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Comparative Evaluation of Two Samples of Trayushnadi Gutika in the Management of Madhumeha w.s.r. to Type 2 Diabetes Mellitus

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In the modern era, lifestyle disorders have emerged as a significant global health concern, primarily due to inadequate awareness regarding Aahara (dietary habits) and Vihara (daily regimen). Among these disorders, Madhumeha (Diabetes Mellitus Type 2) is one of the most prevalent metabolic conditions, extensively documented in Ayurvedic texts. Diabetes Mellitus is characterized by persistent hyperglycemia resulting from insulin resistance or deficiency. The global prevalence of diabetes has been steadily increasing due to urbanization, sedentary lifestyles, unhealthy dietary patterns, obesity, and lack of physical activity. Despite advancements in modern medicine, there is no definitive cure for Diabetes Mellitus. Conventional treatment primarily focuses on glycemic control through lifelong medication, including oral hypoglycemic agents (OHAs) and insulin therapy, which often lead to adverse effects such as gastrointestinal disturbances, weight gain, cardiovascular complications, and renal dysfunction. This has led to an increased interest in Ayurvedic interventions, which offer a holistic approach to managing Madhumeha by addressing its root cause rather than merely controlling symptoms. Among various Ayurvedic formulations, Trayushnadi Gutika has gained attention for its potential efficacy in managing Madhumeha. The present study, Comparative evaluation of two samples of Trayushnadi Gutika in the management of Madhumeha w.s.r. to Type 2 Diabetes Mellitus, aims to assess the therapeutic potential of this classical Ayurvedic formulation. To enhance its efficacy, an alternative sample has been formulated with the same ingredients but with a modified Bhavana (processing method) using Amalaki Swarasa (fresh Amla juice) instead of Gokshur Kwatha.

Keywords: Madhumeha, Diabetes Mellitus Type 2, Lifestyle Disorders, Ayurveda, Trayushnadi Gutika, Prameha, Metabolic Disorders, Traditional Medicine

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Introduction

In today's fast-paced world, the increasing burden of lifestyle disorders has become a major concern for global health. The lack of awareness regarding *Aahara* (dietary habits) and *Vihara* (daily regimen) has led to a surge in metabolic diseases, among which *Madhumeha* (Diabetes Mellitus Type 2) holds a significant place.**[1]** This condition, deeply rooted in Ayurvedic literature, has been extensively described in classical texts, emphasizing its chronic and progressive nature. *Madhumeha* is classified under *Vataj Prameha*,**[2,3]** closely resembling Diabetes Mellitus in modern medical science. It falls under the category of *Asadhaya/Krichha-Sadhya Vyadhi*, indicating that it is difficult to cure and often persists throughout life.

Diabetes Mellitus is a chronic metabolic disorder characterized by elevated blood glucose levels due to insulin resistance or deficiency.**[4]** The prevalence of diabetes has been steadily increasing worldwide, primarily due to urbanization, sedentary lifestyles, unhealthy dietary patterns, obesity, and lack of physical activity.**[5]** According to the World Health Organization (WHO), approximately 422 million people globally suffer from diabetes, with a significant proportion residing in low- and middle-income countries.**[6]** Alarmingly, diabetes is responsible for 1.6 million deaths annually, making it one of the leading causes of morbidity and mortality. The rising incidence of diabetes highlights the urgent need for effective management strategies that go beyond conventional pharmaceutical interventions.**[7-9]**

Despite advancements in modern medical science, there is no definitive cure for Diabetes Mellitus. Conventional treatment primarily focuses on glycemic control through lifelong medication, including oral hypoglycemic agents (OHAs) and insulin therapy.**[10,11]** However, prolonged use of these drugs often leads to adverse effects, including gastrointestinal disturbances, weight gain, cardiovascular complications, and renal dysfunction. This has prompted researchers and practitioners to explore alternative and holistic approaches for diabetes management, with Ayurveda emerging as a promising solution. Ayurveda, ancient Indian system of medicine, offers a comprehensive approach to managing *Madhumeha* by address. its root cause rather than merely controlling symptom.

Ayurvedic principles emphasize dietary modifications, lifestyle adjustments, herbal formulations, and detoxification therapies to restore metabolic balance and enhance overall well-being. Among the various Ayurvedic formulations, *Trayushnadi Gutika***[12]** has gained attention for its potential efficacy in managing *Madhumeha*.

Significance of *Trayushnadi Gutika* in *Madhumeha* Management

The present study, Comparative evaluation of two samples of *Trayushnadi Gutika* in the management of Madhumeha w.s.r. to Type 2 Diabetes Mellitus, aims to assess the therapeutic potential of this classical Ayurvedic formulation. *Trayushnadi Gutika,* mentioned in *Chakradutta - Pramehaadhikar* (verse 52-53), is composed of *Trikatu* (Ginger, Black Pepper, Long Pepper), *Triphala* (*Amla, Haritaki, Bibhitaki*), *Shuddha Guggulu*, and *Gokshur*. These ingredients are well-documented for their anti-diabetic, antioxidant, and rejuvenating properties.

To enhance its efficacy, an alternative sample has been formulated with the same ingredients but with a modified *Bhavana* (processing method) using *Amalaki Swarasa* (fresh Amla juice) instead of *Gokshur*. Amla, known for its rich vitamin C content and potent antioxidant activity, is expected to improve the bioavailability and therapeutic effectiveness of the formulation.

Objectives of the Study

1. Evaluate the efficacy of both samples of *Trayushnadi Gutika* in the management of *Madhumeha*.
2. Assess the impact of Ayurvedic intervention on glycemic control, metabolic parameters, and overall health improvement.
3. Provide scientific validation for the Ayurvedic approach to diabetes management, contributing to integrative medicine.

Materials and Methods

Study Population: For present study, patients having classical sign and symptoms of *Madhumeha* who were attending OPD/IPD of Research Unit of GACH Kadamkuan, Patna, were randomly selected irrespective of age, sex, religion, occupation, etc. known cases of *Madhumeha* patients were also selected but after various investigations.

Study design: Randomized Sampling, Single blind.

Study Type: Interventional Clinical Study.

Sample size: 60 (30 in each group)

Duration of study: 90 days

Follow-up: Every 15 days

Inclusion criteria

- Age between 20-70 years of either sex and any *Sharirik Prakruti*.
- Selected sign and symptoms based on both Ayurvedic and modern context.

Exclusion criteria

- Age group below 20 and above 70 years.
- Insulin Dependent Diabetes Mellitus (IDDM) and those who are under insulin therapy.
- Pregnant and lactating women.
- Patient with Cirrhosis of liver, Pancreatitis, HIV, Hepatitis.
- Patients with acute complications like Hyperglycemia and Hypoglycemic Coma.
- Patient with chronic Diabetic complications like Nephropathy, Neuropathy and Retinopathy.

Intervention

Group A: Treated internally with *Trayushnadi Gutika* (*Gokshur Kwatha Bhavita*)

Group B: Treated internally with *Trayushnadi Gutika* (*Amalaki Swarasa Bhavita*)

Posology

Group A: *Trayushnadi Gutika* (*Gokshur Kwatha Bhavita*) 1g Two times a day after meal with luke warm water.

Group B: *Trayushnadi Gutika* (*Amalaki Swarasa Bhavita*) 1g Two times a day after meal with luke warm water.

Table 1: Ingredients of *Trayushnadi Gutika*

SN	Drugs	Latin name	Parts used	Ratio
1.	Guggulu	Commiphora wightii	Niryasa (Gum-resin)	6
2.	Pippali	Piper longum Linn.	Fruit	1
3.	Maricha	Piper nigrum Linn.	Fruit	1
4.	Shunthi	Zingiber officinale Roscone	Rhizome	1
5.	Haritaki	Terminalia chebula Retz.	Fruit	1
6.	Bibhitaki	Terminalia bellirica Roxb	Fruit	1
7.	Amalaki	Phyllanthus emblica Linn.	Fruit	1
8.	Gokshur	Tribulus terrestris Linn.	Whole	QS

Gokshur Kwatha was replaced with *Amalaki Swarasa* in Group B.

Laboratory investigation

Routine Haematological Examinations like Hb% etc. were done to rule out any other pathological condition.

Biochemical Examinations

A. Blood Sugar: Fasting and post-prandial.
B. Lipid profile: S. Cholesterol, S. Triglyceride, HDL, LDL, etc.

These investigations were done in all the patients before treatment and after completion of treatment.

Assessment criteria

Subjective Criteria:

- *Bahumutrata*
- *Avila Mutrata*
- *Kshudhadhikaya*
- *Pipasadhikya*
- *Kara-Pada-Tala Daha*
- *Daurbalya*
- *Pindikodveshtana*
- *Klaibya*

Objective Criteria:

- Fasting blood sugar level
- Postprandial blood sugar level

Gradation of Assessment criteria

1. Bahumutrata

- Day - 1 to 6 time, Night - 0 to 1 time - 0
- Day - 6 to 7 time, Night - 1 to 2 time - 1
- Day - 7 to 10 time, Night - 2 to 4 time - 2
- Day >10 time, Night >4 time - 3

2. Avila Mutrata

- Absence of albumin in urea - 0
- Present with - + 1
- Present with - ++ 2
- Present with - +++ 3

3. Kshudhadhikaya

- As usual / routine - 0
- Slightly increased (1 - 2 meals) - 1

- Moderately increased (3 - 4 meals) - 2
- Markedly increased (5 - 6 meals) - 3

4. Pipasadhikya

- Feeling of thirst 7 - 9 times/24 hours, either/or Intake of water 5 – 7 times/24 hours with quantity 1.5 – 2.0 liter/24 hours - 0
- Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - 9 times/24 hours with quantity 2.0 - 2.50 liter/24 hours - 1
- Feeling of thirst 11 – 13 times/24 hours, either/or Intake of water 9 – 11 times/24 hours with quantity 2.50 -3.00 liter/24 hours - 2
- Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours - 3

5. Kara-Pada-Tala Daha

- No *Suptata*, *Daha* - 0
- *Daha* incontinuos - 1
- *Daha* continuous but bearable & not severe - 2
- *Daha* continuous and severe & Unbearable - 3

6. Daurbalya

- Can do routine exercise/work - 0
- Can do moderate exercise with hesitancy - 1
- Can do mild exercise only, with difficulty - 2
- Cannot do mild exercise too - 3

7. Pindikodveshtana

- No cramps - 0
- Cramps after walking more than 1 km. - 1
- Cramps after walking ½ km - 2
- Inability in walking even ½ km - 3

8. Klaibya

- Normal - 0
- Decreased frequency with normal performance - 1
- Decrease frequency with insufficiency - 2
- No sexual stimulation at all - 3

Statistical analysis

All information which was based on various parameters was gathered and statistical analysis was carried out in terms of mean (X), Standard Deviation (S.D.), Standard Error (S.E.), Paired test (t) and finally results was incorporated in terms of probability 'p' as-

Table 2: Showing magnitude of an improvement

p>0.05	Insignificant
p<0.05	Improvement
p<0.01	Significant improvement
p<0.001	Highly significant improvement

Observations and Results

For the present study, total 60 patients were selected randomly. Out of 60 patients 30 patients were enrolled in Group A while 30 patients in Group B. Observations of 60 patients are noted.

Table 3: Showing number of patients of Group A.

Group A	Number of patients		Total	Percentage (%)
	Male	Female		
Registered	16	14	30	100
Completed	14	13	27	90
Dropout	02	01	03	10

The above table shows that total 30 patients were registered in group A and 27 patients had completed trial and only 03 patients were drop out.

Table 4: Showing number of patients of Group B.

Group B	Number of patients		Total	Percentage (%)
	Male	Female		
Registered	18	12	30	100
Completed	17	10	27	90
Dropout	01	02	03	10

The above table shows that total 30 patients were registered in group B and 27 patients had completed trial and only 03 patients were drop out.

In Group A, maximum 12 (40%) of patients were in the age group of 51 to 60 years while minimum 1 (3.33%) of the patient was in the age group of 21-30 years. In Group B, maximum 11 (36.66%) of patients were in age group of 51-60 years while minimum 1 (3.33%) of the patients were in the age group of 21-30 years. In Group A, maximum 16 (53.33%) of patients were male and remaining 14 (46.67%) of the patients was females. In Group B, maximum 17 (53.33%) of the patients were male and the remaining 13 (46.67%) patients were female. In Group A, maximum 29 (96.67%) patients were Hindu, 1 (3.33%) was Muslim. In Group B, maximum 28 (93.33%) patients were Hindu, 2 (6.67%) are Muslim.

In Group A, maximum 28 (93.33%) of the patients were married while 0% was unmarried, 2 (6.67%) are widow and widower. In Group B, maximum 29 (96.33%) of the patients were married while 0% was unmarried, 1 (3.34%) are widow and widower. In Group A, 6 (20%) of the patients were from lower economic class, 16 (53.34%) of the patients were from middle class and remaining 8 (26.66%) of the patients were from upper economic class.

In Group B, 3 (10%) of the patients were from lower economic class, 20 (66.67%) of the patients were from middle class and remaining 7 (23.33%) patients were from upper economic class. In Group A, 6 (20%) of the patients were rural and 24 (80%) of the patients were urban. In Group B, 11 (36.67%) of the patients were rural and 19 (63.33%) of the patients were urban.

In Group A, 2 (06.66%) patients had tobacco addiction, 22 (73.33%) were having tea/coffee addiction, 1 (03.33%) were having smoking, and 2 (06.67%) were having other addiction and 4 (13.34%) patients having no addiction. In Group B, 3 (10.00%) patients had tobacco addiction, 21 (70.00%) were having tea/coffee addiction, 0 (0%) was having smoking, and 3 (10.00%) were having other addiction and 2 (06.66%) patients having no addiction. In Group A, 11 (36.67%) patients were vegetarian and 19 (63.33%) were mixed. In Group B, 10 (33.33%) patients were vegetarian and 20 (66.67%) were mix.

In Group A, 5 (16.67%) patients were having *Heena* appetite, 22 (73.33%) were having *Madhyama* appetite and remaining 3 (10%) of the patients were having *Uttama* appetite. In Group B, 6 (20%) patients were having *Heena* appetite, 20 (66.66%) were having *Madhyama* appetite and remaining 4 (13.34%) of the patients were having *Uttama* appetite. In Group A, 15 (50.00%) patients were having regular bowel, 7 (23.33%) patients were irregular bowel and 8 (26.67%) were constipated bowel.

In Group B, 18 (60.00%) patients were having regular bowel, 5 (16.67%) patients were irregular bowel and 7 (23.33%) were having constipated bowel. In Group A, 15 (50.00%) patients were having sound sleep and 11 (36.67%) patients were having disturbed sleep, 7 (23.33%) having reduced sleep at night and 5 (16.66%) were having day-sleep.

In Group B, 23 (76.66%) patients were having sound sleep and 6 (20.00%) patients were having disturbed sleep, 8 (26.66%) having reduced sleep at night and 6 (20.00%) were having day-sleep.

In Group A, 20 (66.67%) patients were having sedentary life, 7 (23.33%) patients were having active life and 3 (10.00%) were having heavy work life. In Group B, 22 (73.33%) patients were having sedentary life, 6 (20.00%) patients were having active life and 2 (06.67%) were having heavy work life.

In Group A, 8 (26.66%) patients were having *Vataj-Pittaja Prakriti*, 10 (33.34%) patients were having *Vataja Kaphaja Prakriti* and 12 (40.00%) patients were having *Kapahja Pittaja Prakriti*. In Group B, 7 (23.33%) patients were having *Vataj-Pittaja Prakriti*, 10 (33.34%) patients were having *Vataja Kaphaja Prakriti* and 13 (43.34%) patients were having *Kapahja Pittaja Prakriti*. In Group A, 2 (06.67%) patients were *Pravara Samhanana*, 27 (90.00%) were having *Madhyama Samhanana* and 1 (3.34%) were having *Avara Samhana*.

In Group B, 0 (0%) patients were *Pravara Samhanana*, 28 (93.33%) were having *Madhyama Samhanana* and 2 (06.67%) were having *Avara Samhana*. In Group A, 3 (10%) patients were *Pravara Satva*, 25 (83.33%) patients were *Madhyam Satva* and (6.67%) were *Avara Satva*. In Group B, 2 (6.67%) patients were *Pravara Satva*, 27 (90%) patients were *Madhyama Satva* and 1 (3.33%) were *Avara Satva*. In Group A, 2 (6.66%) patients were *Pravara Satmya*, 27 (90%) were *Madhyam Satmya* and 1 (3.34%) were *Avara Satmya*.

In Group B, 3 (10%) patients were *Pravara Satmya,* 25 (83.33%) were *Madhyama Satmya* and 2 (6.67%) were *Avara Satmya*. In Group A, 6 (20%) patients were *Heena Rogabala*, 21 (70%) were *Madhyama Rogabala* and 3 (10%) were *Uttama Rogbala*. In Group B, 4 (13.33%) patients were *Heena Rogabala*, 25 (83.33%) were *Madhyama Rogabala* and 1 (03.34%) were *Uttama Rogabala*.

In Group A, 3 (10.00%) patients were *Heena Rogibala*, 25 (83.33%) were *Madhyama Rogibala* and 2 (06.66%) were *Uttama Rogibala*. In Group B, 5 (16.66%) patients were *Heena Rogibala*, 23 (76.67%) were *Madhyama Rogibala* and 2 (06.67%) were *Uttama Rogibala*.

In Group A, 3 (10.00%) patients were having sudden mode of onset and 27 (90.00%) patients were having gradual mode of onset. In Group B, 2 (06.67%) patients were having sudden mode of onset and 28 (93.33%) patients were having gradual mode of onset. In Group A, 2 (06.67%) patients were having less than 1 year's chronicity, 22 (73.33%) patients were having 1 to 10 years and 6 (20.00%) patients were having greater than 10 years chronicity of disease. In Group B, 4 (13.33%) patients were having less than 1 year's chronicity, 21 (70.00%) patients were having 1 to 10 years and 5 (16.67%) patients were having greater than 10 years chronicity of disease.

Signs and Symptom wise distribution

In Group A, 25 (83.33%) patients were having *Prabhuta Mutrata*, 19 (63.33%) patients were having *Avila Mutrata*, 22 (73.33%) patients were having *Trishnadhikya*, 23 (76.66%) patients were having *Kshudhadhikya*, 19 (63.33%) patients were having *Kara-Pada-Tala Daha*, 20 (66.66%) patients were having *Pindikodwesthana* and 24 (80.00%) patients were having *Daurbalya.*

In Group B, 22 (73.33%) patients were having *Prabhuta Mutrata*, 18 (60.00%) patients were having *Avila Mutrata*, 21 (70.00%) patients were having *Trishnadhikya,* 19 (63.33%) patients were having *Kshudhadhikya,* 23 (76.66%) patients were having *Kara-Pada-Tala Daha*, 21 (70.00%) patients were having *Pindikodwesthana* and 26 (86.66%) patients were having *Daurbalya.*

Associated Signs and Symptom wise distribution

In Group A, 20 (66.66%) patients were having *Madhurasyata*, 22 (73.33%) patients were having *Tandra*, 21 (70.00%) patients were having *Gurugatrata* and 16 (53.33%) patients were having *Klaibya*.

In Group B, 19 (63.33%) patients were having *Madhurasyata*, 23 (76.66%) patients were having *Tandra*, 24 (80.00%) patients were having *Gurugatrata* and 18 (60.00%) patients were having *Klaibya*.

Effect of therapy in Group-A: In this group, 27 patients of *Madhumeha* were included. The patients were given *Trayushnadi Gutika* Sample-A with dose of 1 Vati (1 gm) twice a day with Luke warm water, after meal, for the duration of 90 days.

Table 5: Showing effect of therapy in Group-A.

Symptoms	Mean		% Relief	±SD	±SE	T Value	P Value
	BT	AT					
Prabhutra Mutrata (25)	2.70	0.77	71.48↓	0.99	0.19	10.03	<0.001
Avila Mutrata (19)	2.03	0.92	54.67↓	1.03	0.199	5.00	<0.001
Kshudadhikya (23)	2.18	0.66	69.72↓	0.80	0.15	9.83	<0.001
Trishnadhikya (n=22)	2.14	0.85	60.28↓	0.91	0.17	7.38	<0.001
Kara-Pada-Tala Daha (19)	1.92	0.40	79.16	1.12	0.21	7.03	<0.001
Pindikodwestana (20)	2.48	1.18	52.41	0.85	0.16	7.61	<0.001
Daurbalya (24)	2.44	1.29	47.13	0.71	0.13	8.30	<0.001
Associated symptoms:							
Madhurasyata (n=20)	1.96	0.96	51.02	0.83	0.16	6.24	<0.001
Gurugatrata (n=21)	2.29	1.33	41.92	0.87	0.16	5.50	<0.001
Klaibya (n=16)	1.55	0.59	61.93	0.93	0.18	5.32	<0.001

Effect of therapy in Group-B: In this group, 27 patients of *Madhumeha* were included. The patients were given *Trayushnadi Gutika* Sample-B with dose of 1 Vati (1 gm) twice a day with Luke warm water, after meal, for the duration of 90 days.

Table 6: Showing effect of therapy in Group-B.

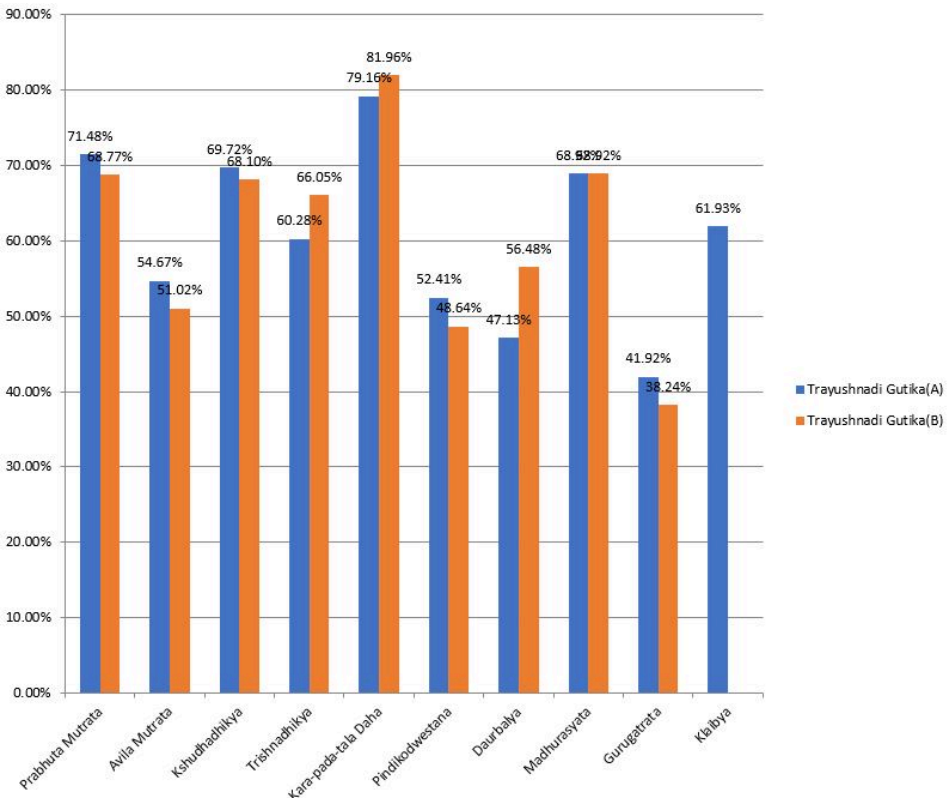
Symptoms	Mean		% Relief	±SD	±SE	T Value	P Value
	BT	AT					
Prabhutra Mutrata (n=22)	2.37	0.74	68.77↓	0.97	0.18	8.52	<0.001
Avila Mutrata (n=18)	1.96	0.96	51.02↓	0.87	0.16	5.92	<0.001
Kshudadhikya (n=19)	1.85	0.59	68.10	0.94	0.18	6.92	<0.001
Trishnadhikya (n=21)	2.18	0.74	66.05	0.93	0.17	8.03	<0.001
Kara-Pada-Tala Daha (n=23)	2.44	0.44	81.96	1.00	0.19	10.39	<0.001
Pindikodwestana (n=21)	2.59	1.33	48.64	0.76	0.14	8.56	<0.001
Daurbalya (n=26)	2.62	1.14	56.48	0.89	0.17	8.61	<0.001
Associated symptoms:							
Madhurasyata (n=19)	1.77	0.55	68.92	0.93	0.17	6.80	<0.001
Gurugatrata (n=24)	2.51	1.55	38.24	0.78	0.15	6.16	<0.001
Klaibya (n=18)	1.77	0.92	48.02	0.90	0.17	4.87	<0.001

Effect on Laboratory Parameters in Group A

Laboratory Parameters	Mean		% Relief	±SD	±SE	T Value	P Value
	BT	AT					
FBS	175.59	115.18	34.40↓	18.48	3.55	16.98	<0.001
PPBS	277.51	196.03	29.36↓	17.98	3.46	23.46	<0.001
Hb (gm)	12.53	13.04	4.07↑	0.559	0.107	-4.98	<0.001
Lipid Profile (S. Cholesterol)	200.33	177.48	11.40↓	12.55	2.41	9.64	<0.001

Effect on Laboratory Parameters in Group B

Laboratory Parameters	Mean		% Relief	±SD	±SE	T Value	P Value
	BT	AT					
FBS	172.95	120.62	30.25↓	23.126	4.450	11.750	<0.001
PPBS	278.88	205	26.49↓	11.13	2.14	34.59	<0.001
Hb%	12.48	12.84	2.88↑	0.305	0.058	-6.112	<0.001
Lipid Profile (S. Cholesterol)	203.03	176.25	13.19↓	13.75	2.64	10.12	<0.001



Comparative study of Percentage Relief by *Trayushnadi Gutika* (sample A) and *Trayushnadi Gutika* (sample B) on various signs and symptoms:

Discussion

The drug *Trayushnadi Gutika*, prepared using *Gokshura Bhavana* in Group A and *Amalaki Swarasa Bhavana* in Group B, was administered to 60 patients over a period of 90 days. However, six patients discontinued the trial, leaving a total of 54 participants whose symptoms and clinical signs were statistically analyzed. Both groups - *Trayushnadi Gutika Sample-A* and *Trayushnadi Gutika Sample-B* - were thoroughly assessed, and a comparative study was conducted to evaluate the differences between the two formulations.

Discussion on demographic profile

Age group: All the patients included in this study were age group of 21 to 70 years. In both group A & B maximum patients are in the age group of 51-60 years. While in group B 33.34% patients belongs to age group of 41-50 years. It shows that maximum prevalence of *Madhumeha* (DM type 2) at Madhyama Avastha.

In both group A & B having 20% prevalence of Madhumeha (DM type 2) in age group of 61-70 years. Generally, it is observed that people above 40 years suffer from DM type 2, above observation support this fact.

Sex: Present study shows that approximately equal number of male & female patients in both groups i.e. male in group A is 53.33 % and female is 46.67 % while in group B, male is 56.66 % and female is 43.34 %. Incidence of disease is approximately similar in Male and Female or may be due to demographic facts.

Religion: From the both group of sample maximum number of patients is Hindu i.e. in group A is 96.66 % is Hindu and 3.34 % is Muslim while in group B having 93.33 % is Hindu and 6.67 % is Muslim. Not specific conclusion can be drawn from this observation. This could be due to Hindu dominated community.

Education: In present study shows that 13.33% patients were illiterate, 46.67% patients were up to school, 23.33% patients were graduate and 16.67% patients were Post-graduate in group A While 10% patients were illiterate, 60% patients were up to school, 20% patients were graduate and 10% patients were Post-graduate in group B.

Prevalence of disease in up to school patients is more may be due to their stressful life.

Marital Status: The study shows that maximum number of patients are married in both group i.e.,

93.33 % patients are married and 6.67 % are widow & widower of group A while 96.66 % patients are married and 3.34 % are widow & widower of group B.

Occupation: In present study shows that 6.67% patients were students, 20% were service, 10% had business, 33.33% were Housewife/Household and 30% are others in group while 3.34% patients were students, 26.66% having service, 16.66% having business, 33.34% are Housewife/Household and 20.00% are others in group B.

This figure shows that disease usually occurs in those people who having sedentary life style like Housewife/Household people, Service man or women, etc. Stress was also most important factor for precipitating of DM type 2.

Socio-economic Status: In this study maximum number of patients belongs to Middle class i.e. 53.34%, 26.66% belongs to Upper class and 20% belongs to Lower class in group A While 66.67% patients belongs to Middle class, 23.33% belongs to Upper class and 10% belongs to Lower class in group B.

Above observation shows that maximum patients belongs to Middle class but not any specific conclusion can be drawn from this observations because this study was carried out in Government Hospital and here patients coming to their socio-economic conditions.

Habitat: Present study shows that 20% of the patients were living in rural area and 80% of the patients were living in urban area in group A While 36.67% of the patients were living in rural area and 63.33% of the patients were living in urban area in group B.

Above observation shows that prevalence of DM type 2 is more in urban than in rural areas. This shows the deranged life style, altered food behavior, etc.

Nature of work: 66.67% patients were having sedentary life, 23.33% patients were having active life and 10.00% were having heavy work life in group A while 73.33% patients were having sedentary life, 20.00% patients were having active life and 06.67% were having heavy work life in group B. Above observation shows that sedentary life play important role to cause *Madhumeha*.

Addiction: Maximum patients were having tea, coffee addiction. i.e., 06.66% patients had tobacco addiction, 73.33% were had tea/coffee addiction, 03.33% were having smoking, and 06.67% were having other addiction and 13.34% patients having no addiction in group A While 10.00% patients having tobacco addiction, 70.00% were having tea/coffee addiction, 0% was having smoking, and 10.00% were having other addiction and 06.67% patients having no addiction in group B.

Diet-pattern: In this study 36.67% patients were vegetarian and 63.33% were mixed in group A While 33.33% patients were vegetarian and 66.67% were mixed in group B.

Above observation shows that maximum people had mixed Diet.

Appetite: In this study shows that 16.67 patients were having *Heena* appetite, 73.33% were having *Madhyama* appetite and remaining 10% of the patients were having *Uttama* appetite in group A. while 20% patients were having *Heena* appetite, 66.66% were having *Madhyam* appetite and remaining 13.34% of the patients were *Uttama* appetite in group B.

Above observation shows that maximum prevalence of appetite is *Madhyama*.

Bowel: Long standing disease can affect the normal Bowel-pattern of patients.50.00% patients were having regular bowel, 23.33% patients were irregular bowel and 26.67% were constipated bowel in group A. while 60.00% patients were having regular bowel, 16.67% patients were irregular bowel and 23.33% were having constipated bowel in group B.

Sleep: 63.33%patients were having sound sleep and 36.67% patients were having disturbed sleep, 23.33% having reduced at night and 33.33% were having day-sleep in group A. while 76.66%patients were having sound sleep and 20.00% patients were having disturbed sleep, 26.66% having reduced at night and20.00% were having day-sleep.

Disturbed sleeping patterns like *Divaswapna* and *Ratrijagarana* are few important etiological factors.

***Sharira Prakriti*:** 26.66% patients were having VP *Prakriti*, 33.34% patients were having VK *Prakriti* and 40.00% patients were having KP *Prakriti* in group A.

While 23.33% patients were having VP *Prakriti,* 33.34% patients were having VK *Prakriti* and 43.34% patients were having KP *Prakriti* in group B.

***Samhanana*:** patients 06.67% patients were *Pravara Samhanana*, 90.00% were having *Madhyama Samhanana* and 3.34% were having *Avara Samhanana* in group A. while 93.33% were having *Madhyama Samhanana* and 06.67% were having *Avara Samhana* in group B.

***Satva*:** 6.67% patients were *Pravara Satva*, 86.66% patients were *Madhyam Satva* and 6.67% were *Avara Satva* in group A, while 6.67% patients were *Pravara Satva*, 90% patients were *Madhyama Satva* and 3.33% were *Avara Satva* in group B.

***Satmya*:** 6.66% patients were *Pravara Satmya*, 90% were *Madhyam Satmya* and 3.34% were *Avara Satmya* in group A, while 10% patients were *Pravara Satmya*, 83.33% were *Madhyama Satmya* and 6.67% were *Avara Satmya* in group B.

***Rogabala*:** 20% patients were *Heena Rogabala*, 70% were *Madhyama Rogabala* and 10% were *Uttama Rogbala* in group A, while 13.33% patients were *Heena Rogabala*, 83.33% were *Madhyama Rogabala* and 03.34% were *Uttama Rogabala* in group B.

***Rogibala*:** 10.00% patients were *Heena Rogibala*, 83.33% were *Madhyama Rogibala* and 06.66% were *Uttama Rogibala* in group A, while 16.66% patients were *Heena Rogibala*, 76.67% were *Madhyama Rogibala* and 06.67% were *Uttama Rogibala* in group B.

Mode of onset: 10.00% patients were having sudden mode of onset and 90.00% patients were having gradual mode of onset in group A, while that 06.67% patients were having sudden mode of onset and 93.33% patients were having gradual mode of onset in group B.

Chronicity: 06.67% patients were having less than 1 years chronicity, 73.33% % patients were having 1 to 10 years and 20.00% patients were having greater than 10 years chronicity of disease in group A, while that 13.33% patients were having less than 1 years chronicity, 70.00% % patients were having 1 to 10 years and 16.67% patients were having greater than 10 years chronicity of dise. in group B.

Treatment History: 26.67% patients were taking Allopathic treatment, 50.00% patients were taking Ayurvedic treatment and 23.33 % patients were taking other treatment in group-A, while 20.00% patients were taking Allopathic treatment, 60.00% patients were taking Ayurvedic treatment and 20.00 % patients were taking other treatment in group-B. This data may be due to middle and lower class more comes in Ayurvedic Hospital.

Family History: 40.00% patients were having positive family history and 60.00% patients were having negative family history in group A, while 33.33% patients were having positive family history and 66.67% patients were having negative family history in group B.

Signs and Symptoms: 83.33% patients were having *Prabhuta Mutrata*, 63.33% patients were having *Avila Mutrata,* 73.33% patients were having *Trishnadhikya*, 76.66% patients were having *Kshudhadhikya,* 63.33% patients were having *Kara-Pada-Tala Daha*, 66.66% patients were having *Pindikodwesthana* and 80.00% patients were having *Daurbalya* in group-A While 73.33% patients were having *Prabhuta Mutrata*, 60.00% patients were having *Avila Mutrata*, 70.00% patients were having *Trishnadhikya*, 63.33% patients were having *Kshudhadhikya*, 76.66% patients were having *Kara-Pada-Tala Daha,* 70.00% patients were having *Pindikodwesthana* and 86.66% patients were having *Daurbalya* in Group-B.

Associated signs and symptoms: 66.66% patients were having *Madhurasyata,* 73.33% patients were having *Tandra*,70.00% patients were having *Gurugatrata* and 53.33% patients were having *Klaibya* in group-A, while 63.33% patients were having *Madhurasyata*, 76.66% patients were having *Tandra,* 80.00% patients were having *Gurugatrata* and 60.00% patients were having *Klaibya* in group-B.

Discussion on effect of the Trial Drug

The results obtained of both sample of *Trayushnadi Gutika* on each parameter are being discussed here as under following heading-

Effect of *Trayushnadi Gutika* (sample A & B) on Chief complaints

Prabhuta Mutrata: In group-A 71.48% relief was observed in *Prabhuta Mutrata* and highly significant (P<0.001), While in group B 68.67% relief was observed and highly significant (P<0.001).

From these observations it can be concluded that Sample-A provided better relief in *Prabhuta Mutrata* than sample B.

Avila Mutrata: In group A 54.67% relief was observed and highly significant (P<0.001), while in group B 51.02% relief was observed and highly significant (P<0.001) .

Trishnadhikya: In group A 60.28% relief was observed in *Trishnadhikya* and highly significant (P<0.001), while in group B 66.05% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample B provided better relief than sample A.

Kshudhadhikya: In group A 69.72% relief was observed and highly significant (P<0.001), while in group B 68.10% relief was observed and highly significant (P<0.001).

Kara-Pada-Tala Daha: In group A 79.16% relief was observed and highly significant (P<0.001), while in group B 81.96% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A & B provide good relief.

Pindikodwesthana: In group A 52.41% relief was observed and highly significant (P<0.001), while in group B 48.64% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A provided better relief than sample B.

Daurbalya: In group A 47.13% relief was observed and highly significant (P<0.001), while in group B 56.48% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample B provided better relief than sample A.

Effect of *Trayushnadi Gutika* (sample A & B) on associated complaints

***Madhurasyata*:** In group A 51.02% relief was observed and highly significant (P<0.001), while in group B 68.92% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample B provided better relief in *Prabhuta Mutrata* than sample A.

***Gurugatrata*:** In group A 41.92% relief was observed and highly significant (P<0.001), while in group B 38.24% relief was observed and highly significant (P<0.001) .

From these observations it can be concluded that Sample A provided relief in *Gurugatrata* than sample B.

***Klaibya*:** In group A 61.93% relief was observed in Klaibya and highly significant (P<0.001), while in group B 48.02% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A provided better relief in *Klaibya* than sample B.

Effect of *Trayushnadi Gutika* (sample A & B) on Objective Parameter

Haemoglobin (gm): In group A 4.07% relief was observed and highly significant (P<0.001), while in group B 2.88% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A provided better relief than sample B.

Fasting Blood Sugar (FBS): In group A 34.40 relief was observed and highly significant (P<0.001), while in group B 30.25% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A provided better relief than sample B

Postprandial Blood Sugar (PPBS): In group A 29.36% relief was observed in *Prabhuta Mutrata* and highly significant (P<0.001), while in group B 26.29% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A provided better relief in *Prabhuta Mutrata* than sample B.

S. Cholesterol: In group A 11.40% relief was observed and highly significant (P<0.001), while in group B 13.19% relief was observed and highly significant (P<0.001). From these observations it can be concluded that Sample A provided better relief than sample B.

Probable mode of action:

- The drugs of *Trayushnadi Gutika* like *Trikatu* (*Pippali, Maricha* and *Sunthi*), *Triphala* (*Haritaki, Bibhitaki* and *Amalaki*), *Guggulu* and *Bhawana* of *Gokshur* and *Amalaki Swarasa.*
- Most of drug like *Haritaki, Bibhitaki* and *Amalaki* are known for their *Rasayana*
- *Triphala* used for appetite stimulation, reduction of hyperacidity, anti-oxidant, Immunomodulation, hypoglycemic effect, etc.

- *Trikatu* having *Katu Rasa, Laghu* and *Tikshna Guna* can improves digestion of food as well as enhance absorption of nutrients.
- In this formulation *Guggulu* is taken equal half. So, its effect will be also more. It promotes weight loss, manage cholesterol level and improve blood sugar level. It also works on urinary disorders.
- *Gokshur* having *Madhura Rasa, Guru* and *Snigdha Guna* and *Sheetavirya* can improve *Agni*, acts as *Vatanulomaka, Mootrala, Kaphanissaraka, Balya, Vrishya,* In other words, it acts as antioxidant, may boost libido, reduce blood sugar level, reduce blood pressure, etc.
- *Amalaki Swarasa* act as diuretic, laxative, stomachic, etc.

Conclusion

Trayushnadi Gutika appears to be effective due to its properties, including *Katu Rasa, Ruksha Laghu Guna, Vatanulomaka, Agnideepana, Kapha-Medo Hara, Mootrala, Rasayana,* and *Ushna Veerya*. These properties play a crucial role in the management of *Prameha* (*Madhumeha*). *Trayushnadi Gutika* samples A and B were prepared according to *Chakradatta Pramehadhikara*. The ingredients of both samples were identical, with the only difference being the *Bhavana* process - Sample A was prepared using *Gokshura Kwatha*, whereas Sample B was prepared using *Amalaki Swarasa.* Both formulations demonstrated significant efficacy. While both samples showed considerable relief in various signs and symptoms of *Madhumeha*, Sample-A exhibited slightly greater improvement compared to Sample B. However, some specific symptoms showed better improvement in *Trayushnadi Gutika* Sample B than in Sample A. The study found both formulations to be highly significant in terms of clinical effectiveness, with a notable percentage of relief observed.

Laboratory investigations revealed maximum improvement in blood sugar levels. Both drugs played an important role in regulating F.B.S. and P.P.B.S., along with contributing to the reduction of S. Cholesterol, thereby aiding in bringing these parameters closer to the normal range. The present study was conducted with certain limitations, restricting laboratory investigations such as HbA1c, TLC, and Lipid Profile.

Further research incorporating these parameters is recommended to strengthen the findings. In this study, clinical relief in signs and symptoms was more pronounced compared to laboratory parameters. Based on the observed improvements in symptoms and laboratory investigations, it can be concluded that *Trayushnadi Gutika* is an effective treatment for *Madhumeha*. No significant side effects were reported during the trial. However, a few patients experienced mild constipation after two months of consuming *Trayushnadi Gutika* Sample A.

References

1. Mohan V, Sudha V, Shobana S, Gayathri R, Krishnaswamy K. Are unhealthy diets contributing to the rapid rise of Type 2 Diabetes in India? J Nutr. 2023;153(4):940-8. doi: 10. *1016/j.tjnut.2023.02.028 [Crossref][PubMed] [Google Scholar]*

2. Murthy KRS. Bhavaprakasa of Bhavamisra. Purvakhand Dvitiyabhaga, Section I, Part II, Chapter 7 (III). 2nd ed. *Varanasi: Krishnadas Academy; 2001. p. 551 [Crossref][PubMed][Google Scholar]*

3. Basavaraju NK. MeharogaNidanaLaksanaChikitsadyayah (9th Chapter). In: Basavarajeeyam. Hyderabad: NIIHM; 2013. *p. 328-31 [Crossref][PubMed][Google Scholar]*

4. Davidson's Principles and Practice of Medicine. 21st ed. Edinburgh: Churchill Livingstone; 2010. p. *798 [Crossref][PubMed][Google Scholar]*

5. Chaudhary V, Johri S, et al. Evaluation of comparative efficacy of Neelkanthi (Ajuga bracteosa), Tejapatra (Cinnamomum tamala) and Methikabeeja (Trigonella foenumgraecum) Churna in the management of diabetes mellitus. Int J Ayurveda Pharma Res. 2015;3(2):80-5. *[Crossref] [PubMed][Google Scholar]*

6. Roglic G, editor. Global report on diabetes. Geneva: World Health Organization; 2016. Available from: https://www. *who.int/publications/i/item/9789241565257 [Crossref][PubMed][Google Scholar]*

7. Joshi SR, Parikh RM. India - diabetes capital of the world: now heading towards hypertension. J Assoc Physicians India. 2007;55:323-4. *[PubMed] [Crossref][PubMed][Google Scholar]*

8. Kumar A, Goel MK, Jain RB, Khanna P, Chaudhary V. India towards diabetes control; key issues. Australas Med J. 2013;6(10):524-31. *[PMC free article] [Crossref][PubMed][Google Scholar]*

9. International Diabetes Federation. IDF Diabetes Atlas. 8th ed. Brussels: International Diabetes Federation; 2017. *[Crossref][PubMed][Google Scholar]*

10. American Diabetes Association Professional Practice Committee. Pharmacologic approaches to glycemic treatment: Standards of care in diabetes-2025. Diabetes Care. 2025;48(Suppl_1):S181-S206. *doi: 10.2337/dc25-S009. PMID: 39651989; PMCID: PMC11635045 [Crossref][PubMed][Google Scholar]*

11. Borgharkar SS, Das SS. Real-world evidence of glycemic control among patients with type 2 diabetes mellitus in India: the TIGHT study. BMJ Open Diabetes Res Care. 2019;7:e000654. *[Crossref][PubMed][Google Scholar]*

12. Chakradatta. Pramehaadhikar. Chapter 35, Verses 52-53, Shlokas 47-48. p. *216 [Crossref] [PubMed][Google Scholar]*