markedly Increased (3 meals extra with routine diet)	3

Table 2.4: *Karapada Daha* (Burning sensation in hand and feet)

Karapada Daha	**Grade**
No *Daha.*	0
Karapada Daha found occasionally, mild bearable.	1
Karapada Daha continuous but bearable and not severe.	2
Karapada Daha continuous and severe and unbearable.	2

Table 2.5: *Swedadhikya* (Perspiration)

Swedadhikya	**Grade**
Sweating after heavy work and fast movement or in hot weather	0
Profuse sweating after moderate work and movement	1
Sweating after little work and movement (Stepping ladder etc.)	2
Profuse sweating after little work and movement	2

Table 2.6: *Galatalusosha* (Dryness of palate & throat)

Galatalusosha	**Grade**
None	0
Mild	1
Moderate	2
Severe	2

Table 2.7: *Madhurasyata* (Feeling sweetness in mouth)

Madhurasyata	**Grade**
None	0
Mild	1
Moderate	2
Severe	3

Table 2.8: *Karapadasuptata* (Numbness)

Karapadasuptata	**Grade**
No *Karapadasuptata*	0
Hasta-Pada-Tala Daha found occasionally, mild bearable.	1
Hasta-Pada-Tala Daha continuous but bearable & not severe	2
Hasta-Pada-Tala Daha continuous and severe & unbearable	3

Table 2.9: *Shithilangata* (Fatigue)

Shithilangata	**Grade**
None	0
Mild fatigue	1
Moderate fatigue	2
Severe fatigue	3

Objective criteria: FBS, PPBS, HbA1c

However, HbA1c was done only at the commencement of trial and at the end of trial.

Other Investigations done:

- Haematological: Hb%, TLC, DLC, ESR.
- Biochemistry: Blood urea, Serum creatinine, Serum Lipid profile, SGOT, SGPT.
- Urine: Routine, Microscopic.

Final Assessment of Results

Statistical Analysis: Data obtained during the trial was tabulated and statistically analysed using Student Paired 't' Test. The results were considered significant or insignificant on the basis of value of 'p'-

- Highly significant $p < 0.001$
- Significant $p < 0.05$
- Insignificant $p > 0.05$

Overall effect of subjective parameters was evaluated on the basis of following criteria

- Marked improvement: 91-100%
- Moderate improvement: 75-90%
- Mild improvement: 26-74%
- No improvement: 0-25%

OBSERVATIONS AND RESULTS

Among 44 registered patients 59% of patients were male and 41% were female. Maximum patients i.e., 31.8% were in the age group of 61-65 years, followed by 22.7% in the age group of 56-60 years, 18.1% in the age group of 41-45 years, 9% were in the age group of 46-50 years and 6.8% were in the age group of 30-35 years. All the patients i.e., 100% were married and of Hindu religion. Most of the patients i.e., 84% were residents of rural area and 16% were from urban area. Education wise 34% were matriculate followed by 32% who had education upto primary level, 23% were illiterate, 9% were graduate and 2% were post graduate. Based on occupation 34% were businessmen/businesswomen followed by 27% who were homemakers, 23% were farmers and 16% were in government jobs. The majority of the patients i.e., 66% were above poverty line and 34% were below poverty line. Maximum patients i.e., 61% used to consume a mixed diet and the rest 39% were vegetarian. Addiction wise 41% had no addiction to smoking and alcohol, followed by 27% who were addicted to smoking and 16% who were addicted to alcohol only and 16% were addicted to both smoking

and alcohol. The majority of the patients i.e., 77% had sedentary lifestyle and the rest 23% had active lifestyle. Maximum patients i.e., 73% had sound sleep and 27% had disturbed sleep. The majority of the patients i.e., 64% had normal thirst and the rest 36% had increased thirst. Maximum patients i.e., 68% had normal appetite and the rest 32% had increased appetite. The majority of the patients i.e., 66% had regular bowel habits, followed by 16% who had irregular bowels habit, 11% who had constipation and 7% who use to have loose stools. Maximum patients i.e., 48% had normal bladder habit, followed by 39% who had polyuria, 11.3% who had burning micturition and the rest 2.2% had scanty micturition. *Prakriti* wise 43% had *Pitta-Kaphaja Prakriti*, followed by 34% who had *Vata-Kaphja Prakriti* and the rest 23% had *Vata-Pittaja Prakriti.*Maximum patients i.e., 75% were in the BMI in the range of 20-24.9kg/m^2, followed by 22.2% in the BMI in the range of 25-30kg/m^2 and only 2.2% had BMI range >30kg/m^2.

Table 3: Incidence of signs and symptoms of Type 2 Diabetes Mellitus in 44 patients

S.No.	Symptoms	Gr. I		Gr. II		Total	
		Pt.	%	Pt.	%	Pt.	%
1.	*Prabhuta Mutrata*	11	50%	13	59.%	24	54.5%
2.	*Avila Mutrata*	8	36.3%	5	22.7%	13	29.5%
3.	*Pipasa-Adhikya*	6	27.2%	5	22.7%	11	25%
4.	*Kshudha-Adhikya*	6	27.2%	6	27.2%	12	27.2%
5.	*Karapadadaha*	10	45.4%	9	40.9%	19	43.1%
6.	*Swedadhikya*	7	31.8%	6	27.2%	13	29.5%
7.	*Galatalusosha*	5	22.7%	8	36.3%	13	29.5%
8.	*Madhurasya*	0	0	0	0	0	0%
9.	*Karapadasuptata*	7	31.8%	5	22.7%	12	27.2%
10.	*Shithilangata*	6	27.2%	6	27.2%	12	27.2%

Out of 44 registered patients, *Prabhuta Mutrata* was observed in 54.5% patients, *Karapadaha* was observed in 43.1% *Swedadhikya*, *Avila Mutrata* and *Galatalusosha* were observed in 29.5%, *Kshudha Adhikya, Karapadasuptata, Shithilangata* were observed in 27.2%, 25% showed *Pipasa Adhikya* and none of the patient showed *Madhurasyta*.

Table 4.1: Effect of Therapy on subjective parameters of *Madhumeha*

S.No.	Symptoms	Group	N	Mean		% relief		SD ±	SE±	't'	P value	Significance
				BT	AT	Diff.	%					
1.	*Prabhuta Mutrata*	**GP-I**	20	0.800	0.350	0.450	56.2%	0.510	0.114	3.943	<0.001	HS<0.001
		GP-II	20	0.900	0.150	0.750	83.3%	0.786	0.176	4.265	<0.001	HS (<0.001)
2.	*Avila Mutrata*	**GP-I**	20	0.400	0.200	0.200	50%	0.410	0.091	2.179	0.042	S<0.05)
		GP-II	20	0.300	0.100	0.200	66.6%	0.410	0.091	2.179	0.042	S(<0.05)
3.	*Pipasaadhikya*	**GP-I**	20	0.350	0.150	0.200	57.1%	0.410	0.091	2.179	0.042	S(<0.05)
		GP-II	20	0.250	0.050	0.200	80%	0.410	0.091	2.179	0.042	S(<0.05)
4.	*Kshuda-adhikya*	**GP-I**	20	0.350	0.150	0.200	57.1%	0.410	0.091	2.179	0.042	S(<0.05)
		GPII	20	0.450	0.200	0.250	55.5%	0.444	0.099	2.517	0.021	S(<0.05)
5.	*Karapada-daha*	**GP-I**	20	0.750	0.500	0.250	33.3%	0.444	0.099	2.517	0.021	S(<0.05)
		GP-II	20	0.700	0.350	0.350	50%	0.58	0.131	2.666	0.015	S(<0.05)
6.	*Swedadikya*	**GP-I**	20	0.350	0.150	0.200	57.1%	0.410	0.091	2.179	0.042	S(<0.05)
		GP-II	20	0.400	0.250	0.150	37.5%	0.366	0.081	1.831	0.083	IS(>0.05)
7.	*Galatalu sosha*	**GP-I**	20	0.350	0.150	0.200	57.1%	0.410	0.091	2.179	0.042	S(<0.05)
		GP-II	20	0.550	0.300	0.250	45.4%	0.550	0.123	2.032	0.055	IS(=0.05)

8.	*Madhura-asyta*	**GP-I**	20	0.0	0.0	0.0	0%	0.0	0.0	0.0	1.0	IS(>0.05)
		GPII	20	0.0	0.0	0.0	0%	0.0	0.0	0.0	1.0	IS(>0.05)
9.	*Karapada-suptata*	**GP-I**	20	0.500	0.300	0.200	40%	0.410	0.091	2.179	0.042	S(<0.05)
		GP-II	20	0.250	0.050	0.200	80%	0.410	0.091	2.179	0.042	S(<0.05)
10	*Shithila-angata*	**GP-I**	20	0.350	0.150	0.200	57%	0.410	0.091	2.179	0.042	S<0.05
		GP-II	20	0.400	0.100	0.300	75%	0.571	0.128	2.349	0.030	S(<0.05)

Effect of therapy on *Prabhuta Mutrata* (Polyuria)

The mean score of *Prabhuta Mutrata* before treatment was 0.800 and after treatment it came down to 0.350 giving 56.2% reduction in the mean score in group I. In group II the mean score before treatment was 0.900 and after treatment it came down to 0.150 giving 83.3% reduction in mean score. The result was statistically highly significant in both groups (p<0.001). (Table 4.1)

Effect of therapy on *Avila Mutrata* (Discolored urine)

The mean score of *Avila Mutrata* before treatment was 0.400 and after treatment it came down to 0.200 giving 50% reduction in the mean score in group I. In group II the mean score before treatment was 0.300 and after treatment it came down to 0.100 giving 66.6% reduction in mean score. The result was statistically significant in both groups (p<0.05). (Table No. 4.1)

Effect of therapy on *Pipasa-adhikya* (Polydipsia)

The mean score of *Pipasa-adhikya* before treatment was 0.350 and after treatment it came down to 0.150 giving 57.1% reduction in the mean score in group I. In group II the mean score before treatment was 0.250 and after treatment it came down to 0.050 giving 80% reduction in the mean score. The result was statistically significant in both groups (p<0.05). (Table No. 4.1)

Effect of therapy on *Kshuda-adhikya* (Polyphagia)

The mean score of *Kshuda-adhikya* before treatment was 0.350 and after treatment it came down to 0.150 giving 57.1% reduction in the mean score in group I. In group II the mean score before treatment was 0.450 and after treatment it came down to 0.200 giving 55.5% reduction in the mean score. The result was statistically significant in both groups (p<0.05). (Table No. 4.1)

Effect of therapy on *Karapadadaha* (burning sensation in hands and feet)

The mean score of *Karapadadaha* before treatment was 0.750 and after treatment it came down to 0.500 giving 33.3% reduction in the mean score in group I. In group II the mean score before treatment was 0.700 and after treatment it came down to 0.350 giving 50% reduction in the mean score. The result was statistically significant in both groups (p<0.05). (Table No. 4.1)

Effect of therapy on *Swedadhikya* (Excessive Sweating)

The mean score of *Swedadhikya* before treatment was 0.350 and after treatment it came down to 0.150 giving 57.1% reduction in the mean score in group I, which was statistically significant (p<0.05). In group II the mean score before treatment was 0.400 and after treatment it came down to 0.250 giving 37.5% reduction in mean score, which was statistically insignificant (p>0.05). (Table No. 4.1)

Effect of therapy on *Galatalusosha* (Dryness in oral cavity)

The mean score of *Galatalusosha* before treatment was 0.350 and after treatment it came down to 0.150 giving 57.1% reduction in the mean score in group I, which was statistically significant (p<0.05). In group II the mean score before treatment was 0.550 and after treatment it came down to 0.300 giving a 45.4% reduction in mean score, which was statistically insignificant (p>0.05). (Table No. 4.1)

Effect of therapy on *Madhurasya* (Sweetness in mouth)

None of the patients presented with the symptoms of *Madhurasya*, hence no calculations were made. (Table No. 4.1)

Effect of therapy on *Karapadasuptata* (Numbness)

The mean score of *Karapadasuptata* before treatment was 0.500 and after treatment, it came down to 0.300 giving 40% reduction in the mean the score in group I. In group II the mean score before treatment was 0.250 and after treatment it came down to 0.050 giving 80% reduction in the mean score. The result was statistically significant in both groups (p<0.05). (Table No. 4.1)

Effect of therapy on *Shithilangata* (Fatigue)

The mean score of *Shithilangata* before treatment was 0.350 and after treatment it came down to 0.150 giving 57% reduction in the mean score in group I. In group II the mean score before treatment was 0.400 and after treatment it came down to 0.100 giving 75% reduction in mean score. The result was statistically significant in both groups (p<0.05). (Table No. 4.1)

Intergroup Comparison of Subjective Parameters

The intergroup testing among two groups was done using unpaired t- test. The results were as follows-

Table 4.2: Inter group comparison of effect of therapy on *Prabhuta Mutrata*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	P value	Significance
GP I vs II	G-I	56.2%	-27.1	0.435	0.137	-1.431	0.161	IS (>0.05)
	G-II	83.3%						

The difference was statistically insignificant between group I & group II.

Table 4.3: Inter group comparison of effect of therapy on *Avila Mutrata*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	50%	-16.6	0.312	0.098	0.00	1.0	IS (>0.05)
	G-II	66.6%						

The difference was statistically insignificant between group I & group II.

Table 4.4: Inter group comparison of effect of therapy on *Pipasa Adhikya*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	57.1%	-22.9	0.332	0.105	-0.370	0.71	IS (>0.05)
	G-II	80%						

The difference was statistically insignificant between group I & group II.

Table 4.5: Inter group comparison of effect of therapy on *Kshudha-adhikya*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	57.1%	1.6	0.280	0.088	-0.370	0.71	IS (>0.05)
	G-II	55.5%						

The difference was statistically insignificant between group I & group II.

Table 4.6: Inter group comparison of effect of therapy on *Karapada Daha*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	33.3%	-16.7	0.413	0.130	-0.607	0.54	IS (>0.05)
	G-II	50%						

The difference was statistically insignificant between group I & group II.

Table 4.7: Inter group comparison of effect of therapy on *Swedadhikya*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	57.1%	19.6	0.205	0.064	0.406	0.68	IS (>0.05)
	G-II	37.5%						

The difference was statistically insignificant between group I & group II.

Table 4.8: Inter group comparison of effect of therapy on *Galatalusosha* (Dryness in mouth)

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	57.1%	11.7	0.423	0.133	-0.326	0.74	IS (>0.05)
	G-II	45.4%						

The difference was statistically insignificant between group I & group II.

Madhurasya- None of patients had presented with the symptoms of *Madhurasya*, hence no calculations were made.

Table 4.9: Inter group comparison of effect of therapy on *Karapadasuptata*

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	40%	-40	0.256	0.081	0.00	1.0	IS (>0.05)
	G-II	80%						

The difference was statistically insignificant between group I & group II.

Table 5.0: Inter group comparison of effect of therapy on *Shithilangata*

Comparison	% of Change		Diff. Of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	57%	-18	0.312	0.098	-0.623	0.54	IS (>0.05)
	G-II	75%						

The difference was statistically insignificant between group I & group II.

Table 6: Effect of Therapy on Objective Parameters of *Madhumeha*

S.No	Objective Criteria	Group	Mean		% relief		SD±	SE±	't'	p value	Significance
			BT	AT	Diff.	%					
1.	FBS	GP-I	192.700	172.800	19.900	10.32%	14.906	3.333	5.970	<0.001	HS (<0.001)
		GP-II	189.250	148.850	40.400	21.3%	12.167	2.721	14.849	<0.001	HS (<0.001)
2.	PPBS	GP-I	252.200	228.750	23.450	9.29%	8.829	1.974	11.879	<0.001	HS (<0.001)
		GP-II	224.150	186.7	37.450	16.7%	27.084	6.056	6.184	<0.001	HS (<0.001)
3.	HbA1C	GP-I	7.335	6.830	0.505	6.8%	0.233	0.052	9.702	<0.001	HS (<0.001)
		GP-II	7.130	6.400	0.730	10.2%	0.367	0.082	8.890	<0.001	HS (<0.001)
4.	Blood Urea	GP-I	24.650	24.600	0.050	0.20%	2.911	0.651	0.0768	0.940	IS (>0.05)
		GP-II	23.950	23.750	0.200	0.8%	4.873	1.090	0.184	0.856	IS (>0.05)
5.	Serum Creatinine	GP-I	0.865	0.860	0.005	0.57%	0.136	0.030	0.165	0.871	IS (>0.05)
		GP-II	0.870	0.865	0.005	0.5%	0.211	0.047	0.106	0.917	IS (>0.05)
6.	SGOT	GP-I	34.450	31.750	2.700	7.8%	5.695	1.273	2.120	0.047	S (<0.05)
		GP-II	32.450	31.800	0.650	2.0%	2.961	0.662	0.982	0.339	IS (>0.05)
7.	SGPT	GP-I	33.300	30.600	2.700	8.1%	5.555	1.242	2.174	0.043	S (<0.05)
		GP-II	30.550	30.100	0.450	1.4%	5.491	1.228	0.366	0.718	IS (>0.05)
8.	Serum Cholesterol	GP-I	195.100	189.100	6.000	3.0%	13.738	3.072	1.953	0.066	IS (>0.05)
		GP-II	181.2	176.5	4.700	2.5%	9.857	2.204	2.132	0.046	IS (>0.05)
9.	Serum Triglycerides	GP-I	154.700	150.800	3.900	2.5%	14.142	3.162	1.233	0.232	IS (>0.05)
		GP-II	158.8	155.7	3.100	1.9%	9.095	2.034	1.524	0.144	IS (>0.05)
10.	Serum LDL	GP-I	126.800	124.800	2.00	1.5%	14.882	3.328	0.601	0.555	IS (>0.05)
		GP-II	103.6	101.4	2.25	2.1%	12.594	2.816	0.799	0.434	IS (>0.05)
11.	Serum HDL	GP-I	45.150	46.000	-0.850	-1.88%	2.961	0.662	-1.284	0.215	IS (>0.05)
		GP-II	39.500	40.400	-0.900	-2.27%	2.100	0.470	-1.917	0.07	IS (>0.05)
12.	Serum VLDL	GP-I	30.850	30.050	0.800	2.59%	3.874	0.866	0.923	0.367	IS (>0.05)
		GP-II	18.850	18.350	0.500	2.6%	4.525	1.012	0.494	0.627	IS (>0.05)
13.	Haemoglobin	GP-I	11.735	11.655	0.0800	0.68%	0.530	0.118	0.675	0.508	IS (>0.05)

		GP-II	12.345	12.250	0.095	0.76%	0.637	0.142	0.667	0.513	IS (>0.05)
14.	ESR	GP-I	14.200	14.100	0.100	0.70%	2.490	0.557	0.180	0.859	IS (>0.05)
		GP-II	9.350	9.200	0.150	1.6%	3.731	0.834	0.180	0.859	IS (>0.05)
15.	TLC	GP-I	6724.0	67120	12.0	0.17%	898.7	179.7	0.066	0.947	IS (>0.05)
		GP-II	8265	8225	40	0.48%	0.793	0.177	0.226	0.824	IS (>0.05)
16.	Neutrophils	GP-I	68.100	67.800	0.300	0.44%	3.854	0.862	0.348	0.732	IS (>0.05)
		GP-II	65.295	65.040	0.255	0.39%	4.256	0.952	0.268	0.792	IS (>0.05)
17.	Lymphocytes	GP-I	33.550	33.300	0.250	0.74%	3.462	0.774	0.323	0.750	IS (>0.05)
		GP-II	35.095	35.000	0.095	0.27%	5.826	1.303	0.072	0.943	IS (>0.05)
18.	Monocytes	GP-I	5.300	5.275	0.025	0.47%	2.042	0.457	0.054	0.957	IS (>0.05)
		GP-II	3.550	3.545	0.005	0.14%	1.319	0.295	0.0169	0.987	IS (>0.05)
19.	Mixed Cells	GP-I	6.225	6.185	0.040	0.64%	1.790	0.400	0.099	0.921	IS (>0.05)
		GP-II	3.550	3.545	0.005	0.14%	1.319	0.295	0.016	0.987	IS (>0.05)
20.	Urine Sugar	GP-I	0.550	0.300	0.200	40%	0.410	0.091	2.179	0.042	S (<0.05)
		GP-II	0.800	0.300	0.500	62.5%	0.761	0.170	2.939	0.008	S (<0.05)
21.	Epithelial Cells	GP-I	0.800	0.500	0.300	37.5%	0.571	0.128	2.349	0.030	S (<0.05)
		GP-II	0.800	0.400	0.400	50%	0.940	0.21	1.902	0.072	IS (>0.05)
22.	Pus Cells	GP-I	1.250	0.800	0.450	36%	2.651	0.759	0.170	0.016	S (<0.05)
		GP-II	1.100	0.850	0.250	22.7%	0.639	0.143	1.751	0.096	IS (>0.05)

Effect of Therapy on Fasting Blood Sugar

The mean score of Fasting Blood Sugar before treatment was 192.7 and after treatment it came down to 172.8 giving 10.3% reduction in the mean score in group I. In group II the mean score before treatment was 189.2 and after treatment it came down to 148.8 giving 21.3% reduction in mean score. The result was statistically highly significant in both groups (p<0.001). (Table No. 6)

Effect of Therapy on Post Prandial Blood Sugar

The mean score of Post Prandial Sugar before treatment was 252.2 and after treatment it came down to 228.7giving 9.2% reduction in the mean score in group I. In group II the mean score before treatment was 224.1 and after treatment it came down to 186.7 giving 16.7% reduction in mean score. The result was statistically highly significant in both groups (p<0.001). (Table No. 6)

Effect of Therapy on Glycosylated Haemoglobin

The mean score of Post Glycosylated Haemoglobin before treatment was 7.335 and after treatment it came down to 6.830 giving 6.8% reduction in the mean score in group I. In group II the mean score before treatment was 7.130 and after treatment it came down to 6.400 giving 10.2% reduction in mean score. The result was statistically highly significant in both groups (p<0.001). (Table No. 6)

Effect of Therapy on SGOT

The mean score of SGOT before treatment was 34.450 and after treatment it came down to 31.750 giving 7.8% reduction in the mean score in group I, which is statistically significant (p<0.05). In group II the mean score before treatment was 32.450 and after treatment it came down to 31.800 giving a 2.0% reduction in the mean score, which was statistically insignificant (p>0.05). (Table No. 6)

Effect of Therapy on SGPT

The mean score of SGPT before treatment was 33.300 and after treatment it came down to 30.600 giving 8.1% reduction in the mean score in group I, which was statistically significant (p<0.05). In group II the mean score before treatment was 30.550 and after treatment it came down to 30.100 giving 1.4% reduction in the mean score, which was statistically insignificant (p>0.05). (Table No. 6)

Effect of Therapy on Urine sugar

The mean score of Urine Sugar before treatment was 0.550 and after treatment it came down to 0.300 giving 40% reduction in the mean score in group I. In group II the mean score before treatment

was 0.800 and after treatment it came down to 0.300 giving 62.5% reduction in the mean score. The result was statistically significant in both groups (p<0.05). (Table No. 6)

Effect of Therapy on Epithelial Cells in Urine

The mean score of Epithelial cells in urine before treatment was 0.800 and after treatment it came down to 0.500 giving 37.5% reduction in the mean score in group I, which was statistically significant (p<0.05). In group II the mean score before treatment was 0.800 and after treatment it came down to 0.400 giving 50% reduction in the mean score which was statistically insignificant (p>0.05). (Table No. 6)

Effect of Therapy on Pus Cells in Urine

The mean score of Pus cells in urine before treatment was 1.250 and after treatment it came down to 0.800 giving 36% reduction in the mean score in group I, which was statistically significant (p<0.05). In group II the mean score before treatment was 1.100 and after treatment it came down to 0.850 giving 22.7% reduction in the mean score which was statistically insignificant (p>0.05). (Table No. 6)

Rest of the Objective Parameters i.e. Haemoglobin, Differential Leukocyte Count, Total Leukocyte Count, E.S.R., Blood Urea, Serum Creatinine, Serum Lipid Profile, were within normal range before and after the treatment therapy and showed statistically insignificant results in Group I and Group II.

Intergroup Comparison on Objective Parameters

The intergroup comparison between two groups was done using unpaired t- test. The results were as follows-

Table 7.1: Intergroup comparison of effect of therapy on FBS

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	10.3%	-11	10.311	3.260	-4.765	<0.001	HS (<0.001)
	G-II	21.3%						

The difference was statistically highly significant (p<0.001) between group I & group II.

Table 7.2: Intergroup comparison of effect of therapy on PPBS

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	9.2%	-7.5	19.849	6.276	- 2.198	0.03	S (<0.05)
	G-II	16.7%						

The difference was statistically significant (p<0.05) between group I & group II.

Table 7.3: Intergroup comparison of effect of therapy on HbA1c

Comparison	% of Change		Diff. of Percentage Relief	SD	SE	't'	p value	Significance
GP I vs II	G-I	6.8%	-3.4	0.283	0.089	-2.314	0.02	S (<0.05)
	G-II	10.2%						

The difference was statistically significant (p<0.05) between group I & group II.

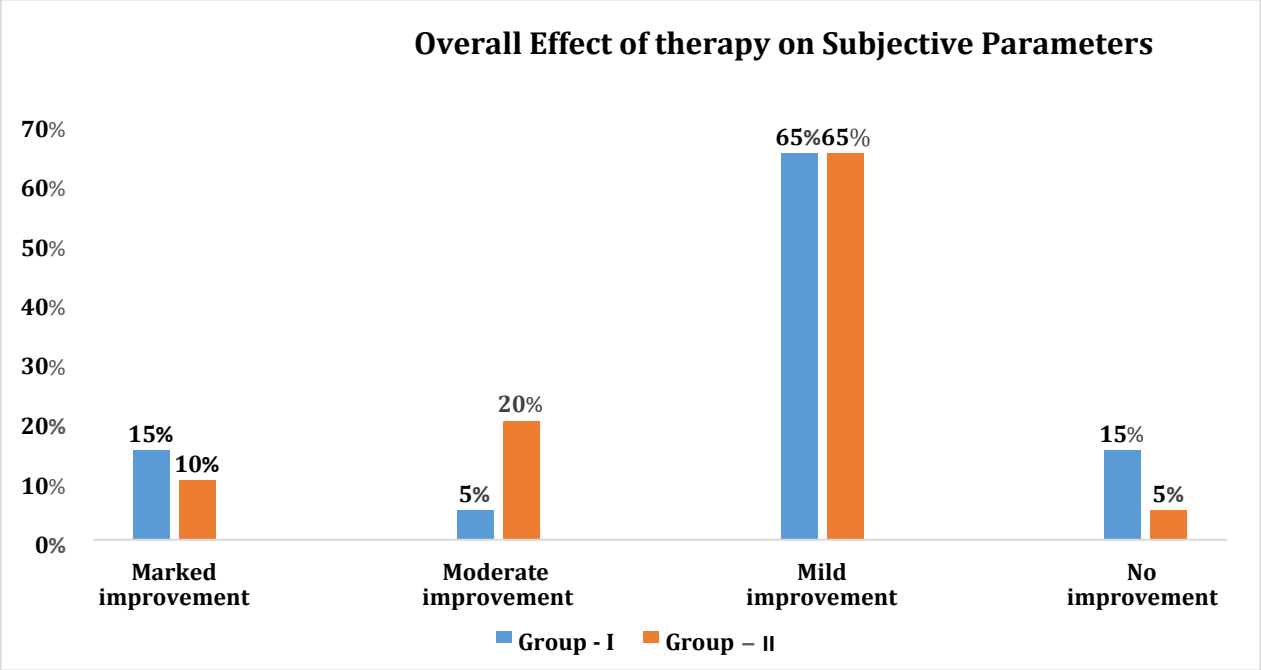
Rest of the objective parameters i.e., haemoglobin, differential leukocyte count, total leukocyte count, E.S.R., SGOT, SGPT, blood urea, serum creatinine, serum lipid profile, sugar in urine, pus and epithelial cells in urine showed statistically insignificant difference between group I and II.

Table 8: Overall Effect of Therapy on Subjective Parameters

S.No.	Improvement	Group - I	Group – II
1.	Marked improvement (91-100%)	3 (15%)	2 (10%)
2.	Moderate improvement (75-90%)	1(5%)	4 (20%)
3.	Mild improvement (26-74%)	13 (65%)	13(65%)
4.	No improvement (0-25%)	3 (15%)	1 (5%)

In Group I: 3 Patients showed marked improvement, 1 patient had moderate improvement, 13 patients had mild improvement and 3 patients had no improvement.

In Group II: 2 Patients showed marked improvement, 4 patients had moderate improvement, 13 patients had mild improvement and 1 patient had no improvement.



Bar Diagram 1.0

DISCUSSION

भूधात्री च त्रिगद्याणं मरिचानां च विन्शति: ।
असाध्यान्साधयेन्मेहान्सप्तरात्रान्न संशयः।।

(योगरत्नाकर उत्तरार्ध -प्रमेह चिकित्सा)

The present trial drug was taken from *Prameha Chikitsa* mentioned in *Yogaratanakara*.

Table 9: Properties of *Bhudhatrayadi Yoga*

S.No.	Drug	*Rasa*	*Guna*	*Veerya*	*Vipaka*	*Doshghanata*
1.	*Bhoomayamlaki*	*Madhur, Tikta, Kashaya*	*Laghu*	*Sheeta*	*Katu*	*Kapha-Pitta shamaka*
2.	*Maricha*	*Katu, Tikta*	*Laghu, Tikshana, Ruksha*	*Ushna*	*Katu*	*Kapha-Vata shamaka*

भूधात्री तु कषायाम्ला पितमेहविनाशनी ।।
शिशिरा मूत्ररोगार्ति-शमनी दाहनाशनी ।।

(राज.निघंटु./पर्पटादि वर्ग 61-63**)**

Kashaya, *Tikata rasa* and *Ruksha*, *Laghu Guna* of *Bhudhatrayadi Yoga* have opposite properties to *Bahudrava Shaleshma, Abadha Meda, Mansa* and *Kaleda* in *Madhumeha. Ushna Veerya* of *Maricha* helps to expel *Kapha* from *Strotas. Bhoomyamlaki* is *Sheeta* in *Veerya* and is *Pitta-Kapha Shamaka* and might help in improving *Karapadaha*. Both the drugs in *Bhudhatrayadi Yoga* have *Katu Vipaka* which acts on *Mutravaha Srotasa, Meda, Kaleda* and might reduce symptoms like *Prabhoot Mutrata*. *Bhoomyamlaki* is *Vata-Pitta Shamaka* which may help in relieving *Kara Pada Daha* (burning in hands and feet). *Maricha* is *VataKapha Hara* which may alleviate symptoms like *Karapada Suptata* (tingling). *Bhudhatrayadi Yoga* has *karma* like *Strotoshodhana* and *Chedana*, which might clear *Doshas* from the *Strotasa. Bhoomyamalaki* is mentioned as *Pitta Meha Nashini* by *Raja Nighantu* and *Pipasa Hara* by *Bhava Prakasha.* The leaves of *Phyllanthus Niruri* are rich in pottasium which is considered responsible for their powerful diuretic effect. Stem contains saponin.[4] *Phyllanthus niruri* has shown its beneficial effects on various Diseases like Hepatitis, Urinary Tract infections and Diabetes Mellitus. [5,6]

CONCLUSION

After the review of the present clinical study entitled “A comparative clinical study to determine the

efficacy of *Bhudhatrayadi Yoga* and Metformin in the management of *Madhumeha* w.s.r. to Type II Diabetes Mellitus" following conclusions were drawn.

- The trial drug, *Bhudhatrayadi Yoga* showed statistically highly significant results in the subjective parameters- *Prabhuta Mutrata* and statistically significant results in *Avila Mutrata, Pipasadhikya, Kshudhadikya, Karapadaha, Swedadhikya, Galatalusosha, Karapada Suptata* and *Shithilangata.*
- The Trial drug, *Bhudhatrayadi Yoga* showed statistically highly significant results in objective parameters - F.B.S., P.P.B.S., HbA1c and statistically significant results in SGOT, SGPT, sugar in urine, Epithelial and Pus cells in urine.
- No adverse effects of *Bhudhatrayadi Yoga* were reported during the trial period.
- Thus, on the basis of the present clinical study it can be concluded that *Bhudhatrayadi Yoga* is efficient in improving signs and symptoms of *Madhumeha* and can be recommended as an oral hypoglycaemic drug to *Madhumeha* patients.

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