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A clinical study on the effect of *Lodhradi Kashaya* on *Madhumeha* with special reference to Diabetes Mellitus (Type-2)

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ABSTRACT

Introduction: *Ayurveda* describes *Prameha* as a disease entity which involves a number of diseases with various physical and chemical changes in urine. *Madhumeha* is included under *Vatik Prameha* where astringency is associated with sweetness in urine. The manifestation of metabolic abnormality as well as urinary tract pathology are included in two symptoms: *Prabhuta Mutrata* (excessive urination) and *Avila Mutrata* (urine turbidity). Sedentary life style, indulgence of *Kapha-meda Vardhaka Ahara*, avoidance of regular exercise, day sleep indicate *Santarpanajanya* origin of the disease. **Methods:** *Lodhradi Kashaya* with *Lodhra, Musta, Katphal* and *Haritaki* as described in *Vasavarajeeyam* is taken for this clinical study on 60 patients and its efficacy was compared with a standard drug metformin. **Results:** During the study it was found that both *Lodhradi Kashaya* and Metformin provided significant result in improving Signs and Symptoms like polyuria, turbid urination, Polydipsia, polyphagia, burning sensation, numbness, weakness, lassitude, pruritus, muscle cramps, and increased sweating. The test of significance shows that both the trial drug and control drug were highly significant at 0.1% level with p-value <0.001 to improve glycosuria, FBS, PPBS and HbA1c in patients. Comparative analysis of the effectiveness of *Lodhradi Kashaya* and metformin w.r.t. objective sign and symptoms showed that both the treatments are almost equally effective to improve glycosuria, FBS, PPBS and HbA1c while *Lodhradi Kashaya* gives better clinical improvement than metformin in long term use in Diabetes. *Lodhradi Kashaya* is an efficient anti diabetic drug.

Key words: *Madhumeha, Lodhradi Kashaya, Metformin, Comparative study.*

INTRODUCTION

Prameha is a disease entity which comprises of a number of diseases with various physical and chemical changes in urine.[1] It is characterized by urinary disorder but it may not be inferred that all the urinary disorders caused by urinary tract pathology may be included in *Prameha*. The word *Prameha* is derived from the "*Miha sechane*" which means watering.[2] '*Pra*' means excess of urine in both quality and frequency. Thus, the manifestation of metabolic abnormality as well as urinary tract pathology are included in two symptoms: *Prabhuta Mutrata* (excessive urination) and *Avila Mutrata* (urine turbidity).[3] As per description if not cured or treated properly, in due course of time, *Prameha* changes into *Madhumeha. Madhumeha* is included under *Vatik Prameha* where astringency associated with sweetness in urine distinguishes it from *Ikshumeha* where urine is extremely sweet without any trace of astringency.[4,5]

Madhumeha can be related to Diabetes mellitus where the concept of hyperglycemia, polyuria and glycosuria exists. The prevalence of diabetes mellitus, which is considered as NCD (non-communicable disease), is rising all over the world due to population growth,

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aging, urbanization and an increase of obesity and physical inactivity. Diabetes mellitus is reaching potentially epidemic proportions in India. The level of morbidity and mortality due to diabetes and its potential complications like hypertension, dyslipidemia and obesity are enormous, and this metabolic syndrome pose significant healthcare burdens on both families and society.

There are two broad categories of DM, designated type 1 and type 2. Type 1 DM is the result of complete or near-total insulin deficiency. Type 2 DM is a heterogeneous group of disorders characterized by variable degrees of insulin resistance, impaired insulin secretion, and increased glucose production. Other etiologies for DM include specific genetic defects in insulin secretion or action, metabolic abnormalities that impair insulin secretion, mitochondrial abnormalities, and a host of conditions that impair glucose tolerance.[6] Long standing diabetes leads to several complications including neuropathy, cardiovascular diseases, renal issues, retinopathy and foot ulcer etc.[7] The IDF reported about 5 million deaths worldwide from diabetes in 2015.[8]

Diabetes is a most common metabolic disorder in India and affecting more than 30 million people with type 2 diabetes. Therapies of western medicines carry the risk of adverse effects and are often too costly especially for the developing country like India, where ethnic as well as environment also differ. Ayurveda is an indigenous ethnic medical system, which is popular practiced in the Indian subcontinent since the pre-biblical era. The system's core strength is its holistic approach to health and disease using natural remedies derived from medicinal plants and minerals. There are many popular herbs with medicinal value and which are still continued to be used in India.

In this study, an effort is being made to provide an effective oral hypoglycaemic herbal drug preparation described in our Ayurvedic texts, keeping in view its cost effectiveness, availability and safety. The trial drug '*Lodhradi Kashaya*' was formulated as per the description in '*Vasavarajeeyam*'.[9] And eventually during my study it was found that researches and scientific evaluation of its individual components are already being carried out in pharmacological sectors proving their hypoglycaemic effect. The study has been conducted taking 60 no. of cases, divided into two groups, for a trial period of 90 days. *Lodhradi Kashaya* has been used as trial drug and in contrary Metformin as standard control drug.

All the clinical features and blood features; and their post development have been recorded systematically. They are assessed with the help of appropriate statistical parameters and presented in the form of tables and charts.

Aim

A clinical study on the effect of *Lodhradi Kashaya* on *Madhumeha* with special reference to Diabetes mellitus (Type-2).

Objective

1. Therapeutic evaluation of trial drug *Lodhradi Kashaya*.
2. Therapeutic evaluation of standard drug Metformin.
3. Comparative study of both the treatments.

Hypothesis: It is assumed that "*Lodhradi Kashaya*" is an effective treatment to control *Madhumeha* (Type-2 Diabetes mellitus). (Ref- *Vasavarajeeyam*, 9th Chapter)

Materials and Methods

Following the criteria of selection, total 60 patients of *Madhumeha* (Type-2 Diabetes mellitus) were selected from O.P.D. and I.P.D. of G.A.M, Puri for the propose of clinical study and registered randomly into two groups i.e. Group-A and Group-B. Out of them, during the study, 3 patients of Group-A and 2 patients of Group-B discontinued the treatment. At last, 55 patients have completed the study (Table - 1).

Table 1: Showing observations of 60 patients according to registration and study completion.

Groups	Group-A	Group-B	Total
Registered	30	30	60
Drop out	3	2	5

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Completed	27	28	55

Duration of study: 3 months. The assessments were carried out in each 30 days of the treatment.

Ethical clearance: With due approval by the IEC (Institutional Ethical Committee), GAM, Puri the study has been conducted among the patients registered for the purpose. Written consent was obtained from each patient participated in the study with prior proper information.

Criteria for selection of patients

Inclusion Criteria

- Age - 30-70 years
- Sex - Both male and female

Clinical features

a) *Bahumutrata* (Polyuria)

b) *Trushadhikyata* (Polydipsia)

c) *Kshudhadhikyata* (Polyphagia)

d) *Dourbalya* (Weakness) etc.

Biochemical Features

a) Fasting Plasma Glucose ≥ 126 mg /dl

b) Post prandial Plasma Glucose ≥ 200 mg /dl

c) Glycated Hemoglobin (HbA1c) ≥ 6.5

d) Glycosuria

Exclusion Criteria

- Age below 30 years and above 70 years
- Type-1 Diabetic mellitus
- Fasting Plasma Glucose ≥ 200mg/dl
- Angina or Myocardial Infraction
- Nephropathy
- Pancreatitis
- Pregnancy
- Pyrexia and any other systemic disorders
- Case having medical emergencies.

Diagnostic investigations

1. FBS
2. PPBS
3. HbA1c
4. Urine-RE, ME

Posology

1. Trial drug: *Lodhradi Kashaya*

- The drug was supplied in *Kwatha Choorna* form and 12 gms of the trial drug was boiled with 200ml water and reduced to 50ml.
- Always fresh *Kwath* was made for use.
- **Dose -** 50 ml BD in empty stomach.

2. Control drug: Tab. Metformin

- Sustained release tablets of Metformin (500mg) were used.
- **Dose -** Starting dose 500 mg /day in two divided doses with food
- After assessment of FBS after 2 weeks, the dose might increase if glycemic control is not seen
- **Diet and Exercise -** Patients were advised to take *Pathya* diet for *Prameha.*

Study design

1. Single group design

Group A	**BT vs AT**	Effectiveness of trial drug *Lodhradi Kashaya* is assessed
Group B	**BT vs AT**	Effectiveness of control drug is assessed

BT- Before Treatment, AT- After Treatment

2. Double group design

Group-A	**vs**	**Group-B**	Effectiveness of *Lodhradi Kashayam* w.r.t. Metformin will be assessed.

Criteria of assessment

The effect of the treatments was assessed by assessing-

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- Clinical signs and symptoms before and after treatment.
- FBS, PPBS and urine sugar levels before and after treatment.

For the assessment of the changes, scoring method has been selected. Gradation of signs and symptoms and biochemical parameters has been done and their score before treatment and after treatment are observed.

Gradation Criteria for Specific sign and symptoms score is as follows: -

1. ***Prabhuta Mutrata*** **(Polyuria)**

   G0 - 3 to 5 times/day, no or rarely at night

   G1 - 5 to 7 times/ day, 1 to 2 times per night

   G2 - 7-10 times/ day, 3-4 times per night

   G3 - >10 times/ day, >5 times per night

2. ***Pipasadhikya*** **(polydipsia)**

   G0 - Normal, 2 to 2.5 lit/ day (24 hrs)

   G1 - Increased but frequency of drinking can be controlled, 2.5 to 3 lit/ day

   G2 - Increased with frequency of water intake, 3 to 3.5 lit / day

   G3 - Very frequent water intake, > 3.5 lit /day

3. ***Abila Mutrata*** **(Turbidity in urine)**

   G0 - Crystal clear fluid

   G1 - Faintly cloudy and smoky slight turbidity

   G2 - Turbidity clearly present and newsprint easily read through test tube

   G3 - Newsprint not easily read through test tube

   G4 - Newsprint cannot be visualized through test tube

4. ***Kshudhadhikyata*** **(Polyphagia)**

   G0 - Normal Appetite, 1 to 2 meals/ day

   G1 - Slightly Increased, 1 to 2 meals/ day

   G2 - Moderately Increased, 2 to 3 meals/ day

   G3 - Markedly increased, 4 to 5 meals/ day

5. ***Kara-Pada Daha*** **(Burning sensation)**

   G0 - No *Daha*

   G1 - *Kara-Pada Daha* not continuous

   G2 - *Kara-Pada Daha* continuous but bearable

   G3- *Kara-Pada Daha* continuous & unbearable

6. ***Kara-Pada Suptata*** **(Numbness)**

   G0 - No *suptata*

   G1 - *Kara-Pada Suptata* not continuous

   G2 - *Kara-Pada Suptata* continuous but bearable

   G3 - *Kara-Pada Suptata* continuous & unbearable

7. ***Dourbalya*** **(Weakness)**

   G0 - Can do routine exercise/ work

   G1 - Can do moderate exercise with hesitancy

   G2 - Can do mild exercise only, with difficulty

   G3 - Cannot do mild exercise

8. ***Alasya/ Utsahahani*** **(Lassitude)**

   G0 - No *Alasya*, doing satisfactory works with proper vigor and in time

   G1 - Doing satisfactory works with late initiation (Likes to stand in comparison to walk)

   G2 - Doing unsatisfactory works with late initiation, (likes to sit in comparison to stand)

   G3 - Doing unsatisfactory works with very late initiation, (likes to lie down in comparison to sit)

   G4 - Does not like to work with no initiation, (likes to sleep in comparison to lie down)

9. ***Kandu*** **(Pruritus)**

   G0 - No itching

   G1 - Mild itching, not disturbing normal activity

   G2 - Occasional itching, disturbs normal activity

   G3 - Itching present continuously & even disturbing sleep

10. ***Pindicodbestana*** **(Cramps)**

    G0 - No Cramps

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G1 - Cramps after walking more than 1 km

G2 - Cramps after walking ½ km

G3 - Unable to walk even ½ km

11. *Nidradhikyata* (Sleep)

G0 - 6-8 hrs/ day (24 hrs) with feeling of lightness

G1 - Sleep for 8-9 hrs/ day with slightly heaviness in body

G2 - Sleep for 9-10 hrs/ day with heaviness in body associated with *Jrimbha*

G3 - Sleep for >10 hrs/ day with heaviness in body associated with *Jrimbha* and *Tandra*

12. *Swedadhikya* (Excess Perspiration)

G0 - Sweating after some strenuous or heavy work or in hot and humid weather

G1 - Profuse sweating after moderate work and movement

G2 - Sweating after little extra work than routine and movement

G3 - Profuse sweating after routine work

G4 - Sweating even at rest or in cold climate

13. Glycosuria

G0 - Absent

G1 - 0.1 – 0.5 mg

G2 - 0.6 – 1.0 mg

G3 - 1.1 – 1.5 mg

G4 - 1.6 – 2.0 mg

14. Fasting Blood Sugar (FBS)

G0 - < 126 mg/dl

G1 - 126 - 150 mg/dl

G2 - 151 - 175mg/dl

G3 - 176 - 200 mg/dl

15. Post Prandial Blood Sugar (PPBS)

G0 - < 200 mg/dl

G1 - 200 – 249 mg/dl

G2 - 250 – 300 mg/dl

G3 - 300 – 300 mg/dl

16. HbA1c

G0 - < 6.5

G1 - 6.5 – 6.9

G2 - 7.0 – 7.4

G3 - 7.5 – 7.9

G4 - ≥ 8.0

Assessment for result

The degree of severity as per above gradation criteria and data was collected from pathological investigations before treatment (BT) (Table -2), after 30 days (AT1) (Table 3), 60 days (AT2) (Table 4) and 90 days (AT3) (Table 5) of treatment and were assessed. The assessment has been done in two stages as follows-

Table 2: Showing the degree of severity of different clinical sign and symptoms before treatment in Group-A and Group-B.

Sign/ Symptom	Group-A (N1=27)					Group-B (N2=28)				
	Degree of severity					Degree of severity				
	G1	G2	G3	G4	Total	G1	G2	G3	G4	Total
Subjective sign and symptoms										
Polyuria	0	16	11	-	27	1	15	12	-	28
Turbid Urination	20	6	0	-	26	15	13	0	-	28
Polydipsia	0	16	11	-	27	1	15	12	-	28
Polyphagia	4	4	0	-	8	7	1	0	-	8
Burning sensation	7	14	0	-	21	10	10	0	-	20
Numbness	9	8	1	-	18	4	7	0	-	11
Weakness	1	25	1	-	27	3	21	3	-	27

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Lassitude	1	2	0	-	3	3	8	0	-	11
Pruritus	5	7	0	-	12	3	5	2	-	10
Muscle cramps	8	14	0	-	22	9	12	0	-	21
Excess Sleep	1	0	0	-	1	4	1	0	-	5
Increased sweating	3	3	0	-	6	2	4	0	-	6
Objective sign and symptoms										
Glycosuria	0	0	3	24	27	1	2	2	23	28
FBS	10	11	6	-	27	11	13	4	-	28
PPBS	12	10	5	-	27	12	11	4	-	27
HbA1c	8	10	6	3	27	9	10	8	1	28

N1, N2= No. of patients in respective group; G1, G2, G3, G4 are the degree of severity

Table 3: Showing the degree of severity of different clinical sign and symptoms after 30 days of treatment in Group-A and Group-B

Sign/ Symptom	Group-A (N1=27)						Group-B (N2=28)					
	Degree of severity						Degree of severity					
	G0	G1	G2	G3	G4	Total	G0	G1	G2	G3	G4	Total
Subjective sign and symptoms												
Polyuria	0	14	13	0	-	27	2	14	12	0	-	28
Turbid Urination	9	17	0	0	-	26	11	17	0	0	-	28
Polydipsia	0	14	13	0	-	27	2	14	12	0		28
Polyphagia	3	4	1	0	-	8	2	6	0	0	-	8
Burning sensation	11	10	0	0	-	21	1	18	1	0	-	20
Numbness	3	13	2	0	-	18	0	9	2	0	-	11
Weakness	7	18	2	0	-	27	5	19	3	0	-	27
Lassitude	0	3	0	0	-	3	3	8	0	0	-	11
Pruritus	3	6	3	0	-	12	1	7	2	0	-	10
Muscle cramps	15	7	0	0	-	22	6	14	1	0	-	21
Excess Sleep	1	0	0	0	-	1	0	5	0	0	-	5
Increased sweating	2	4	0	0	-	6	2	4	0	0	-	6
Objective sign and symptoms												
Glycosuria	0	5	8	11	3	27	0	6	5	9	8	28
FBS	3	16	8	0	-	27	5	19	4	0	-	28
PPBS	4	19	4	0	-	27	7	18	2	0	-	27

N1, N2= No. of patients in respective group; G0, G1, G2, G3, G4 are the degree of severity

Table 4: Showing the degree of severity of different clinical sign and symptoms after 60 days of treatment in Group-A and Group-B.

Sign/ Symptom	Group-A (N1=27)						Group-B (N2=28)					
	Degree of severity						Degree of severity					
	G0	G1	G2	G3	G4	Total	G0	G1	G2	G3	G4	Total
Subjective sign and symptoms												
Polyuria	13	14	0	0	-	27	14	14	0	0	-	28
Turbid Urination	25	1	0	0	-	26	28	0	0	0	-	28
Polydipsia	9	18	0	0	-	27	16	12	0	0	-	28
Polyphagia	7	1	0	0	-	8	8	0	0	0	-	8
Burning	21	0	0	0	-	21	4	15	1	0	-	20

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sensation												
Numbness	6	12	0	0	-	18	2	9	0	0		11
Weakness	22	5	0	0	-	27	20	7	0	0	-	27
Lassitude	3	0	0	0	-	3	11	0	0	0	-	11
Pruritus	10	2	0	0	-	12	8	2	0	0	-	10
Muscle cramps	22	0	0	0	-	22	19	2	0	0	-	21
Excess Sleep	1	0	0	0	-	1	1	4	0	0	-	5
Increased sweating	6	0	0	0	-	6	6	0	0	0	-	6
Objective sign and symptoms												
Glycosuria	8	10	8	0	1	27	7	12	7	2	0	28
FBS	16	11	0	0		27	16	12	0	0		28
PPBS	17	10	0	0		27	18	9	0	0		27

N1, N2= No. of patients in respective group; G0, G1, G2, G3, G4 are the degree of severity

Table 5: Showing the degree of severity of different clinical sign and symptoms after 90 days of treatment in Group-A and Group-B.

Sign/ Symptom	Group-A (N1=27)						Group-B (N2=28)					
	Degree of severity						Degree of severity					
	G0	G1	G2	G3	G4	Total	G0	G1	G2	G3	G4	Total
Subjective sign and symptoms												
Polyuria	25	2	0	0	-	27	24	4	0	0	-	28
Turbid Urination	26	0	0	0	-	26	28	0	0	0	-	28
Polydipsia	26	1	0	0	-	27	28	0	0	0	-	28
Polyphagia	8	0	0	0	-	8	28	0	0	0	-	8
Burning sensation	21	0	0	0	-	21	10	10	0	0	-	20
Numbness	11	7	0	0	-	18	6	5	0	0		11
Weakness	27	0	0	0	-	27	27	0	0	0	-	27
Lassitude	3	0	0	0	-	3	11	0	0	0	-	11
Pruritus	12	0	0	0	-	12	10	0	0	0	-	10
Muscle cramps	22	0	0	0	-	22	21	0	0	0	-	21
Excess Sleep	1	0	0	0	-	1	4	1	0	0	-	5
Increased sweating	6	0	0	0	-	6	6	0	0	0	-	6
Objective sign and symptoms												
Glycosuria	24	3	0	0	0	27	19	8	1			28
FBS	25	2	0	0	0	27	27	1	0			28
PPBS	26	1	0	0	0	27	26	1	0			27
HbA1c	20	7	0	0	0	27	19	9	0	0	0	28

N1, N2= No. of patients in respective group; G0, G1, G2, G3, G4 are the degree of severity

Clinical assessment

The percentage of patients got improved and the average percentage improvement in the severity of different clinical sign and symptoms was calculated. The overall clinical assessment has been done considering the sign and symptoms as follows-

1. Well Controlled: 100% relief in signs and symptoms like polyuria, polydipsia, polyphagia, turbid urination, weakness, glycosuria, FBS and PPBS in Trial Period.
2. Maximum Control: 75- 99% relief in signs and symptoms.

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3. Moderate Control: 50- 74% relief in signs and symptoms.
4. Mild Control: 25- 49% relief in signs and symptoms.
5. Unsatisfactory: < 25% relief in signs and symptoms.

Statistical analysis

The objective data, like levels of Glycosuria, FBS, PPBS and HbA1c, gathered from the patients was subjected for statistical analysis. Data were analyzed statistically in terms of Mean, Standard Deviation (S.D.), Standard Error (S.E.), t-value and p- value. The statistical analysis after 30 days (AT1), 60 days (AT2) and 90 days of treatment (AT3) has been done. For the effectiveness of trial drug and control drug paired 't' test and unpaired t- test has been used. The effectiveness of trial drug and control drug has been assessed through the p- value. The p-value was interpreted as-

1. >0.05 statistically insignificant at 5% level
2. <0.05 significant at 5% level
3. <0.01 significant at 1% level
4. <0.001 highly significant at 0.1% level

Results and Discussion

The present clinical study conducted at Dept. of Kayachikitsa GAM, Puri includes *Madhumeha* patients from both the sexes within the age group of 30-70 years. Only Type 2 DM cases without any complications were accepted and all the cases of Type 1 DM and Type 2 DM with any complication were excluded.

The cause of exclusion is that the type 1 DM cases do not respond to oral hypoglycaemic agents, so insulin is inevitable for them. Also Type 2 DM cases with any complications would need another associated medication simultaneously. In both these cases the study results would be erroneous, thus excluded.

Clinical assessment of result

The clinical assessment was done basing on the sign and symptoms, polyuria, Turbid urination, polydipsia, polyphagia, weakness, glycosuria, FBS and PPBS which were provided with gradation for proper assessment. To declare the result certain scales were formulated and the language against recovery was fixed as well controlled, maximum control, moderate control, mild control and unsatisfactory.

Table 6: Showing Clinical assessment of Result in Group-A and Group-B

Clinical Assessment	AT1				AT2				AT3			
	Group-A		Group-B		Group-A		Group-B		Group-A		Group-B	
	F	%	f	%	f	%	f	%	f	%	f	%
Well Controlled	0	0	0	0	4	14.81	4	14.29	22	81.48	18	64.28
Maximum Control	3	11.12	3	10.71	15	55.56	18	64.28	5	18.52	10	35.71
Moderate Control	12	44.44	15	53.57	8	29.62	6	21.43	0	0	0	0
Mild Control	12	44.44	10	35.72	0	0	0	0	0	0	0	0
Unsatisfactory	0	0	0	0	0	0	0	0	0	0	0	0

The clinical assessment of result in Group-A (Trial Group) and Group-B (Control Group) presented that, after 30 days of treatment 11.12% got maximum control, 44.44% each got moderate and mild control in Group-A. After 60 days of treatment 14.81% got well controlled, 55.56% got maximum control, and 29.62% each got moderate control. After 90 days, 81.48% got well controlled and 18.52% got maximum control.

In the other side after 30 days of treatment Group-B got 10.71% maximum control, 53.57% moderate control and 35.72% mild control. After 60 days of treatment 14.29% got well controlled, 64.28% got maximum control and 21.43% got moderate and mild

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control. After 90 days of treatment 64.28% got well-controlled and 35.72% got maximum control. This shows that long term use of the trial drug in Group-A shows better response than the control drug in Group-B with higher percentage of improvement.

Statistical analysis

Statistical analysis was done basing on the objective parameters (i.e. glycosuria, FBS, PPBS and HbA1c) fixed under the assessment scale. Analyzing the effectiveness of treatment -1 and treatment -2 (Table no-7), the test of significance shows that both the trial drug and control drug were highly significant at 0.1% level with p-value <0.001 to improve glycosuria, FBS, PPBS and HbA1c. Statistical analysis of the effectiveness of *Lodhradi Kashaya* in comparison to metformin w.r.t. objective sign and symptoms (Table no. 8) showed that both the treatments are almost equally effective to improve glycosuria, FBS, PPBS and HbA1c.

Table 7: Statistical analysis showing the effectiveness of treatment-1 and treatment-2 with respect to the sign and symptoms.

Sign / Symptom	Group		Mean ± SD	Mean diff ±SD	df	SE	t	p	Remarks
Glycosuria	Group-A	BT	1.94 ± 0.16						
		AT 1	1.19 ± 0.52	0.75 ± 0.47	26	0.091	8.2663	< 0.001	*
		AT 2	0.45 ± 0.53	1.49 ± 0.51	26	0.098	15.2571	< 0.001	*
		AT 3	0.03 ± 0.10	1.92 ± 0.18	26	0.035	55.4375	< 0.001	*
	Group-B	BT	1.84 ± 0.39						
		AT 1	1.28 ± 0.66	0.58 ± 0.49	27	0.092	6.07798	< 0.001	*
		AT 2	0.44 ± 0.50	1.40 ± 0.51	27	0.097	14.4201	< 0.001	*
		AT 3	0.06 ± 0.19	1.78 ± 0.40	27	0.076	23.2336	< 0.001	*
FBS	Group-A	BT	159.85 ± 15.38						
		AT 1	139.56 ± 12.56	20.30 ± 6.75	26	1.298	15.6307	< 0.001	*
		AT 2	122.78 ± 11.70	37.07 ± 8.38	26	1.613	22.9883	< 0.001	*
		AT 3	108.89 ± 11.07	50.96 ± 8.68	26	1.671	30.4922	< 0.001	*
	Group-B	BT	158.54 ± 14.48						
		AT 1	136.75 ± 11.52	21.79 ± 6.91	27	1.307	16.6731	< 0.001	*
		AT 2	121.50 ± 11.88	37.04 ± 7.10	27	1.343	27.5829	< 0.001	*
		AT 3	107.57 ± 10.69	50.96 ± 7.78	27	1.47	34..6768	< 0.001	*
PPBS	Group-A	BT	267.41 ± 36.38						
		AT 1	226.26 ± 23.37	47.15 ± 18.07	26	3.478	13.5548	< 0.001	*
		AT 2	190.63 ± 19.52	76.78 ± 22.14	26	4.261	18.0194	< 0.001	*
		AT 3	167.81 ± 17.33	99.59 ± 27.32	26	5.258	18.9399	< 0.001	*
	Group-B	BT	256.89 ± 35.77						
		AT 1	214.61 ± 24.21	42.29 ± 20.63	27	3.899	10.8	< 0.	*

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							458	001	
		AT2	184.39 ± 20.73	72.50 ± 26.21	27	4.953	14.6389	<0.001	*
		AT3	162.18 ± 18.29	94.71 ± 26.76	27	5.056	18.7321	<0.001	*
HbA1c	Group- A	BT	7.31 ± 0.47						
		AT3	6.29 ± 0.31	1.02 ± 0.30	26	0.058	17.3775	<0.001	*
	Group- B	BT	7.18 ± 0.46						
		AT3	6.14 ± 0.41	1.04 ± 0.16	27	0.031	33.9333	<0.001	*

S.D= standard deviation, df= Degree of freedom, t= test of significance, p=probability; * = Highly significant at 0.1% level.

Table 8: Statistical analysis showing the effectiveness of *Lodhradi Kasaya* in comparison to Metformin w.r.t. sign and symptoms after 30 days, 60 days and 90 days.

Sign/ Symptom	Treat. Period	Assessment type	Mean diff ± SD	SE of diff.	df	t-value	p-value	Remarks
Glycosuria	AT30	Group-A Vs Group-B	0.75 ± 0.47 0.58 ± 0.49	0.129	53	1.5073	>0.05	*
	AT60	Group-A Vs Group-B	1.49 ± 0.51 1.40 ± 0.51	0.138	53	0.6985	>0.05	*
	AT90	Group-A Vs Group-B	1.92 ± 0.18 1.78 ± 0.40	0.085	53	1.6901	>0.05	*
FBS	AT30	Group-A Vs Group-B	20.30 ± 6.75 21.79 ± 6.91	1.843	53	0.8082	>0.05	*
	AT60	Group-A Vs Group-B	37.07 ± 8.38 37.04 ± 7.10	2.092	53	0.0183	>0.05	*
	AT90	Group-A Vs Group-B	50.96 ± 8.68 50.96 ± 7.78	2.221	53	0.00006	>0.05	*
PPBS	AT30	Group-A Vs Group-B	47.15 ± 18.07 42.29 ± 20.63	5.238	53	0.9284	>0.05	*
	AT60	Group-A Vs Group-B	76.78 ± 22.14 72.50 ± 26.21	6.553	53	0.6528	>0.05	*
	AT90	Group-A Vs Group-B	99.59 ±27.32 94.71 ± 26.76	7.292	53	0.669	>0.05	*
HbA1c	AT90	Group-A Vs Group-B	1.02 ± 0.30 1.04 ± 0.16	0.065	53	0.3205	>0.05	*

S.D= standard deviation, SE diff.= Standard error of difference, df= Degree of freedom, t= test of significance, p=probability; □ = Insignificant at 5% level.

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Mode of action of Trial Drug

The trial drug *Lodhradi Kashaya* contains four constituents namely *Lodhra, Musta, Haritaki* and *Katphala*. Each one is reported in *Ayurvedic* classics to have action of reducing *Prameha*.[10,11] From *Rasa Panchaka* analysis it has been observed that-

- There is predominance of *Kashaya, Tikta* and *Katu Rasa*; *Laghu, Tikshna* and *Ruksha Guna*; *Ushna Virya* and *Katu Vipaka*. Hence the drug acts as *Kapha Shamana* by virtue of its *Rasa*, *Guna*, *Virya* and *Vipaka*; *Pitta Shamana* with *Madhura Rasa* and *Seeta Virya*; *Vata Samana* with *Madhura Rasa, Ushna Virya* and *Madhura Vipaka*. As a whole the drug acts as *Tridosha Samaka*. Hence effective in controlling *Madhumeha*.
- Most of the drugs are having *Kapha-Medahara* property which ultimately corrects the vitiated *Slesma, Meda* and *Mamsa Dhatu*.
- All the herbs are having *Deepan-Pachan* property. Thus, the prepared medicine is potential to correct the *Agni* i.e., *Jatharagni* and *Dhatwagni*. They help in smooth management of body metabolism. Ultimately it helps in proper nourishment of *Dhatus*. It has the capacity to improve the tones of *Sapta-Dhatus*.
- *Madhumeha* is a disease related to *Mutrabaha Srotas* with cardinal symptom of polyuria (*Prabhuta Mutrata*). Most of the drugs are having *Grahi* and *Stamhbhana* property with predominance of *Kashaya* (astringent) and *Tikta* (bitter) *Rasa* as well. These helps to decrease excess urination and prevent the system from vitiation.
- *Haritaki* clears all the *Srotas* (paths) so it is called as *Pathya.* It alleviates the *Margabarodha* (obstructions) in *Madhumeha.* It also nourishes all *Dhatus* with its *Rasayana* property.
- *Musta* is potent in *Trishna Nigrahana*. So, it corrects the *Purbarupa* stage like *Trishna, Galatalu Sosha* etc. in *Madhumeha*.
- *Raj Nighantu* describes *Katphala* as *Ugradahahara*. *Musta* also have *Daha Nasaka* property. It cures the burning and tingling sensations in upper and lower extremities (*Hastapada Daha*).
- *Lodhra* is having *Chakshushya* (good for eyes) property, which may alleviate the chances of retinal complications in type 2 DM.

Hence from *Ayurvedic* point of view *Lodhradi Kashaya* is capable enough to fulfil all the treatment modalities of *Madhumeha* (type 2 DM).

Modern science strengthens the concept of *Madhumehaghna* (antidiabetic) property of all the four herbs. It is believed that the basis of the chemical constitution of different herbal drugs and various medicinal/ plant extracts contain active flavonoids, alkaloids, phenolic compounds, terpinoids, saponins, and phytosterol type chemical constituents that are effective in the management of diabetic complications. This effect might be attributed to the amelioration of persistent hyperglycemia, oxidative stress, and modulations of various metabolic pathways involved in the pathogenesis of diabetic complications.[12]

- The experimental studies on antidiabetic activities of *Lodhra* (*Symplocos racemose*), *Musta* (*Cyperus rotundus*), *Haritaki* (*Terminalia chebula*) and *Katphala* (*Myrica esculenta)* has been cited in the drug review section.
- Experimental studies show a significant reduction in blood glucose levels in DM animal models.
- Brahmakar R.B. *et al.* has reported the hypoglycemic effects of *Lodhradi Kashaya*. In their study, *Lodhradi Kashaya Ghana Vati* (LKGV) showed a significant decrease in blood sugar level both compared to a diabetic non-treated control group and to a group treated with a standard anti-diabetic drug, glibenclamide, in a streptozotocin-induced hyperglycemic rat model. It is reported that LKGV acts by stimulating the pancreatic beta cells of the pancreas and increasing sensitivity of the peripheral tissue to insulin.[13]
- All the components of the trial drug have antioxidant, antibacterial, antifungal, antiulcer, hepato-protective, hypolipidemic and anti-inflammatory activities.[14-17]

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The above data proves that the trial drug *Lodhradi Kashaya* is capable enough to manage *Madhumeha* (type-2 DM) in all aspects.

Conclusion

Madhumeha is a *Tridoshaja Vyadhi* with the main culprit *Dosha- Kapha* and *Vata*. Diabetes mellitus, which is a metabolic disorder, can be compared with *Madhumeha* according to presentation of disease as well as according to etiological factors involved. Sedentary life style, indulgence of *Kapha-Meda Vardhaka Ahara*, avoidance of regular exercise, day sleep is such findings of study which indicate *Santarpanajanya* origin of disease. Taking in to consideration into the various observations, results obtained during study and discussion, it can be said that Both *Lodhradi Kashaya* and Metformin provided significant result in improving Signs and Symptoms. Both drugs had improved levels of Glycosuria, F.B.S., P.P.B.S. and HbA1c in patients. *Lodhradi Kashaya* gives better clinical improvement than metformin in long term use. Hence it is proved to be an efficient anti diabetic drug.

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