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Research Article

A COMPARATIVE PHARMACO-CLINICAL STUDY OF (*Ficus racemosa* Linn.) AND *INDRAVARUNI PHALA CHURNA* (*Citrullus colocynthis* Schrad.) IN THE MANAGEMENT OF *MADHUMEHA* (TYPE-2, DIABETES MELLITUS)

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ABSTRACT

One of the contemporary global health issues is diabetes mellitus. Because of their *Pramehaghna* (anti-diabetic) qualities and the numerous clinical trials in diabetes, *Indravaruni Phala Churna* are used to treat *Madhumeha* (diabetes mellitus). In order to compare the effects of *Indravaruni Phala Churna*, which are both manufactured in capsule form, on type 2 diabetes, the current study was conducted. **Materials and methods:** 60 patients with type 2 diabetes were treated with lukewarm water (1gm) and *Indravaruni Phala Churna* with lukewarm water (500mg) twice daily before meals for 60 days in this prospective, randomized, single-blind clinical experiment. Assessments were made of the alterations in hemoglobin, blood sugar, HbA1c, lipid profile, hepatic, renal, and clinical complaints. **Results:** and *Indravaruni Phala Churna* experienced a significant decrease in fasting blood glucose levels and a significant decrease in postprandial blood glucose levels following a 60-day treatment regimen. During the trial period, no adverse effects were reported. **Conclusion:** Compared to *Ama Udumbara Phala Churna, Indravaruni Phala Churna* is more successful, enhancing patients' quality of life while also providing significant glycemic control and having no negative side effects.

INTRODUCTION

The only effective treatment for pain is Ayurveda. This is not a reference to any specific author's work. The collection of life principles known as Ayurveda came into being as a whole and is unchangeable anywhere or at any time[1]. *Prameha*, the creator himself, also found these ideas and implemented them in several of his works. The name of this original work was Ayurveda. Later, ancient sages realized that no one could master this vast collection in a lifetime; therefore, it was divided into eight divisions, some of which they could focus on more than others (*Astanga Ayurveda*)[2].

One of the major worldwide health issues of our time is diabetes mellitus, which can lead to major long-term consequences like heart disease, neuropathy, nephropathy, retinopathy, and even mortality. Ayurveda lists *Madhumeha* as one of the prevalent disorders, and both the frequency and amount of urination increase[3]. Diabetes is a metabolic disease that causes the synthesis of insulin to be inadequate or dysfunctional. In Ayurveda, there are 20 varieties of *Prameha*, all of which share the same symptoms. It transforms into *Madhumeha* if left untreated. One type of *Vataja Prameha* is *Madhumeha*[4]. Ayurvedic literature has provided information on the causes, risk factors, and treatment of *Madhumeha*, as well as its use for diabetes mellitus.

Of all the treatments available, even in the *Prameha* group, *Madhumeha* (diabetes mellitus) is the most prevalent. Intense urine with several irregularities brought on by *Doshic* imbalances is a hallmark of a group of urinary illnesses known as *Pramehas*[5]. Lack of exercise and poor eating habits are the main causes of *Prameha*. This sickness is primarily caused by *Ushna, Snigdha,* and *Guru*. Examples include *Snigdha*, fish, and curd. The meal

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that raises *Kapha, Medha*, and *Mutra* determines the etiological characteristics of *Prameha*[6]. "*Meha"* signifies passing urine, while *"Prameha*" is taken from the Greek term for excess. Additionally, *Prameha* has turbid urine and frequent urination ("*Prabhootha Avila Mootrata*").

Pathophysiology of diabetes mellitus type 2

Defects in the action or secretion of insulin are part of the pathophysiology of diabetes, resulting in glucose intolerance and the eventual development of full-blown illness. When muscles or adipose tissue become increasingly resistant to the effects of insulin, pancreatic B-cell hyperstimulation is necessary to overcome the tissue resistance[7]. This process keeps going until the cells can compensate for insulin resistance, but eventually, they get increasingly worn out, which causes the glucose levels to rise in tandem.

MATERIALS AND METHODS

Trial design Patients attending the outpatient and inpatient departments of Dravyaguna Vigyana, OPD No. 52, Government Dhanwantari Ayurveda Hospital, Near Chimanganj Mandi, Ujjain, India, were investigated for the diagnosis of *Madhumeha* (type 2 diabetes). A total of 75 patients having complaints of polydipsia, polyuria, polyphagia, burning sensation in hands and soles, and pain/cramps were screened for the present clinical trial and diagnosed with *Madhumeha* as per the National Diabetes Data Group and WHO guidelines for T2DM. Among them, 60 patients fulfilling the inclusion criteria were included in the study. It was a randomized, single-blind clinical trial. Selected patients were randomly divided into two groups, irrespective of their age, sex, caste, and religion, by a computer-generated randomization method. All the patients registered in the study were informed about the nature of the treatment, and informed consent was taken. The institutional ethics committee approved the study later (No./2023/ 5080/6-12-2023), and it was registered in the Clinical Trial Registry of India, ICMR, New Delhi, vide CTRI/ 2024/09/074351. No modern medication was advised during the trial period, and it was also not discontinued for the patients already taking it. Detailed clinical research proforma, incorporating all the points of history taking and physical examination, with weekly clinic attendance for assessment, drug collection, and any adverse events, were maintained for record and analysis purposes. The recommended dietary schedule was advocated to avoid any dietary aberration. A proforma was prepared to follow the continuation of a similar lifestyle schedule, i.e., a dietary and exercise schedule.

Criteria of Selection of Patients

The present clinical trial was conducted in the department of Dravyaguna, Dhanwanthari Ayurveda Medical College and Hospital Ujjain, M.P, on 60 patients of *Madhumeha* in O.P.D no.52 after due clearance from the Institutional Ethics Committee.

Patients selected randomly for the study were divided into two groups, each containing 30 patients. They were subjected to the above-mentioned investigation. An extensive proforma was prepared consisting detailed history like onset, progress of disease, chief and associated sign and symptoms etc. The mean of Ayurveda and modern medical science carried out the complete general and physical examination of the patient. In patients who were taking oral hypoglycaemic drugs, the blood sugar level at the time was considered the basal level. Then the study drugs were administered according to the below-mentioned dose. The plan of study is as follows.

Inclusion Criteria

Male or female patients aged 20–65 who have been diagnosed with type 2 diabetes and exhibit the classic symptoms of *Madhumeha*, including fasting blood sugar (FBS) ≥126mg/dL or postprandial blood sugar (PPBS) ≥180mg/dL, positive urine sugar, and symptoms of polyuria, polyphagia, and polydipsia, and who are willing to provide written informed consent.

Patients fulfilling the following general and diagnostic criteria were selected for the present study:

1. Patients of both sexes in the age group of 20 to 65 years.
2. Both obese and non-obese patients.
3. Patients showing classical signs and symptoms of *Madhumeha,* as mentioned below, were included in the study:
   Prabhuta Mutrata
   Avil Mutrata
4. *Pipasa Adhikya*
5. *Alasya* with *Utsaha hani*
6. *Ksudha Adhikya*
7. *Pindikodveshthana*
8. *Karapadatala Daha*
9. *Karapadatala Suptata*
10. *Sweda Adhikya*
11. *Galatalu Shosha*
12. *Daurbalya*
13. *Shrama Shwasa*
14. *Nidra Adhikya*

Criteria for diagnosis of diabetes mellitus by the American diabetic association:

1. Fasting blood sugar >126 mg/dl up to 200 mg/dl or

2. Post-prandial blood sugar > 140 mg/dl up to 250 mg/dl
3. HbA1c- 5.7% to 6.5 %

Exclusion Criteria

Participants in the study had to be between the ages of 20 and 65, receiving insulin (FBS) ≥200 mg/dL or postprandial blood sugar (PPBS) ≥350mg/dL, and suffering from chronic debilitating conditions like ischemic heart disease, tuberculosis, or sexually transmitted diseases. They also had to be pregnant or nursing, have chronic kidney disease (CKD), or have an emergency case of diabetes mellitus. The study also excluded patients with long-term microvascular and macrovascular problems.

1. Patients having other complications of diabetes like DKA, marked HTN, and urinary tract infection were excluded.
2. Patients less than 20 years and more than 65 years
3. Patient having insulin-dependent diabetes mellitus and receiving insulin.
4. Excessive blood glucose FBS > 200 mg/dl and PPBS >250 mg/dl
5. Emergency cases of diabetes mellitus.

Criteria for Assessment

Subjective parameters

All the patients registered for the present trial will be looked for any improvement in the symptoms mentioned in Ayurveda and Modern texts and changes in their growing feelings of wellbeing will be assessed with grading of symptoms.

1) Frequency of urine
2) *Pipasaadhikya*
3) *Kshudhaadhikya*
4) *Swedaadhikya*
5) *Karapadataladaha*
6) *Karapadasuptata*
7) *Prabhutamutrata*
8) *Avilamutrata*
9) *Pindikodveshthana*
10) *Dourbalaya*

It is graded on salient features and scored as 0, 1, 2, 3 on the count for severity of *Lakshanas*

	Subjective parameters	**Grading**
1.	**Frequency of Urine**	
	• 3-5 times/day, nil or rarely at night	0
	• 6-8 times /day, 1-2 times at night	1
	• 9-11 times /day, 3-4 times at night	2
	• >11 times /day,>4 times at night	3
2.	***Pipasa Adhikya***	
	• Feeling of thirst 7-9 times/24 hr	0
	• Feeling of thirst 9-11 times/24 hr	1
	• Feeling of thirst 11-13 times/24 hr	2
	• Feeling of thirst >13 times/24 hr	3
3.	***Kshudha Adhikya***	
	• As usual/ routine	0
	• Slightly increased	1
	• Moderately increased	2
	• Markedly increased	3
4.	***Sweda Adhikya***	
	• Sweating after heavy work or in hot and humid weather	0
	• Sweating after moderate work and movement	1
	• Sweating after routine work	2
	• Sweating even at rest or in cold climates	3
5.	***Avila Mutrata***	
	• Crystal clear fluid	0
	• Slight cloudy or hazy (i.e., slight turbidity)	1
	• Turbidity is clearly present but newsprint can be read.	2
	• More turbidity and newsprint can't be read	3
6.	***Gala -Talu Shosha***	
	• No *Shosha*	0
	• Feeling of thirst off and on can be managed by simply a glass of water.	1
	• Feeling of thirst is severe but can be managed drinking sufficient amount of water	2
		3

	• Severe feeling of thirst remains even after drinking water & very frequent feeling of thirst.	
7.	***Kara-Pada-Tal Daha***	
	• No *Daha*	0
	• Mild to moderate sensation (occasional)	1
	• Moderate to severe (very often and regular activity not hampered).	2
	• Very severe (whole day and regular activity hampered).	3
8.	***Kara-Pada-Suptata***	
	• No *Suptata*	0
	• Mild to moderate occasional sensation	1
	• Moderate to severe (very often and regularly activity not hampered.	2
	• Very severe (whole day and regular activity hampered)	3

Objective Criteria

Various objective parameters will be assessed to calculate the effect of the treatment.

- FBS
- PPBS
- HbA1C
- Urine test - Routine & microscopic test
- Lipid profile (If needed)
- Liver biochemistry (If needed)
- Urine test - Routine & microscopic test
- Lipid profile (If needed)

Blinding and Posology

Before the clinical trial started, the trial medications were blinded. Blinding was revealed at the end of the trial; therefore, patients in Group A received while those in Group B received *Indravaruni Phala churna*. The dosage of 1 1gm (1000mg) was described in the classics of *Dravyaguna Vigyana* API. Two 500mg capsules were taken twice daily for 60 days with lukewarm water before meals, and one 500 mg capsule was taken twice daily for 60 days with lukewarm water after breakfast. After fifteen days, there was a follow-up. According to Ayurveda and modern medicine, patients were advised not to take any foods that could cause or aggravate their condition.

Investigations

The following studies were conducted both before and after the 60-day treatment period. Haemoglobin, red blood cell (RBC) count, total white blood cell (WBC) count, differential WBC count, and erythrocyte sedimentation rate are all routine hematological tests. Comprehensive lipid profile, Hba1c, physical, chemical, and microscopic urine tests, as well as fasting and postprandial.

Assessment Criteria

Following treatment, the therapy's effectiveness was evaluated based on improvements in the patients' signs and symptoms as determined by contemporary and Ayurvedic criteria, as well as pre- and post-treatment research. The symptom grading system used for the overall therapeutic effect was taken from earlier studies. It was recommended that registered patients make many visits to the outpatient department within a 15-day period. In the case record form, subjective and objective parameters pertaining to the aforementioned laboratory tests and the improvement in glucose levels were noted.

Data Analysis

The mean, standard deviation, W-value, and P-value for each group as determined by the Wilcoxon signed Rank test are displayed in the tables below. The Mann-Whitney U test evaluates how interventions affect different groups. The overall effect of therapy on each scale was calculated in terms of % improvement in all symptoms, and the unpaired data were compared using the Student's t-test to evaluate the significance between groups at $P < 0.05$. To determine how therapy affected non-parametric data before and after treatment, a paired t-test was used. To compare parametric data between the groups, an unpaired t-test was used. Following treatment, the resulting observations were statistically analyzed and are shown below.

OBSERVATIONS AND RESULTS

60 patients were split into two groups at random for the current single-blind clinical investigation. Of these, thirty patients in Group A and thirty in Group B finished the treatment. Figure 1 shows the CONSORT flow chart. The age group of 56–65 years old accounts for the largest percentage of patients (48.33%). Males made up 61.67% of the registered patients. In the study, dyslipidaemia was present in 34% of the patients, followed by hypertension and surgery in 23% and 12% of the patients, respectively. Diabetes mellitus ran in 8% of

the patients' families. 27% of the patients had a propensity to consume sweet foods, or *Madhura Ahara*. Intake of *Drava Ahara* (liquid diet) and *Diwaswap* (day sleep) was seen in 21.67% of the patients. *Swapna Sukham* (too much sleep) and *Asyasukham* (to sit comfortably) were elicited in 16.67% and 28.33% of the patients, respectively. Of the patients, 55.00% had just received a DM diagnosis. Dietary incompatibilities, or *Viruddhashana,* were detected in 48.9% of the patients, whereas *Vishamashana* was triggered in 46.67% of the patients. The majority of study participants (70%) led sedentary lives, whereas 16.67% engaged in physical labour. Alcohol and tobacco addiction affected 1.67% and 10% of the study's subjects, respectively. The symptoms of *Prabhuta Mootrata* (polyuria), *Kshudhadhikyata* (polyphagia), and *Trishnadhikyata* (polydipsia) were reported to have significantly improved in both treated groups. (Table No. 1). Significant relief was observed in *Avila Mootrata* (turbid urine), *Karapadataladaha* (burning sensation of hands and feet), and *Daurbalya* (generalized weakness).

Table 1: Symptom-wise observation percentage reduction in the number of patients after treatment

Symptoms	Group-A			Group-B		
	BT	AT	% Reduction	BT	AT	% Reduction
Prabhuta mutrata	29	3	89.66	30	3	90.00
Aavila mutrata	29	10	65.52	29	5	82.76
Kara-pada tal daha	28	7	75.00	24	4	83.33
Kara-pada suptata	25	3	88.00	27	2	92.59
Kshudhadhikya	26	5	80.77	27	2	92.59
Trushna	27	4	85.19	26	2	92.31
Dourbalyata	17	2	88.24	23	4	82.61
Pindikodweshtana	24	1	95.83	26	4	84.62
Shithilagatrata	27	3	88.89	28	2	92.86
Aasyamadhurya	22	3	86.36	24	6	75.00
Atisweda	22	2	90.91	24	3	87.50
Visrashariragandha	20	2	90.00	24	5	79.17
Tandra	24	3	87.50	17	3	82.35
Klama	21	2	90.48	21	2	90.48
Galtalushosha	21	4	80.95	21	2	90.48

Table 2: Effect of *Ama Udumbara Phala* on subjective parameters

Symptoms	Mean		Mean Diff.	% Relief	SD Diff.	SE Diff.	Wilcoxon Signed Rank Test and P-value
	BT	AT					
Prabhuta Murata	1.200	0.100	1.100	91.67	0.30	0.06	W=465 P=0.000 HS
Aavila mutrata	1.433	0.167	1.267	88.42	0.52	0.09	W=435 P=0.000 HS
Kara-pada tal daha	1.167	0.133	1.033	88.52	0.72	0.13	W=276 P=0.000 HS
Kara-pada suptata	1.033	0.067	0.966	93.51	0.49	0.09	W=351 P=0.000 HS
Kshudhadhikya	1.067	0.067	1.000	93.72	0.44	0.09	W=378 P=0.000 HS
Trushna	0.933	0.067	0.867	92.93	0.43	0.09	W=325 P=0.000 HS
Dourbalyata	0.967	0.133	0.833	86.14	0.59	0.11	W=253 P=0.000 HS
Pindikodweshtana	1.100	0.133	0.967	87.91	0.56	0.10	W=325 P=0.000 HS
Shithilagatrata	1.133	0.067	1.067	94.17	0.52	0.09	W=378 P=0.000 HS
Aasyamadhurya	0.933	0.233	0.700	75.03	0.65	0.12	W=221 P=0.000 HS
Atisweda	0.967	0.100	0.867	89.66	0.63	0.11	W=253 P=0.000 HS

Visrashariragandha	1.100	0.167	0.933	84.81	0.69	0.13	W=253 P=0.000 HS
Tandra	0.700	0.100	0.600	85.71	0.62	0.11	W=136 P=0.000 HS
Klama	0.828	0.069	0.759	91.67	0.56	0.11	W=210 P=0.000 HS
Galtalushosha	0.833	0.067	0.767	92.08	0.63	0.11	W=210 P=0.000 HS

Table 3: Effect of *Indravaruni Phala* on subjective parameter

Symptoms	Mean		Mean Diff.	% Relief	SD Diff.	SE Diff.	Wilcoxon Signed Rank Test and P-value
	BT	AT					
Prabhuta mutrata	1.367	0.100	1.267	92.68	0.521	0.095	W=435 P=0.000 HS
Aavila mutrata	1.467	0.400	1.067	72.33	0.640	0.117	W=325 P=0.000 HS
Kara-pada tal daha	1.433	0.233	1.200	83.74	0.610	0.111	W=435 P=0.000 HS
Kara-pada suptata	1.100	0.100	1.000	90.91	0.643	0.117	W=300 P=0.000 HS
Kshudhadhikya	1.133	0.167	0.967	85.35	0.615	0.112	W=276 P=0.000 HS
Trushna	1.233	0.133	1.100	89.21	0.662	0.121	W=378 P=0.000 HS
Dourbalyata	0.800	0.067	0.733	91.63	0.828	0.151	W=136 P=0.000 HS
Pindikodweshtana	1.000	0.033	0.967	96.70	0.669	0.122	W=300 P=0.000 HS
Shithilagatrata	1.233	0.100	1.133	91.89	0.629	0.115	W=351 P=0.000 HS
Aasyamadhurya	0.967	0.100	0.867	89.66	0.629	0.115	W=253 P=0.000 HS
Atisweda	0.900	0.067	0.833	92.56	0.699	0.128	W=210 P=0.000 HS
Visrashariragandha	0.833	0.067	0.767	92.08	0.626	0.114	W=210 P=0.000 HS
Tandra	0.967	0.133	0.833	86.14	0.747	0.136	W=244 P=0.000 HS
Klama	0.867	0.067	0.800	92.27	0.714	0.130	W=190 P=0.000 HS
Galtalushosha	0.828	0.138	0.690	83.33	0.541	0.101	W=190 P=0.000 HS

FBS decreased significantly (P < 0.001) in groups A and B. Comparatively speaking, Group B's FBS decreased by 10.15% compared to Group A's (14.89%). PPBS were significantly lower in groups A and B (P < 0.001). Compared to Group A (20.75%), Group B (10.20%) displayed a significantly greater percentage decrease in PPBS. Urine sugar decreased more in Group B (28.33%) than in Group A (11.41%). There was no discernible difference between Groups A and B using the one-way Wilcoxon signed-rank test. Drug A can be regarded as slightly superior to the other test medicines in terms of glycaemic management based on these objective measures. The hemogram of the two groups did not show significant differences. Changes in serum creatinine, proteins, albumin, globulin, and uric acid were found to be statistically nonsignificant in both groups. When comparing the hepatic and lipid profiles of the two groups using the paired t-test, no statistically significant change was seen. There were no discernible clinically significant variations in the groups' safety metrics (biochemical, hematological) or clinical indicators of mercury toxicity in the administered groups.

DISCUSSION

DM is difficult to treat due to the contrasting treatment measures as per *Ayurveda.* It is commonly manifested as an elevation in blood glucose levels (hyperglycemia), resulting from either a defect in insulin secretion from the pancreas or insulin resistance in cells (8). Ayurvedic herbs are effective in a minimal dose with quick action, possess an eclectic therapeutic range, and were chosen as an intervention. People who are unaware of the pharmaceutical processing of single *herbs* are raising concerns about the toxic nature of such preparations. Hence, facts and figures on the efficacy of *Indravaruni Phala Churna* on *Madhumeha* (type 2 diabetes) should be generated with different forms of cost-effective and efficacious quality-assured products. This single-blind clinical trial has established the blood glucose-lowering effect of *Ama Udumbara Phala* and *Indravaruni Phala* in patients with type 2 diabetes. *Ama Udumbara Phala* and *Indravaruni Phala* content may exhibit several health hazards if not properly prepared or administered as per the classics; hence, to assure safety and enrich evidence of safety, biochemical parameters of renal and hepatic function, hemogram,

and clinical presentation and clinical manifestations due to consumption of single herbs. Classics of *Dravyaguna Vigyana* have emphasized the antidiabetic potential of the *Ama Udumbara Phala* and *Indravaruni Phala*. The majority of patients were 51–60 years old. This age shows the dominance of *Vata Dosha*. At the same time, *Guru* (heavy*), Snigdha* (unctuousness), *Madhura Bhojana* (sweet diet), and *Diwaswap* (day sleep) cause *Kapha, Meda, and Dushti.* This causes an imbalance in the hormonal and nervous regulation of the body and makes the person susceptible to many hormonal disorders, including DM. The majority of patients in this study were male. This observation correlates with the previous observation of a 3:1 male: female ratio, where, sex-wise, the incidence of DM was mentioned. The poor literacy rate also shows that patients may have a lack of knowledge about healthy dietary habits, which may lead to metabolic disorders such as DM. WHO predicts that more than 70% of people with diabetes are living in middle-income countries. Group B was found to be more effective in reducing FBS. FBS is determined primarily by hepatic glucose output. Drugs may have increased basal insulin secretion and decreased hepatic breakdown of glucose in the fasting state, thereby reducing FBS. Group B showed more significant results in comparison to Group A in reducing postprandial blood sugar levels. This may be due to reduced peripheral insulin resistance, leading to improved uptake of glucose by the tissues, especially by skeletal muscles, and increased biphasic secretion of insulin after food intake. There is an inverse correlation between plasma-free fatty acids and insulin sensitivity. Improvement in lipid profile would reduce the peripheral insulin resistance, which is evident by the reduced PPBS level. Hyperglycemia exceeds the renal threshold for reabsorption of glucose, which in turn causes glycosuria. Glycosuria induces an osmotic diuresis and results in polyuria (9). A decrease in blood glucose level may lead to decreased osmotic diuresis, which in turn results in a reduced volume of urine. Improper metabolism of *Meda Dhatu* (a morbid increase of fat) and *Agni Vikruti* (disturbance in digestive factors) leads to *Kshudhadhikya* (polyphagia), *Trishnadhikyata* (polydipsia), and these symptoms were reduced markedly in both the treated groups; it may be due to *Medo pachana* (digestion of fat tissue) and *Agni Vrudhi* (increase in digestive factors) action of both drugs.

EFFECT OF THERAPY ON OBJECTIVE CRITERIA

There was a significant decrease in the number of patients following therapy for FBS and PPBS in both groups, as indicated by the group-wise number and percentage of patients before and after treatment for various objective measures. Before therapy, 27 (90%) of the patients in Group A had FBS levels greater than 126.00 mg/dl; following treatment, this number dropped to 16 (53.33%). Prior to and following treatment, Group B's equivalent FBS values were 21 (70.00%) and 19 (63.33%), respectively. In Group A, the proportion of patients with PPBS > 200 mg/dl decreased from 20 (66.67%) prior to treatment to 9 (30.00%) following it. Similarly, Group B's PPBS patient count decreased from 19 (63.33%) prior to therapy to 10 (33.33%) following treatment.

In terms of HbA1c, it was discovered that the therapies led to a greater proportion of patients with <6.5% HbA1c, which made up 63.33% and 50.00% of Group A and Group B, respectively, as opposed to 43.33% and 36.67% of these groups before treatment.

Table 4: Effect of therapy on total symptom scores of all the subjective parameters

Sr.No. of Subjects	Group-A				Group-B			
	Total Symptom Score			Remark	Total Symptom Score			Remark
	BT	AT	%		BT	AT	%	
1	9	1	88.89	Complete	20	4	80.00	Complete
2	16	3	81.25	Complete	16	3	81.25	Complete
3	18	5	72.22	Marked	19	4	78.95	Complete
4	10	3	70.00	Marked	20	2	90.00	Complete
5	17	6	64.71	Marked	11	1	90.91	Complete
6	27	5	81.48	Complete	11	2	81.82	Complete
7	14	3	78.57	Complete	17	2	88.24	Complete
8	14	1	92.86	Complete	15	1	93.33	Complete
9	9	1	88.89	Complete	24	10	58.33	Marked
10	8	1	87.50	Complete	19	4	78.95	Complete
11	14	1	92.86	Complete	17	2	88.24	Complete
12	17	4	76.47	Complete	20	8	60.00	Marked

13	12	1	91.67	Complete	14	2	85.71	Complete
14	22	2	90.91	Complete	14	2	85.71	Complete
15	16	3	81.25	Complete	22	6	72.73	Marked
16	13	0	100.00	Complete	20	5	75.00	Marked
17	16	3	81.25	Complete	13	2	84.62	Complete
18	19	2	89.47	Complete	19	4	78.95	Complete
19	21	7	66.67	Marked	12	2	83.33	Complete
20	11	4	63.64	Marked	11	1	90.91	Complete
21	17	2	88.24	Complete	14	1	92.86	Complete
22	18	2	88.89	Complete	16	2	87.50	Complete
23	18	3	83.33	Complete	9	1	88.89	Complete
24	19	2	89.47	Complete	13	1	92.31	Complete
25	16	1	93.75	Complete	13	1	92.31	Complete
26	21	5	76.19	Complete	10	2	80.00	Complete
27	20	6	70.00	Marked	11	1	90.91	Complete
28	14	2	85.71	Complete	14	1	92.86	Complete
29	19	3	84.21	Complete	10	1	90.00	Complete
30	18	3	83.33	Complete	18	1	94.44	Complete

EFFECT OF THERAPY ON SUBJECTIVE CRITERIA

Subjective criteria such as *Aavilamutrata, Kshudhadhikya*, *Karapadataladaha*, *Prabhutamutrata*, *Pindikodveshtana, Swedadhikya*, and *Karpadasuptata* were all met by all of the patients. Group B outperformed Group A in all subjective parameters, although *Prabhutavilamutrata* and *Kar-Pada-tal-daha* performed better in Group A. This might be because *Acharya Charaka* includes *Udumbara* in *Kashaya Varga (Cha. Vi. 8/144*). Since *Kashaya Rasa* is crucial to *Stambhana Karma, Prabhutavilamutrata* might be an excellent work. Compared to Group A, Group B *Indravaruni Phala* received better treatment for elevated blood sugar levels and *Pindikodveshtana.*

Table 5: Effect of Therapy on Fasting Blood Sugar (FBS)

Group	Mean		Mean Diff.	% Change	SD Diff.	SE Diff.	Within group Paired t-Test
	BT	AT					
Group-A	161.23	137.22	24.01	14.89	49.55	9.05	t = 2.65 P=0.013 S
Group-B	155.43	139.67	15.77	10.15	37.88	6.92	T = 2.28 P=0.030 S
Between groups Unpaired t-test	t = 3.49, P = 0.001 HS						

Table 6: Effect of Therapy on Postprandial Blood Sugar (PPBS)

Group	Mean		Mean Diff.	% Change	SD Diff.	SE Diff.	Within group Paired t-Test
	BT	AT					
Group-A	225.53	178.77	46.80	20.75	60.40	11.00	t = 4.24 P=0.000 HS
Group-B	210.03	188.60	21.43	10.20	46.59	8.51	T = 2.52 P=0.018 S
Between groups Unpaired t-test	t = 1.82, P = 0.074 NS						

Table 7: Effect of Therapy on glycated haemoglobin (HbA1 c)

Group	Mean		Mean Diff.	% Change	SD Diff.	SE Diff.	Within group Paired t-Test
	BT	AT					
Group-A	0.0700	0.062	0.0072	10.29	0.010	0.002	t = 3.76 P=0.001 HS

		8					
Group-B	0.0711	0.0674	0.0037	5.20	0.008	0.001	T = 2.44 P=0.021 S
Between groups Unpaired t-test	t = 1.39, P = 0.170 NS						

OVERALL EFFECT OF THERAPY

Based on the overall therapy outcome, 60% of patients in Group A *(Ama Udumbara Phala)* saw substantial improvement, 35% experienced remarkable improvement, and 5% experienced modest improvement in subjective metrics. 60% of patients in Group B (*Indravaruni Phala)* had a considerable improvement in their subjective metrics, whereas 40% experienced a moderate improvement. Not a single instance was reported as unaltered in any of the Groups, and nobody received total alleviation in subjective criteria.

Figure 1: Effect of treatment on symptoms

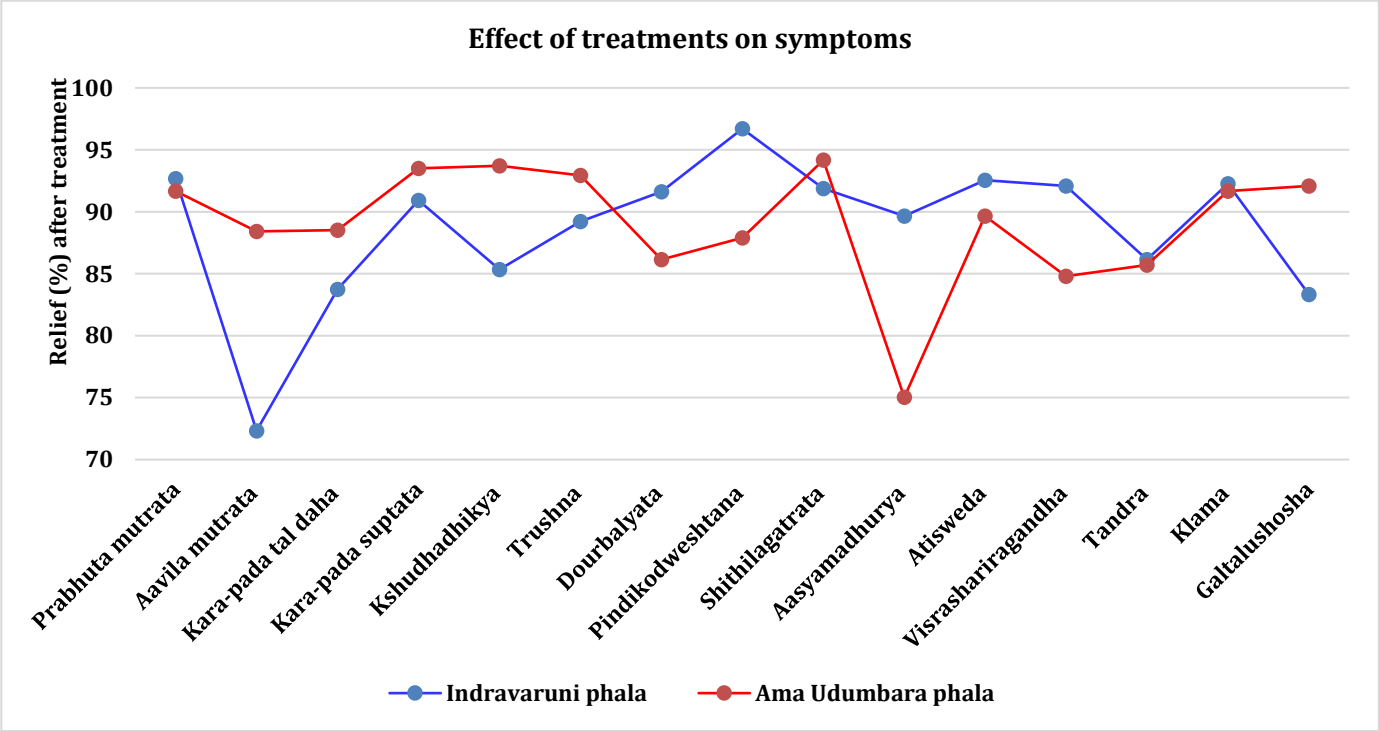
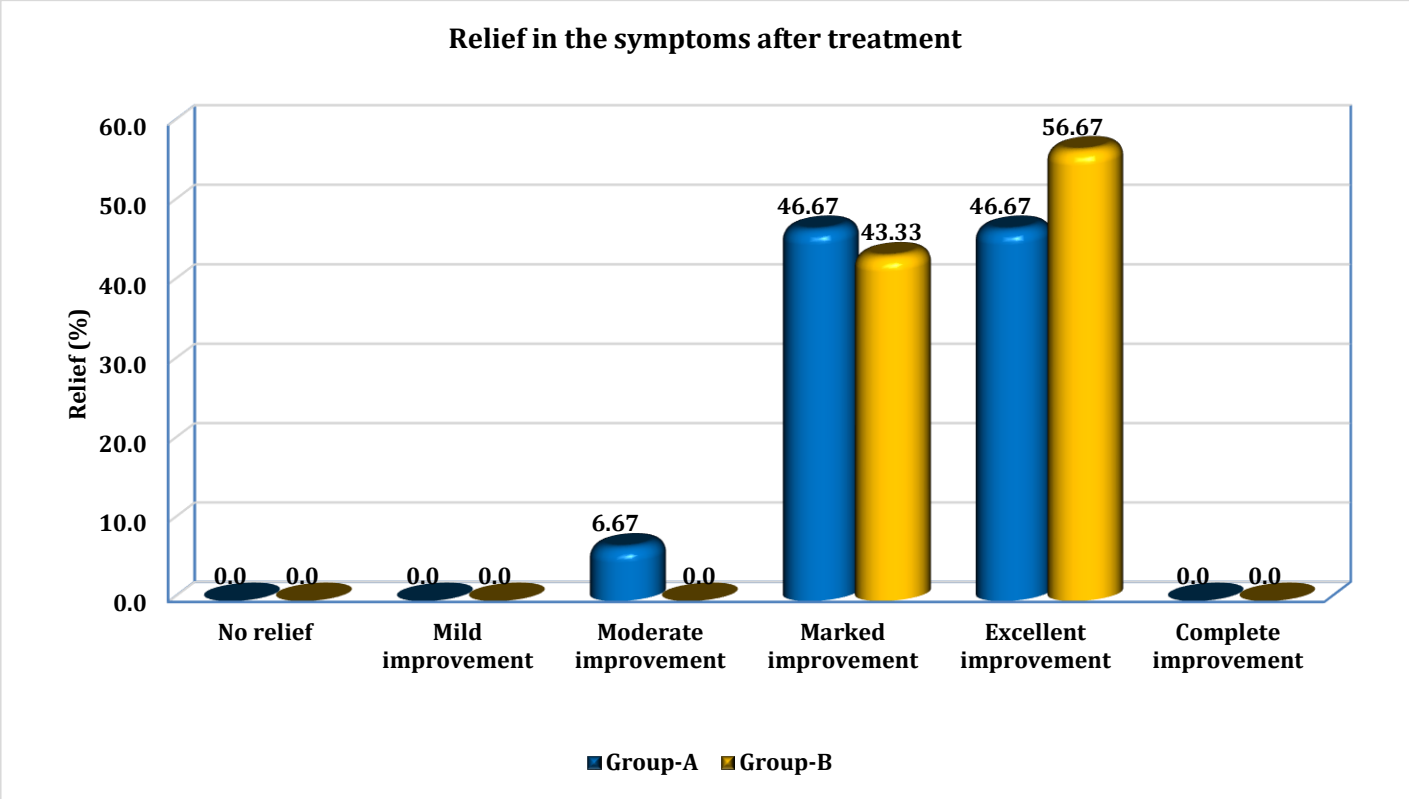


Figure 2: Relief in the symptoms after treatment



The purpose of the clinical trial was to determine how *Ama Udumbara Phala Choorna* and *Indravaruni Phala Choorna* affected *Madhumeha.* For the current study, 60 patients in total were recruited. Thirty patients in Group A received *Ama Udumbara Phala Choorna* as *Anupana* along with lukewarm water. Thirty patients in Group B received *Indravaruni Phala Choorna* as *Anupana* along with lukewarm water. Every patient finished their course of treatment within the allotted time. Subjective criteria such as urine frequency, *Pipaadhikya, Kshudhadhikya, Swedadhikya, Karapadataladaha, Karpadasuptata, Prabhutamutrata, Aavilamutrata, Pindikodveshtana*, and *Daurbalya* were all answered by all of the patients. 46.67% of patients in Group A (*Ama Udumbara Phala Churna*) and 43.33% of patients in Group B *(Indravaruni Phala Churna*) have shown a marked improvement. However, patients also experienced total alleviation. 46.67% of patients in Group A saw total improvement, whereas 56.67% of patients in Group B experienced total alleviation. Compared to group A, group B saw a greater overall therapeutic outcome. Both groups' objective parameters showed considerable changes. Better glycemic control has been achieved by both groups, which has improved patient quality of life without causing any negative side effects.

CONCLUSION

A clinical study examining the effects of *Ama Udumbara Phala Choorna* and *Indravaruni Phala Choorna* in *Madhumeha* involved 60 patients. Both groups showed marked improvement in objective parameters, with 46.67% of patients showing improvement in the *Indravaruni Phala Churna* group and 43.33% in the control group. However, complete relief was also achieved in both groups. The overall effect of therapy was better in group B. Both groups improved patients' quality of life without untoward effects.

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