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COMPARATIVE & CLINICAL EVALUATION OF THE ROLE OF *KODRAVA* (PASPALUM SCROBICULATUM) & *MANDUA* (ELEUSINE CORACANA) IN PREDIABETES W.S.R. TO *PRAMEHA*

[1]*Dr. Shweta Verma, [2]Prince Bhardwaj and [3]Dr. Tuhin Kumar

[1]Asso. Proff. and Hod; Deptt. of Dravyaguna, Dims Dehradun, Uttrakhand.

[2]Bams, Final Year, Dims Dehradun, Uttrakhand.

[3]Joint Director, Mhfw, Dehradun, Uttrakhand.

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***Corresponding Author**
Dr. Shweta Verma
Asso. Proff. and Hod; Deptt. of Dravyaguna, Dims Dehradun, Uttrakhand.

ABSTRACT

Prediabetes is a condition of hyperglycemia with Glycated Hemoglobin in the range of 5.7% - 6.4%, Fasting blood sugar (FBS) levels between 100 and 125 mg/dl and Post Prandial blood sugar (PPBS) levels between 140 and 200 mg/dl. Prediabetes is the precursor stage before Diabetes Mellitus, in which not all of the symptoms required to diagnose diabetes are present, but blood sugar is abnormally high. The modification of one's lifestyle should be the first aim to restrict such problems, beside this prime objective, some medication which is safe and efficacious to be introduced. Management of Prediabetes, includes oral hypoglycemic drugs and some diet regimens including improved Life style. So, a clinical study with 30 patients has been conducted on Prediabetes with *'Kodrava'* and *'Mandua'* in such 2 groups of treatment. The two drugs are carrying such properties which acts in *Samprapti vighatana* (prevent pathogenesis) of the disease. It can be seen that there is statistically highly significant difference ($p<0.001$) in case of FBS and Hb1AC. However no significant difference ($p>0.005$) is observed in other parametric and non – parametric parameters such as *Karapaddaha, Mukhkanthatalushosha, Alasya, Prabhootmutrata, Pipasadhikya,* Diastolic Blood Pressure, PPBS and weight. On Comparative study of Physiological parameters in both the Groups Group A *(Kodrava)* was found to be more effective than Group *B (Mandua).*

KEYWORDS: *Prameha, Kodrava, Mandua, Karapaddaha, Mukhkanthatalushosha, Alasya, Prabhootmutrata, Pipasadhikya.*

INTRODUCTION

Acharya Chakrapani proposed the concept that *Aushadha* is important on the basis of Potency *(virya)* which is considered to be the active principle and *Ahara* is important on the basis of Taste *(Rasa),* which is responsible for Primary Metabolites.[1] As mentioned in *Sushruta Samhita* Diet is also an important factor for the origin, maintainance and dissolution of the different words, as those of *Brahma,* etc. thus *Ahara dravyas* are equally important for the treatment of disease. So both *Ahara dravya* and *Aushadha dravya* plays an important role in the Management of any disease.[2] *Ahara dravya* will directly act upon the *dhatus* (tissues) like *Rasa* (FIuid), *Mamsa* (Muscle), *Medas* (Fat) and helps in their nourishment and enrichment.[3] Today is the era of erroneous lifestyle in which people are not able to follow the rules of Healthy & Happy living due to Sedentary life style, social or professional obligations and our peoples prone to suffer from premature ageing and a number of diseases like Obesity, Hypertension, Diabetes Mellitus, Stress and many diseases. From these diseases Diabetes is the most common. In almost all the Ayurvedic Classical texts, *Prameha* has been defined as *Ashta mahagada* (eight disease with great importance).

Metabolic disorders such as diabetes, obesity and dyslipidemia pose significant global health concerns. The above conditions are often associated with chronic inflammation, oxidative stress, impaired glucose and fat metabolism.[4] Prediabetes is defined as having blood glucose (sugar) levels that are higher than normal, but not yet at the point that defines diabetes. For people with prediabetes, blood sugar levels can increase slowly over time. When you eat, the digestive process breaks down the food into a simple sugar called glucose, which enters your bloodstream. Glucose is fuel for your body's cells and organs. A hormone called insulin helps deliver the glucose to the cells in your body. Insulin is produced in the pancreas, a gland behind the stomach.[5]

Prediabetes and diabetes may develop if the pancreas does not make enough insulin to deliver glucose to the cells and too much glucose builds up in the blood. Another cause is when the cells stop allowing the insulin to deliver the sugar, a condition called insulin resistance. Lifestyle approaches, including healthy eating, regular physical exercise and weight management, are effective measures in preventing or delaying the progress of prediabetes to diabetes. Furthermore, a study is needed on lifestyle interventions in prediabetes.[6] ***Kodrava***

can be well traced in different *Samhitas*. *Acharya Charaka* described *kodrava*, where it was indicated in disorders of *Kapha* and *Pitta*. *Kordusha (kodrava)*, is astringent, sweet, light, aggravates *Vata*, *Mandua* alleviates *Kapha* and *Pitta*, cold, constipating and absorbent. *Kapha* and *Pitta*, Unctuous, Aphrodisiac, Cold, Astringent, Easily digestible, Reducing urine, Binding faeces.[7]

MATERIAL AND METHODS

Clinical research is the back bone of any medical science. It is the most important among all other research because in clinical research there is direct interaction with patients.

Prediabetes is the Medical Stage in which not all the Symptoms required to label a Person as Diabetic are present, but blood sugar is abnormally high. This increase in ability to Utilize glucose for energy production may be due to two important reasons:

1) Slow destruction of Insulin Secreting Beta cells (*madhusudini vikriti*).

2) Relative Insulin Deficiency *(vraht vayudosha)*.

Because of the above two reasons there are certain changes in the body physiology leading to a few symptoms, which caution against the impending big problem, 'Diabetes Mellitus'. Development of Diabetes is a long process and takes a time of many years. This long period prior to overt Diabetes may be referred to as pre-diabetic stage and symptoms of this stage can be called prodormal symptoms of Diabetes which can easily seen in *Ayurvedic Samhitas* as *Poorvarupa of Prameha*. Certain symptoms can be easily recognised but there are few symptoms/signs which can only be identified by investigations as blood or urine analysis. If efforts are made to check and prevent these prodormal symptoms, it will be possible to put a check on Diabetes. Everybody interestedin preventing Diabetes in oneself, should know how to recognize these early symptoms, because of developing diabetes at one stage or the other life, exists with everyone in modern days.

Diabetes mellitus, which is the later stage of Prediabetes, is a metabolic disease characterized by deregulation of carbohydrate, protein and lipid metabolism. The primary feature of Prediabetes & Diabetes Mellitus is elevation in blood glucose levels (hyperglycaemia), resulting from either a defect in insulin secretion from the pancreas, a change in insulin action, or both. Sustained hyperglycaemia has been shown to affect almost all tissues in the body and is associated with significant complications of multiple organ systems, including the eyes, nerves, kidneys and blood vessels.

These complications are responsible for the high degree of morbidity and mortality seen in the diabetic population. At present Diabetes is managed with hypoglycaemic agents, introduced in 1954. Earlier to the introduction of modern therapies, traditional system of medicine managed diabetes for more than 2000 years.

In spite of tremendous advancement of modern system of medicine till date, an ideal drug which can cure diabetes is not yet available. The modern medicine is not satisfactory because the hazardous side effects of hypoglycaemic agents after long term use are incurable. The natural products are known to reduce the blood sugar levels without producing any hypoglycaemic episodes.

Ayurveda believes that it occurs mainly due to *Medo dusti*. This *Medo dushti* vitiate *Mamsa, Rakta, kleda* and *Ojas*. All the *Dhatus* and *Malas* & all three *Doshas* are involved in the disease procedure. To treat a disease it is very essential to know the *Samprapti* of the disease as it is said that treatment is nothing but the breakdown of *Samprapti*.

SELECTION OF THE PATIENTS

The patients fulfilling the diagnostic criteria of Prediabetes reporting from Uttaranchal Ayurvedic Hospital, Dehradun, were selected on the basis of careful history taking, examination & Investigations.

Inclusion Criteria

- 1. Patients with age group of 30 years to 70 years.
- 2. Patients having *Poorvarupa* of *Prameha* as described.
- 3. Patients having Fasting blood sugar level, According to American Diabetes Association-

  FBS- 100 mg/dl to 125mg/dl.

  HbA1C – 5.7% to 6.4 %.

Exclusion Criteria

1. Patient below 30 years and above 70 years
2. Diagnosed cases of Diabetes Mellitus.
3. Diagnosed cases of Severe Systemic illness.
4. Diagnosed with IDDM.

PRE- MEDICATION INVESTIGATION OF THE PATIENTS

Before starting the medicine, blood sample (Before and after meal) of each patient was taken and send to Laboratory for confirmation of Prediabetes. The aim of this pre-medication investigation was to select the real patients of Prediabetes and second to compare with the post medication investigations to assess the effect of medicine.

MEDICATION OF PATIENTS

After selection of the patients the clinical trial of the medicine was conducted in the O.P.D of Uttaranchal Ayurvedic Hospital, Dehradun, the drug was given 100g; BD, two times in a day for 8 weeks and they were advised to take these drugs in the form of Rice(Drug A) and Flour(Drug B) in the form of *chapaati*.

Dietary precautions: During medication, sweets, heavy food etc. were prohibited.

COMPLAINTS OF THE PATIENTS DURING MEDICATION

All patients have taken the proper dose of medicine as prescribed to them and no patient approached with any complaints.

POST MEDICATION INVESTIGATIONS

After every 2 weeks of medication blood sample (fasting & post prandial) of each patient was taken till 8 weeks, for comparative study of it with the pre- medication investigations.

The present clinical study was conducted for the following aims and objectives:

AIMS AND OBJECTIVES

- Scientific evaluation of *Paspalum scrobiculatum & Eleusine coracana.* Through *Ayurvedic* and Modern aspects.
- To evaluate the clinical efficacy of *Paspalum scrobiculatum & Eleusine coracana* in Prediabetes.
- To compare the effect of both groups
  Group –A *Paspalum scrobiculatum*
  Group-B *Eleusine coracana*
- To provide a drug which is very effective, economic and easily available
- To provide a drug which have no side effects

- To compile the data generated and to evaluate statistically so as to draw the conclusion accordingly.
- To study the spectrum of clinical symptoms of Prediabetes in all the patients.
- To study the pathogenesis of disease in the light of *Ayurvedic* and with Modern correlation.

STATISTICAL ANALYSIS

The information collected on the basis of observation made during the treatment were analysed on a statistical criteria in terms of mean score (X), standard deviation (S.D.) Paired t test, Unpaired t test was carried at the level of 0.05, 0.01, 0.001 of p level. Thus the obtained results were interpreted as:

P> 0.05 Not Significant

P< 0.01 & <0.05 significant

P< 0.001 highly significant

To, more specifically quantify the percentage of improvement in each patient, this was also calculated using the formula (BT – AT) X 100 / BT

STUDY DESIGN

Randomised, Single-blind, two group, Pre & post test study

A) SELECTION OF PATIENTS

- **Setting:** Outpatient Department and of the Hospital, Uttaranchal Ayurvedic College, Dehradun.
- **Number of cases:** 30 patients were registered for present clinical study.

B) Drug used - Seeds of *Paspalum scrobiculatum & Eleusine coracana.*

C) METHODOLOGY

- Genuine material of plant has been collected from
- 1. *Paspalum scrobiculatum* - Jhansi
- *2. Eleusine coracana* - Dehradun**;** in rainy season [August to September]
- Scientifically evaluation of the clinical efficacy of both the drugs

D) Selection of the preparation

For this work we selected preparation of medicine in the form of Rice (Drug A) & Flour (Drug B)

E) Preparation of the drug

Drug A has been used without Pericarp (Seed cover) in the form of Rice and Drug B has been used with Pericarp in the form of Flour.

F) MEDICATION SCHEDULE

These drugs were prescribed for 8 weeks and the patients were advised to follow up in 2 weeks intervals for assessment & improvement of the symptoms and laboratory reports.

G) DRUG ADMINISTRATION

The drug administration is an important part in the treatment of any disease. For this research work I have selected the oral route of drug administration.

H) TRIAL GROUP

The patients were selected randomly and divided into two groups,

- **Group A** – In this group, 15 registered patients were treated from *Paspalum scrobiculatum* for 8 weeks.

- **Dose**

100 gms; BD in the form of rice**.**

- **Group – B** - in this group, 15 registered patients were treated from *Eleusine coracana* for 8 weeks.

- **Dose**

100 gms; BD in the form of flour *(chapaati)***.**

Follow up study

Patients were followed up after 45 days with Laboratory investigations were repeated after completing treatment. Improvement and other effects were recorded.

DIET

All patients were advised to dietary restriction during the trial period particularly sweets, curds, heavy foods & junk foods etc. as per information available in different *Ayurvedic* texts for the dietic regimen of diabetic patients.

1. DIAGNOSTIC CRITERIA

All the patients were diagnosed on the basis of following criteria:-

1. Clinical Signs and Symptomatology of *Prameha* were observed in patients for diagnosis.
2. Various Investigations

a. Blood Examinations.

i. FBS. (Fasting Blood Sugar)

ii. PPBS (Post Prandial Blood Sugar)

iii. HbA1c

All investigations were done before starting and after every 2 weeks till the completion of the treatment.

2. GENERAL OBSERVATIONS

Demographic Profile

The patients registered under the present trial were closely interviewed according to the proforma of the study. In incidence of their age, sex, socio-economic status, marital status, religion, habitat, dietary habits, nature of Job and other relevant information's were worked out Patients were screened subjectively and objectively for side effects of treatment.

Criteria for Assessment

After the completion of the treatment, the results were assessed by adopting the following criteria.

- Improvement in signs and symptoms of disease on the basis of symptoms score.
- Improvement in laboratory Investigation (i.e. reduce levels) on the basis of lab reports.
- Reduction in Objective assessment parameters.

For clinical evaluation the criteria can be divided in to two types:

1. Subjective Assessment
2. Objective Assessment

1. SUBJECTIVE ASSESSMENT

Subjective Assessment based on the feeling of patients, so researcher has to depend on his patient for assessment. It is known as 'simple verbal scale' In this particular research work, subjective criteria are mentioned below.

1. *Karpadaho* (Burning sensation in palm and feet)

0 – Absent

1 - Occasional

2 – Continuos & not disturbing daily routine

3 - Continuos & disturbing normal activity

2. *Mukh -talu -kanth sosha* (mouth-palate-throat dryness)

0 – Absent

1 - Occasional

2 - Continous but Mild

3 - Continous but Excessive dryness

3. *Aalasya* (Lassitude)

0 – Normally Active

1 – Hesitate to start work but if once start complete

2 – Start but does not complete

3 – Start work under Compulsion

4. *Pipasaadhikya* (Polydipsia)

0 - 8 to10 glass of water daily

1 - 10 to 15 glass of water daily

2 – 15 to 20 glass of water daily

3 – 20 to 25 glass of water daily

5. *Karpadasupt*i (Numbness in Hands & feets)

0 - Absent

1 - Occasional

2 – Continuos & not disturbing daily routine

3 - Continuos & disturbing normal activity

6. *Nidra* (Sleep)

0 – 6 to 8 hrs sleeping

1 – 8 to 10 hrs sleeping

2 – 10 to 15 hrs sleeping

3 – more than 15 hrs

7. *Tandr*a (Drowsiness)

0- No Drowsiness

1- Drowsiness present

2- Drowsiness with tiredness

3- Tendency to Sleep

8. *Mukhmadhuryam asyata* (Sweetness in Mouth)

0- No feeling of Sweetness in mouth

1- Ocassional feeling of sweetness in mouth

2- Continuous but mild sweetness in mouth

3- Excessive sweetness in mouth

9. *Prabhootmutrata* (Polyuria)

0- 3-4 times/day, rarely at night

1- 4-6 times/day, 0-2 times at night

2- 6-8 times/day, 2-4 times at night

3 - >8 times/day, >4 times at night

2. OBJECTIVE ASSESSMENT

Assessment of Blood examination

FBS, PPS

OTHER EXAMINATION

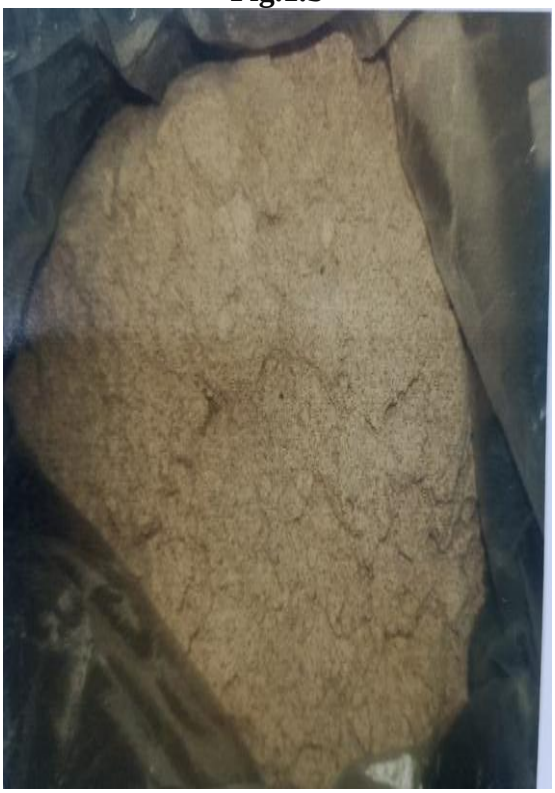
HbA1c

Preparation of Drugs

Fig. 1.a

Drug A - mandua seeds

Fig.1.b



Drug A - powder in the form of Flour

Fig. 2.a

Drug B - Kodrava seeds (with husk)

Fig. 2.b

Drug B - Kodrava seeds (without husk)

In the form of Rice

RESULTS AND DISCUSSION

Statistical Analysis

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

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

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

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

Table No. 1: *Purvaroopa* wise distribution in 30 patients of *Prameha.*

S.No.	*Purvaroopa*	Group A	Group B	Total	%
1.	*Pipasadhikya*	14	14	28	93.33
2.	*Karapaaddaaha*	11	8	19	63.33
3.	*Kara padasupti*	4	8	12	40.00
4.	*Mukhakanthatalushosha*	14	15	29	96.67
5.	*Aalasya*	15	14	29	96.67
6.	*Nidra*	11	12	23	76.67
7.	*Tandra*	15	15	30	100.00
8.	*Mukhmadhuryamasyata*	5	5	10	33.33

Table no. 2: Relative incidence of symptoms *(Lakshanas*) seen in *Prameha.*

S.No.	Symptoms	Group A	Group B	Total	%
1.	*Prabhootamutrata*(Polyuria)	4	7	11	36.67
2.	*Avilmutrata* (Turbidity in urine)	0	0	0	-

Table No. 3: Showing pattern of symptomatic improvement after therapy in patients in 15 (Group A) patients.

S. No.	Symptoms	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	t	P	Result
1.	*Karapadadaaha*	1.45	0.54	0.90	62.50	0.40	0.09	6.70	<0.001	H.S
2.	*Mukhkanthatalushosha*	1.50	0.78	0.71	47.61	0.46	0.12	5.70	<0.001	H.S.
3.	*Aalasya*	1.53	0.53	1.00	65.21	0.53	0.13	7.24	<0.001	H.S
4.	*Pipasadhikya*	1.21	0.64	0.57	47.05	0.64	0.17	3.30	<0.01	S
5.	*Karapaadasupti*	1.25	0.75	0.50	40.00	0.57	0.28	1.70	<0.01	S
6.	*Nidra*	1.09	0.36	0.72	66.67	0.46	0.14	5.16	<0.001	H.S

7.	*Tandra*	1.73	0.73	1.00	57.69	0.37	0.09	10.24	<0.001	H.S
8.	*Mukhamadhuryamasyata*	1.73	0.73	1.00	57.69	0.37	0.09	10.24	<0.001	H.S
9.	*Prabhootmutrata*	1.25	0.50	0.75	60.00	0.50	0.25	3.00	<0.01	S

Table no. 4: Showing pattern of symptomatic improvement after therapy in patients in 15 (Group B) patients.

S. No.	Symptoms	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	t	P	Result
1.	*Karapaaddaaha*	1.12	0.62	0.5	44.44	0.53	0.18	2.64	<0.01	S
2.	*Mukhkanthatalushosha*	1.40	0.86	0.53	40.00	0.51	0.13	4.00	<0.001	H.S
3.	*Aalasya*	1.50	0.71	0.78	52.38	0.57	0.15	5.07	<0.001	H.S
4.	*Pipasadhikya*	1.46	0.92	0.53	36.84	0.51	0.14	3.74	<0.001	H.S.
5.	*Karapaadsupti*	1.62	0.75	0.87	53.84	0.35	0.12	7.00	<0.001	H.S
6.	*Nidra*	1.33	0.75	0.38	43.75	0.51	0.14	3.92	<0.001	H.S
7.	*Tandra*	1.93	1.13	0.80	41.37	0.41	0.10	7.48	<0.001	H.S
8.	*Mukhamadhuryamasyata*	1.80	1.00	0.80	44.44	0.44	0.20	4.00	<0.001	H.S
9.	*Prabhootmutrata*	1.00	0.57	0.42	42.85	0.53	0.20	2.12	<0.01	S

Table no. 5: Showing pattern of changes in certain laboratory parameters in 15 patients after therapy (Group A).

S. No.	Lab Investigation	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	t	P	Result
1.	FBS	118	112	6	5.08	2.50	0.64	9.48	<0.001	H.S
2.	PPBS	215.86	198.33	16.86	8.12	6.92	1.78	9.43	<0.001	H.S
3.	HbA1c	6.02	5.88	0.14	2.32	0.76	0.016	8.57	<0.001	H.S

Table no. 6: Showing pattern of changes in certain laboratory parameters in 15 patients after therapy: (Group B).

S. No.	Lab Investigation	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	t	P	Result
1.	FBS	118.4	115.6	2.8	2.37	3.9	0.50	5.50	<0.001	H.S
2.	PPBS	213.53	196.93	16.60	7.77	26.9	6.94	2.39	<0.01	S
3.	Hb1AC	5.94	5.90	0.04	0.14	0.04	0.012	2.64	<0.01	S

Table no.7: Showing pattern of physiological changes in 15 patients after therapy (Group A).

S. No.	Physiological parameters	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	t	P	Result
1.	Body Wt. (Kg)	68.52	67.75	0.77	1.11	0.61	0.15	2.05	<0.05	S
2.	Systolic blood pressure(mmHg)	127.46	124.93	2.53	1.98	3.24	0.83	2.50	<0.01	S
3.	Diastolic Blood Pressure(mmHg)	83.60	80.80	2.40	3.34	2.52	0.65	1.61	>0.05	N.S.

Table no. 8: Showing pattern of physiological changes in 15 patients after therapy (Group B).

S. No.	Physiological parameters	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	S.D.	S.E.	t	P	Result
1.	Body Wt. (Kg)	68.80	68	0.80	0.41	0.32	0.08	2.70	<0.01	S.
2.	Systolic blood pressure(mmHg)	126	125.2	0.8	0.63	2.59	0.67	1.19	>0.05	N.S.
3.	Diastolic Blood Pressure(mmHg)	82.53	81.33	1.2	1.45	1.82	0.47	2.55	<0.05	S

Table no. 9: Showing the comparative study of symptomatic improvement in Group A and B.

Symptoms	Group A			Group B		
	% Relief	P value	Results	% Relief	P value	Results
Karapaadadaaha (Burning Sensation in hands and feets)	62.50	<0.001	H.S	44.44	<0.01	S
Mukhkanthatalushosha(Dryness in Throat and Mouth)	47.61	<0.001	H.S	40.00	<0.001	H.S
Aalasya (Lassitude)	65.21	<0.001	H.S	52.38	<0.001	H.S
Pipasadhikya (Polydipsia)	47.05	<0.01	S	36.84	<0.01	S.
*Karapaadsupt*i (Numbness in hands and feets)	40.00	<0.01	S	53.84	<0.001	H.S
Nidra(Tendency to sleep)	66.67	<0.001	H.S	43.75	<0.001	H.S
Tandra (Tiredness)	57.69	<0.001	H.S	41.37	<0.001	H.S
Mukhmadhuryamasyata(Sweetness in mouth)	57.69	<0.001	H.S	44.44	<0.001	H.S
Prabhootmootrata(Polyuria)	60.00	<0.01	S	42.85	<0.01	S

Table No. 10: Showing the comparative study of Lab investigation in Group A and B.

Lab Investigation	Group A			Group B		
	% Relief	P value	Results	% Relief	P value	Results
FBS	5.08	<0.001	H.S	2.37	<0.001	H.S
PPBS	8.12	<0.001	H.S	7.77	<0.01	S
HbA1c	2.32	<0.001	H.S	0.14	<0.01	S

Table no. 11: Showing the comparative study of Physiological parameters in Group A and B.

Physiological parameters	Group A			Group B		
	% Relief	P value	Results	% Relief	P value	Results
Body Wt. (Kg)	1.11	<0.05	S	0.41	<0.01	S.
Systolic blood pressure(mmHg)	1.98	<0.01	S	0.63	>0.05	N.S.
Diastolic Blood Pressure(mmHg)	3.34	>0.05	N.S.	1.45	<0.05	S

Discussion on incidence of *Purvaroopa*

Alasya constituting 96.67%, *Mukha kantha talu shosha* constituting 96.67%, *Kara pada daha* were present in 63.33 % cases, *Karapaadsupti* in 40 % cases, *Tandra* in 100% cases, *Nidra* in 76.67%, *Mukhmadhuryamasyata* in 33.33% cases, *Pipasadhikya* in 93.33% of cases.The study confirms that most of the *purvaroopa* are converted into *rupa* which shows that *purvaroopa* are prior manifestations of disease.

Discussion on incidence of *Rupa*

Here we can see that in the patients of *Prameha,* the incidence rate of *Prabhootmutrata* was only 36.67% and there was no patient having symptoms of *Avilamutrata.*

DISCUSSION ON EFFECT OF THERAPY

Table No. 12: On Objective & Subjective parameters.

	Group A		Group B				
Symptoms	**Mean BT**	**Mean AT**	**Mean BT**	**Mean AT**	**t**	**p**	
Symptomatic							
Karpaaddaaha	1.454	0.636	1.12	0.62	1.83	>0.05	N.S
Mukhkanthatalus hosha	1.50	0.785	1.4	0.87	1.00	>0.05	N.S
Alasya	1.53	0.53	1.5	0.71	2.03	>0.05	N.S
Pipaasadhikya	1.214	0.642	1.46	0.92	0.15	>0.05	N.S
Karapadsupti	1.25	0.75	1.62	0.75	2.00	>0.05	N.S
Nidra	1.090	0.363	1.33	0.75	0.80	>0.05	N.S
Tandra	1.733	0.733	1.93	1.33	1.38	>0.05	N.S
Mukhmadhuryam syata	1.733	0.733	1.80	1.00	1.32	>0.05	N.S
Prabhutmootrata	1.25	0.75	1.00	0.57	1.90	>0.05	N.S
Lab I/V							
FBS	118	112	118.4	115.6	4.00	>0.001	H.S
PPS	215.8	198.3	213.53	196.9	0.03	>0.05	N.S
Hb1AC	6.02	5.88	5.94	5.90	5.171	>0.001	H.S
Physiological Parameters							
Systolic BP	127.4	124.9	126	125.4	1.491	>0.05	N.S
Diastolic BP	83.6	80.8	82.53	81.33	1.614	>0.05	N.S
Weight	68.52	67.75	69.50	69.21	2.00	>0.05	N.S

Thus we can see in Table No. 12, that Drug A & Drug B both have statistically similar results and Non-significant in all the symptoms i.e *Karapaaddaah, Mukhkanthatalushosha, Alasya, Pipasadhikya, Karapaadsupti, Nidra, Tandra, Mukhmadhuryamasyata and Prabhutmootrata*

but in FBS and Hb1AC both the drugs were highly significant and these are non significant in PPS, Systolic BP, Diastolic BP and Weight.

Effect on Symptoms (Group A)

Statistical analysis reveals that 62.50%, 47.61%, 65.21%, 66.67%, 57.69%, 57.69%, reduction in *Karapaaddaah, Mukhkanthatalushosha, Aalasya, Nidra, Tandra, Mukhmadhuryamasyata*, which is statistically highly significant and reduction in 47.05%, 40%, 60% *Pipasadhikya, Karapaadsupti, Prabhootmutrata,* respectively which is statistically significant.

Effect on Symptoms (Group B)

It is evident that 44.44%, 40%, 52.38%, 36.84%, 53.84%, 43.75%, 41.37%, 44.44%, reduction in *Mukhkanthatalushosha, Aalasya, Pipasadhikya, Karapaadsupti, Nidra, Tandra, Mukhmadhuryamasyata* respectively which are statistically highly significant and 44.44%, 42.85% reduction in *Karapaaddaah, Prabhhotmutrata* respectively which are statistically significant.

EFFECTS OF THERAPY ON VARIOUS LAB PARAMETERS

In (group A)

The study reveals the fact that 5.08%, 8.12%, 2.32%, reduction is seen in Fasting Blood Sugar, PPBS, Hb1Ac which are statistically highly significant.

In (group B)

In the clinical trial changes in the laboratory shows that 2.37% and reduction is seen in Fasting Blood Sugar but this is statistically highly significant and in Post Prandial Blood Sugar, Hb1Ac reduction is seen i.e. 7.77%, 0.14% which are statistically significant.

EFFECT ON BODY WEIGHT, SYSTOLIC BLOOD PRESSURE AND DIASTOLIC BLOOD PRESSURE

In (Group A)

In the clinical trial Physiological changes shows that 1.11%, 1.98% reductions are seen in Body weight, Systolic blood pressure which is statistically significant and 3.34% reductions are seen in Diastolic Blood Pressure but revealed statistically not significant.

In (Group B)

In the clinical trial Physiological changes shows that 0.41% and 1.45% reduction are seen in Body weight, Diastolic blood pressure which are statistically significant and Systolic Blood Pressure revealed statistically not significant reduction at $p>0.05$ though percentage improvement was 0.63%.

COMPARATIVE STUDY OF SYMPTOMATIC IMPROVEMENT IN GROUP A AND B

Group A *(Kodrava)* was found to be more effective than Group B *(Mandua)* in relieving symptoms like *Karapaaddaaha* (Burning Sensation in hands and feets), *Mukhkanthatalushosha* (Dryness in mouth and throat), *Aalasya* (Lassitude), *Pipasadhikya* (Polydipsia), *Karapaadsupti* (Numbness in hands and feets), *Nidra*(Tendency to sleep), *Tandra* (Tiredness), *Mukhmadhuryamasyata* (Feeling of Sweetness in Mouth), *Prabhootmutrata* (Polyuria).

COMPARATIVE STUDY OF LAB INVESTIGATION IN GROUP A & B

Group B *(Mandua)* was found to be less effective than Group A *(Kodrava)* in lowering Fasting & Post prandial Blood sugar. Group A (Kodrava) was highly effective than Group B *(Mandua)* in lowering Glycated Hemoglobin.

COMPARATIVE STUDY OF PHYSIOLOGICAL PARAMETERS IN GROUP A AND B

Group A *(Kodrava)* is found to be more effective than Group B *(Mandua)* in percentage relief in physiological parameters like Body weight, Systolic blood pressure and statistically it is significant Percentage relief in Diastolic blood pressure is 3.34% but statistically it is Non significant.

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