

Prospective clinical study to evaluate efficacy of *Vasantkusumakar Rasa* (Herbomineral preparation) on Psychological health of patients of *Madhumeha* (Diabetes Mellitus)

Research Article

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Abstract

Diabetes Mellitus although a modern terminology it has been known to mankind since long through ancient *Ayurvedic* treatises with name *Prameha* (Diabetes). As the incidence & prevalence of DM with complications along with its ill effects on psychological health is growing rapid. Due to Consistent stress blood sugar control becomes difficult. So, to search a drug which may improve psychological health is need of an hour. *Vasantkusumakar Rasa* is one of such drugs mentioned in *Ayurveda* compendia as treatment protocol of *Prameha* (Diabetes) also the one which is reputed for its rejuvenating property. This Herbomineral composition is also known to improve psychological health. Its efficacy to improve psychological state in patients of DM i.e. *Madhumeha* (DM) is evaluated in this study. Herbomineral compound i.e. *Vasantkusumakar Ras* 125mg two times a day with Luke warm water before meal for one month to 37 patients in experimental group as a add on therapy in continuation to their standard medicines. In control group 31 patients were continued their regular standard protocol medicines for DM. To study the effect of drug following parameters were analyzed on 0th day and on 30th day of study. Parameters included for study are Blood sugar level, Symptoms of *Madhumeha* (DM), *Manas Bhav* (Psychological traits) and psychiatric rating scale. These parameters show significant improvement in experimental group but no such effect was found in Control group.

Key Words: *Madhumeha*, Diabetes Mellitus, *Vasantkusumakar Ras*, *Manas Bhava*, Brief Psychiatric Rating Scale, Stress.

Introduction

Diabetes is known to mankind since long. It is described in brief in *Vedas*. It is counted among the five major diseases responsible for morbidity and mortality. In US alone every one in four patients attending the physician are of Diabetes Mellitus. Diabetes Mellitus is responsible for I.H.D., E.S.R.D., and non traumatic amputation of limbs.(1)

At least 171 million people worldwide have diabetes; this figure is likely to be more than double by 2030. Around 3.2 million deaths every year are attributable to complications of diabetes; six deaths every minute. The top 10 countries, in numbers of sufferers, are India, China, USA, Indonesia, Japan, Pakistan, Russia, Brazil, Italy and Bangladesh. The disease has varied wide aspect of its origin, progression

and development. Today's knowledge about the disease has increased to a great extent but it is not even the half way of total understanding. It is so because it has multi factor involvement and hence more work has to be done in the details of the diseases and the treatment.(2)

People with diabetes are 2 to 3 times more likely to have depression than people without diabetes. Only 25% to 50% of people with diabetes who have depression get diagnosed and treated. But treatment—therapy, medicine, or both—is usually very effective. And without treatment, depression often gets worse, not better.(3)

When you have type 2 Diabetes, stress may make your blood sugar go up and become more difficult to control – and you may need to take higher doses of your diabetes medications or insulin.(4)

In *Charak Prameha Nidan*(5) & *Chikitsa* and *Sushruta Prameha Nidan*(6), *krodha* (anger) is among one of the etiological factors in *Paittika Prameha* and *Shoka* (grief), *Bhaya* (fear), *Udvega* (anxiety) and *Chinta* (worry) for the *Vatika Prameha* (*Madhumeha* is among *Vatika Prameha*), which leads to derailment of glucose metabolism. According to *Sushruta Ajiranadhikar*(7) and *Charak Trividhakushiya Viman* (8), disturbed state of psyche (*Manas*- Mind) is not able

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to digest the food even if taken in normal quantity and leads to formation of *Ama* (Toxins or Free Radicals). The above description is related with the gastric digestion, but it is said that the *Jathargni* (Digestion power) only nourishes the *Dhatvagni* and *Bhootagni*. So, the disturbed psychological state also disturbs the *Dhatvagni* and *Bhootagni*. In anxiety and stress prone individuals the pathology starts from the vitiation of *Agni* (Digestive fire) leading to *Amotpatti* and that *Ama* when settles in *Basti* (Urinary Bladder) leads to *Prameha* as mentioned in chapter *Grahani Roga*(9).

While managing the disease following factors are needed to be taken into consideration: Psychological state of the patient, *Dhatu agni*, *Ojo dushti*. According to *Ayurveda* a drug must be one that can effect on all the factors of the disease. In this study formulation named as *Vasantkusumakar Ras* described in *Yogratanakara-Prameha Chkitsadhyaya* is selected. This herbomineral preparation is known to improve mental health by relaxing and nourishing the nervous system.(10)

The present study has been undertaken with the objectives to evaluate the efficacy of *Vasantkusumakar Ras* on psychological health in diabetes mellitus.

Aims and Objectives

- To assess the effect of *Vasantkusumakar Ras* on psychological health in DM.
- To assess the effect of *Vasantkusumakar Ras* on Blood sugar level in DM.

Materials and Methods

A detailed Case record form is prepared to note down all the details about disease and the patient. The patients suffering from salient feature of diabetes mellitus inclusive impaired glucose tolerance and established cases of diabetes mellitus are selected approaching to OPD.

Study Design: - Prospective clinical randomized control study.

Sample size: It has been observed not all patients suffering from DM have got Psychological effect. So total 68 Patients were randomly selected suffering from DM and with Psychological impact. The study was carried out and reported adhering to CONSORT statement.

Inclusion Criteria

- Patients of uncontrolled DM (Blood sugar level Fasting or PP or both below 250 mg/dl) with psychological symptoms like Depression, Stress, Anxiety etc.
- Patients suffering from DM for more than 5 years and on OHA.
- Age of Individual above 40 years of both Sex (Male or female)

Exclusion Criteria

- Patient complicated with any cardiac problem.
- Patients with diabetic nephropathy.

Data Collection

All the patients were selected randomly and distributed in two groups. Patients with uncontrolled diabetes mellitus were not stopped from whatever drugs (oral hypoglycemic) they were taking,

- Group I: The patients are given Tab. *Vasantkusumakar Ras* 125mg two times a day with Luke warm water before meal for one month.
- Group II: Control Group Patients are managed by giving placebo tablets 1BD with luke warm water for one month.

Blinding

Patients from both groups were masked (single blind technique) for the identity of anti diabetic trial ayurvedic medicine or placebo which so ever they were receiving.

Study Parameters

- Blood sugar level Fasting and Post Prandial
- *Manas Bhava* (Psychological Traits as per *Charak Samhita*) - Gradation of *Manasa pariksha bhavas*: In *Charaka Samhita*, 22 *Manasika Bhavas* and their methods of examination are mentioned.(11) Here, in this study an attempt is made to provide the objectivity by scoring each *Bhavas* (trait). The role of psychological factors affecting the disease is assessed on the basis of abovementioned *Ayurvedic* description and brief psychiatry rating scale.(12)
- Examination of Mental health by Brief Psychiatry rating scale.
- General symptoms of *Madhumeha* (DM) as per *Ayurveda*. - *Prabhuta Mutrata* (Polyuria), *Avil Mutrata* (Turbid Urine), *Trushyadhikya* (Polydypsia), *Galatalushosa* (dryness of mouth), *Prabhuta Kshudha* (polyphagia), *Shithilangata* (Fatigue), *Angagandha* (bad odour), *Kara-pad Daha* (burning sensation in hand and leg) *Kara-pad Suptata* (tingling/ numbness in hand and leg), *Madhurasya* (sweetness in mouth) (13)

After recruiting a patient a detailed case record form is filled up on 0 day and on 30th day i.e. before and after completion of treatment. Data was collected and processed using appropriate statistical methods.

Contents of Herbomineral preparation - *Vasantkusumakar Rasa*

The drug described in *Yog Ratnakara- Prameha Chkitsadhyaya* containing *Swarna Bhasma* Gold 2 parts, *Rajat Bhasma*. Silver 2 parts, *Vang Bhasma*. Tin 3 parts, *Nag Bhasma* Lead 3 parts, *Kantak* (*Kanta Loha*) *Bhasma*. Iron 3 parts, *Abhrak Bhasma* Mica 4 parts, *Praval* (*Bhasma*) Coral 4 parts, *Mauktik* (*Bhasma*) Pearl 4 parts, *Godugdha milk* Cow milk Q.S. (for *Bhavana*), *Ikshu ras* (Sugarcane juice)/juice Stem *Saccharum officinarum* L. Q.S. (for *Bhavana*), *Vasa rasa* (juice Leaf *Adhatoda vasica* Nees. Q.S.), *Laksha rasa* (juice exudate *Laccifer lacca* Q.S.), *Udicya* (*Sugandha balaka rasa* juice Root *Andropogon vetiveria* L. Q.S.), *Rambha kanda* (*kadali kanda rasa* Stem *Musa paradisiacal* Q.S.), *Sata Patra prasunaka rasa* (*Gulab pushpa svarasa*) - (Flower ext *Nelumbium speciosum* Willd. Q.S.),

Malatikusumodaka Flower (*Jasminum grandiflorum* L.), *Mrigamada* (*Kasturi* Exudate Musk) prepared in tablet form of 125 mg each.(14)

Assessment of Safety

Safety was assessed by clinical review of all safety parameters, including the adverse event reporting, as applicable, Vital signs including allergic reactions etc., All Adverse Events data were listed per subject including severity grading, relationship with investigational product and relationship of the adverse event to other causality, action taken and outcome of the adverse event. Any clinically significant changes in laboratory parameters were reported.

Statistical Analysis

Patients data collected as per case record form before and after completion of study. Symptoms of *Madhumeha* (Diabetes Mellitus) & *Manas Bhava* as per Ayurvedic texts are considered as subjective parameters to assess the effect of treatment. Effect of treatment on Symptoms of *Madhumeha* (Diabetes Mellitus) & *Manas Bhavas* are graded on four points scale. 0- Absent Score, 1-Mild, 2- Moderate & 3- Severe. The Brief Psychiatric Rating Scale (BPRS) is a rating scale which a clinician or researcher may use to measure psychiatric symptoms such as depression, anxiety, hallucinations and unusual behaviour. The scale is one of the oldest, most widely used scales to measure

psychotic symptoms and was first published in 1962. The BPRS consists of 18 items measuring the following factors: anxiety, emotional withdrawal, conceptual disorganization, guilt feelings, tension, mannerisms and posturing, grandiosity, depressive moods, hostility, suspiciousness, hallucinatory behavior, motor hyperactivity, uncooperativeness, unusual thought content, blunted affect, somatic concern, excitement, and disorientation. It uses a seven-item Likert scale with the following values: 1 = not present, 2 = very mild, 3 = mild, 4 = moderate, 5 = moderately severe, 6 = severe, 7 = extremely severe. The test is administered in tandem with a series of interviews conducted by at least two clinicians to ensure inter rater reliability of the assessment.(15) Data collected from subjective parameters is analyzed with paired t test to draw results.

Observations and Results

Total 68 patients registered in two groups, out of them 52 patients completed the course and 16 patients left against medical advice.

Demographic details - There was a total of 33 (63%) male patients and 19 (37%) female patients in the study. The average age of 52 patients in the study was 51.47 ± 8.04 . Maximum number of patients (43.33%) were in the age group of 50 to 60 years followed by (26.66%) between the age group of 40-50 years.

Table 1: Number of Patients registered in trial

Group	Group I	Group II	Total
Completed	30	22	52
LAMA	7	9	16
Registered	37	31	68

Table 2: Effect of Treatment on Symptoms of *Madhumeha* (DM) (Group I)(16)

Sr. No.	Symptoms	BT	AT	% Relief	SD	SE	t	P
1	<i>Prabhuta Mutrala</i> (Polyuria)	2.27	1.18	48%	0.701	0.211	5.169	<0.001
2	<i>Avil Mutrala</i> (Turbid Urine)	0.54	0.27	50.01%	0.467	0.141	1.938	<0.1
3	<i>Trushyadhikya</i> (Polydypsia)	1.45	0.45	68.75%	0.633	0.169	5.249	<0.001
4	<i>Gatalushosa</i> (dryness of mouth)	1.27	0.54	57.14%	0.786	0.237	3.071	<0.05
5	<i>Prabhuta Kshudha</i> (polyphagia)	0.54	0.27	50.01%	0.467	0.141	1.938	<0.1
6	<i>Shithilangata</i> (Fatigue)	1.45	0.90	37.50%	0.522	0.157	0.288	NS
7	<i>Angagandha</i> (bad odour)	0.18	0.09	50%	0.302	0.091	1.000	NS
8	<i>Karpad Daha</i> (burning sensation in hand and leg)	0.63	0.09	85.72	0.688	0.207	2.635	<0.05
9	<i>Karpad Suptata</i> (tingling/ numbness in hand and leg)	0.72	0.27	62.51	0.688	0.207	2.194	<0.1
10	<i>Madhurasyata</i> (sweetness in mouth)	0.27	0.09	66.67%	0.405	0.122	1.490	<0.1

In Group I patients, at 5 % level of significance and degrees of freedom 29, significant result was observed from the treatment group, in most of Symptoms of *Madhumeha* (DM) relative to the Control Group.

Table 3: Effect of Treatment on Symptoms of Madhumeha (DM) (Group II)(17)

Sr. No.	Symptoms	BT	AT	% Relief	SD	SE	t	P
1	Prabhuta Mutrata (Polyuria)	1.37	0.5	63.64%	0.640	0.227	3.776	<0.01
2	Avil Mutrata (Turbid	0.12	0.12	0.0%	0	-	-	-
3	Trushyadhikya	1.5	1	33.33%	0.534	0.189	2.261	<0.05
4	Galtalushosa (dryness of mouth)	1	0.37	62.50%	0.517	0.183	3.105	<0.01
5	Prabhuta Kshudha (polyphagia)	0.75	0.5	33.33%	0.462	0.164	1.524	NS
6	Shithilangata (Fatigue)	0.75	0.25	66.67%	0.755	2.680	0.185	NS
7	Angagandha (bad odour)	0	0	-	-	-	-	-
8	Karpad Daha (burning sensation in hand and leg)	1.25	0.5	60.00%	0.885	0.314	2.388	<0.05
9	Karpad Suptata (tingling/ numbness in hand and leg)	1	0.5	50.00%	0.534	0.189	2.645	<0.05
10	Madhurasyata (sweetness in mouth)	0	0	-	-	-	-	-

In control group patients, at 5 % level of significance and degrees of freedom 21, results are not that significant in Symptoms as patients were receiving Placebo treatment.

Table 4: Effect of Treatment on Manas Bhavas (Group I)(18)

Sr. No.	Symptoms	BT	AT	% Relief	SD	SE	t	P
1	Mana (Prestige)	0.82	0.55	32.93%	0.47	0.14	1.94	<0.1
2	Raga (Hatred)	1.45	0.91	37.24%	0.52	0.16	3.47	<0.01
3	Krodha (Anger)	1.73	1.09	36.99%	0.5	0.15	4.19	<0.01
4	Dwesh (Hate)	0.82	0.55	32.93%	0.47	0.14	1.94	<0.1
5	Moha (Temptation)	0.45	0.09	80.00%	0.5	0.15	2.39	<0.05
6	Shoka (Sorrow)	1.18	0.55	53.39%	0.92	0.28	2.29	<0.05
7	Upadha (Fame)	1.55	0.91	41.29%	0.67	0.2	3.13	<0.05
8	Chinta (Tensions)	1.73	0.91	47.40%	0.4	0.12	6.72	<0.001
9	Vishad (Sorrow)	0.73	0.27	63.01%	0.52	0.16	2.89	<0.05
10	Bhaya (Fear)	0.27	0	100.00%	9.65	2.91	1	NS
11	Harsha (Excitement)	0.73	1	36.99%	0.47	0.14	1.94	<0.1
12	Preeti (Love)	0.45	0.64	42.22%	0.4	0.12	1.49	NS
13	Dhairya (Daring)	0.27	0.91	237.04%	0.5	0.15	4.19	<0.01
14	Veerya (Brave)	0.27	0.73	170.37%	0.5	0.15	2.39	<0.5 NS
15	Avasthan (Mind set)	1.82	2.45	34.62%	0.81	0.24	2.61	<0.5 NS
16	Shraddha (Belief)	0.73	1.09	49.32%	0.5	0.15	2.39	<0.5 NS
17	Medha (Intelligence)	1	1.36	36.00%	0.5	0.15	2.39	<0.5 NS
18	Dhruti (Fortitude)	0.91	1	9.89%	0.54	0.16	0.56	NS

In Group I patients, at 5 % level of significance and degrees of freedom 29, some significant results are observed from the treatment in most of Negative Manas Bhava & results are not significant in positive Manas Bhava.

Table 5: Effect of Treatment on Manas Bhavas (Group II)(19)

Sr. No.	Symptoms	BT	AT	% Relief	SD	SE	t	P
1	Mana (Prestige)	0.50	0.38	24.00%	0.35	0.13	1.00	NS
2	Raga (Hatred)	0.50	0.13	74.00%	0.52	0.18	2.04	<0.1
3	Krodha (Anger)	1.25	0.75	40.00%	0.53	0.19	2.64	<0.05
4	Dwesh (Hate)	1.50	0.75	50.00%	0.71	0.25	2.07	<0.1
5	Moha (Temptation)	0.88	0.75	14.77%	0.35	0.13	1.00	NS
6	Shoka (Sorrow)	0.63	0.13	79.37%	0.76	0.27	0.80	NS
7	Upadha (Fame)	1.38	0.63	54.35%	0.71	0.25	2.99	<0.05
8	Chinta (Tensions)	1.25	0.63	49.60%	0.52	0.18	3.41	<0.01
9	Vishad (Sorrow)	1.63	0.50	69.33%	0.35	0.13	8.97	<0.001
10	Bhaya (Fear)	1.13	0.63	44.25%	0.53	0.19	2.64	<0.5

11	Harsha (Excitement)	0.75	1.13	50.67%	0.52	0.18	-2.04	<0.5
12	Preeti (Love)	0.63	0.75	19.05%	0.35	0.13	-1.00	<0.5
13	Dhairya (Daring)	0.63	1.13	79.37%	0.53	0.19	-2.64	<0.5
14	Veerya (Brave)	0.25	0.75	200.00%	0.76	0.27	-1.87	NS
15	Avasthan (Mind set)	2.25	2.38	5.78%	0.35	0.13	-1.00	<0.1
16	Shraddha (Belief)	1.00	1.38	38.00%	0.74	0.26	-1.42	NS
17	Medha (Intelligence)	0.88	1.75	98.86%	0.64	0.23	-3.85	<0.5
18	Dhruti (Fortitude)	1.13	1.25	10.62%	0.35	0.13	-1.00	NS

In Control group patients, at 5 % level of significance and degrees of freedom 21, results are not significant in both types of Negative & Positive *Manas bhavas* as patients were receiving Placebo treatment.

Table 6: Effect on Brief Psychiatric Rating Scale (Group I)(20)

Sr. No.	Symptoms	BT	AT	% Relief	SD	SE	t	P
1	Somatic concern	3.55	1.45	58.98%	0.70	0.21	9.91	<0.001
2	Anxiety	4.36	2.09	52.08%	0.90	0.27	3.32	<0.01
3	Emotional withdrawal	1.45	0.64	56.25%	0.87	0.26	3.11	<0.01
4	Conceptual disorganisation	0.00	0.00	-	-	-	-	-
5	Guilt feelings	0.27	0.09	66.67%	0.60	0.18	1.00	NS
6	Tension	2.82	1.27	54.84%	1.37	0.41	3.75	<0.01
7	Mannerisms and Positioning	0.45	0.09	80.00%	0.81	0.24	1.49	NS
8	Grandiosity	0.00	0.00	-	-	-	-	-
9	Hostility	0.00	0.00	-	-	-	-	-
10	Suspiciousness	0.18	0.18	0.00	0.00	0.00	0.00	-
11	Hallucinatory behaviors	0.00	0.00	-	-	-	-	-
12	Motor retardation	0.00	0.00	-	-	-	-	-
13	Unco-operativeness	0.00	0.00	-	-	-	-	-
14	Unusual thought content	0.00	0.00	-	-	-	-	-
15	Blunted affect	0.00	0.00	-	-	-	-	-
16	Excitement	0.00	0.00	-	-	-	-	-

In Group I patients, at 5 % level of significance and degrees of freedom 29, some significant results are observed from the treatment group, in mental factors relative to the Control Group.

Table 7: Effect on Brief Psychiatric Rating Scale (Group II)(21)

Sr. No.	Symptoms	BT	AT	% Relief	SD	SE	t	P
1	Somatic concern	3.38	1.25	62.96%	0.64	0.23	9.35	<0.001
2	Anxiety	4.13	1.38	66.67%	1.17	0.41	6.66	<0.001
3	Emotional withdrawal	0.63	0.25	60.00%	0.74	0.26	1.42	NS
4	Conceptual disorganisation	0.50	0.25	50.00%	0.46	0.16	1.52	NS
5	Guilt feelings	0.00	0.00	-	-	-	-	-
6	Tension	1.38	0.50	63.64%	0.83	0.30	2.96	<0.05
7	Mannerisms and Positioning	0.00	0.00	-	-	-	-	-
8	Grandiosity	0.00	0.00	-	-	-	-	-
9	Hostility	0.00	0.00	-	-	-	-	-
10	Suspiciousness	0.25	0.00	100.00%	0.71	0.25	1.00	NS
11	Hallucinatory behaviors	0.00	0.00	-	-	-	-	-
12	Motor retardation	0.00	0.00	-	-	-	-	-
13	Unco-operativeness	0.00	0.00	-	-	-	-	-
14	Unusual thought content	0.00	0.00	-	-	-	-	-
15	Blunted affect	0.00	0.00	-	-	-	-	-
16	Excitement	0.00	0.00	-	-	-	-	-

In Control group patients, at 5 % level of significance and degrees of freedom 21, results are not significant in mental factors as patients were receiving Placebo treatment.

Table 8: Effect of treatment on Blood Sugar Level (Group I)

Parameter	BT	AT	% Result	SD	SE	t	P
FBS	204.5	198.75	2.81%	30.97	10.98	0.523	NS
PPBS	293.75	284.75	3.06%	51.76	18.35	0.490	NS

In Group I, it is observed that Fasting Blood sugar decreased by 2.81%-NS; PPBS decreased by 3.06%-NS but seemed not significant.

Table 9: Effect of treatment on Blood Sugar Level (Group II)

Parameter	BT	AT	% Result	SD	SE	t	P
FBS	189.48	207.09	9.29%	60.927	18.351	0.916	NS
PPBS	280.9	287.82	2.46%	87.092	26.23	0.004	NS

In Group II, it is observed that Fasting Blood sugar increased by 9.29%-NS, PPBS increased by 2.46%-NS but seemed not significant.

Discussion

Out of total 10 Symptoms of *Madhumeha* (DM), it has been observed that in Group I, 8 symptoms showed significant improvement & in Group II none of Symptoms showed any improvement.

In case of total 18 *Manas Bhavas* (Psychological traits), 9 out of 10 Negative *Manas Bhavas* (Psychological traits) shown significant improvement and none of 8 positive *Manas Bhavas* (Psychological traits) showed any improvement in group I. And in Group II, none of symptoms i.e., negative or positive *Manas bhavas* (Psychological traits) showed any improvement.

In case of Brief Psychiatric Rating Scale, 4 out of 16 symptoms showed significant improvement in Group I and in Group II only 3 symptoms showed some significant changes which are almost negligible.

Effect of treatment on Blood Sugar Level both in Group I & Group II almost showed no significant results.

It has been observed that alteration in the brain function may change blood sugar. Electrical stimulation of Vento lateral hypothalamus (VLH) which is Vagal centre causes decrease in blood sugar and an increase in plasma insulin whereas electrical stimulant of Vento medial hypothalamus (VMH) which is a sympathetic centre causes a decrease in plasma insulin. According to Woods and Porte (1974) pancreas receive a generous supply of nerve fibers which enters the gland through its arteries, namely parasympathetic from Vagus, sympathetic and visceral afferent fibers. The Islets of langerhans receive a rich supply through these nerves. Adrenaline inhibits the secretion of insulin whereas it stimulates the glucagon secretion. Thus it is very clear that autonomic nervous system plays an important role in the secretion of insulin and glucagon.(22)

Analysis of the data shows the disturbance in the *Mansika Bhavas* (Psychological traits) up to a great extent. These disturbed psychic factors work like stressor causing excessive stimulation of sympathetic nervous system leading to decreased insulin secretion. Moreover, glucagon secretion also increases during various types of stress ultimately increasing the blood sugar. Symptoms common to both diabetes mellitus and sympathetic over activity include raised blood sugar levels, decreased glucose tolerance, increased lipolysis, glycogenolysis and ketosis. It can be said that reversal of increased catecholamines content may be an

important step towards its full control. Hence better management of the disturbed *Mansika Bhavas* (Psychological traits) in different therapeutic groups by administering mental health promoting drug having effect on neuroendocrine system has additive effect in controlling somatic symptoms of DM.

The drug formulation having *Kashaya (Astringent) Pradhana Madhur (sweet) Rasa (Taste), Sheet Veerya* and *Snigdha Guna*, helps in eliminating vitiated *Vat Pitta Dosha* with *Balya* (improves strength) effect, *Medhya* (improves psychological function) effect.

On the basis of this study it could be suggested that the formulation with ingredients possessing *Rasayana, Balya* effects along with mental health promoting effect will be useful in disintegrating the pathophysiology of disease. Moreover, if the drug combination has blood sugar lowering and insulin promoting action then it will be having additive effects.

None of the patients showed worsening in their overall condition. These findings suggest that *Vasantkusumakar Ras* safely & effectively improves Psychological health in patients suffering from DM. None of the patients showed poor tolerability to *Vasantkusumakar Ras*.

Conclusion

It has been observed that the drug showed more significant results in trial group relative to the control group with respect to the symptoms of *Madhumeha* (Diabetes Mellitus). Also the drug showed more significant improvement in negative *Manas Bhava* in trial group relative to the control group and in case of Brief Psychiatric Rating Scale, symptoms showed some significant improvement in trial group relative to the control group. Therefore we can conclude that the trial drug is effective to control symptoms of *Madhumeha* (Diabetes Mellitus) as well as effective to improve psychological health of patients suffering from DM.

Effect of treatment on Blood Sugar Level both in trial group & control group almost showed no significant results.

In this study we observed improvement in symptoms in treated group therefore we conclude that the drug by correcting the *Dosha* improves QOL of patients suffering from DM. Also achieve additive effect to improve psychological health of patients.

The results of the present study are drawn from patients registered for chronic DM of more than 5 years with a treatment plan of one month. If the patients have less chronicity and longer duration of treatment then perhaps better results could be achieved.

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